Conflict of interests or transparency at the World Health Organization? An analysis of the framework of engagement with non-state actors and the member states' positions during the negotiations process (2012-2016)

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To Lucas, who makes my journey through life be filled with peace and lightness.

To Nilce and Euclides, for always putting my education first.

To all those who believe in the power of education.

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CERTIFICATE OF DEFENSE APPROVAL FOR DOCTORAL THESIS

Certificate of public defense approval for the Doctoral Thesis of **Mrs. Maíra da Silva Fedatto** in the International Relations Postgraduate Program of the Institute of International Relations of the University of São Paulo (IRI-USP).

As part of the requirements to obtain a PhD degree, on the 09th of September 2020 Mrs. Maíra da Silva Fedatto defended his doctoral thesis entitled:

"Conflict of Interests or Transparency at the World Health Organization? An analysis of the Framework of Engagement with non-State actors and the Member States' positions during the negotiations process (2012-2016)"

After the public defense was opened, the president gave the floor to the candidate for his oral presentation. Following the student's presentation, the examiners questioned the candidate in accordance with defense procedures. The committee members then signed this form indicating the result:

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Committee's Evaluation
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The committee recommends that the candidate does additions to the final version of the dissertation, particularly when it comes to making clear in the introduction and in the conclusion the dissertation's methods, concepts, how documents were employed, and main findings and contributions to the literature.

This certificate was drawn up by Victor Yuji Shirai, Secretary of the Postgraduate Office, on the 09th of September 2020.

Ann Horton Kelly
(Examiner 1)

Felipe Pereira Loureiro
(Examiner 2)

Danielle Hanna Rached
(Examiner 3)

Deisy de Freitas Lima Ventura
President of the Committee

The defense was approved by the Postgraduate Studies Committee on _____ and, therefore, the student has received the title of PhD in Sciences, awarded by the International Relations Program.

President of the Postgraduate Studies Committee

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ABSTRACT

FEDATTO, MS. Conflict of Interests or Transparency at the World Health Organization? An analysis of the Framework of Engagement with non-State actors and the Member States' positions during the negotiations process (2012-2016). 2020. 348p. Thesis (Joint PhD in International Relations) – International Relations Institute, University of São Paulo, São Paulo and King's College London, London, 2020.

Underfunded and overburdened, the World Health Organisation has been unable to respond swiftly and effectively to existing and conceivable global health challenges. It became perceptible after the slow and highly criticised response to the Ebola outbreak in West Africa, in 2014. Currently, while the WHO has been facing a financial crisis, the growing participation of several non-State actors such as non-governmental organisations, pharmaceutical companies, transnational organisations, philanthropic foundations and others has led to a weakening of the Organisation's leadership. The involvement of these 'new' actors can undoubtedly bring institutional, technical, political and financial resources not only to global public health but also to support the WHO in accomplishing its guiding and coordinating role. However, the rise of several non-State actors also creates challenges for coordination and raises questions about the roles these organisations should play, the rules by which they play, and who should set those rules. Considering the intense relationship of the WHO with a vast number of non-State actors, Member States have historically been trying to establish a policy to regulate these relations. In 2012, the Framework of Engagement with non-State Actors (FENSA) was presented with the main goal of regulating the relation of the WHO with non-governmental organisations, the private sector, philanthropic foundations and academic institutions. By investigating the negotiation process through document analysis and interviews, I seek to identify the positions of the most active Member States during the negotiation of the Framework and to understand the different coalitions that were designed. I would also take in to account the perspective of the non-State actors embraced by FENSA and pertaining to the WHO itself. By disclosing FENSA, specifically its context and the negotiation process, the ongoing powerful influence of some non-State actors on global health governance, and consequently at the WHO, becomes easier to understand.

Key-words: FENSA, World Health Organization, Global Health, Non-State Actors, Global Governance.

RESUMO

FEDATTO, M. Conflito de Interesse ou Transparência na Organização Mundial da Saúde? Uma análise do Framework of Engagement with non-State actors e a posição dos Estados Membros durante o processo de negociação. (2012-2016). 2020. 348p. Thesis (Joint PhD in International Relations) – International Relations Institute, University of São Paulo, São Paulo and King's College London, London, 2020.

Subfinanciada e sobrecarregada, a Organização Mundial da Saúde tem sido incapaz de responder de forma rápida e eficaz aos desafios de saúde global. Isso se tornou bastante perceptível após a lenta - e altamente criticada - resposta ao surto de Ebola na África Ocidental, em 2014. Simultaneamente, enquanto a OMS enfrenta uma crise financeira, a crescente participação de vários atores não estatais como organizações não-governamentais, empresas farmacêuticas, organizações transnacionais, fundações filantrópicas e outras, levou a um enfraquecimento da liderança da Organização. O envolvimento desses "novos" atores, de fato, contribui para trazer novos recursos institucionais, técnicos, políticos e financeiros, não apenas para a saúde pública global, mas também para o trabalho da OMS no cumprimento de seu papel de liderança e coordenação de assuntos de saúde. No entanto, o surgimento de novos atores cria também desafios para a coordenação de ações e levanta questões sobre os papéis que essas organizações devem desempenhar, as regras que devem cumprir e quem deve defini-las. Assim, tendo em vista a intensa relação da OMS com um grande número de atores não estatais, os Estados Membros, historicamente, têm tentado estabelecer uma política para regular essas relações. Em 2012, o Marco de Colaboração com Atores Não Estatais (FENSA, do inglês Framework of Engagement with non-State Actors) foi apresentado, tendo como principal objetivo regular a relação da OMS com organizações não-governamentais, setor privado, fundações filantrópicas e instituições acadêmicas. Ao investigar o processo de negociação por meio de uma análise de documentos e de entrevistas, procuro identificar as posições dos Estados Membros mais ativos durante a negociação do FENSA e entender as diferentes coalizões possivelmente formadas. Além disso, também levo em consideração a perspectiva dos atores não estatais abarcados pelo FENSA e da própria OMS. Ao minuciar o FENSA - seu contexto e o processo de negociação - a poderosa (e crescente) influência de alguns atores não estatais na governança global da saúde, e consequentemente na OMS, torna-se mais fácil de entender.

Palavras-chave: FENSA, Organização Mundial da Saúde, Saúde Global, Atores não Estatais, Governança Global

ACRONYMS

AC	Assessed Contributions
BINGO	Business Interest NGO
BMGF	Bill and Melinda Gates Foundation
CC	Collaboration Center
CSO	Civil Society Organisation
CVC	Core Voluntary Contributions
DG	Director-General of the WHO
EB	Executive Board of the WHO
EBF	Extra budgetary Funds
PHEIC	Public Health Emergency of International Concern
FENSA	Framework of Engagement with non-State Actors
GB	Governing Body
LNHO	League of Nations Health Organization
MS	Member State
NGO	Nongovernmental Organisations
NSA	Non-State Actor
OEIGM	Open-Ended Intergovernmental Meeting
PAHO	Pan-American Health Organisation
PBAC	Programme, Budget and Administration Committee
PPPs	Public-Private Partnerships
UN	United Nations
WB	World Bank
WHA	World Health Assembly
WHO	World Health Organisation

CONTENTS

INTRODUCTION

Since the aftermath of World War II, we can observe a wide range of international organisations that help manage problems that transcend not only national borders but States' autonomy. Traditionally seen as authority holders in International Relations (IR), the supremacy of nation States as well as the exclusion of all external powers started to be challenged by IR literature. The limitations of mainstream theories like realism in explaining the role and importance of other actors that can influence the actions of States became clear; a multi-level and interconnected international system started to be analysed without clear hierarchy between levels and actors.

The World Health Organisation (WHO), established in 1948 with headquarters in Geneva (Switzerland), is the institution that, over the last seventy years, has shaped the landscape of international health and remains the key institution when it comes to global health. Despite facing many challenges, specifically a financial and legitimacy crisis, in the last three decades, its recommendations still have a forceful impact not only on local public health but also on tourism and the economy. To illustrate, in recent times, international emergencies related to the AH1N1 flu and Ebola caused, in addition to thousands of deaths, significant economic damages to the most affected countries. According to a report developed by the World Bank, the economic impact, which outlasts the epidemiological impact, in Guinea, Liberia and Sierra Leone was at least $2.8 billion (WORLD BANK, 2016). The socioeconomic cost of the association between the Zika virus, neurological disorders, and congenital malformations and their spread through Latin America was an estimated $7-18 billion between 2015 and 2017, according to the Impact Assessment launched by the United Nations Development Programme (UNDP, 2017).

Legitimacy is crucial for international institutions to be able to exercise authority as well as to gain acquiescence with rules, decisions and recommendations rather than coercion, even because IOs do not have the tools to coerce sovereign governments. Ruger (2014) points out that while the WHO was established as ‘a social contract conception of legitimacy’, since signatories states agreed to follow the institution’s rule, it cannot demand recognition by those not party to the contract, including amongst the increasing number of global health initiatives. Most important for this thesis is the author’s argument that the WHO’s legitimacy relies on democratic processes, as will be explained in chapter 2, the

WHO's governing bodies have the 'one State, one vote' rule, which is vulnerable to power relations that underlie such processes. The negotiation of the Framework of Engagement with non-State actors (FENSA), the main object of this thesis, brings together power and legitimacy debates as it is a unique effort of the WHO amongst all international organisations worldwide to reassure its legitimacy not only between Member States, but among non-State actors (NSAs) and, above all, public opinion. Likewise, FENSA disclosed the influence of powerful actors and power imbalances at the organisation confirming Shiffman's (2015) argument that global health, besides being an arena made up of actors driven by normative concerns and by the aim of addressing health inequities, is also led by power dynamics and non-normative interests.

When it comes to non−State actors, they can be defined as individuals or organisations with economic, political or social power and the ability to influence at a particular level, or all levels, while not belonging to or being allied to any specific country or state. They have increasingly taken part in international conventions, forums and negotiations, consequently being seen as part of 'public diplomacy', which is defined by Gregory (2011, p.276) as 'an instrument used by states, associations of states, and some sub−state and non−state actors to understand cultures, attitudes and behaviour; to build and manage relationships, and to influence thoughts and mobilise actions to advance their interests and values'.

The role of States has been reshaped, and when it comes to health, Kickbusch and Szabo (2014) assert that as the movement of people and goods across borders intensifies, not only epidemic control has become internationalised, but health issues have started to require a multi-level governance that embraces several actors. The concept of global health, therefore, has been associated with the increasing weight of new actors as well as governmental and intergovernmental agencies and organisations, such as the media, foundations and transnational corporations (Brown, 2012). Since health issues cannot be restricted to geographical boundaries nor to the traditional actors of International Relations, I started to think about the importance of these actors, particularly at the WHO, beyond their huge financial contribution. Hence, the main object of this thesis is to understand the increasing role of the so-called non-State actors (NSAs) at the World Health Organisation.

While the involvement of these 'new' actors can undeniably bring institutional, technical and financial resources to health policies, it is important to question how best these

contributions be can marshalled towards the global health agenda. On one hand, there are entities in defence of the right to health and on the other, we find entities that directly or indirectly represent the interests of powerful actors. The exercise of power permeates global governance processes and include multiple ways in which one actor can influence the thinking or actions of others. But the discussion about how international relations' scholars have conceptualised power in global governance is beyond the scope of this thesis. The current literature, for instance, portrays the Bill and Melinda Gates Foundation as the most influential actor in global health nowadays, promoting 'philanthrocapitalism' as argued by Birn (2014). Furthermore, the influence of the private sector, especially from the pharmaceutical industry, upon on the WHO has been denounced countless times, as this thesis will further expose in chapter three.

It is essential to enquire: do non-State actors have any participation in the decision-making processes at the World Health Organisation? When trying to answer this question, the issue of social participation at the WHO arises, and, consequently, a wide range of actors.

In May 2016, after five years of debate, extensive consultations and 17 months of intergovernmental negotiations, the Sixty-ninth World Health Assembly (WHA) approved the Framework of Engagement with Non-State Actors (FENSA). It recognises four non-State actors: Non-Governmental Organisations (NGOs), Philanthropic Foundations, the Private Sector and Academic Institutions and foresees five types of engagement: participation; resources; evidence; advocacy; and technical collaboration.

If on one hand the Framework identifies five benefits of the engagement between the WHO and NSAs, seven risks are pointed out. The benefits are: the contribution to the work of the Organisation; additional resources; influence on the social, economic and environmental determinants of health; improvements in compliance with WHO policies, norms and standards; and wider dissemination of WHO policies. Meanwhile, the risks are enumerated as: conflicts of interest; undue influence; negative impact on the WHO's integrity, credibility or reputation; NSAs being primarily benefited instead of public health; conferring an endorsement of the NSA' name, brand, product, views or activity; competitive advantage for the NSA; whitewashing of NSA's image by association with the WHO.

Therefore, the great tension behind the discussion about the participation of non-State actors at the WHO is to understand if giving more space would favour actors truly concerned

about global health or rather would institutionalise and legitimise undue influence and vested interests of some actors. It is also worth noting that the greater or lesser capacity of influence of non-State actors on the WHO has repercussions not only in international forums, in which they can manifest themselves, but also in the ability to impact the opinions of Member States and, therefore, their positions and votes in the governing bodies. In order to assess such influence, the specific case study proposed is to outline the positions taken by Member States during the negotiation of the new rules for participation of non-State actors at the World Health Organisation, which ended with FENSA's approval.

Given the discussions about more involvement of non-State actors at the WHO, the potential contribution of these actors to the work of the organisation is highlighted as well as a possible negative influence on the global health agenda and priorities. Among the arguments in favour of a closer and deeper interaction is the fact that a larger influence of the WHO on civil society would consequently increase its impact on global public health as well as ensure better compliance with WHO standards, policies and recommendations. Additionally, there are expected economic contributions. On the other hand, the enlargement of the participation of non-State actors requires transparency of the processes, the development of standards for identification and inclusion of new actors and the proof of outcomes (Sanchez, 2007). Thus, while part of civil society believes that FENSA can be an important tool to safeguard the independence of the WHO from private interest and undue influence, others severely criticised its elaboration and negotiations, arguing that the Framework gives identical treatment for public interest and for-profit interest groups. Nevertheless, it is unquestionable that FENSA establishes a precedent as it is the first comprehensive regulatory Framework within the United Nations system that covers all categories of interaction with NSAs (Seitz, 2016).

When I started to follow the FENSA debate inside and outside the WHO, I could easily notice that the development of these collaboration rules occurred in a complex scenario of conflict of interest at different levels, both in the public and private sector. Moreover, divergences arose not only among the Member States but also between different non-State actors, especially NGOs and the private sector. The central motivation for this thesis was, firstly, the importance of the inclusion, as well as the development of themes related to global health, health diplomacy and global health governance in the international relations research

agenda. Moreover, there is a lack of scientific literature about the complex and important process of negotiation of non-State actors' collaboration with the WHO. Apart from the official documents available at the WHO website, only a few watchdog NGOs such as the Third World Network and the Global Policy Forum regularly published articles about the negotiations.

Due to its complexity and the potential for it to be used as a model for future regulatory frameworks of other UN agencies in their engagement with non-State actors, FENSA has the potential to establish a new paradigm for the participation of non-State actors in international organisations, while trying to regulate their influence on the WHO and, consequently, on global health priorities. Notwithstanding, FENSA is an object of study that must be analysed through several perspectives and with a multidisciplinary approach, as it involves power, legitimacy, influence and conflict of interest – these can all impact global health priorities. It is therefore fundamental to understand which interests prevailed during the negotiation process and through which Member States, as FENSA was mainly negotiated behind closed doors and without the direct participation of non-State actors. In order to accomplish this, I have combined an extensive literature review with the analysis of primary sources, composed of archival material, public documents and interviews. While the literature provided the general background and framing of the research, the primary sources constituted the basis upon which I reconstructed the negotiation process to analyse the perspectives and positions of all actors involved.

It is important to bear in mind that despite some difficulties and setbacks, which will be detailed in this thesis, the WHO is still recognised as the world's health conscience that seeks equity and 'health for all' and provides a moral and public interest agenda for health. This enduring role cannot be undermined through the subordination of health standards and priorities to profit objectives.

The Research Pathway

The literature research conducted revealed the almost non-existence of scientific literature about FENSA and, at the same time, exposed signs of influence by NSAs on WHO policy processes. Hence, the research problem is if the positions and coalitions assumed by the most active Member States during the negotiations of FENSA are somehow connected to the interests of the four categories of non-State actor embraced by the Framework. Therefore,

the following hypotheses were initially proposed:

I. The North/South division that characterises the WHO's history (CHOREV, 2012) was reflected in FENSA negotiations with the formation of two groups of negotiators: developed and developing countries;
II. The final text of FENSA reflects the positions of North countries more than those of the Global South;
III. The positions taken by the most active Member States in the negotiations embraced the interests of non-State actors, especially philanthropic foundations and the private sector.

In order to assess the research problem, I sought to identify the positions of the most active WHO Member States during the FENSA negotiation process and the probable coalitions that were shaped. At the same time, I observed if a North/South cleavage in the States' alignment occurred, and if there is any association between the considered positions and the desires of the non-State actors.

Methodological Considerations

Considering that a case study is a 'detailed examination of an aspect of a historical episode to develop or test explanations that may be generalisable to other events' (George and Bennet, 2005, p.5), a qualitative case study was chosen, as it provides tools to scrutinise complex phenomena within their contexts. Moreover, it is an empirical investigation aiming to comprehend a contemporary problem, for this research, the FENSA negotiation, contextualised around the application of exhaustive analysis, interpretation and discussion, frequently resulting in recommendations for actions or for improving prevailing situations. Given that my main objective is to delineate the positions taken by the Member States and their potential co-related influences, it is worth highlighting that case studies are designed to bring out the details from the viewpoint of the participants by using multiple sources of data. (Tellis, 1997)

According to Yin (2001), a case study should be considered when the focus of the research is to answer 'how' and 'why' questions. My main objective is to understand how the Member States settled and advocated their positions on the participation of non-State actors at the WHO and why, especially by wondering if there were unknown motivations. A case study, therefore, is used to investigate a contemporary phenomenon in its real context, allowing the explanation of causal connections of singular situations (YIN, 2001).

Furthermore, case studies are a multi-perspectival analysis - they reflect not only the voices and perspectives of the actors directly involved but also of the relevant groups and individuals and the interaction between them.

Through a qualitative approach, characteristics considered fundamental were pursued, including the interpretation of available data considering the context; the progressive search for new enquiries; the complete and profound description of the fact and the context; the use of a variety of sources of evidence; and particularly the exposure of the different perspectives about the object of study. The use of multiple data sources is a strategy to improve data credibility (Patton, 1990; Yin, 2003). Potential data sources may include but are not limited to documents, archival records, interviews, direct observations, and participant-observation. In this sense, the use of more than one method to collect data to assure the validity of research is known as triangulation. According to Yin (2012), triangulation is 'constantly check[ing] and recheck[ing] the consistency of the findings from different as well as the same sources (…) or establishing converging lines of evidence'. However, the purpose of triangulation is not necessarily to cross-validate data but rather to capture different dimensions and perspectives of the same phenomenon. It is the reason why this research combines document analysis and interviews.

One should note that although the negotiation of FENSA is a contemporary event, the historical background is essential in order to understand its conception. Likewise, considering the importance of exploring some preliminary concepts in order to make this research an interdisciplinary study related to both global health and international relations research agendas, an in-depth historical literature review about the participation and impact of non-State actors on Global Health was also conducted. The aim is to outline the background against which the FENSA was proposed. For this, it is also significant to understand how the (economic and legitimacy) crisis at the World Health Organisation led to FENSA. A document examination will complement this dense literature review, official and unofficial documents were used, including meetings reports, policies, documents prepared by non-State actors, publications from watchdog organisations in the main media, among others.

The second step was to analyse the negotiation process itself, based primarily on documents about the FENSA process, available at the WHO's homepage, including decisions, resolutions, protocols of consultations and background papers. Additionally, all the legal

basis documents were also important as they underlie all the discussions that involve relations between the WHO and non-State actors. The documents were then organised into three groups, as shown in Table 1: (a) documents derived from WHO decision-making bodies; (b) basic documents; and (c) documents directly used in the negotiations or meetings. Additionally, papers, pronouncements, letters and any relevant documents from non-State actors were considered. Similarly, manifestations from any sectors of civil society and particularly the watchdog organisations' reports, all related to the participation of non-State actors at the WHO or the content of FENSA, were also essential.

Table1: documents on which this research was based

Documents from Governing Bodies	**Basic Documents**	**FENSA related Documents**
World Health Assembly	WHO Constitution	Drafts
Executive Board	Principles governing the relations between the WHO and NGOs	Agendas
	Guidelines on interaction with commercial enterprises to achieve health outcomes	Reports
	Guide for WHO Collaborating Centres	Consultations
	Regulations for Study and Scientific Groups, Collaborating Institutions and other Mechanisms of Collaboration.	Proposals submitted by the Member States

Basic Documents, such as the WHO Constitutions and the policies that were replaced by FENSA, were crucial in understanding not only the gaps in the relationship with NSAs but also in detailing what changes the FENSA brought. Considering the intergovernmental nature of the WHO, FENSA was discussed at the World Health Assembly and the Executive Board; this is why documents from governing bodies were important - the seven FENSA versions analysed in chapter four were presented to the WHA and the EB, and through their analysis it was possible to track modifications, suggestions and amendments. Notwithstanding, reports from the Secretariat from the Programme, Budget and

Administration Committee were also presented to the WHA and the EB and were essential to contextualise and deepen the analysis. Finally, with regards to FENSA-related documents, informal consultations and comments sent by Member States and NSAs were extremely valuable to map the positions taken, as well as financial and administrative implications reports, non-papers developed by the Secretariat, and reports of regional meetings.

The documentary analysis was chosen because once analysing documents, the researcher can be fully aware of the origins, purpose and the original audience of the documents (Grix 2001). Therefore, documentary sources become necessary if past behaviour can be inferred from its material traces and represent visible signs of what happened at some previous time. A documentary analysis seeks to identify factual information in the documents from questions or hypotheses of interest.

Taking into consideration theoretical concepts of International Relations, the book 'WHO between North and South' (Chorev, 2012), and the pursuit of an unbiased representation, five developing and five developed countries were chosen, despite an awareness that this represents an outdated definition.[1] The method used to choose the countries (once more aiming for impartiality) was to firstly count how many times the States made modifications, suggestions, amendments or interventions in the available documents. Subsequently, I analysed all the available reports from the watchdog organisations that were following the FENSA negotiations in order to observe if the countries which were mentioned more due to their participation were the same ones observed in the documents. Those with greater participation were selected and, lastly, confirmed during the initial interviews. The countries initially selected were: the United States of America, the United Kingdom, France, Canada, Norway, Brazil, India, Mexico, Bolivia and Zambia.

Qualitative semi-structured interviews were also carried out and analysed. Diplomats, negotiators and individuals from the most active Member States, WHO high-level personnel involved with FENSA, and representatives of the non-State actors who were directly or indirectly involved in the negotiation process were chosen for interview. According to Yin (2001), there are generally three types of interview: in-depth, focused and survey. The

[1] For the aims of this thesis, Porter et al. (2002) will be taken into consideration, given that the phases of economic development are distinguished based on a country's gross domestic product (GDP) per capita and the share of primary goods relative to its total exports: factor−driven, efficiency−driven, and innovation−driven. The developing countries are all efficiency−driven economies, while the developed countries are all innovation−driven economies.

focused interview (more widely known as semi-structured), was chosen, considering that it remains open-ended and is addressed as a conversation, but the interviewer must follow some specific questions previously formulated. The use of semi-structured interviews is justified because it allows similar questions to be asked of all the interviewees, despite the necessary adaptation to the particularities of certain actors. With this dynamic in place, no interruption takes place and the interviewees can express themselves in different ways. Besides, it allows for the confirmation (or otherwise) of already known data, and the acquisition and revelation of different perspectives and more details of the matter in question.

In social research, the term 'triangulation' is used to refer to the observation of the research issue from at least two points of view (Flick, 2004). Considering that between-method triangulation aims to validate the interpretation of the data collected, by interviewing different actors and analysing the official documents it is possible, to some extent, to crosscheck the information gathered.

It is important to highlight that, before the semi-structured interviews, exploratory interviews were needed, due to the difficulty accessing official documents and the negotiators or individual involved in the FENSA negotiations. Moreover, given that the FENSA was unexplored by academic researchers or by the media, it was essential to improve the understanding of the dynamics and the content of the negotiations, as they happened mainly behind closed doors. According to a personal source: 'no one is warmly welcoming researchers analysing hot political potatoes, which FENSA obviously is. Hence expect some frustrations and biting nails. Thus, keep on pushing, contacting, following up on messages' (personal message received on 11th July 2018).

Interviews

Through twenty-one interviews, a material that is not documented (or in a document inaccessible to the public) was collected and confronted with speeches and narratives of different actors to understand how the negotiation process happened. One should note that on the 16th July 2018, a request was sent to the WHO Records and Archives to access documents related to FENSA and non-State actors between 2012 and 2016. Access, however, was denied, due to the WHO Archives access policy, which determines that 'WHO archives are accessible to researchers once the records are at least 20 years old'. (Message received from WHO Archives <erardr@who.int> on 16th July 2018)

The ideal sample of interviewees would have included individuals from the three levels of the WHO (headquarters, regional and country offices), from all the most active Member States during FENSA negotiations, and all four groups of NSAs covered by the new rules of engagement (NGOs, private sector entities, philanthropic foundations and academic institutions). However, this is beyond the control of the researcher. This ideal sample was insistently pursued through numerous contacts via email. The request for an interview was sent, alongside an explanation of the research, as well as its aims and scope. Generally, it can be said that almost no one seemed to be open to participate as an interviewee. While staff, or former staff from the WHO headquarters were more open, professionals from the regional offices denied or did not answer the request to take part in this research. With regards to the Member States, developed countries were more accessible and open than developing countries, which is the reason why not all the initially selected countries were interviewed. Non-State actors were, on the whole, less reserved than Member States, even though many NSAs denied or never replied to my request for an interview.

Table 2: interviews made

Reference	Kind of Interview	From	Number and type of interview
Interviewee 1	Exploratory	Former staff of NGO	email exchange
Interviewee 2	Exploratory	Former staff of NGO	email exchange
Interviewee 3	in-depth	Watchdog Organisation	email exchange, skype call, face-to-face talk
Interviewee 4	semi-structured	Member State: Brazil	Face-to-Face, one time
Interviewee 5	semi-structured	Member State: Brazil	Face-to-Face, one time
Interviewee 6	semi-structured	Member State: Norway	Face-to-Face, two times
Interviewee 7	semi-structured	Member State: United Kingdom	Face-to-Face, one time
Interviewee 8	semi-structured	Member State: Germany	Face-to-Face, one time
Interviewee 9	semi-structured	Member State: United States	Face-to-Face, one time Skype call, one time

Interviewee 10	semi-structured	Member State: European Union	Face-to-Face, one time
Interviewee 11	semi-structured	Member State: Egypt	Skype call, one time
Interviewee 12	semi-structured	Member State: Zambia	Skype call, one time
Interviewee 13	semi-structured	Member State: Argentina	Skype call, one time
Interviewee 14	semi-structured	NGO: Medicus Mundi	Face-to-Face, one time
Interviewee 15	semi-structured	Private Sector: IFPMA	Face-to-Face, one time
Interviewee 16	semi-structured	Private Sector: IFBA	Skype call, one time
Interviewee 17	semi-structured	Philanthropic Foundation: Bill and Melinda Gates	Skype call, two times
Interviewee 18	semi-structured	Philanthropic Foundation: UN Foundation	Skype call, one time
Interviewee 19	in-depth	WHO – former staff	Face-to-Face, one time
Interviewee 20	semi-structured	WHO – former staff	Face-to-Face, one time Skype call, one time
Interviewee 21	semi-structured	WHO – current staff	Face-to-Face, one time
Total: 21 individuals			

The interviews were conducted between September 2018 and October 2019; most of them were face-to-face, took around 60 minutes and were recorded in audio format via the iPhone Voice Memo facility. All the interviewees were asked to give their written consent. The majority of interviewees choose to talk in anonymity and confidentiality, which can be explained due to the political sensitivity of FENSA. Moreover, it is the reason why the level, post or kind of participation weren't revealed. After conducting the interviews, they were transcribed and the result amounted to over 200 pages. Apart from the Brazilian individuals and a former WHO high-level staff member, the interviews were conducted in English and their transcriptions were written out with the support of the program 'Temi'. Depending on the recording quality and the English proficiency of the interviewee, a brief or more

extensive manual revision was required on occasion.

Considering that FENSA was mainly negotiated behind closed doors and that 'external researchers may access archival records once the records are 20 years old' (WHO Access Policy), the interviews made were crucial to understand just how contentious the negotiating process was. Moreover, as a result of the interviews, it was possible to map similar positions advocated by non-State actors and Member States and crosscheck them with different versions of the FENSA (a comparative analysis was conducted in chapter 4), and trace a cause-consequence relationship of the positions taken, which, in turn, reveals the influence of NSAs in the WHO policymaking process.

Structure of the Thesis

The thesis is organised into seven chapters. Chapter 1 has a key role in contextualising the overall motif: the importance of the four non-State actors embraced by the FENSA: NGOs, academic institutions, private sector and philanthropic foundations, for the global health agenda. It is an important literature review as FENSA understands non-State actors to be essential in addressing health challenges because they complement WHO leadership in the health field. Chapter 2 provides an institutional background by analysing the World Health Organisation in a historical perspective, focusing essentially on the financial and legitimacy crisis, and, consequently, the context in which the FENSA was developed. Chapter 3 reveals how was the participation of the four non-State actors at the WHO before FENSA. It is not possible to investigate the FENSA negotiation process without understanding how the Organisation used to engage with NSAs, as the old rules, which were mainly replaced by the Framework, were an important variable to the FENSA proposal. Chapter 4 is an extensive description of the content and process of the FENSA, including how the selected Member States behaved, according to official documents. Chapter 5 describes the interviews made with individuals from the selected active Member States and chapter 6 outlines the perspectives of non-State actors affected by the FENSA. Chapter 7 presents the analysis of results, alongside final remarks.

CHAPTER ONE: NON-STATE ACTORS AND GLOBAL HEALTH, WHY IS IT IMPORTANT TO UNDERSTAND?

The growth of governance beyond the historical dominance of states and international organisations (IOs) has been characterised as one of the most important political developments of the past half-century (Bexell et al., 2010). Over time, there has been a gradual perception not only that other actors should engage in the different topics of a global agenda, but also that other options should be sought, given the political and financial limitations that constrain the actions of governments and IOs. Accordingly, it is widely recognised that States have gradually reduced their influence in several international issues, such as terrorism, environment and epidemics, amongst others.

The formulation of global health policies must, then, be analysed and understood considering the existence of complex systems, which encompass not only governments but also a multiplicity of actors, such as NGOs, pharmaceutical companies and other powerful businesses, international organisations, and civil society. Ruggie (2004) argues that, given the major transformation that the traditional international political world has experienced, researchers are increasingly reaching beyond the traditional focus on the roles performed by States, since several non-State actors play important roles in the definitions and strategies for access to health and other health-related topics. Moreover, health determinants are gradually being influenced by circumstances external to the health sector, which demands even stronger joint action between agendas, levels and actors.

In fact, the concept of global health has been associated with the growing importance of different actors and can be defined in several ways, depending on the backgrounds and perspectives of these actors. In this sense, Kickbush (2006, p. 561) describes global health as ‘health issues that transcend national boundaries and governments and call for action on the global forces that determine the health of people. It requires new forms of governance at national and international levels which seek to include a wide range of actors’. Global health is defined as ‘an area of study, research, and practice that places a priority on improving health and achieving health equity for all people worldwide’ (Koplan et al., 2009, p.1995), whereas a third, shorter definition posits global health as ‘collaborative international research and action for promoting health for all’ (Beaglehole and Bonita, 2010, p.1).

These three different definitions illustrate the difficulty in obtaining one approach for tackling global health challenges. Despite a similarity regarding the intention of promoting health, they do contain differences and therefore result in distinct methods to solve problems. While the definitions by Beaglehole and Bonita (2010) and Kickbush (2006) focus on the notion of *health for all*, they do not consider equity. According to Marmot's (2007) study, equity in health means taking the necessary steps so that all countries are capable of providing equally good care and basic needs, not by imposing the same strategies but by attributing country-specific ones. Similarly, Koplan et al. (2009) and Beaglehole and Bonita (2010) refuse to acknowledge geographic boundaries when discussing global health due to the different ways in which they can appear. Despite Beaglehole and Bonita's (2010) being the most recent definition, it mainly focuses on sharing information and acquiring knowledge, rather than instructive action to tackle global issues.

Conscious of the limitations of all the definitions presented, this doctoral thesis will use the one delineated by Kickbusch (2006), understanding that it addresses global health as an issue that can be discussed in the context of foreign policy – one with a multidisciplinary approach that includes international relations studies. It is worth noting that although historically health and international relations have been in dialogue since the eighteenth century, the focus was exclusively on the control of epidemics and diseases, which could jeopardise international trade. Health-related issues secured a permanent place on the global political agenda with the establishment of the League of Nations Organisation in 1922, which will be discussed further in the second chapter. However, it was not until the 1990s, when the so-called *New World Order* arose, that health started to enjoy greater prestige as part of the international agenda and, consequently, in foreign policies. The increasing presence of health topics on the international agenda alongside the performance of specific agencies in this field led to a new focus within the scope of diplomacy, the so-called 'global health diplomacy'.[2]

The chosen definition is seen as the best option, given my proposed interdisciplinary debate, and also to fill a gap observed by Stoeva (p.97, 2016): 'the marginal place of the global politics of health in the discipline of IR is surprising, given the richness of political

[2] According to the World Health Organisation, the "global health diplomacy brings together the disciplines of public health, international affairs, management, law and economics and focuses on negotiations that shape and manage the global policy environment for health. The relationship between health, foreign policy and trade is at the cutting edge of global health diplomacy". Available at: https://www.who.int/trade/diplomacy/en/ . Last access on 28/01/2020.

interactions, the diverse of public and private actors involved, and the existential value of health politics for people across the world'.

After World War I (particularly after World War II and the Cold War) the participation of civil society institutions and social movements in the international agenda started to increase. These multiple civil initiatives were seeking to build participatory democracies, to preserve collective interests, and to influence decision-making processes. When it comes to health, social participation is broadly recognised as essential to promote health equity and to empower affected communities. For instance, interaction, consultation, and cooperation with civil society have been encouraged by the World Health Organization since the launch of its constitution in 1948. It is important to note, however, that the growing influence of non-State actors in the health field, alongside the need to achieve global and national health goals, has prompted a review of non-State actors' roles in health, both within and beyond the WHO.

In order to comprehend the role and importance of these (not so) new actors, it is imperative not only to understand the different concepts of global health but also those related to health governance. Rosenau (2000) distinguishes governance from governments by relating governance with activities united by common goals, supported or not by formal responsibilities, that do not rely on coercive power to be accepted. Thus, health governance implies 'the use of formal and informal institutions, rules and processes by states, intergovernmental organisations, and non-State actors to deal with challenges to health that require cross-border collective action to address effectively' (Fidler 2010, p. 3).

According to Dodgson, Lee and Drager (2002), the essential elements of global health governance are: (1) deterritorialisation, i.e. to ignore the geographical boundaries of states; (2) the definition of determinants of health from a multi-sectoral perspective; and (3) the involvement, both formally and informally, of a broader range of actors and interests.

As mentioned above, once restricted to domestic politics, health has increasingly become an important macroeconomic and political factor in all societies and, as a consequence, governments, businesses, communities, and citizens are more engaged in health-related issues. Additionally, pluralism, a political theory that aggregates a set of other theories such as complex interdependence, institutionalism, and decision-making, assumes that, despite politics and decision-making mostly being placed within the framework of government, all types of actors can affect political outcomes. This means that international

diplomacy and action cannot operate on a separate sphere, excluded from global civil society. Although it is not possible to estimate the precise number of current non-State actors, especially because these categories are very difficult to define and to monitor, Willetts (2001, p. 358) illustrates the importance of non-State actors numerically:

> While there are less than 200 governments in the global system, there are approximately: 60,000 major transnational companies (TNCs), such as Shell, Coca Cola, Ford, Microsoft, or Nestlé, with these parent companies having more than 500,000 foreign affiliates; 10,000 single-country non-governmental organizations (NGOs), such as Freedom House (USA), Médecins sans Frontières (France) (…); 250 intergovernmental organizations (IGOs), such as the UN, NATO, the European Union, or the International Coffee Organization; and 5,800 international non-governmental organizations (INGOs), such as Amnesty International, the Baptist World Alliance, the International Chamber of Shipping, or the International Red Cross, plus a similar number of less-well-established international caucuses and networks of NGOs.

Given this scenario, this first chapter aims to discuss the importance of the four non-State actors considered by FENSA - non-governmental organisations, private sector, philanthropic foundations, and academic institutions - in the global health agenda. A literature review was conducted aiming to synthesise the current studies and to identify the gaps of NSAs, Global Health and International Relations research.

Considering that an academic literature review selects the available papers on the topic 'to fulfil certain aims or express certain views on the nature of the topic (…) and [to carry out] effective evaluation of these documents in relation to the research being proposed' (Hart, 1998), the main objective of this chapter is to demonstrate how the research topic fits into a wider context. The goal is, by examining the background that involves non-State actors' influence on the global health agenda, to be able to understand why FENSA should be an important tool to improve transparency and advocacy with regard to the increasing role of these actors, and unequal power dynamics.

The proposed literature review involves more than merely summarising the findings of the existing literature. My main goal is to contextualise the role of each non-State actor in global health through an examination of ideas and perspectives. The aim of the chapter is to answer two questions. Firstly, what are the current political issues and debates related to the four non-State actors? Secondly, what is the current state of knowledge about them concerning global health and international relations?

Two databases were chosen considering their notoriety regarding the health and social sciences perspectives: Web of Science and PubMed. The inclusion and exclusion criteria

were outlined with included papers focusing on the general role or impact of each NSA in the global health agenda. The first step was to use the same search terms in both search engines to see how many works related to them are available, as the table below exemplifies:

Search Terms	PubMed	Web of Science
'non-governmental organizations'; 'global health.'	155	61
'private sector'; 'global health.'	830	95
'philanthropic foundations'; 'global health.'	9	14
'academic institutions'; 'global health.'	437	53

To avoid double counting, I checked if any article appeared as a result in both search engines. Titles and abstracts of articles obtained from database searches were reviewed to identify which articles should be analysed. Articles that were seen as potentially relevant were assessed further through a full-text review. Articles were excluded at this stage if the information presented was not related to the influence of the NSA on the global health agenda and governance. To summarise, this first chapter can be seen as a classic and 'traditional' narrative review. In other words, a review of the existing literature whilst making a qualitative interpretation of prior knowledge.

Paré and Kitsiou (2017) argue that a narrative review summarises or synthesises what has been written on a particular topic but does not work towards a generalisation about what is being reviewed. Rather, the goal is to synthesise the literature in order to reveal the importance of a particular perspective. The authors, however, warn that the traditional narrative review is criticised due to the subjectivity of selecting information from primary articles, and also because it does not have clear criteria for inclusion, leading to potentially biased interpretations. Regardless of these criticisms, the narrative review is valuable when gathering and synthesising a great amount of literature in a specific subject.

When conducting the literature review, the term *philanthropic* might have skewed the

results, given that foundations can be described in different ways, such as 'charitable foundations', or simply by their names, e.g. Bill and Melinda Gates Foundation, Global Health Foundation. However, the goal is to analyse the NSAs in the Global Health scenario as defined by the World Health Organisation, therefore, the search terms used were those named in the Framework of Engagement with non-State actors. Moreover, as will be explained further, one of the weaknesses of current research relating to philanthropic foundations is the focus on a small number of institutions without a critical analysis of the broad context.

1.1 Non-Governmental Organisations

The Oxford Dictionary defines a non-governmental organisation (NGO) as 'a non-profit organisation that operates independently of any government, typically one whose purpose is to address a social or political issue'.[3] For the World Bank (WB) it is a 'private organisation that pursues activities to relieve suffering'.[4] The term was coined in 1945 as the United Nations needed, in its Charter, to distinguish the participation rights for intergovernmental agencies and private organisations. Overall, NGOs can be described as organisations that are independent of governmental control and can embrace private individuals or associations, organised on a non-profit and voluntary basis to reach common purposes in specific areas. NGOs can operate at the local, national or international level.

There is no accurate data about how many NGOs there are in the world, but their growth since the 1990s is undeniable. According to the Human Development Report, only the United Nations Economic and Social Council grant consultative status to more than 4,500 non-governmental organisations (UNDP, 2016). It is speculated that across the world the number of NGOs operating internationally is around 40,000. If considering local and national NGOs, some estimate that there may be 10 million worldwide.[5]

Non-governmental organisations have become key actors in many countries due to their cooperation with basic social services like health care and education. However, it is important to distinguish NGOs from philanthropies, as NGOs diverge from the notion of charity. NGOs are not-for-profit and can be political without being partisan, while keeping

[3] Definition available at: https://en.oxforddictionaries.com/definition/ngo . Accessed on 20/05/2019
[4] Definition available at: http://documents.worldbank.org/curated/en/809681468319759319/pdf/multi0page.pdf
[5] In 2013, when announcing the release of its annual Top 100 NGOs, *The Global Journal* affirmed that according to estimations of the Public Interest Registry (PIR), the sector encompassed close to 10 million organisations. Available at: http://www.theglobaljournal.net/group/15-top-100-ngos-2013/article/585/

straight cooperative relations with governments. Their distinctive characteristic is providing alternatives to conventional institutional practices whilst, at the same time, working close to these traditional actors. NGOs normally have technical competence, a category of 'professional activists' that although keeping a distance from religion, universities, or political activists, preserve connections with them. Moreover, NGOs usually have a direct and efficient dialogue with international entities and bodies, such as the United Nations and its specialised agencies – a relation that is central to this thesis.

Also, a very unique characteristic of non-governmental organisations is that their board members and business donors are mainly from 'developed' Western countries while the 'recipients' are 'developing' countries. It is precisely due to this complexity that NGOs have been adapting themselves to different conjunctures and specific fields.

As previously mentioned, civil society actors have considerably increased their involvement in global and local policy processes, including in the health field. According to the WHO (n/d), NGOs 'include (…) groups that represent consumers and patients, associations with humanitarian, developmental, scientific and/or professional goals and not-for-profit organisations that represent or are closely linked with commercial interests'. Considering that the civil society is helping to shape global health milestones, (like for example, the Framework Convention on Tobacco Control[6]), this topic of the chapter focuses on the literature review of non-governmental organisations and their role in the global health agenda. Of the 216 articles found in PubMed and Web of Science, 53 were not considered due to double counting. Then, after reading titles and abstracts, the articles below were believed to have contributed to the understanding of the role of NGOs in global health and will be explored.

Non-governmental organisations are important players in addressing global health challenges as they complement the efforts of international governmental organisations while balancing the self-interest emphasis of States and private business. Therefore, by using the International Society of Physical and Rehabilitation Medicine (ISPRM) as a case study,

[6] The WHO Framework Convention on Tobacco Control (WHO FCTC) is the first treaty negotiated under the auspices of the World Health Organization. (…) The treaty, which is now closed for signature, has 168 Signatories, including the European Community, which makes it one of the most widely embraced treaties in UN history. Member States that have signed the Convention indicate that they will strive in good faith to ratify, accept, or approve it, and show political commitment not to undermine the objectives set out in it. (…) The Convention entered into force on 27 February 2005 - 90 days after it had been acceded to, ratified, accepted, or approved by 40 States. Available at: https://www.who.int/fctc/text_download/en/ Last access on 04/03/2020

Reinhardt et al. (2009) analyse the multifaceted responsibilities that NGOs have, especially those in official relations with the WHO. According to the authors, NGO roles can be summarised as follows: 1) to catalyse international support for the improvement of public or collective goods and collaborate to compensate market and/or government failure due to an effective community involvement; 2) to influence the world media and policy agenda and consequently the public opinion as well as to spark social movements; 3) to mobilise resources and to deliver health services in a faster and flexible way; 4) to support the minorities and powerless majority groups; 5) to enable transnational research; 6) to define the field of competence, appropriate education and training curricula of professions as well as to set standards of knowledge and skills needed; 7) to bring players from diverse societal areas together, subsequently enabling a comprehensive problem-orientated discourse.

On the other hand, the authors argue that NGOs lack formal authority and may be biased due to conflicts of interest, which can arise from the influence and resources of their partners or donors. Moreover, as NGOs are commonly from the North-Western world, they may also act based on incorrect assumptions about the implementation capacities of developing countries, which could lead to unsustainable health systems and 'brain drain' of health professionals when monetary support is withdrawn. Although analysing a particular NGO, the article *International non-Governmental organisations in the emerging world society: the example of ISPRM* concisely depicts the increasing role of NGOs in activities once managed exclusively by states and international state initiatives. Finally, it is argued that besides official relations with the WHO, NGOs can also seek alliances with key external actors. They are, therefore, becoming powerful players within health policies, including when it comes to influencing the design of policies.

Regarding research capacity and correlated roles, Reinhardt et al. (2009) and Delisle et al. (2005) explain that although NGOs can take part in all phases of the research cycle: promotion and support of pertinent topics, priority setting, resource mobilisation, production, application and management of knowledge, and capacity development, this is normally due to partnership with universities, research and funding agencies, and other stakeholders. NGOs' goal, therefore, is to support the pursuit of effective global health research by ensuring that all these groups can work together. Regarding evidence collection, NGOs' role is greatly highlighted, as they often have close and trusting relations with citizens, given their

reputation for being very supportive in the development and distribution of information and evidence. To illustrate, human rights NGOs such as Human Rights Watch and International Amnesty have been collecting evidence and stories from victims and witness for decades.

Finally, the authors point out that NGOs can efficiently translate knowledge into action. At the same time, their research capacity efforts can increase research leadership (especially in low and middle-income countries (LMIC)) and support workforce capacity, both seen as part of implementation activities. The main critique, however, is that some NGOs might be selective about health research and the dissemination of findings, contributing to increased knowledge gaps. (Reinhardt et al. (2009) and Delisle et al. (2005)).

NGOs are also experts in spreading opinion and influencing political issues, contributing to what is called *world public opinion*, and giving them the potential to catalyse social movements that address specific issues. In this regard, Reich (2002) affirms that the information technology revolution has boosted new sources of power through a speedy flow of ideas, information, alliances and strategies; consequently, the hierarchy of States started to weaken. These technologies reduce States' monopoly of information and also increase the dissemination of alternative ideas.

Therefore, 'considering that the citizens of many countries do have no means to make their voices heard even locally, the notion of a global public opinion refers mainly to the confrontation in the world arena of a still limited number of citizens and elites' (Sorj, 2005, p.20). Sorj argues that some of the most important topics of the contemporary world such as human rights, feminism and environmentalism have shaped transnational public opinion through a complex process of forming global agendas. Accordingly, Reinhardt et al (2009) assure that NGOs can influence policy agendas and reorientate government priorities through public opinion.

As previously observed, one of the main capacities of non-governmental organisations is their leadership in addressing problems, whether local or global. It is possible due to their ability to cross borders and link perspectives from different social areas and groups. Moreover, NGOs often have a comprehensive problem-orientated discourse, focusing on the formulation of goals. In this regard, the literature shows that both international and domestic NGOs can help to institutionalise community-focused health strategies in partnership with national health systems as they normally have leaders who already cultivate relationships with government officials, communities, and other people of influence.

Clarke (1992) argues that NGOs can complement, reform, and/or oppose the State. Thus, according to Reich (2002), States are being reshaped by NGOs as some can take over social services previously delivered by governments at the national level. As mentioned previously, NGOs can usually be quicker and more flexible when translating knowledge into action, which means converting policy principles into social and political realities. Moreover, their role in managing and implementing programmes and policies is well-known, as well as providing support and acting between local communities and local governments, while endorsing civil rights principles and public interests. This can be seen as part of their actions as a 'watchdog'.

An illustration of NGOs' relevance at the local level is found in the article *Securitizing HIV/AIDS: a game-changer in state-societal relations in China?* Lo (2016) argues that although China has experienced impressive economic development, it happened alongside a harsh health crisis, marginalisation of infectious diseases and persisting deficiencies in public health provision. Moreover, concurrently to the economic reform, the HIV/AIDS epidemic was discovered and spread through the entire country. The author points out that due to the low priority of health policies since the economic reform and the restriction to 'third sector' activities in authoritarian China, combined with the political sensitivity of HIV/AIDS in the country, NGOs were constrained. However, acknowledging the prevalent health problems, the Chinese government adopted a 'state-led approach' to manage civil society: 'civil society is created by and belong to the State, thus the independence and autonomy of civil society are at all-time bounded by the state' (Lo, 2018, p.4). This approach, alongside the awareness of the impacts that health problems and infectious diseases could have on economic and social development, made the Chinese government stimulate the expansion of health-related non-governmental organisations to respond and support the failures of the government in delivering public health.

Regarding a more international role of NGOs, their open dialogue and tight cooperation with international entities and agencies like the World Health Organisation, the United Nations Children's Fund, the Food and Agricultural Organisation, and the World Bank are essential. They have played a major role in setting up cooperation with other partners, including bilateral donors and the private sector, which can work jointly to improve awareness of health issues at the international, regional, and national levels amongst

policymakers and the general population.

The sociological debate about how NGOs can be an alternative created by governments in order to delegate the accomplishment of some public services to civil society goes beyond the objective of this research. However, it is important to note some problems presented by NGOs. The main one is probably legitimacy, considering that NGOs often have no formal authority or right to speak on behalf of others. A lack of transparency can also be mentioned, and, finally, the biased approach due to conflicts of interest that can arise from the influence of partners or donors. During FENSA negotiations, a Manichaean perspective emerged, in which NGOs were presented by many as the blameless agents of benevolence, and as private sector, evil entities seeking profit at any cost. However, as it will be detailed in chapter six, mainly by Interviewee 11 from Zambia, NGOs have increasingly accommodated the wishes of their donors to work within the system, instead of challenging it.

1.2. Private Sector

Among all the non-State actors analysed, the private sector was the one with more results in both databases, PubMed and Web of Science. Articles about private sector-specific actions in certain places were in general discarded as well as those related to their relationship with the WHO, considering that the third chapter will detail this. Hence, the aim was to select articles that could contribute in any way to an overall understanding of the actions and involvement of the private sector in the global health agenda.

As obvious as it may be, the private sector is the part of the national or local economic system that is not under direct state control, but is managed by individuals and companies, to make a profit. When it comes to health, the private sector includes any channel, facility or person that provides clinical or diagnostic services. (Bennett et al, 2017). Historically, it was since the 1990s that partnerships with the private sector in health-related issues became relevant, not only regarding the health agenda overall but specifically health systems in low- and middle-income countries. In this regard, the WHO (2018, p.2) states that ‘the private sector provides a mix of goods and services including direct provision of health services, medicines and medical products, financial products, training for the health workforce, information technology, infrastructure and support services’.

Advances in science and technology are perceived as the turning point for the participation of the private sector in health summed to the awareness that previous

interventions were not enough to address the increasing health challenges. To understand the challenges and opportunities that encompass the private sector, a first step is to recognise how extensive and heterogeneous it is in terms of size, objectives, and quality. The private sector in health can range from nomadic drug traders and individual clinical practitioners to business hospital chains and international private insurers. It is impossible to talk about the private sector in health without talking about the pharmaceutical industry - the main entity responsible for drugs and vaccines, essential to the prevention and treatment of disease. If on one hand it is widely recognised that the pharmaceutical industry brings numerous positive effects on health and, consequently, to the welfare of citizens worldwide; on the other hand it has become exceedingly commercialised, aiming to maximise profit.

Pagliusi, Ting and Lobos (2017) argue that after decades of intense competition for high-value markets, collaboration with developing countries has become critical, and the involvement of public and private sector investments essential, in order to develop new vaccines against emerging infectious diseases. However, while the global health community has advanced in providing already-existing vaccines to developing countries, there is a gap in the development of vaccines without a market in the North-Western world that should be addressed, as advocated by Barocchi and Rappuoli (2015).

This gap is commonly justified by the lack of economic incentives for the private sector to support investments needed for vaccine development. The authors clarify that sometimes industries may have the technology but do not use the resources in the development of vaccines to specific diseases because the priorities are utterly based on economic considerations, without taking into account the mortality, morbidity and/or potential social and economic impacts. The 2014–2015 Ebola outbreak in West Africa illustrates how a vaccine that was achievable years before was only developed after a humanitarian disaster forced the global health community to contribute efforts and resources. As the title *Delivering vaccines to the people who need them most* suggests, it is argued that a lack of leadership in decision-making bodies led decision-makers to use an erroneous economic analysis to decide on vaccine development. The authors also suggest a global effort that would include ‘a clear policy, global coordination of funds dedicated to the development of neglected disease and an agreement on regulatory strategies and incentives for the private sector’ (Barocchi and Rappuoli, 2015, p.1).

Regarding healthcare, although focusing on the performance of the private sector in malaria, Bennett et al (2017) explain that the private sector is often the first source of primary healthcare services, probably due to the availability and access to private providers, sometimes accounting for three-quarters of all treatments. In rural and poor areas, (and consequently with higher risks of malaria infection), informal private providers are frequently used. From this article, it can be inferred that countries where diseases like malaria, with high potential of spread, are common, and the population has limited access to the public sector, which itself is also very limited, support from the private health sector to provide healthcare is required. In this direction, Wadge et al. (2017) argue that health systems in many low-income and middle-income countries, such as those in Sub-Saharan Africa, rely on private providers.

In September 2018, Amina J. Mohammed, the UN Deputy Secretary-General, gave a speech[7] highlighting that 'one-third of health expenditure in Africa comes from private sources, (…) additionally, the private sector accounts for up to 60 per cent of the value chain for health, whether for medical provisions, manufacturing, distribution or retail'. Although it is not yet possible to achieve health targets without the contributions of the private sector, there are concerns about its role, mainly regarding accountability. Brinkerhoff (2004) argues that accountability is generally vague and undocumented, even though healthcare represents a key budgetary expenditure in all countries. The author suggests that suitable and transparent auditing should be a priority.

It is also important to note other problems that come with private sector engagement in health: inadequate regulation, insufficient access for the poor, increased risk of inappropriate treatment that maximises provider profit, and over-reliance on public sector trained staff (Wadge et al., 2017). According to Wadge et al., governments normally focus their efforts on primary care and prevention, aiming that the private sector can collaborate in the form of secondary and tertiary care. Private sector actions, however, must be complementary, fill gaps and always act in a manner that is integrated with local health system. This same vision is shared by Nachtnebel et al. (2015), who believe that the private sector can fill gaps even in the provision of primary health care while taking into account contextual factors, appropriate mechanisms for services provided, and governance arrangements. Nevertheless, simply

[7] Africa's Health Targets Cannot be Met Without Contributions of Private Sector - Deputy Secretary-General Tells High-level Dialogue (2018) Available at: https://www.un.org/press/en/2018/dsgsm.doc.htm

filling a gap is not enough, actions must be integrated within local health system and actors, including civil society, and an investigation of local context and capacities should be conducted.

The involvement of the private sector in health systems, especially in providing health services in low and middle-income countries, is under extensive debate both amongst academics and policymakers. Hallo de Wolf and Toebes (2016) highlight some arguments favouring an expansion of the private sector's role, which can be more resourceful and sustainable in providing higher-quality services and also offer a significant complement to usually deficient government-provided services. In contrast, opponents argue that private healthcare services are predisposed to market failure, whilst often delivering low-quality care. Moreover, the common use of private providers and high out-of-pocket expenditures, particularly in low- and middle-income countries, alongside low public financing of healthcare means they will not achieve universal health coverage.

The access to quality healthcare is a key component of universal health coverage. In this sense, Grépin's article *Private Sector an Important But Not Dominant Provider Of Key Health Services In Low- And Middle-Income Countries* (2016) shows that there is a varied range of health service providers in both the public and private healthcare sectors. While the private sector is known to provide more than half of all treatment for sick children in low- and middle-income countries, public providers seem to remain the dominant source of care for delivery, antenatal care, and modern contraception. Apart from differences in private sector usage according to socioeconomic status, urban and wealthier women tend to use the private sector more frequently than rural and poorer women. This, therefore, supports the argument that private provision is inherently inequitable as it naturally favours those who are more able to afford it.

When analysing the historical experience of the private sector in health, Jeremy Youde (2016) argues that 'private actors and philanthropies played similar roles and faced similar questions about their intentions and how they fit into the larger cross-border health governance processes'. He supports the argument that the emergence of both private actors and philanthropies is a consequence of gaps left by state-based actors. However, it is not because private actors are filling gaps where services are not being provided, that they cannot work together, transparently, with national governments and international organisations.

Although recognising efforts by international donors and national governments to strengthen public health systems in low- and middle-income countries, as well as the important role played by the private sector, especially in the delivery of maternal and child health services, the literature review reaffirms a remarkable variation in the use of the private sector worldwide and points out a lot of ongoing discussion about the right way to engage with it. Moreover, the private sector's biomedical perspective should be further discussed, as there is a lack of focus on addressing the social determinants of health and basic healthcare services. Private actors tend to prioritise scientific research and pharmaceutical development, not to mention a more technological approach. This is understandable, due to their orientation towards profit.

The private sector has undoubtedly become a core part of the global health scenario, and this was reflected during FENSA negotiations, as chapter 4 will show. Malloch-Brown (2017), however, emphasises that 'private-sector (sic) investments need to be responsible investments that accept the social contract that comes with being invited into the development sector (…) The world's poorest, most marginalised, and vulnerable people cannot be subjected to market capitalism that focuses only on short-term investment returns rather than long-term needs'.

Private sector investments, therefore, need to embrace governments and communities that are being assisted to guarantee the investment is responsible and long term. Finally, if the aim is to become a trust partner, the private sector needs to be transparent and accountable for its claims and commitments. When analysing the literature on the private sector role in health, it became clear why its participation at the World Health Organisation, which was legitimised through FENSA, was the main point of the negotiation process. Due to its profit-focused nature as well as historical episodes of undue influence, the private sector is generally seen as an actor that requires more attention, and this was reflected during FENSA negotiations.

1.2.1. Public-Private Partnerships

At the beginning, the literature review did not aim to contextualise the Public-Private Partnerships (PPP) in global health. But when looking at the participation of NGOs and the private sector, it was observed that many of the studies were about PPP. Moreover, during my field research I took part in several civil society meetings in Geneva, in parallel to WHO

Governing Bodies' conventions, and they were mostly very critical of the overspread concept of multi-stakeholder partnerships. The articles analysed in this subsection were selected from NGOs and private sector results. The goal is to briefly understand the collaboration between the business and public sectors in health.

According to the World Bank website,[8] a PPP is 'a long-term contract between a *private* party and a government entity, for providing a *public* asset or service, in which the *private* party bears significant risk and management responsibility, and remuneration is linked to performance'. The World Economic Forum[9] refers to it as 'a voluntary and collaborative agreement for cooperation among participants of equal capacities from various fields to accomplish a communal objective or to meet a particular requirement that carries with it a collective risk, liability, measure, and capability'.

Kraak et al. (2012) explain that not only agencies from the UN system but also public health experts have encouraged governments, non-governmental organisations and civil society organisations to tackle complex public health challenges by working together with the private sector through PPP. The WHO defines a public-private partnership for health as a 'wide variety of ventures involving a diversity of arrangements, varying about participants, legal status, governance, management, policy-setting prerogatives, contributions and operational roles. They range from small, single-product collaborations with industry to large entities hosted in United Nations agencies or private not-for-profit organizations'.[10] Broadly speaking, PPPs are coalitions planned to accomplish common goals that are expected to benefit society; however, part of the literature criticises the inadequate advocacy of these partnerships, since NGOs are compelled to act under corporate norms of work.

Historically, public-private partnerships ascended in the latter half of the 1990s, in a context where bureaucracies were seen as inefficient, and market mechanisms seen as a solution to efficiently promote development. Therefore, the influence of private actors in the decision-making process (on both a national and international level), and in global health governance, has grown exponentially with an increase in their political power, articulated to the growth of resources for health. According to Buse and Walt (2000), the term was coined

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[8] Available at: https://ppp.worldbank.org/public-private-partnership/overview/what-are-public-private-partnerships

[9] Available at: https://www.weforum.org/reports/strategic-infrastructure-steps-prepare-and-accelerate-public-private-partnerships Last access on 04/03/2020

[10] Definition available at: https://www.who.int/trade/glossary/story077/en/

in 1969 in the report *Partners in Development: Report of the Commission on International Development*, coordinated by Lester B. Pearson, former Prime Minister of Canada. However, until the 1970s, public-private partnerships within multilateral organisations did not exist, but some rare ones were established directly between donors and national governments.

Almeida (2017) explains that the economic crisis of the mid-1970s and the global rise of neoliberal politics provided the perfect scenario for the World Bank and the International Monetary Fund (IMF) to encourage structural macroeconomic adjustments, and to open public policies to the private sector. By overestimating the market and the entrepreneurial perspective concurrently to the disqualification of the State, social policies and the provision of public goods, PPPs became part of this dynamic. By joining resources and knowledge amongst industries, research institutions, governments and non-profit organisations, PPPs are seen by many as the solution to global health challenges, because they have expressively increased the resources available to global health action. For instance, funds allocated to the Global Fund to Fight AIDS, TB and Malaria and Global Alliances for Vaccines and Immunizations (GAVI) have grown from US$1.67 billion to US$4.9 billion over the ten years between 2005 and 2015 (Hawkes, Buse and Kapilashrami, 2017). PPPs are also perceived to have promoted enhancements in efficiency, equity, value for money, and outcomes of health challenges.

However, some authors have been extremely critical of this increasing, and sometimes unnoticed, participation of PPPs in health. Judith Ritcher (2012), for instance, argues that when the Global Alliance for Vaccines and Immunization (GAVI) was launched by UNICEF's Executive Director at the World Economic Forum in 2000 and the Global Alliance for Improved Nutrition (GAIN) at the UN General Assembly Special Session on Children in 2002, the presence of the main financial sponsor Bill Gates, also CEO of the Microsoft Corporation, revealed that the PPP model put private sector representatives on the decision-making board from the national to the global level.

It is important to note that those who advocate a more significant role of PPPs often argue about the non-distinction between the different actors involved, since they are all called partners, indiscriminately, regardless of their role in society. Almeida (2017), however, makes us aware that this biased uniformity hides the fact that public actors and different private actors do not have the same status, nor the same objectives and interests, and it ends up

relativising the legal role and legitimacy of intergovernmental public organisations. Taylor (2018) supports this argument by calling attention to power imbalances within this new form of governance that are hidden by the use of the term 'partnership'. Buse and Harmer (2004, p. 49) affirm that the 'northern elite wields power through its domination of governing bodies and also through a discourse which inhibits critical analysis of partnership while imbuing partnership with legitimacy and authority'.

Some authors attest that the growth of PPP has opened spaces for civil society participation in global health governance, which can not only contribute to legitimacy, but also democratise global governance processes. However, others argue that although civil society participation is almost universally recognised, there is scarce evidence of such engagement within contemporary global health governance mechanisms and processes - therefore giving civil society a place in decision-making processes of global health would represent a way to respond to critiques regarding the legitimacy and authority of the partnerships. (Storeng and Bengy Puyvallée, 2018). The public-private partnership model is also criticised for its hint at privatisation, undue influence on decision-making processes and promotion of an excessive focus on high-tech solutions for health problems, ignoring the social determinants of health. A result-driven approach, therefore, also has to be considered.

Notwithstanding increasing criticism, public-private interactions are expected to rise across all sectors, mainly health. The partnerships are seen, or are promoted, as mechanisms that can integrate the strengths of private actors (such as innovation, technical knowledge and managerial efficiency), with the role of public actors, (such as social responsibility, social justice, public accountability and local knowledge). The United Nations Agenda 2030 for Sustainable Development, for instance, enthusiastically advocates for countries to 'encourage and promote effective public, public-private and civil society partnerships, building on the experience and resourcing strategies of partnerships'.[11]

A stronger joint workforce is widely recognised as a way to boost public health goals. However, it is important to bear in mind that PPPs have become increasingly powerful actors. They constitute a major source of funding for health programmes in low- and middle-income countries and exert influence over health decision-making at national and global levels (Storeng and Bengy Puyvallée, 2018), which raises justified worries about legitimacy,

[11] Target 17.17: Public, private and civil partnerships. Available at: https://stats.unctad.org/Dgff2016/partnership/goal17/target_17_17.html . Last access on 04/03/2020

priority-setting, resource allocation and accountability.

1.3 Philanthropic Foundations

Of all non-state actors analysed in this chapter, philanthropic foundations were the least researched topic. Only 14 articles were found in PubMed and Web of Science when using the broad term 'philanthropic foundation'. However, when using 'Bill and Melinda Gates Foundation' and 'global health', the results increased to 287 articles on PubMed. It is interesting to note that Interviewee 1 warned to 'not just focus only the BMGF. The Ted Turner Foundation, for instance, is just as important. It had a 'secondment' at the highest level in WHO as Member States found out after asking repeatedly for a list of secondments'. It can be noted that even though philanthropic foundations have a historical role in health (such as the Rockefeller Foundation, as it will be further detailed), the Bill and Melina Gates Foundation is almost the only emphasis of the current literature. Therefore, it can be concluded that apart from BMGF, philanthropic foundations are still an unexplored subject, despite their incontestable relevance.

Firstly, it is important to highlight that as Anheir and Daly (2005) describe, 'philanthropy is a culturally and historically specific concept that, in the most general terms, refers to the voluntary use of private assets (finance, know-how, among others) to the benefit of specific public causes'. Historians such as Karl and Katz (1987) point out that the earliest philanthropic foundations have distinguished themselves from charities by directly addressing public and social problems, to systematically explore their causes and generate long-term solutions, rather than just relieve them. Further, Salamon (1994) argues that the inherent limitations of States, allied with growing citizen activism, triggered a significant increase in private non-profit activity in every corner of the world. One should also consider the rise in inequality. According to Oxfam (2002),[12] the richest 1% of billionaires have more than twice as much wealth as 6.9 billion people, and normally prefer providing through private foundations instead of paying to governments.

One could inquire, in times of economic crisis and consequent cuts in essential social sectors, what could be wrong with voluntary donations from private wealth to benefit the people?

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[12] Available at: https://www.oxfam.ca/news/worlds-richest-1-have-more-than-twice-as-much-wealth-as-6-9-billion-people-says-oxfam/ Last access 09.03.2020

Supporters of philanthropy argue that foundations can improve existing international health structures by not only injecting additional resources but also dealing with the control and eradication of infectious diseases. Thus, foundations tend to be vehicles for the semi-privatisation of certain tasks that are not so easily or efficiently carried out by States, given the limitations of public administration.

Although rules apply differently from country to country, private foundations tend to be exempt from federal taxes. Behind the bewildered generosity of billionaires who don't know what to do with their money, is the recognition that philanthropy cannot substitute the tax system and public investments in poverty alleviation, infrastructure, economic opportunity, and social protection. Therefore, private foundations should not benefit private (or their own) interests, particularly because their tax exemption implies that their work justifies the redistribution of taxes from their private accounts to public programs. As philanthropic assets can sometimes replace public funds, it is important to keep in mind that the public fund mirrors the priorities of public policies, and should ensure resources for the financing of necessary social policies. Moreover, as Rausch (2018) points out in her article *The Birth of Transnational U.S. Philanthropy from the Spirit of War*, foundations can ignore the State's – where it comes from – position and policies and act according to its interests, as happened during the First World War in the case of the Rockefeller Foundation.

On the other hand, besides advocating objectivity and non-involvement, since their main goal is to promote development, the actions of philanthropic foundations can be dubious and interest-driven, as Rausch (2018, p.652) explains: 'the outbreak of war in Europe seemed a suitable laboratory to pursue their managerial, progressive visions for optimising the state of American affairs (….) Rockefeller philanthropists also pursued a preparedness agenda for intervention abroad'. In this sense, the article details how the RF moulded the wartime philanthropic agenda, specifically through committing to European relief work - a strategy linked to US government plans to use foreign aid as a stabilising instrument for intervention in the post-war world.

When it comes to the health agenda, Rausch (2018) elucidates that the anti-tuberculosis campaign in France, led by the Rockefeller Foundation, was less a consequence of the uncommon circumstances of war than a domestic and international strategy to promote the professionalisation of medical experts focused on campaigns against hookworm, malaria,

tuberculosis, and yellow fever. Accordingly, the RF started to widen its interventions (a so-called 'civilising mission') outside the U.S. borders through 'operations against diseases and epidemics in Latin America (Cuba and Panama) and the British Caribbean before expanding further into the tropical sphere' (Rausch, 2018, p.656). Besides using the American-occupied places as 'laboratories for implanting racialised medicine and health concepts', according to the author, the Rockefeller health interventions were made aiming not only to fit the Foundation in an inter-imperial public health system with the European powers, but also to focus on regions either with potential for American colonial expansion or that had gained geopolitical strategic attention due to the First World War.

Finally, Rausch's critiques of the RF's operations in the WWI period is quite similar to those made of contemporary philanthropic foundations. For example, involvement in regions with geo-strategic importance, actions and projects that are based on standardising the laboratory-biomedical approach, which normally downplays social-economic contexts and long-term solutions. Contrary to Rausch's article, the role of new actors, specifically philanthropic foundations, is often seen as having many positive elements without critical analyses of their problematic and negative outcomes. For example, Santos and Franco-Paredes (2011) argue that public health initiatives from philanthropic foundations, non-governmental organisations, and bilateral or multilateral international donor organisations have produced considerable improvements in Latin America. The authors emphasise that the Rockefeller Health Foundation contributions were essential for public health in Latin America in the first half of the twentieth century. The contributions started targeting the reduction of port diseases associated with the maritime exploration of commercial routes – e.g. yellow fever, cholera, malaria, and other tropical diseases. Later, programs to improve living conditions were included, with nutritional interventions and maternal-foetal health.

By way of comparison, the article Philanthrocapitalism (2014), written by Anne Emanuelle Birn, severely criticises these influential global health players. Birn (2014) argues that the Rockefeller Foundation presence enabled and naturalised the dissemination of a structure of institutions and policies, and also ideologies and practices which were all defined by the foundation, often to the detriment of local knowledge and interests. Moreover:

> 'RF's efforts went well beyond health, stabilising colonies and emerging nation-states by helping them meet the social demands of their populations, encouraging the transfer and internationalisation of scientific, bureaucratic, and cultural values, stimulating economic development and growth, expanding consumer markets, and

> preparing vast regions for foreign investment, increased productivity, and incorporation into the expanding system of global capitalism' (BIRN, 2014, p. 4)

In this sense, Anheier and Leat (2002) in the book *From charity to creativity, philanthropic foundations in the 21st century* claim that organised philanthropies operate outside of social and economic realities.

The article *Challenges for nationwide vaccine delivery in African countries* written by Mario Songane (2018) investigates the role of the Global Alliance for Vaccines and Immunizations (GAVI)[13] in the development, purchase, and delivery of vaccines, and how the Bill and Melinda Gates Foundation (BMGF) acted as a sponsor. To illustrate, the author gives Zambia as one example of a government that, due to the small percentage of their national budget, dedicated to routine immunization programmes, needs support from GAVI, currently the largest external funding source for vaccine purchases in Africa.

According to Songane (2018), since 1999, the BMGF has spent over US$2.5 billion on GAVI projects. However, the money is precisely addressed to 'the multiple challenges in vaccine delivery (…) and these grants could be used to build and equip research laboratories and manufacturing units in various African countries' (p. 214). Regarding this, Birn (2014) warns that whereas the BMGF has injected 'life' into the global health field, it follows a technically-oriented approach, with programs planned to achieve positive evaluations, and launches the global health agenda through narrowly-defined goals, focusing on short term achievements. These actions, while important, do not embrace the 'Health for All' movement of the World Health Organisation, which proposes that resources for health should be consistently distributed and essential health care accessible to everyone. The 'Health for All' focus is on long-term solutions to tackle health inequalities.

In a context of financial stagnation, a crisis of legitimacy of foreign aid, and the growing burden of chronic diseases and cutting social expenditures, the role of philanthropic foundations in global health has been increasing in tandem with health challenges. In this sense, Owain D. Williams' article *Access to medicines, market failure and market intervention: A tale of two regimes* (2012) analyses how philanthropic foundations interfere in the global pharmaceutical market 'either with respect to drug prices (through subsidisation,

[13] GAVI is a public-private partnership created in 2000 and includes key United Nations (UN) agencies, governments, the pharmaceutical industry, the private sector and civil society. The Bill and Melinda Gates Foundation gave US$750 million for its creation (SONGANE, 2017)

negotiation or other forms of financing), or in terms of innovation and R&D, and sometimes with combinations of these two basic strategies'. Consequently, they have created what the author calls a multifaceted global pro-access regime to medicines.

According to Williams (2012), international development, associated with the Millennium Development Goals, has shaped philanthropic foundations' activities in increasing access to medicines. It was in this context, led primarily by the G8 and World Bank, that the new global health governance regime was created, and with it, initiatives such as the Global Fund and GAVI. What should be noted is that a template for what these agencies should do in global health, as well as their governance role, was mainly settled by major donors. These 'new actors' describe themselves as a new modality of health assistance and their actions were presented as an essential step towards (economic) growth and poverty alleviation through selected disease interventions. Additionally, their programmes need to demonstrate results in the short term to legitimise their worth and satisfy donors.

Another point that is important to emphasise is the global health agenda focus on the 'big three diseases' (malaria, HIV/AIDS and tuberculosis) - philanthropic foundations actively contributed to this, instead of bringing attention to the lack of acknowledgement of other diseases, such as the neglected tropical diseases (NTDs). Fenwick, Zhang, and Stoever (2009) argue that among the NTDs, seven are preventable by simple yearly oral drug treatment, and the elimination of one NTD would be possible after seven years of annual treatment. The article *Control of the Neglected Tropical Diseases in sub-Saharan Africa: the unmet needs* illustrates that despite a growing recognition of the importance of NTDs, a greater integration of NTD control from WHO, the Gates Foundation and the USAID, (and consequently more funds dedicated to controlling these diseases), it is not enough as the funds in total are less than a quarter of the continent's needs. The authors also point out that some existing programmes had funding for only a few years, and without guaranteed funding, control programmes cannot be sustainable. McCoy et al. (2009) argue that the BMGF's strategy is to concentrate efforts on priority diseases which enables their focus on vaccines and technology - clearly not the case of the NTDs. They also affirm that the Gates Foundation's power is boundless, and many academics feel inhibited to confront them, also because the Foundation sponsors several researchers based in elite academic institutions in the global North countries.

This led to and supports Laurie Garret's (2007) main argument that if the biggest problem in global health was once the lack of resources accessible to tackle increasing health challenges, nowadays, while a lot of money is available, the actions are largely uncoordinated and mostly directed to specific diseases, rather than at public health in general. In addition, Anne Emanuelle Birn (2014) maintains that philanthropic foundations take the State's role in social protection, cherishing voluntary efforts in place of citizen's rights and, consequently, weakening the State in the face of private initiative in the provision of social welfare services. Critical voices such as Nielsen (1972) also point to the inherent democratic deficit of foundations, since they are not subject to market forces or consumer preferences, nor do they have an affiliation or constituency to oversee their decisions and performance.

Potential conflicts of interest resulting from the action and influence of philanthropic foundations on the global health agenda is also observed, and was extensively discussed, during FENSA negotiations. The legal meaning of conflicts of interest under US law is 'a situation in which there is a real or apparent incompatibility between private interests and public or fiduciary duties.'

Stuckler et al. (2011) explain that, historically, foundations have kept the management of their donations and the decisions of donations separated. However, these practices and the degree of separation can differ in each foundation. Despite the existence of explicitly designed policies to mitigate potential conflicts of interest, the boundaries between foundations, their investments, and their parent companies or private lenders, may become blurred. Often directors of founding councils also sit on the board of private companies, taking on multiple roles. In this regard, Birn (2014) shows that constant accusations surrounding investment in pharmaceutical companies, industries associated with environmental and health crises, as well as private companies that profit from philanthropic support of global health initiatives, have led to the Gates Foundation giving up their role in the pharmaceutical sector in 2009.

Finally, one should not overlook the importance of philanthropic foundations, or of any actor involved and interested in improving global or public health, as it is shown that although governments remain the major source of Development Assistance for Health (DAH), accounting for about 70% of the total, private sources (foundations, NGOs and corporations) have grown from 6% in 1990 to 16% in 2000, and to 17.3% in 2014, with the

largest single contributor being the Bill & Melinda Gates Foundation (Moon and Omole, 2017).

Ravishankar et al. (2009) point out that the proportion of DAH conducted by UN agencies and development banks decreased, whereas the Global Fund to Fight AIDS, Tuberculosis and Malaria, the Global Alliance for Vaccines and Immunization (GAVI), and non-governmental organisations became key channels for health actions and interventions. This escalation, in both funds and actions, was mainly possible due to increased philanthropic donations and in-kind contributions from corporate donors. It may also be worth noting that the Bill and Melinda Gates Foundation funded the study.

Although it is undeniable that the WHO crisis of legitimacy (that will be further discussed in chapter 2) added to a context of economic stagnation encouraged by the participation of other actors in the global health agenda, there is an alarming lack of transparency and undue power over the public good - specifically an increasing and uncontrolled dependence on philanthropic foundations' resources.

1.4 Academic Institutions

Academic institutions, normally referred as research institutions, are key actors that set the overall agenda, develop expertise in global health, and specifically address health inequalities. However, when it comes to policy and decision-making processes, they unfairly become overlooked players. When discussing the influence of non-State actors in health, the focus is on where the money comes from - the private sector and the contemporary increasing role of philanthropic foundations.

Despite the gradually increasing presence of academic institutions in the world of health care (there are much more articles about academic institutions and global health than about NGOs or philanthropic foundations), little has been done to unveil how, by whom and to what ends they operate, nor how they can influence the global health agenda. Therefore, this literature review shows that most of the research is narrowly focused on international curriculum and academic partnerships to tackle specific problems and diseases, or domestic gaps in scholarly activities, especially in low and middle-low income countries (LMIC).

Kickbusch and Hanefeld (2017), however, point out that think tanks and academic institutions can (and must) 'play a key role in political decisions that aim to tackle inequalities, shape healthy living and working environments, and ensure universal health

coverage at both a national and global level' (p.2), given their indispensable partnerships with international agencies and foundations, international organisations, non-governmental organisations, and the private sector, among others. The authors advocate that academic institutions could also behave as mediators between stakeholders from many areas, not only to develop relations and networks but also to allow better dialogue amongst the general public, decision-makers, and civil society.

Bennett et al. (2012) indicate that, recently, a rise in the number of independent health policy analysis institutes is being observed, especially in the LMICs, as a consequence of the limitation of governments' analytical capacity and pressures for accountability. These NSAs are important both nationally and supra-nationally, as they can bring together global policy actors with national level implementers, and those most affected by global policies. However, only 15 articles out of the 437 found in the Pubmed database have this perspective.

In this regard, the main argument of the article *Academic Medical Support to the Ebola Virus Disease Outbreak in Liberia* written by McQuilkin et al. (2017) is that academic medical support has 'resources to offer in humanitarian crises, including the ability to leverage funding and faculty members with expertise and experience in basic and clinical sciences'. The worldwide mobilisation of researchers during the new COVID-19 epidemic[14] is a current example of synchronised action within academia. Conversely, if unprepared, it can hinder or slow the humanitarian response, as firstly happened in Liberia during the Ebola outbreak. The American residents and fellows had their return to West Africa limited because of the risk of contracting Ebola, whilst Liberian trainees were left on the frontline without support. As the epidemic progressed, few faculty members kept teaching and hospitals were under siege, trying to treat infected patients. The outcome was drastic - Liberia lost 8% of its already-limited health care workforce during the epidemic.

Another example to emphasise the role of academic institutions as partners of important stakeholders is the Medical Education Partnership Initiative (MEPI), established in 2010 to increase the number of medical graduates, the quality of their education, and their retention in Africa. Noormahomed et al. (2017) explain that the partnership's goal was to strengthen medical research capacity and was supported by the U.S. President's Emergency

[14] A pneumonia of unknown cause detected in Wuhan, China that was first reported to the WHO Country Office in China on 31 December 2019 and declared a Public Health Emergency of International Concern on 30 January 2020. On the date of this thesis, there are 93.000 cases confirmed globally.

Plan for AIDS Relief (PEPFAR), which allowed African institutions to receive grants to implement MEPI from 2010 to 2015. Apart from enabling growth in the numbers enrolled in medical school , the partnership supported curricula revision, recruitments, the expansion of clinical skills laboratories and the strengthening of computer and telecommunications capacity. Overall, a more robust community of practice in medical education and research was formed by bringing together governments and academic institutions.

In this direction, when analysing the Global Fund to Fight AIDS, Tuberculosis and Malaria, Kiefer et al. (2017) highlight the importance of operational and implementation research. The main goal is to support an evidence base for context-specific execution of global interventions, and recognise what prevents programmes from operating successfully. The leading implementers of studies funded through Global Fund grants were the Ministries of Health (MoH), but NGOs and academic institutions were also involved. The main barrier identified was research capacity, specific technical capacity (research methods, for example), time, and funding. According to the authors, 'technical capacity has often been reported to be concentrated within selected institutions (for example government research institutes and academic institutions), resulting in qualified staff and technical capacities being heavily centralised in the capital cities' (Kiefer et al., 2007, p.5). The recommendation from the Global Fund secretariat is that academic and research stakeholders should be closely involved in the elaboration of concept notes. The authors also point out that policy-making and decision-making are not always evidence-based, and this argument is supported by Allen, Lavis, and Shemer (2016).

According to the WHO (n/d),[15] health policy and systems research (HPSR) is an emergent field that seeks to understand and improve how societies organise themselves to accomplish collective health goals, and how different actors can co-operate in the policy and implementation processes, to contribute to the outcomes. It can be observed, hence, that to integrate HPSR into decision-making is simultaneously essential challenging, since it primarily involves two actors: researchers (the knowledge producers) and the policy-makers (the knowledge users). However, Allen, Lavis, and Shemer (2016) argue that, frequently, health policies and management decisions are made without using or consulting the greatest research evidence offered, which can lead to ineffective and inefficient health systems.

[15] Available at: https://www.who.int/alliance-hpsr/about/en/ . Last access on 05/03/2020

The authors conducted a study case of Israeli health systems to find out the limits of the use of academic knowledge and evidence in the policy-making process. It was recognised that researchers are one of the key actors to ensure the use of evidence, while 'government/ provider relations, policymakers lacking the expertise for acquiring, assessing, and applying HSPR and priorities in the health system drawing attention away from HSPR' are the barriers (Allen, Lavis and Shemer, 2016, p.7). It was also noted by the same authors that, (at least in the case of their study), health insurance funds and physician organisations also have a strong influence in the policy-making process.

Considering the articles analysed, it can be argued that health systems and, consequently, health outcomes, would have undoubted benefits and advantages if researchers could work efficiently together with governments and other stakeholders.

Furthermore, academic institutions are recognised to play an important role in healthcare workers supply, distribution, and migration in the context of an increasing brain drain, as defended by Jennifer Kasper and Francis Bajunirwe (2012). The WHO and World Bank currently estimate a potential worldwide lack of 18 million skilled healthcare workers (SHWs) by 2030, with the weight projected to fall largely on LMICs, particularly sub-Saharan Africa (WHO, 2016). Considering that nowadays 57 countries face severe shortages in their healthcare workforce, it is not a surprise that the migration of SHWs is recorded as one of three main factors that threaten health systems in SSA. With this scenario, the authors argue that inter-country collaborations between organisations and researchers could offer more opportunities for professional progress without migrating.

As analysed in this item, a vast range of organisations, actors, coalitions, activities, and interactions work together to shape the policy-making health processes. Although academic institutions are included in this miscellaneous crowd, a common complaint about lack of evidence-based actions shows that they are undervalued actors, especially concerning policy-making. It was clear during the investigation of the FENSA negotiation process, as academic institutions were the non-State actor less involved and less mentioned by the interviewees.

Thus, there is a clear opportunity for health institutions (academia, think thanks) to positively engage in promoting evidence-informed decision-making in governments as well as support the development of solutions to some challenges, for example, some degree of independence in governance and financing. Moreover, establishing partnerships with health

service delivery platforms (such as non-governmental organisations or the public sector) would also strengthen patient care and public health interventions by exploiting expertise on the research and training of academic institutions.

Finally, academic institutions should not only be centres of excellence in research but should also seek to dialogue with policymakers at all levels, not only due to an evidence base, but also to improve integrated monitoring and strengthen evaluation mechanisms. Accountability is crucial and should be pursued by academic institutions, since current global health actions lack independent monitoring of policy commitment.

CHAPTER TWO: THE CRISIS AT THE WORLD HEALTH ORGANIZATION AND THE GESTATION OF THE FRAMEWORK OF ENGAGEMENT WITH NON-STATE ACTORS, WHY DID IT ALL START?

To understand how the Framework of Engagement with non-State actors was conceived, it is important to take some steps back and see how, after 60 years of respected leadership, the World Health Organisation got involved in a crisis of identity characterised by underfunding, incoherent policy prioritisation and administrative disputes. This second chapter aims to present a historical perspective of the WHO by clarifying its governance, structure, policies, priorities, financing and management. The first question for this approach will be whether history-driven analysis has relevance to global health, broadly speaking, or to the FENSA negotiation process. The historical perspective on health can be clarified with reference to Hobsbawm (1972). The author introduces the idea of the 'social function of the past' as a tool to understand how the transformation of society occurs. In this research, the transformation of the International Health scenario, specifically its institutions, is characterised by the constant tension between past and present. This research recognises history as scientific knowledge, essential to understanding the present.

In this second chapter I propose a historical perspective that methodologically and analytically perceives health strategies and policies as phenomena linked to the nuances of the social and historical context. What will lead to a deeper understanding of the WHO's complexities and, consequently, to a truthful comprehension of the governance of the WHO? What is the role of FENSA in this context?

2.1 A Historical Perspective of the World Health Organisation

History has a key function in enabling the understanding of the past and increasing the comprehension of the present. It is impossible to understand a complex negotiation like FENSA without returning to the history of international public health, and consequently, the creation of international health institutions. According to Pires-Alves, Paiva & Hochman (2008), the return to history is not an isolated movement in the field of public health; since the mid-1980s the Anglo-Saxon social sciences have been bringing back the past, not only in training and practice, but as part of the analysis of health policies, due to an understanding that 'public policy is always history'. Correspondingly, the authors point out that Charles

Rosenberg claims that history's greatest contribution to health policy would be its fundamental sense of complexity, and also as a way to prevent depoliticised contexts.

Although it was not until 1948 that the World Health Organisation was established as a specialised agency of the United Nations, joint efforts focusing on international health cooperation began almost a century before, with the first International Sanitary Conference in Paris in l851. Due to the increasing trade and travel that, consequently, aggravated outbreaks of diseases in Europe, 'the French Government was inspired by the (…) desire that international agreement should be reached on the standardisation of quarantine regulations aimed at preventing the importation of cholera, plague, and yellow fever' (Aginam, 2005, p.62). The early International Sanitary Conferences are considered a first attempt to establish a mechanism for international cooperation for disease prevention and control. When analysing the history of international health, it can be said that, between 1851 and 1902, the focus was on meeting and agreements to share information on epidemic outbreaks. In 1892, for instance, the International Sanitary Convention for the control of cholera was adopted.

Later, the period that starts with the creation of the International Sanitary Bureau (a precursor to the Pan American Health Organisation, PAHO) in 1902 and continues until 1939 is considered a time of institution-building. In Europe, L'Office International d'Hygiene Publique (OIHP), commonly known as the 'Paris Office', was established in 1907. Its main responsibility was 'to collect and bring the knowledge of the participants states the facts and documents of a general character which relate to public health and especially as regards infectious diseases, notably cholera, plague, and yellow fever, as well as the measures to combat these diseases' (Wortley, 1974, p.133).

Global health literature generally considers the OIHP to be the first formal international health institution, due to its permanent staff and main office. However, after the First World War, its limitations were exposed as the OIHP wasn't able to successfully mediate and communicate, in wartime, with deteriorated conditions, in order to address diseases. For illustration, between 1918 and 1919, it is estimated that influenza killed around 50 million people, as troops could not be warned about the outbreak of the disease.

Soon before the creation of the League of Nations Health Organisation (LNHO), in 1919, in Geneva, some health-related non-state actors started to arise. In 1913, the Rockefeller Foundation (RF) was created, aiming to develop 'the well-being of mankind

through the world'. Through the International Health Board, charged with the 'promotion of public sanitation and the spread of knowledge of scientific medicine', the RF became not just a significant player but went on to shape international health actions and interventions, as was analysed in the previous chapter.

Regarding the LNHO, according to Birn, Pillay and Holtz (2009), the initial idea was to include the Paris Office in the health office to be created as part of the League of Nations. The French government, however, wanted to preserve the OIHP, while the United States declined to join the League, and consequently hampered the union. Initially, the LNHO's main goal was the epidemic crisis after the First World War. Nonetheless, as an international organisation, it also assumed both a technical and social role. It is important to note that at this moment, there were three independent official international health institutions: the OHIP (Paris Office), the International Sanitary Bureau in Washington and the LNHO in Geneva.

It is worth noting that the creation of the LNHO occurred in a context that Hedley Bull calls 'idealistic' in his article *The Theory of International Politics 1919-1969*, which generically is characterised by several theorists who believed in the idea of progress and the possibility of an evolution in international relations, in order to lead to a more peaceful world. The creation of international organisations would therefore be a way to promote the ideal of peace and security among States in a post-war scenario. In this regard, Weindling (2006) points out that the idealistic view inspired the LNHO that the equitable provision of health and welfare could reduce internal social conflicts, and, consequently, help to avoid another war. The emergence of idealism theory in international relations spread the perspective of transferring internal stability to the international stage. The focus of idealistic theorists was not to comprehend historical experiences, but to elaborate new models and solutions, while arguing why the future should not have to repeat the past. The League of Nations was the idealists' envisaged outcome, as it emphasised the harmony of interests between all peoples disregarding the superficial conflicting interests of their states or governments.

Apart from setting biological standards, producing medical statistics and disseminating best practices, the LNHO also supported initiatives to advance medical science, as part of an agenda of social modernisation, and to improve health and living conditions. Its activities were, therefore, far wider and more ambitious than those of the OIHP, in the earlier decades.

As a consequence of the outbreak of the Second World War, international health work was mostly suspended. The LNHO, however, was able to continue activities with a military focus. Borowy (2010) reminds us that, despite assuming worldwide responsibilities, in practical terms, the LNHO was a small institution, and although at the end of the war 43 States were still Members of the League of Nations, for all intents and purposes, it had succumbed. Nevertheless, an official termination of the organisation was necessary; a final and official disposition transferred the League of Nations' properties to the United Nations.

In 1945, the United Nations Conference on International Organisation (UNCIO) in San Francisco, (commonly known as the San Francisco Conference), approved a recommendation made by Brazil and China to establish a new and independent international organisation, entirely dedicated to public health. The proposed organisation was meant to unite the different health organisations that had been established in various countries around the world. In June 1948, the first World Health Assembly (WHA) took place and the WHO Headquarters was officially established in Geneva, aiming for the 'attainment by all peoples of the highest possible levels of health'.

In its constitution, the WHO defines health as not merely the absence of disease but 'a state of complete physical, mental and social well-being' (WHO, 1946). It is worth noting that this sentence can be seen as an eagerness to overcome the perception that public health should focus on standardisation and the accomplishment of successful campaigns for disease control. In this direction, the preamble goes beyond the technical and biological dimension, presenting health as a human right: 'the enjoyment of the highest attainable standard of health is one of the fundamental rights of every human being without distinction of race, religion, political belief, economic or social condition' (WHO, 1946). It is important to highlight that with this social approach to health, the WHO was a pioneer, given that the Universal Declaration of Human Rights was adopted by the UN only two years after, in 1948. In the article '*El proceso de creación de la Organización Mundial de la Salud y la Guerra Fría*,' Cueto, Brown and Fee (2011, p. 137) argue that:

> la definición del preámbulo versaba sobre lo que debía ser la salud, no sobre la salud pública, y esto se hacía a diferencia de otras agencias de la ONU –como la Unesco o la FAO– que no se sintieron urgidas a definir lo que era la educación o el desarrollo agrícola. De esta manera, ello sugiere que existió una motivación idealista y en favor

de una equidad universal, que en muchos sentidos era nueva.[16]

From the beginning, the WHO has been involved in public health campaigns more focused on the improvement of sanitary conditions, and became known as the organisation within the United Nations system with leading responsibility for international health. However, Brown, Cueto and Fee (2011) point out that it wasn't such an easy path, firstly because its constitution had to be ratified by the Member States, which was a slow process - by 1949, only 14 countries had signed it; secondly, due to the timeless contradictory role played by the United States, one of the main contributors to the WHO budget. According to the authors (2011, p.64), on one hand, the United States supported the UN system regarding the comprehensive international goals, on the other, the country was concerned with UN sovereignty. Therefore, the US maintained the right to intervene unilaterally in the Americas in the name of national security.

Health agencies and their activities are shaped by political context. Therefore, in a Cold War milieu, two opposing ideological views of public health were aggravated by the tensions between the two blocs. While for the communist countries, there was an inseparable nature of social, economic and health problems, this perspective was divergent to the disease control approach, conducted specifically by the Rockefeller Foundation. Thus, the Soviet Union, along with its allies Ukraine, Byelorussia, Bulgaria, Romania, Albania, Poland, Czechoslovakia and Hungary decided to withdraw from the WHO in 1949. The countries believed that the United States was controlling the WHO and the United Nations in general. The Soviets then decided to boycott the agencies (Fee, Cueto and Brown, 2016, p.1912).

The tension between the superpowers and, consequently, the relationship of the Soviet Union with the UN and the WHO changed in 1953, when Joseph Stalin died, and the de-Stalinization process started. Subsequently, Nikita Khrushchev stressed that foreign affairs would be guided by 'peaceful coexistence' and 'friendly competition' with the non-communist world - a policy that was reflected both within and outside the UN system as all the communist countries (with the exception of China) returned to the WHO in 1956. In this direction. Birn, Pillay and Holtz (2009) argue that political tensions added to the withdrawal of Soviet bloc countries, and pushed the WHO to prove its commitment to improving health

[16] It is important to note that the definition of the preamble was about what health should be, not about public health, and this was done unlike other UN agencies - such as UNESCO or FAO - that did not feel urged to define what was education or agricultural development. Thus, this suggests that there was an idealist motivation in favour of a universal equity, which in many ways was new. (Translated by the author)

in underdeveloped countries.

In the early 1970s, decolonisation represented another political milestone that influenced the WHO's policies. Subsequently, the New International Economic Order (NIEO) was promulgated as a United Nations declaration in 1974. The NIEO was most extensively debated transnational governance reform initiative of the 1970s, of which the main objetive was to 'eliminate injustice and inequality (…) and to accelerate the development of developing countries, believing that the overall objective of the new international economic order is to increase the capacity of developing countries, individually and collectively, to pursue their development' (UN, 1975). With that in mind, Chorev (2012) argues that developing countries' demands challenged the WHO Secretariat, as they expected the organisation to develop policies and projects that were in agreement with NIEO principles such as health conditions under the apartheid regime in South Africa.

During the Seventh Special Session of the UN General Assembly in September 1975, the resolution *Development and International Economic co-operation (3362 S-VII)* declared:

> The World Health Organization and the competent organs of the United Nations system, in particular the United Nations Children's Fund, should intensify the international effort aimed at improving health conditions in developing countries by giving priority to prevention of disease and malnutrition and by providing primary health services to the communities, including maternal and child health and family welfare (UN, 1975).

Moreover, in 1979, the Regional Office for the Eastern Mediterranean published the paper *Health and the New International Economic Order* as the Technical Discussions Session in the Executive Board of the following year would be 'Contribution of Health to the New International Economic Order'. The document should give the background to support the Member States on the discussions by pointing out the interrelationship of health and the New International Economic Order, and also discussing how to increase political commitment at a national and international level. At the Thirty-Third World Health Assembly in 1980, given this context, health was advocated to be 'an output and an input in the development process and is essential to a man-centred development, being the main and first ingredient of the quality of life' (WHO, 1979, p.3).

In more practical terms, the straightforward outcome of the NIEO at the WHO was the majority of votes from developing countries at the WHA and consequently a dependence on least developing countries as the governing bodies follow a one-country/one-vote rule. The

so-called G77[17] group was, therefore, able to sustain a reliable coalition, and they were consistently unified in how they voted. Chorev (2012) explains how, since at that time the WHO's budget was mainly based on compulsory rather than voluntary contributions,[18] the level of the WHO's dependence on rich countries for resources was fairly low. Accordingly, they also did not have much power on budget decisions.

In 1981, the Global Strategy for Health for All by the Year 2000 was published by the WHO. The main idea was a nationwide health system based on primary healthcare, as described in the Report of the International Conference on Primary Health Care, Alma-Ata, 1978.[19] The Thirty-Fourth World Health Assembly adopted an Executive Summary of the strategy (Resolution WHA34.36), and the literature sees it as an effort to redirect the WHO back to its constitutional commitments as:

> it means simply the realisation of WHO's objective of "the attainment by all peoples of the highest possible level of health"; and that as a minimum all people in all countries should have at least such a level of health that they are capable of working productively and of participating actively in the social life of the community in which they live. (WHO, 1981, p. 15)

In the 1980s, the WHO started to face the growing influence of the World Bank, which, although established in 1946 to assist in the reconstruction of Europe, extended its mandate to deliver credits, grants, and technical assistance to developing countries. In the first instance, the main focus of the World Bank was investment in capital and infrastructure, however it soon started financing population control, health, and education.

The dispersal of power and authority among different levels of governance from the end of the 1980s and beginning of the 1990s began to weaken the authority and control of the World Health Organisation. In a complex post-Cold War scenario with multifaceted demands, an underfunded and overly politicised WHO had its roles diminished in the face of other international organisations and private entities. Although still capable of retaining its prominence as the primary reference on health-related topics, the WHO's stagnation and crisis, which will be discussed further in this chapter, led to the inevitable reform of the Organisation. In this scenario of crisis, reform, and the increasing participation of different

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[17] The Group of 77 at the United Nations is a coalition of 134 developing nations, designed to promote its members' collective economic interests and create an enhanced joint negotiating capacity in the United Nations

[18] The budgetary structure of WHO will be explained later in this chapter.

[19] The International Conference on Primary Health Care took place in Alma-Ata/URSS and expressed the need for urgent action by all governments, all health and development workers, and the world community to protect and promote the health of all the people of the world. Available at: https://www.who.int/publications/almaata_declaration_en.pdf

institutions, FENSA was conceptualised.

2.2 Structure and Functions

The World Health Organisation is one of 15 autonomous specialised agencies linked to the United Nations and has 194 Member States (all UN Member States, except Liechtenstein, plus Niue and the Cook Islands that are not a member of the UN but are part of the WHO). Territories, or groups of territories which are not responsible for their international relations, may be admitted as Associate Members by the Health Assembly, upon application made on their behalf by the Member, or other authority responsible for their international relations. Associate members have full access to information, but limited participation and voting rights; currently, the WHO has two Associate Members: Puerto Rico and Tokelau.

Membership of the WHO is open to all States, and members of the United Nations may become members of the WHO by signing or accepting its Constitution. States may otherwise be admitted as members when a simple majority vote can approve their application of the Health Assembly. The non-member States and other entities may be invited to attend sessions of the Health Assembly in an observer status, as Taiwan did from 2009 to 2016. The Vatican, the Palestinian Authority, the Order of Malta, the International Committee of the Red Cross, and the Inter-Parliamentary Union have also participated as observers. Representatives of the United Nations, its specialised agencies, programmes and funds, and other International Governmental Organisations (IGOs) frequently attend sessions of the Health Assembly in an observer capacity (OECD, 2016).

When it comes to WHO staff, the Secretariat has 7916 employees and the most recent budget (for the financial period 2020-2021) is US$ 4840.4 million (WHO, 2019). The WHO is partly financed by duties payments from the Member States, which must pay according to the country's wealth and population. Additional financing comes from voluntary contributions which, in recent years, have accounted for more than three-quarters of the Organisation's financing (WHO, 2016). Voluntary contributions come from the Member States and partner organisations such as foundations and civil society. Contributions from the private sector, usually in the form of in-kind donations,[20] provide less than 1% of the WHO's financing.

[20] In-kind donation is a kind of charitable giving in which, instead of giving money to buy needed goods and services, the goods and services themselves are given. Gifts in kind are distinguished from gifts of cash or stock.

Apart from providing leadership on global health topics, the WHO is responsible for 21 other functions, according to its Constitution, including to:

> establish and maintain effective collaboration with the United Nations, specialised agencies, governmental health administrations, professional groups, and such other organisations as may be deemed appropriate. (WHO, 1948, p.2)

Overall, the work of the WHO can be divided into three categories: (1) normative functions, like international conventions and agreements, regulations and non-binding standards and recommendations; (2) directing and coordinating functions, including health for all, poverty and health, essential medicine activities and its specific disease programs; (3) research and technical cooperation functions, including disease eradication and emergencies. A non-exhaustive list of WHO functions includes assisting governments, giving technical assistance, conducting health research, promoting international standards regarding food, pharmaceutical and others, activities related to teaching and training, and also to carry out diagnostic procedures. Clause K of article 2 states that the Organisation has a responsibility to 'propose conventions, agreements and regulations, and make recommendations with respect to international health matters, a function that supports FENSA proposal and negotiation.

To enable these twenty-two responsibilities, the WHO engages with various stakeholders, and works closely with decision-makers such as Ministries of Health, government agencies, and other government departments at the national level. According to the WHO website, the engagement with the United Nations at the global, regional, and country level is also a major duty. Therefore, the WHO has six regional offices: the Regional Office for Africa in Brazzaville (Congo), the Regional Office for the Americas in Washington, D.C. (United States), the Regional Office for the Eastern Mediterranean in Cairo (Egypt), the Regional Office for Europe in Copenhagen (Denmark), the Regional Office for South-East Asia in New Delhi (India), and the Regional Office for the Western Pacific in Manila (Philippines).

Although the regional offices can adopt their own rules of procedure, they are part of the Organisation and, consequently, must follow the Constitution. Many authors from global health literature argue that the independence and autonomy of the six regional offices is one of the most evident weaknesses in the WHO's decentralised structure. Regional offices and Regional Directors (RDs) try to obtain more sovereignty from the Geneva headquarters to focus on programmes of their preference. Furthermore, RDs have to keep a good working

relationship with delegates from host countries who are largely politicians, which leads to an excessive political influence at the regional offices.

Similar to the Healthy Assembly and the Executive Board, the regional offices meet with their member states regularly. They also have a great deal of flexibility in setting their agendas and deciding how much they want to cooperate with Geneva. This was proven during FENSA negotiations, where the PAHO was seen as a thorn in the WHO's side.

On the local level, the WHO operates 149 country offices, the majority of which are in low- and middle- income countries (LMICs). Overall, regional offices have seven functions which include to 'formulate policies governing matters of an exclusively regional character' and to 'cooperate with the respective regional committees of the United Nations and with those of other specialised agencies and with other regional international organisations having interests in common with the Organisation' (WHO, 1948, p.12). Thus, according to the WHO website, the main responsibility of the regional offices is to support the Member States in the generation and use of appropriate health information, to support decision-making, healthcare delivery and management of health services, at the national and sub-national levels.

As explained above, the PAHO precedes the WHO, and it may be the reason why their relationship is more complex than with other regional offices. It is worth noting that this effort to keep PAHO's independence is historically exposed when analysing the XII Pan American Sanitary Conference, in 1947. Although the 21 American republics signed the WHO Constitution, they insistently drew attention to the fact that they wanted to cooperate with and participate in the Organisation, but they were not interested in being completely incorporated.

The XII Conference decided to consolidate the Bureau's separate identity, reorganising it as the Pan American Sanitary Organization (PASO),[21] with four organs: the Pan American Sanitary Conference, as the supreme governing body of the Organisation; the Directing Council, with one representative from each Member Country; the Executive Committee; and the Pan American Sanitary Bureau, the Director and his staff. The Conference also requested a draft of a Constitution for the Pan American Sanitary Organisation.

To establish a relationship between the regional and global health bodies, the Executive Committee acted as a negotiator with the World Health Organisation on the

[21] In 1958, the first Latin American Director, Dr. Abraham Horwitz of Chile, was elected and PASO changed its name to PAHO (Fee and Brown, 2002)

conditions that the Pan American Sanitary Organisation should continue to function as an independent identity. It can be noted that Article 54 from the WHO Constitution states that:

> The Pan American Sanitary Organization represented by the Pan American Sanitary Bureau and the Pan American Sanitary Conferences, and all other inter-governmental regional health organisations in existence prior to the date of signature of this Constitution, shall in due course be integrated with the Organization. This integration shall be effected as soon as practicable through common action based on mutual consent of the competent authorities expressed through the organisations concerned. (WHO, 1948, p.13)

Therefore, in May 1949, the first Director-General of the WHO, Dr Brock Chisholm, along with the Director of the Bureau signed an agreement officially establishing the relationship between the two organisations. As a result, the Bureau was converted into a regional office of the World Health Organisation, whilst being able to preserve its identity as the Pan American Sanitary Bureau.

Various interviewees endorsed this effort of the PAHO to maintain its own rules, procedures and decisions; a former adviser to WHO Director-General (Interviewee 19) described PAHO behaviour as ‘false independence’. According to the interviewee, when it is appropriate, the PAHO listens to what Geneva says but ‘if there is something that PAHO does not like, then claim its independence to not apply’. Furthermore, some Member States, like Germany, the United Kingdom, and Norway, stated that with regard to FENSA, there was a concern about guaranteeing that the PAHO would apply the framework in its entirety. This, however, will be discussed further in chapter four.

Concerning the World Health Organisation’s structure, it consists of the World Health Assembly (WHA), the Executive Board (EB) and the Secretariat. The World Health Assembly is the supreme decision-making body with its own rules of procedure. It is composed of delegates that represent the Member States. The WHA meets annually to discuss a specific health agenda prepared by the Executive Board. Article 18 from the WHO Constitute determines thirteen functions for the Health Assembly - the most important is to determine the policies of the Organisation. It is also important to highlight that the decision-making body is also responsible for appointing the Director-General, for supervising financial policies and reviewing and approving the proposed programme budget. When it comes to functions related to the participation of non-State actors, the WHA shall:

> g) to instruct the Board and the Director-General to bring the attention of Member and of international organisations, governmental or non-governmental any matter with regard to health which the Health Assembly may consider appropriate; h) to invite any organisation, international or national, governmental or non-governmental,

> which has responsibilities related to those of the Organization, to appoint representatives to participate, without right of vote, in its meetings or in those of the committees and conferences convened under its authority, on conditions prescribed by the Health Assembly; but in the case of national organisations, invitations shall be issued only with the consent of the Government concerned. (WHO, 1948, p.6)

The WHA has the authority to approve and implement conventions or agreements with respect to any matter within the competence of the Organisation. As already mentioned, the decision-making process of the WHO is formally ruled by the principle of 'one state, one vote'. The Rules of Procedure of the Health Assembly and the Executive Board, regarding decision-making, is a simple majority, apart from decisions on significant questions like the adoption of conventions or agreements and amendments to the Constitution. In these cases, a two-thirds majority of Members present is required, along with a vote. However, realistically, almost all decisions are adopted by consensus. Regarding the leadership and the mandate of the WHO, Iboro Ekpo Nta notes in his Master's Dissertation that it cannot be ignored:

> the fact that like the UN, the basic governing units of the WHO are national governments, who by their very characterisation represent groups of interests which would either cooperate or compete with each other's spheres of influence as they struggle to set agenda. This is the nature of international relations and WHO is not exempt from its sway. (NTA, 2011, p.20)

The Executive Board is composed of thirty-four members,[22] technically qualified in the field of health, designated by the Member States to serve for three years, with the possibility of re-election. The Board meets at least twice a year, with its own rules of procedure, and is led by a Chairman, elected among the Member States. According to the Constitution, the Board has nine functions, which include putting into practice the decisions and policies of the World Health Assembly, to advise the WHA and generally facilitate its work by, for instance, preparing the agenda. The Executive Board is also responsible for emergency actions, regarding the functions and financial resources of the Organisation, to handle events requiring immediate action.

Responsible for the daily administrative and financial transactions, the Secretariat comprises the technical and administrative personnel of the organisation, and the Director-General (DG) is the procedural and directorial chief. The DG is appointed by the World Health Assembly and is subject to the authority of the EB. Currently, the DG is Tedros Adhanom Ghebreyesus, an Ethiopian politician, academic, and public health authority.

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[22] The 34 members are drawn from six regions: 7 represent Africa, 6 represent the Americas, 5 represent the Eastern Mediterranean, 8 represent Europe, 3 represent South-East Asia, and 5 represent the Western Pacific. Available at: http://apps.who.int/gb/gov/en/composition-of-the-board_en.html . Last access on 14/05/2019.

During FENSA negotiations, Margaret Chan held the position. Article 37 states that ‘in the performance of their duties the Director-General and the staff shall not seek or receive instructions from any government or any authority external to the Organisation’ (WHO, 1948, p.37). However, according to interviewee 19, a former staff member at the WHO, when the first ideas for engagement with non-State actors were being delineated, the ‘Secretariat changed its position due to a lot of pressure from some Member States’. Perceived incoherent actions of the Secretariat will be discussed further in this thesis.

2.3 Crisis at the WHO: Leadership and Budgetary Challenges

Since its establishment, the World Health Organisation has passed through political and historical moments in which its leadership was challenged. In a transformed international political context, with the globalisation of trade, information, human rights and diseases, global health became more plural, encompassing an increasing number of actors and voices. Additionally, health debates have shifted from reclusive and exclusive health departments at the WHO to regularly be part of various multilateral meetings. Global health governance, therefore, gradually requires more coordination to address health priorities successfully and to direct investments.

The World Health Organisation, once seen as the unquestioned leader of international health, started to face a crisis due to budget deficits and deteriorating status - particularly with the growing influence of new and powerful players. Although global health has benefited significantly from these new funds, actors and actions, it has also suffered a splintering due to an increasingly fragmented, uncoordinated, and incongruent agenda.

Ventura and Perez (2014) argue that amongst the many difficulties faced by the WHO in carrying out its functions, the five main elements of the crisis at the organisation are: the erosion of its leadership; both the insufficiency and the type of financing; conflicts of interest of experts which came to light during the administration of influenza pandemic (H1N1); communication difficulties; and problems of internal governance.

Moreover, some critics in the literature point to a ‘politicisation’ of the WHO led by the developed countries, especially the United States, to whom the organisation should be merely a technical agency and its activities based only on biomedical evidence. As previously mentioned, in the Cold War scenario, particularly during Ronald Reagan's government (1981-1989), the dissatisfaction of the United Nations with ‘the dominance of Third World

countries in UN agencies' (Chorev, 2012, p. 125) was clear. The Reagan-Thatcher Era, and their socioeconomic and political agenda can be seen as the beginning of the WHO's weakening. The prominent role of the World Bank and its spending on health are other important elements of the crisis.

The World Bank's first noteworthy health project was the *Onchocerciasis Control Programme* launched in 1975 in West Africa. While the WHO had established a program to support global efforts to combat neglected infectious diseases that excessively affect poor and marginalised populations, a different perception from the dominant health policy discourse started to arise, as the World Bank was discouraging 'unnecessary health care and charging for services at their real cost' (Fidler, 2010).

According to the *Health Sector Policy Paper* developed by the World Bank in 1980, formal health policy was adopted in 1974 'after several years of informal activity in the sector'. From the 1980s on, therefore, the Bank started investing in the health sector, mainly in 'basic health infrastructures, the training of community health workers and para-professional staff, the strengthening of logistics and the supply of essential drugs, maternal and child health care, improved family planning and disease control' (World Bank, 1980, p.8). According to Birn, Pillay and Holtz (2009), this new involvement was driven by the perceived inefficiency of the WHO and the UN bureaucracy. The World Bank quickly became the world's main external financier of health in low-income countries focusing on the predominance of the market. Additionally, the decision-making and funding priorities were decided by the donors. To illustrate, in 1993 the World Bank published the *World Development Report: Investing in Health*, emphasising private-sector competition and cost-effectiveness as governing principles for the health sector:

> governments need to promote greater diversity and competition in the financing and delivery of health services. Government financing of public health and essential clinical services would leave the coverage of remaining clinical services to private finance, usually mediated through insurance, or to social insurance. Government regulation can strengthen private insurance markets by improving incentives for wide coverage and for cost control. Even for publicly financed clinical services, governments can encourage competition and private sector involvement in service supply and can help improve the efficiency of the private sector by generating and disseminating key information. The combination of these measures will improve health outcomes and contain costs while enhancing consumer satisfaction (WORLD BANK, 1993, p.iii).

While the World Health Organisation was facing a crisis, the World Bank became notable in developing international health policy and strategy, focusing on external

assistance, especially for antimalarial drugs and vaccines. When the fight against HIV became a global priority, the Bank launched the Multi-Country AIDS Programme. However, due to the appearance of new players and initiatives such as the Global Fund, the US President's Emergency Plan for AIDS Relief (PEPFAR) and the Gates Foundation, the Bank's dominance in health started to shrink. The spread of the HIV pandemic from the start of the 1990s (in 1990, 8.9 million people were living with HIV, by 1997 this had risen to 23.1 million) is also seen, by some authors, as another occurrence that impacted WHO authority. Lidén (2014) argues that the creation of The Joint United Nations Programme on HIV/AIDS (UNAIDS), autonomously from the WHO, in 1996, reinforced the perception that the Organisation was not prepared to tackle such a 'modern' disease. Dealing with HIV required a complex and multifaceted response, as it also involved other issues like discrimination, behavioural change, and prevention strategies, that confronted cultural and religious customs.

The 1990s, for the WHO, can be seen as a period of listening to critics and trying to find a way to overcome its deep crisis. To this effect, Fiona Godlee (1994, p.1424), wrote that 'the World Health Organisation has an image problem. People know that it exists, and most people know that it eradicated smallpox, but few have a clear idea of what it does'. This was part of a series of articles in the *British Medical Journal* (BMJ) analysing and criticising the WHO's administration, efficiency, strategies, negotiations, and its weak operational capacity.

During this period, in 1992, the Executive Board established a working group to report on the 'WHO Response to Global Change'. The aim was to analyse the WHO's efficiency in implementing the main functions. The Working Group made some detailed recommendations, such as the necessity to pursue 'changes in structure and process with a view to improving health status and health care throughout the world' (WHO, 1993, p. 13) through better-defined policies and procedures. In the following years, the Executive Board chased several different paths that came under the rubric of WHO reform. For instance, from May 1996 to November 1997, the Executive Board special group for the review of the Constitution held six meetings, at which the WHO's mission and functions were analysed. A report was published, and the special group suggested adjustments in coordination (by reviewing the WHO's core functions), health policy development, norms and standards, advertising and technical cooperation.

Another report from the Executive Board special group was published in 1998, on a necessary review of the WHO's Constitution. One should note that in the 1990s, it was already concerning that extra-budgetary programmes were driven by donor interests, rather than mirroring health priorities. Therefore, the report recommended that 'if a Member fails to meet its financial obligations to the Organisation, the Health Assembly may, on such conditions as it thinks proper: (i) suspend the voting privileges to which the Member is entitled' (WHO, 1998, p.1).

According to Ventura and Perez (2014), the swine influenza pandemic, which lasted from early 2009 to late 2010, characterises the largest public disclosure of the WHO's dysfunctions. The sanitary crisis became an indissociable epidemiological, political and governmental crisis. In June 2009, the H1N1 Pandemic was declared a Public Health Emergency of International Concern (PHEIC),[23] and this was the first time that the new version of the International Health Regulations (IHR), adopted in 2005, was used. The Organisation was widely accused of exaggerating the alarm due to ties with the pharmaceutical industry. A report in the BMJ alleged that three scientists at the WHO not only received payments from Roche and GlaxoSmithKline (manufacturers of antiviral drugs), but also helped to draw up the 2004 pandemic guidelines, which included the use of antivirals.

However, the WHO's Director-General, Margaret Chan, claimed that she did not believe that the threat had been exaggerated. In September 2010, during the International Health Regulations Review Committee, she stated that:

> For the pandemic, WHO has received some praise and support from early assessments published in the medical and scientific literature, in addition to support and feedback from our Member States. WHO has also received some criticism. Large sums of money were invested in commodities that were not used, sometimes because the public saw no need for them or questioned their safety. The definition of a pandemic and the pandemic phases have been questioned. The clinical value of oseltamivir has been questioned. Conflicts of interest and their influence on decisions have become an issue. (…) When I announced the move to phase 6, I reminded the world that the number of deaths worldwide was small and that we did not expect to see a sudden and dramatic increase in this number. I stressed that the overwhelming

[23] The term Public Health Emergency of International Concern is defined in the IHR (2005) as "an extraordinary event which is determined, as provided in these Regulations: 1) to constitute a public health risk to other States through the international spread of disease; and 2) to potentially require a coordinated international response". This definition implies a situation that: is serious, unusual or unexpected; carries implications for public health beyond the affected State's national border; and may require immediate international action (WHO). Available at: https://www.who.int/ihr/procedures/pheic/en/ Access on 10/05/2019.

majority of patients recovered fully without any medical care. (WHO, 2010)[24]

Nevertheless, Fiona Godlee (2010) wrote an editorial at BMJ arguing that the WHO's credibility was damaged and the Organisation should '[publish] its own report without delay or defensive comment; [make] public the membership and conflicts of interest of its emergency committee; and [develop, commit to, and monitor] stricter rules of engagement with industry that keep commercial influence away from its decision making'.

An independent committee, made up of experts from 24 countries, was created to review WHO's management of the outbreak. As a result, in 2011, a Report of the Review Committee on the Functioning of the International Health Regulations[25] (2005) and on Pandemic Influenza A (H1N1) (2009) was published with three key objectives: to assess the functioning of the International Health Regulations; to assess the ongoing response to H1N1 pandemic (including the role of the WHO), and to identify lessons learned for strengthening preparedness and response for future pandemics and public health emergencies.

The Organisation was mainly criticised due to a 'needlessly complex' definition of a pandemic which had six levels of alert based on the virus's geographical spread, not on its lethality. Moreover, references to severity were removed from online pages. Regarding the conflict of interests with the vaccine industry, the expert advisers pointed out that the WHO did not overcome the misunderstanding in a timely way. The report also stated that there existed a 'lack of openness over the working of the Emergency Committee and communications in general' and the bureaucracy created 'an unmanageable number of documents' as countries were requested on a weekly basis to submit laboratory-confirmed cases, even though knowing hospitalisation and death rates would have been enough. This overwhelmed some countries, particularly those with limited epidemiological and laboratory capacity. Additionally, countries that needed technical help could not obtain it suitable languages.

The panel recommended the creation of a global reserve workforce for emergencies

[24] Speech available at: http://www10.who.int/dg/speeches/2010/ihr_review_20100928/en/ Last access on 19/02/2020

[25] The updated IHR was adopted by the 58th World Health Assembly in 2005, and officially entered into force in June 2007. Under the terms of the IHR 2005 member states tasked themselves with developing national disease surveillance and response capacities to prevent the international spread of disease, while instructing the WHO to provide technical support to those countries struggling to meet these requirements. In addition, new powers were conferred upon the secretariat to utilise non-government sources of information to detect disease outbreaks, and to 'name and shame' countries that refused assistance or attempted to cover up public health risks.

that would be placed for service in countries that requested assistance. The goal was to:

> significantly expand the current Global Outbreak and Alert Response Network by strengthening its composition, resources and capacity, with a view towards better support for sustained responses to public-health emergencies. At present, WHO's capacity to prepare and respond in a sustained way to any public-health emergency is severely limited by chronic funding shortfalls, compounded by restrictions on the use of funds from Member States, partners and other donors. Mindful of concerns about efficiency and accountability that motivate some of the restrictions, the Committee concludes that the establishment of a contingency fund outside of WHO, but available for deployment by WHO at the time of a public health emergency, will be a prudent step to assure an immediate and effective global response (WHO, 2011, p.137)

The report also urged vaccine makers to reserve 10 per cent of their production for poor countries and criticised some international rules. Nonetheless, it concluded, 'no critic of WHO has produced any direct evidence of commercial influence on decision-making'.

Despite the measures recommended to strengthen the WHO's capacities for managing a PHEIC more effectively, three years later, in 2014, the Ebola Virus Disease (EVD) outbreak in West Africa killed 11.310 people out of a total of 28.616 suspected cases (almost 40%)[26] and put the Organisation under scrutiny again. It was noted that limited progress had been made in implementing emergency measures, and many of the recommendations remained unaddressed.

Due to its reduced budget and, consequently, reduced capacity to respond, the WHO was largely sidelined in the global response to Ebola. However, Kamradt-Scott (2016) argues that it is erroneous to accuse the Organisation of doing nothing - a response team was sent to Guinea to assist local health authorities as soon as it was confirmed that 'the virus [that] had been circulating undetected for some three months (…) initially suspected to be Lassa Fever, within hours of confirming that the etiological agent was Ebola'. Moreover, the author alleges that in May 2014, technical experts were sent to assist the health authorities in Guinea, Liberia, Sierra Leone and at the WHO African regional office (AFRO). It is important to remember, however, that the first case was reported in December 2013 and rapidly spread to Guinea's capital city of Conakry by March, making the Ministry of Health in Guinea issue an alert for an unidentified illness. On March 23, with 49 confirmed cases and 29 deaths, the WHO officially declared the Ebola outbreak.

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[26] In July 2019, a new outbreak of Ebola in the Democratic Republic of Congo was declared a Public Health Emergency of International Concern. According to updated information at WHO website, "the Ebola virus can cause severe viral haemorrhagic fever (Ebola HF) outbreaks in humans with a case fatality rate of up to 90%". Available at: https://www.afro.who.int/health-topics/ebola-virus-disease . Last access on 19/02/2020

According to the Associated Press, staffers from the AFRO recommended that the WHO's Geneva headquarters declare a PHEIC in April, but they were told that invoking the IHR 2005 could 'anger the African countries involved, hurt their economies or interfere with the Muslim pilgrimage to Mecca'.[27] Moreover, Dr Bart Janssens, director of operations for Médicins Sans Frontières (MSF) said that 'we raised the alarm publicly again on 21 June, declaring that the epidemic was out of control and that we could not respond to a large number of new cases and locations alone' (MSF, 2015, p. 7). Ebola was only declared a PHEIC on August 8, five months after the WHO first received the warning information. At that point, there had already been 1711 cases and 932 deaths. This delay undoubtedly contributed to the unprecedented scale of the outbreak.

The delay in declaring Ebola as a PHEIC was one of many critical problems, but tensions between the WHO and Médicins Sans Frontières (MSF) highlighted other weaknesses, including a failure to lead. According to the report *Push to the Limit and Beyond,* released by MSF in 2015, there was little sharing of information between countries, with officials relying on the WHO to act as a connection between them, and it was not until July when new leadership was brought into the WHO country offices and insisted on the urgent need for extra support.

In September 2014, non-governmental organisations led by MSF, the WHO and representatives from affected countries were invited to the United Nations Headquarters in New York. An unprecedented call for urgent military intervention, declaring the response 'lethally inadequate'. After the speech of the MSF international president at the UN General Assembly in New York, the UN Security Council approved the resolution UNSC 2176 and Ebola was declared a threat to international peace and security. According to the MSF report:

> this was a very unusual call for MSF, known for keeping a safe distance from military and security agendas to protect its independence in conflict zones. However, the catastrophe unfolding on the ground could clearly not be brought under control by international aid organisations alone – a desperate call of last resort had to be made. (MSF, 2015, p.13)

Kamradt-Scott (2016) elucidates that although the Organisation's reputation became unquestionably damaged during the Ebola outbreak, the WHO continued activities such as training healthcare workers in infection control, community engagement activities, and providing epidemiological data. The Organisation also issued several technical guidance

[27] UN Health Agency resisted declaring Ebola emergency. Available at: https://www.apnews.com/2489c78bff86463589b41f3faaea5ab2 Accessed on 10/05/2019.

documents, hosted meetings on vaccine possibilities, and expanded laboratory services. However, none of these actions provided the infection control that was needed. Christopher Stokes, MSF general director, said: 'the WHO should have been fighting the virus, not MSF'. One should note that funds allocated for emergency response had been drastically reduced in previous years at the WHO, according to the *Report of the Ebola Interim Assessment Panel* (2015):

> the Panel has concluded that WHO should be the lead health emergency response agency. This requires that a number of organizational and financial issues be addressed urgently. The Panel considers that WHO does not currently possess the capacity or organizational culture to deliver a full emergency public health response. Funding for emergency response and for technical support to the International Health Regulations (2005) is lacking. Currently, less than 25% of WHO's Programme budget comes from assessed contributions (and the remainder from voluntary funds). There are no core funds for emergency response. The longstanding policy of zero nominal growth policy for assessed contributions has dangerously eroded the purchasing power of WHO's resources, further diminishing the Organization's emergency capacity. Although a significant number of Member States were in favour of increasing assessed contributions, the Sixty-eighth World Health Assembly decided to maintain the zero nominal growth policy. The Organization's capacity for emergency preparedness and response must be strengthened and properly resourced at headquarters, regional and country levels (WHA, 2015, p.6)

With a wide-ranging consensus in the global health community that the WHO had failed in its leadership responsibilities and due to a vacuum of international leadership in the operational response (which was, on the whole, expected to be accomplished by the WHO), the patient care and infection control were left to other institutions, including MSF, the United Nations Mission for Ebola Emergency Response (UNMEER) and even domestic and international militaries.

Although the confusing and late response to the Ebola outbreak is undeniable, some literature, e.g. McInnes (2015), Gostin & Friedman (2015) and Yach (2016), points out the distinction between the normative and operational roles of the WHO, which has been largely ignored in academic and journalistic analysis. Yach (2016), for instance, stresses that the WHO's fundamental role is as the global health conductor of an emerging health diverse group. The authors, therefore, claim that despite the delay, the WHO fulfilled its normative function through the declaration of the PHEIC, the production of technical advice, community engagement activities, the sharing of epidemiological data, support with the development of vaccines and training activities. However, international community attention was on the operational role, which the WHO proved, remarkably, not to be able to provide.

In this regard, we must keep in mind that since the WHO's creation, there have been

debates and disagreement over whether it is mainly a normative organisation that develops norms and standards, leads and coordinates health researches; an operational organisation supposed to eradicate diseases, control pandemics and tackle humanitarian crises; or an amalgamation of the two. While a consensus is not achieved internally or externally, divergences between expectations and what the WHO is delegated (and able) to do will persist. Notwithstanding the lack of leadership (essential to comprehend the WHO crisis), financial vulnerability also played a major role.

The WHO's Programme Budget is financed through a mixture of assessed (based on countries' population and income) and voluntary contributions. Historically, assessed contributions were seen as the 'core' funding, as they are flexible funds which are normally used to cover general expenses and program activities. Voluntary contributions, on the other hand, are 'specified' funds and can come from Member States (in addition to their assessed contribution), or from other partners.

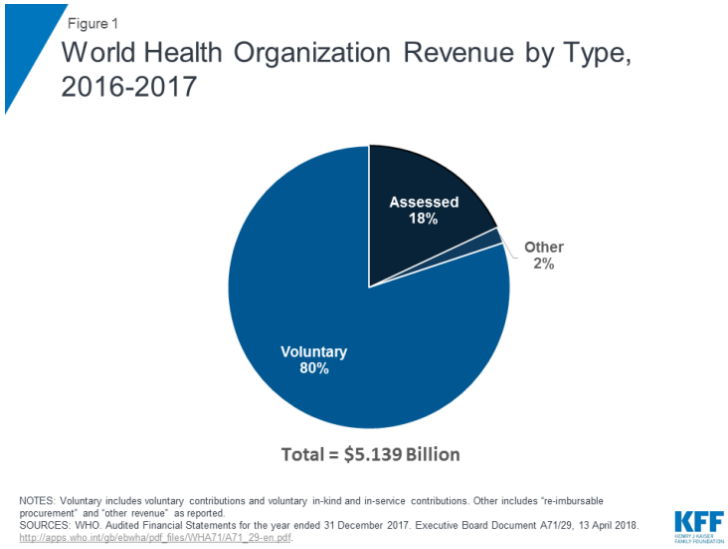
Currently, the WHO's new website[28] on Budget and Financing divides the source of financing into Voluntary Contributions, Specified, and Flexible Funds. Flexible Funds can be Assessed Contributions (AC), Core Voluntary Contributions Account (CVCA) and Programme Support Costs (PSC). Voluntary contributions can be earmarked or flexible.

Core voluntary contributions are funds provided to the WHO that are fully flexible at the level of the Programme Budget, or highly flexible at the category level. Greater flexibility of funding is, therefore, a key principle of the WHO Financing Dialogue. However, as the Organisation mainly has to use the assessed contributions to pay salaries and other establishment-related expenses, the programmes end up being mainly financed through voluntary contributions.

From 1948 until the early 1980s, the WHO was dependent on the assessed mandatory membership contributions for the regular budget. However, the exogenous environment, both political and economic, affected the Organisation. As was previously described, since the 1960s a political awakening of developing countries called for an improvement in their terms

[28] Information of the Organization's work, financing and implementation progress can be found at the WHO's Programme Budget Portal. As part of the reform, the budget portal is updated every quarter and provides a breakdown of the WHO's work by categories, programmes and outputs.

of trade[29] and tariff reductions, an increase in development assistance and a joint negotiating



capacity in the United Nations. Nevertheless, in the 1980s, they experienced a debt crisis. Being unable to repay the debt, they had to ask for help. The problem exploded in August 1982 as Mexico declared inability to service a $62 billion debt to the United States, and a similar problem quickly spread to the rest of the world. Therefore, macroeconomic compression and structural adjustment (known as liberalisation and privatisation) were requested as a conditionality of the IMF and the World Bank, since governments of developing countries were unable to repay the debt, and financial rescue operations became necessary.

Internally, in this same period, the World Health Assembly adopted a policy of zero growth for the regular budget. As a consequence, it started to dramatically rely on voluntary contributions, called extra-budgetary funds (EBFs).[30] It is important to highlight that although, since its creation, the WHO utilised EBFs,[31] especially for key initiatives like malaria and smallpox eradication programmes, they were not a central component of the WHO budget. Additionally, some developed countries started paying voluntary donations

[29] In the 1950s, the economist and former Central Bank president Raúl Prebisch created the concept of "deteriorating terms of trade". Prebisch analysed how income and outcomes of technical progress were distributed in countries with different economic and social structures. He argued that the prices of export products from the centre and the periphery were formed on very disparate wage levels, generating high levels of inequality. Moreover, as primary goods have negative income elasticity of demand, the demand for this type of goods increases less than income.

[30] The UN defines extrabudgetary funds as 'all resources, other than those of the regular budget, administered by the Organisation'.

[31] It is authorised by the Article 57 of WHO Constitution: "The Health Assembly or the Board acting on behalf of the Health Assembly may accept and administer gifts and bequests made to the Organization provided that the conditions attached to such gifts or bequests are acceptable to the Health Assembly or the Board and are consistent with the objective and policies of the Organization"

instead of mandatory contributions. For instance, the United States, the United Kingdom, Germany and Japan are amongst the greatest donors to the WHO. While 26.53% of American funding is Assessed Contributions, 73.47% is Specified Voluntary Contributions.[32] It has been causing a donor-control over these funds, leading to major implications for the WHO's international role as the leader for health topics. Vaughan et al. (1996, p.229) explain:

> between 1984-85 and 1992-93 the real value of the EBFs apparently increased by more than 60% and in the 1990-91 biennium expenditure of extrabudgetary funds exceeded the regular budget for the first time. All WHO programmes, except the Assembly and the Executive Board, receive some EBFs. However, three cosponsored and six large regular programmes account for about 70% of these EBFs, mainly for vertically managed programmes in the areas of disease control, health promotion and human reproduction. 80% of all EBFs received by WHO for assisted activities have been contributed by donor governments, with the top 10 countries (in Europe, North America and Japan) contributing about 90% of this total, whereas the UN funds and the World Bank have donated only about 6% of the total to date. By contrast, about 70% of the regular budget expenditure has been for organisational expenses and for the support of programmes in the area of health systems.

Chorev (2012) argues that Ronald Reagan took advantage of this scenario of financial susceptibility in order to push the American neoliberal agenda into the United Nations' system; he inflexibly opposed any New International Economic Order demands or negotiations that were seen as a politicisation of technical issues. Consequently, the United States and other industrial countries could exploit the resource dependence of international organisations as by 1986, according to the UN Secretary-General, 'the United Nations [was facing] the most serious financial crisis in its history'.

To understand how the growing dependence of the WHO on earmarked funds has been influencing the priorities in global health agenda in favour of donors' interests in specific diseases or treatments, it is important to comprehend how the Organisation's programmes and activities are financed. According to the WHO website, the Programme budget is a tool for the Member States to set and approve the priorities of the Organisation, and, also, to set out the resources required to address the jointly-defined goals as well as to supervise their achievement. The WHO's actions are financed based on the biennial Programme - resultant from the General Programme of Work approved by the Member States - using both regular and extra-budgetary funds. The direction of the Organisation is guided by a 5-year plan of action endorsed by the Assembly. However, actual expenditures may diverge from the budgeted amount, such as when extra expenses occur in response to health emergencies.

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[32] Available at: http://open.who.int/2018-19/contributors/contributor Last acess on 05/03/2020

As previously mentioned, the budget was frozen by the World Health Assembly in the early 1980s due to the policy of zero real growth for the regular budget. Therefore, the countries' contribution to the budget started falling in real terms, and the Organisation has increasingly depended on extra-budgetary contributions from donors. As explained previously, the majority of the WHO's revenue in past decades came from assessed contributions, but over time, voluntary contributions surpassed them. For instance, the biennial 2016-2017, *assessed contributions* equalled $927 million (18% of revenue), while *voluntary contributions* equalled $4.116 billion (80%) and 'other revenue' equalled $96 million (less than 2%) as can be seen in Figure 2. And this is worsening as nowadays assessed contributions accounts for 13.39% of WHO budget[33].

The budget is considered a central element of the WHO crisis for three main reasons: 1) the fear that the unconcealed reliance on earmarked funds would boost member states' indifference to the regular budget; 2) the unavoidable answerability and reliance that follows receiving sponsor money; 3) the weakened collective ability for the WHO to independently prioritise and execute projects. Therefore, the main critique present in global health literature is that the WHO's priorities reflect donors' preferences instead of the democratically-decided priorities.

Moreover, instead of rationally allocating the resources, the specified voluntary contributions give the Secretariat no flexibility to use the funds in a manner that meets the prioritised programme set by member states, which is seen as a problem of governance. Additionally, Reddy, Mazhar and Lencucha (2018, p. 2) argue that:

> Some of the acute financing challenges facing the WHO include misalignment between programme budgets and member states financial commitments, unpredictability of financing, lack of transparency of financing, and efficiency in resource management, vulnerability due to just 20 contributors funding 75% of the programme budget, and inflexibility of financing.

In recent years, the agency's $2.3 billion annual budget has been increasingly allocated up before it reaches the WHO, earmarked by donors for their priorities such as polio, HIV/ AIDS, or malaria. Simultaneously, giving larger health priorities - notably, the development of basic healthcare infrastructure seems like tender mercies. For instance, when analysing the 2018-19 budget,[34] the voluntary contributions specified fixed 775,635K to Polio, 655,977K

[33] Funding by contributor. Available at: https://open.who.int/2020-21/contributors/contributor
[34] Available at: http://open.who.int/2018-19/budget-and-financing/gpw-overview Accessed on 13/05/2019.

to communicable diseases and only 194,017K to promote health through the life-course. One could question whether this contradicts the Health for All strategy.

Many critics argue that the WHO is no longer setting the agenda of global health, since 20 contributors, of which 11 are non-State actors, account for 80% of all voluntary contributions.[35] Moreover, in 2012, the year in which FENSA started being negotiated, contributions from NSAs represented 25.5% of WHO total income. Although all these contributions are now registered at the WHO Budget and Financing website, the agreements between donors and the Organisation remain closed to the public domain. As the WHO does not have any regulation to prevent donor-driven implementation, it is difficult to analyse the real influence of NSAs at the WHO, which might be much higher.

In January 2010, Margaret Chan organised an informal consultation on the future of financing for the WHO. The initial motivation for this meeting came from budget discussions at the Executive Board and the World Health Assembly in 2009. The key issues the debate focused on were: how to more efficiently align the Organisation's priorities with the funds available to finance them, and how to ensure better certainty and stability of financing in order to promote more realistic planning and effective management. Additionally, there was an awareness that the existing reality, in which 80% of WHO income relies on voluntary donor contributions, predominantly earmarked for specified purposes, was not sustainable. Hence, without extreme changes, better alignment with agreed priorities would be unachievable because 'we [the WHO] have to rely on a financing system which favours some parts of the budget, leaving many areas and functions dangerously under-funded'. (WHO, 2010).

According to the report *The Future of Financing for WHO* of 2010, the participants analysed the changing landscape for global health, acknowledging the growing number of actors involved, the consequent risks of fragmentation and duplication of effort, and the growing number of competing demands on the WHO's resources:

> Partnership with others is key in all aspects of WHO's work. The term covers the relationships with all the donors to WHO, with other UN agencies and with a wide range of partners in civil society and the private and voluntary sectors. While some partnerships are founded on contractual arrangements, all require trust. To focus the debate, participants sought to define different types of partnership and their implications for the business of WHO (…) Certain issues require a response that is both rapid, focused and that engages stakeholders - as equal partners - that are not automatically part of WHO's normal constituency. Proponents on both sides of the

[35] Available at: http://open.who.int/2018-19/contributors/contributor Accessed on 13/05/2019.

> argument, however, acknowledged that there was a case to be made for all purpose-specific partnerships to have a finite lifespan (WHO, 2010, p.15)

The report concluded that because there was little possibility that Assessed Contributions would increase to past levels, new approaches were needed, for example, new procedures for raising funds to subsequently increase predictability and flexibility.

The report was criticised by many non-State actors in official relations with the WHO. During the 64th session of the World Health Assembly, the People's Health Movement statement claimed that:

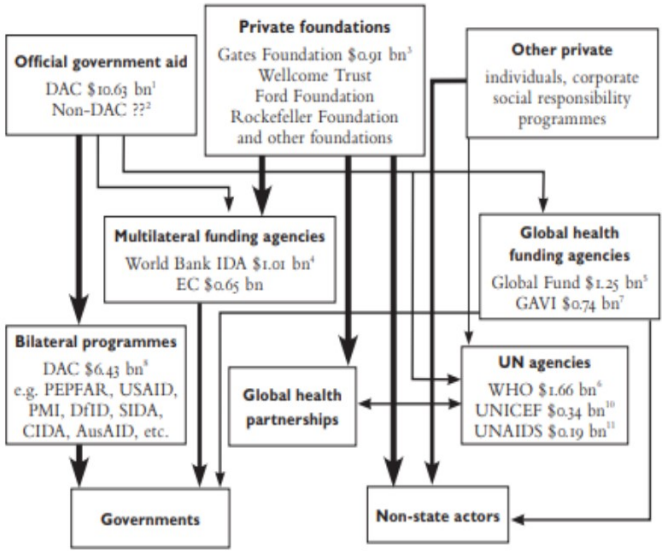
> (…) the current crisis could compromise WHO's capacity to play this role. The report is short on detail. The detailed reform program was only available on the website late last week, and this also lacks specifics on the reforms. We are concerned that the scope of operations of the Secretariat could be reduced with 'mainstreaming' of some important functions and that private foundations and corporates will have new opportunities to influence the WHO agenda through the proposed World Health Forum. While we support innovative mechanisms and consultations and public hearing sessions with public interest groups, we believe that the task of setting WHO's agenda and the decision-making process should always remain with the member states. (…) To fulfil its mandate the WHO needs a budget that is adequate, predictable and untied. The growing imbalance between assessed and voluntary contributions undermines the organisation's independence. We propose that member states collectively commit to increasing assessed funding so that it reaches 50% of the overall budget over the next five years. This would help WHO to be more independent of private philanthropies and the corporate sector and thus better serve its member states and people and implement the priorities decided by the assembly. (PHM, 2011, p.1)

In the same direction, Medicus Mundi stated that while welcoming 'the spirit of inclusiveness in the related proposals by the Secretariat', it could not agree with any influence of the private sector through financing, or other means, in WHO priorities and programmes. It can be noted that the position of Medicus Mundi, regarding the role of non-State actors, was clear before the negotiations of FENSA, as in 2010 the NGO was requesting a clear definition of NSAs and their roles, goals and conflict of interests. Finally, MMI declared that 'it is crucial that the reform package is characterised by a process in which the space for contributions is based on the voice and needs of people, not the power of money'. Visibly, the contrasting perspectives among the Member States and non-State actors were perceptible before FENSA was properly proposed.

This chapter offers an analysis of how the international health scenario, which once was characterised by the predominance of a single multilateral institution, the World Health Organisation and a few international donors, progressively entangled a vast number of actors, both politically and financially. Multilateral organisations (the World Bank, UNICEF, and others), multi-donor funds (the Global Fund to Fight AIDS, Tuberculosis and Malaria), non-

governmental organisations (Doctors Without Borders), philanthropic foundations (the Bill & Melinda Gates Foundation, UN Foundation, Wellcome Trust), think tanks and institutes (Institute Pasteur network), plus a few hybrid institutional arrangements (the GAVI Alliance), all became a part of global health governance. This can be seen in Figure 3.

FIGURE D1.1.1 **Overview of global funding in health in 2006**



The increased presence of several actors created new challenges for coordination and also raised questions about the roles they should play, the rules by which they should play, and indeed who should set those rules. According to Chorev (2012), the 'authority crisis' of the WHO started when other international organisations, such as the World Bank, established global health policies and programs that directly clashed with WHO activities. Additionally, a lack of coordination between these new actors (some with great political and economic power) and the WHO resulted in a duplication of effort, deficiency of coherence in positions and priorities, and a wasting of resources. This served to worsen the WHO crisis.

2.4. Reform of the World Health Organisation

As analysed above, the enduring financial constraints amounted to increased challenges and demands on the international health system, alongside the rise of new actors and leaderships, making the WHO recognise that an adjustment was needed. For years, the WHO has discussed a rationalisation of its complex structure, governance and financing to make it more efficient, and consequently regain its authority as the global leader for health issues. The advancement of the reform, however, has been embarrassingly slow. The decisive

pressure for change started after a series of mishaps. Whilst still agonising over accusations that it had overreacted to the 2009-10 H1N1 flu pandemic, the WHO was faced with contemptuous criticism for not responding fast enough to the Ebola crisis.

Nevertheless, serious consideration over the need for reform began in the late 1980s and early 1990s. The first formal call was in 1993, with the *Report of the Executive Board Working Group on the WHO Response to Global Change,* which stated that the Organisation should conduct 'efforts to make WHO more responsive to changing needs at the global, regional and country levels and improve dialogue between the various Regional Offices and between them and Headquarters' (WHO, 1993). Already in the 1990s, the literature was indicating a crisis in international health as inequalities were increasing, whilst the access to healthcare for the world's most vulnerable populations was worsening.

It is important to contextualise the health crisis with the Washington Consensus - the neoliberal economic policy prescriptions which arose from a meeting in Washington, D.C. in 1989. A reform package for developing countries was created by representatives of international organisations, such as the International Monetary Fund (IMF), the World Bank, the Inter-American Development Bank (IDB) and some liberal economists. The meeting defined the lines of macroeconomic policy; market deregulation, the opening of trade and finance, balancing public accounts, privatisation, among others - to be implemented in several peripheral countries. The path towards privatisation and the commodification of health care altered the status of health as an inherent right for all people to a market-based commodity - one that is subject to cost and profiteering. This, in turn, reduced the emphasis on, and indeed the provision of, primary and preventive care, leading to health inequalities.

However, it is important to highlight that, in the 1990s, the Executive Board special group for the review of the Constitution[36] held six meetings, from May 1996 to November 1997. An amendment to the WHO's core functions was recommended, in order that it would become more focused on coordination, international health policy development, setting norms and standards and technical cooperation. Furthermore, the group proposed a revision of article 7, 'Consequences for Members failing to meet financial obligations', to tighten the

[36] Resolution WHA48.14 requested the Executive Board to examine whether the WHO Constitution needed to be revised and, if so, the best way for the revision to proceed. At its ninety-seventh session the Board considered a report by the Director-General on the matter and adopted decision EB97(11) which established a special group of members of the Board to undertake an examination of the Constitution and to report to the Board at its ninety-ninth session. (WHO, 1997, p.1)

existing sanctions.

Ruger and Yach (2009) point out that, at the same time, the Pocantico Center, part of the Rockefeller Foundation, published *Enhancing the Performance of International Health Institutions* (1996). The conclusion was a need for strengthening and updating the WHO's primarily normative functions, as the Organisation should be the 'normative conscience for world health'. On the other hand, new global health actors should address primarily operational functions, regardless of the WHO's emphasis on technical assistance.

A few years later, in 2001, the Civil Society Initiative (CSI) was launched by the WHO General Director and represented a milestone, because it aimed to:

> establish a programme of evidence collection, consultation with a broad range of actors and analysis – within and outside WHO – to identify and develop propositions for more effective and useful interfaces and relationships between civil society and the WHO. This work will be developed within the context of WHO's mandate, the expressed interests of the Executive Board and the World Health Assembly, and in response to interest shown by groups from civil society. (Civil society here includes social movements, voluntary organisations, nongovernmental organisations, grassroots organisations and other non-state and not-for-profit actors.) It is anticipated that within a year this initiative will be followed by concerted action at country, regional and Geneva levels. (BRUNDTLAND, 2001)

At that time, these non-State actors were known as Civil Society Organisations. According to the 2002 Review Report on the *WHO's interactions with Civil Society and Nongovernmental Organisations*, the general constraints for WHO-CSO relations were: a) a lack of distinction between types of CSOs/NGOs; b) insufficient safeguards on conflict of interest; c) lengthy, onerous and rigid procedures; d) an imbalance between the participation of organisations from North/West and South/East.

It is important to note that according to interviewee 14, the Civil Society Initiative was shut down by China and others as 'they saw it as a liberal Western agenda to introduce non-State actors influencing the direction of WHO', and they wanted 'Member States [to] remain in the elite. China was the main one, but [there were] also other countries'. This affirmation was confirmed by interviewees 19 and 20, both former high-level staff at the WHO.

With the failure of this initiative, it took almost a decade for the Director-General, Dr Margaret Chan, to organise an informal consultation with regards to WHO funding, which happened only in 2010. It is worth noting, however, that according to interviewee 14, in 2008 Professor Ilona Kickbusch alongside Gaudez Silberschmidt, the main party responsible for FENSA, 'proposed to create a Commission C at the World Health Assembly, that was shut down by Member States because they didn't want to have an extra governance body or

meeting within WHO'.

The informal consultation of 2010 was attended by senior officials and ministers of health, development, finance and foreign affairs, and as a result *The future of financing for WHO: report of an informal consultation convened by the Director-General, Geneva Switzerland, 12-13 January 2010* was developed. Afterwards, in May 2011, it was discussed in Committee A of the 64th World Health Assembly under the chairmanship of Dr Walid Ammar, Lebanon.

The report was heavily criticised by some NGOs such as Medicus Mundi International (MMI). Thomas Schwarz, the Executive Secretary of MMI, wrote his comments on *WHO reform: construction work ahead* and argued that the title of the report was confusing as the reform should be addressing other things and not only the financing; according to him, the WHO's deep crisis was also a crisis of legitimacy. Schwarz also critiqued the creation of a World Health Forum, as proposed by the Resolution WHA64.2.

Therefore, despite uncoordinated past efforts, the WHO Reform Programme was effectively launched in 2011 during the 64th World Health Assembly as it:

> endorsed the agenda for reform as set out in the Director-General's report; urged Member States to support the implementation of the reform programme; requested the Executive Board to establish an appropriate process to examine the issues related to WHO's governance identified in the report;

Moreover, the Director-General was requested 'to present a detailed concept paper for the November 2012 World Health Forum, setting out objectives, a number of participants, format and costs to the Executive Board at its 130th Session in January 2012'.

The WHA64 can be seen as a breakthrough for the (future) involvement of non-State actors at the WHO as, apart from the request for creation of the World Health Forum to deal with NSAs, Bill Gates, Co-chair of the Bill & Melinda Gates Foundation, was among the 'distinguished guests' and made a speech claiming that:

> As we think about how to deploy our resources most effectively, one intervention in particular stands out: vaccines. Today, I would like to talk to you about how you can provide the leadership to make this the Decade of Vaccines (…) We have a great opportunity in this campaign, and we need to seize it. If we don't seize it in the years ahead, we will have setbacks. This entire decade is an opportunity; we can achieve the ambitious goals for the Decade of Vaccines. Everybody will have to do their part. Donor countries will have to increase investment in vaccines and immunization systems, even as they cope with budget crises. The GAVI Pledging meeting coming up in June gives you and your governments the opportunity to show strong support. With generosity, we will have the chance to prevent 4 million deaths by 2015 and 10 million deaths by 2020. The pharmaceutical industry must make sure that we have new vaccines and that they're affordable for poor countries through a commitment to tiered pricing. And all 193 Member States, you must make vaccines a high priority

> in your health systems, in order to ensure that all your children have access to existing vaccines now – and to new vaccines as they become available. Our foundation is committed to working with all our partners – civil society, donors, drug companies, and national governments – to help you to do these difficult but necessary things. (WHA, 2011)

One must consider that such is the influence of the Gates Foundation at the WHO that the article *Meet the world's most powerful doctor: Bill Gates,* published by Politico[37] alleged that 'some billionaires are satisfied with buying themselves an island. Bill Gates got a United Nations health agency in Geneva'. The dissatisfaction of many global health actors with the involvement of such influential institutions at the WHO became increasingly clear during the reform process, especially in FENSA negotiations.

Subsequently, the 129th Executive Board requested that DG Margaret Chan develop three concept papers on the governance of the WHO, an independent evaluation of WHO, and the World Health Forum. Consultations among the Member States on these papers took place in July and September 2011, at the WHO headquarters. A platform for web-based consultations was also required.

The report *WHO reform for a healthy future: an overview*[38] clarified that, to address the health challenges of the 21st century, Member States had recognised priority topics to narrow the WHO's work that should lead to more efficiency and more adequate financing. These topics were: '(1) health systems and institutions; (2) health and development; (3) health security; (4) evidence on health trends and determinants; and (5) convening for better health'. Then, in November 2011, a special session of the Executive Board took place so that all Member States could review and discuss a proposal for WHO reform, prepared by the Secretariat.

According to the WHO (2011, p.1), the purpose of the World Health Forum was to explore 'in an informal and multistakeholder setting, ways in which the major actors in global health can work more effectively together – globally and at country level'. The World Health Forum was a consultative forum composed of governments, health-related organisations, regional organisations, multilateral and bilateral agencies, philanthropic entities, civil society organisations and private organisations, among others (VENTURA, 2013). The World Health Forum concept paper was the result of this initiative, and recognised the complex growth of organisations involved with Global Health, stating:

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[37] Available at: https://www.politico.eu/article/bill-gates-who-most-powerful-doctor/ Accessed on 14/05/2019
[38] Available at: https://www.who.int/dg/reform/en_who_reform_overview.pdf

> while the growing prominence of health in international affairs is welcome, there is a need to promote greater coherence and to provide an opportunity for a more inclusive dialogue between the many different actors involved. At present, however, there is no single platform that allows interaction between governments, global health organisations, partnerships, regional organisations, multilateral and bilateral agencies, philanthropic foundations, CSOs, private sector organisations and other relevant stakeholders (WHO, 2011, p.1)

The initiative, however, was deeply criticised by NGOs during the WHA. For instance, the World Health People's Health Movement (PHM) wrote the statement *Stop the World Health Forum* arguing that 'as proposed, (WHF) undermines the principles of democratic governance and the independence and effectiveness of WHO. It increases the power of the already disproportionately powerful for-profit sector'. Moreover, IBFAN requested that the Member States reject the draft resolution for the creation of the World Health Forum, for three reasons:

> 1) WHO is an intergovernmental organization (…) [and] must protect its independence, integrity in decision making and its reputation. It must also guard against manipulation of its governing bodies by private interest actors. We believe this forum will undermine WHO's ability to fulfil its mandate. Paragraph 20 (ii) of the report A 64/4 illustrates this point. It states that the expected outcomes of the WHO reform will "Improve health outcomes, with WHO meeting the expectations of its Member States and partners". The reassurances given in paragraph 86 that "a multi-stakeholder forum […] will not usurp the decision-making prerogatives of WHO's own governance" are not credible. How can the WHF meet the expectations of commercial actors without usurping the prerogatives of WHO's own governance? 2. In paragraph 87 of the report A64/4, it is proposed that the multi-stakeholder forum will "identify future priorities in global health". This is a reason for serious concern as it is the WHA's responsibility to set health priorities, benchmarks and standards which will effectively protect health for all. Previous experience with multi-stakeholder initiatives has shown that health priorities are distorted when they have to be agreed by for-profit actors, whose duties and responsibilities are ultimately to their shareholders and employees (…) 3. The WHF institutionalizes conflicts of interests as the norm within WHO by extending the role of policy and decision shaping to for-profit actors that have an interest in the outcome. WHF poses an unjustifiable risk, in that it may compromise and distort international and national agreed public health priorities and policies. This is ever more worrying in the absence of a strong and clear WHO policy on conflicts of interests. Transparency, currently promoted as the answer to the problem of conflicts of interests, is an essential requirement but it is not a sufficient safeguard in itself. It helps identify conflicts of interests but does not deal with them (IBFAN, 2011).

After the failure of the World Health Forum initiative, in February 2012, a Member States meeting on programmes and priority setting intended to develop a joint report to be presented at the WHA in May 2012.

According to the WHO website, 'a comprehensive series of reforms' have been underway since 2012, and the reform proposals were grouped under three topics: 1) programmatic (programmes and priority setting); 2) governance (to increase coherence in global health); and 3) management. The relation between the WHO and the increasing non-

State actors was seen by many as crucial for WHO reform. In 2012, therefore, the WHA requested that the Director-General submit a draft of a 'policy document on WHO's collaboration with NGOs' to the Executive Board. It would become known as FENSA (Framework of engagement with non-State actors), the object of this research.

This second chapter aimed to provide background and historical perspective - both extremely relevant to understand how the Framework of Engagement with non-State Actors (FENSA) was shaped. It has been a while since the World Health Organisation is not the singular player in global health and, as analysed above, it has struggled with how to create rules to better engage with these (not so) new actors. No one can effectively understand FENSA without comprehending the broader context of global health governance. The next chapter will examine how the relationship used to be between non-State actors and the World Health Organisation, before FENSA.

CHAPTER THREE: BUILDING BRIDGES, A BACKGROUND OF THE PARTICIPATION OF NON-STATE ACTORS AT THE WORLD HEALTH ORGANISATION.

The World Health Organisation, as well as the United Nations system as a whole have tried to find effective ways to engage with non-State actors, considering their increasing financial and political influence in global topics, as broadly analysed in the literature review completed in the first chapter. Although the WHO has been engaging with NSAs since its establishment in 1948, their growing participation and interdependence have boosted new architectures of global governance. In September of 1999, for instance, the United Nations Department of Public Information (DPI) held the Conference *Challenges of a Globalised World: Find New Directions*. The focus was on the ways in which the United Nations and civil society, particularly non-governmental organisations, could influence policies more effectively. Since the 1978 Declaration of Alma-Ata, people's participation has been recognised as crucial for primary healthcare and accepted as an essential element of many public health interventions. Civil Society Organisations (CSO) are seen as a tool to share benefits while minimising emerging problems.

Given the heterogeneity of non-State actors, some concepts need to be clarified in order to comprehend their participation in the global health scenario and, specifically, at the WHO. CSOs are not-for-profit, voluntary entities, organised at the local, national or international level, representing a wide range of interests, but are separated from the State and the market. They can include community-based organisations and NGOs. Civil society organisations have played an essential role in supporting the WHO in accomplishing its mandate, through advocating topics of public health promoted by the Organisation, meanwhile raising awareness in a wide-ranging public. Moreover, they have been performing a watchdog function, pursuing the promotion of transparency and accountability and acting as a representative of public interest by giving a voice to the marginalised or under-represented. CSOs are also key partners of the WHO at the national level due to their role as capacity builders. They are, therefore, able to boost domestic health systems' ability to implement WHO programmes and recommendations. Although CSOs have a greater degree of agility due to a somewhat loose organisational structure, allowing more efficient actions without formal supervision, they could be considered to have a disproportionate and

unmonitored influence.

The WHO definition of NGOs is very comprehensive, and it was recognised by Margaret Chan, in 2012:

> No one questions the contribution your organisations make to the work of WHO. Worldwide, your numbers have increased dramatically in recent years, as have your influence on health policies, and your impact on health conditions. Your influence is most visible during the negotiation of instruments for global health governance, such as those for tobacco control or access to medicines. Your impact is most visible at the country level, where many of you work as implementing agencies. As I have said on several occasions, improvements in health outcomes within countries are the most important measure of the effectiveness of all WHO activities. NGOs occupy a unique political space. You gather and express the social power of ordinary people, as opposed to the coercive and regulatory powers of governments and the economic power of the market. NGOs operationalise WHO technical recommendations, taking them in particular to poor and marginalised populations. In conflict situations, or in very poor or poorly governed countries, NGOs can be the main providers of health services. The same is true during humanitarian emergencies. You bring coalitions of researchers, professional societies, medical schools, and medical students to bear on specific health problems. You crusade for human rights. (…) I fully understand your concern about insufficient safeguards against conflicts of interest, a concern strongly voiced by our Member States. At the same time, the NGO community is not a uniform group of altruistic organisations. I understand there are many subcategories, like BINGOS (business-interest NGOs), PINGOS (public-interest NGOs), GONGOS (government-operated NGOs), even CONGOS (community-organised NGOs) and TANGOS (technical-assistance NGOs). Organisational and operational frameworks differ. The size of operations vary, as do degrees of effectiveness and sustainability of results (…) Nothing is clearly black and white. (CHAN, M. 2012. WHO Director-General addresses NGO community. 18 October 2012. Geneva)

This understanding, however, contradicts the most notorious definitions of NGOs, which should have a non-profit nature.

The WHO used to accept that NGOs that were representing private sector entities into official relations. One example is the International Federation of Pharmaceutical Manufacturers & Associations (IFPMA). The controversy surrounding how ‘business-interest NGOs’ representing big companies were allowed to have official relations with very little oversight will be discussed further in this chapter.

It is important to note that, although there is an extensive academic debate about the concept of civil society, to make this research practical, I have decided to work with the WHO’s conceptual framework, considering that Member States were consensual about it. It is worth clarifying that this thesis will not critically analyse the use of these concepts. As a starting point, the main concepts adopted for research are presented in the following table.

Table 4: Definition of non-state actors under FENSA / WHO

<table>
<tr><td rowspan="2">Private sector</td><td colspan="3">Commercial enterprises, that is to say businesses that are intended to make a profit for their owners. The term also refers to entities that represent, or are governed or controlled by, private sector entities. This group includes (but is not limited to) business associations representing commercial enterprises, entities not ‘at arm’s length’ (if it is independent of the other entity, it does not take instructions and is clearly not influenced or clearly not reasonably perceived to be influenced in its decisions and work by the other entity) from their commercial sponsors, and partially or fully State-owned commercial enterprises acting like private sector entities. (§11)</td></tr>
<tr><td>International business associations</td><td colspan="2">Private sector entities that do not intend to make a profit for themselves but represent the interests of their members, which are commercial enterprises and/or national or other business associations. For the purposes of this framework, they shall have the authority to speak for their members through their authorized representatives. Their members shall exercise voting rights in relation to the policies of the international business association. (§11)</td></tr>
<tr><td>Non-governmental organizations (NGO)</td><td colspan="2">Non-profit entities that operate independently of governments. They are usually membership-based, with non-profit entities or individuals as members exercising voting rights in relation to the policies of the non-governmental organization, or otherwise consist of non-profit, public-interest goals. They are free from concerns which are primarily of a private, commercial or profit-making nature. They could include, for example, grassroots community organizations, civil society groups and networks, faith-based organizations, Professional groups, disease-specific groups, and patient groups. (§10)</td><td rowspan="2">The WHO will determine through its due diligence if a non-State actor is subject to the influence of private sector entities to the extent that the non-State actor has to be considered itself a private sector entity. Such influence can be exerted through financing, participation in decision-making or otherwise. Provided that the decision-making processes and bodies of a non-State actor remain independent of undue influence from the private sector, the WHO can decide to consider the entity as a non-governmental organization, a</td></tr>
<tr><td>Philanthropic foundations</td><td colspan="2">Non-profit entities whose assets are provided by donors and whose income is spent on socially useful purposes. They shall be clearly independent of any private sector entity in their governance and decision-making. (§12)</td></tr>
</table>

Academic institutions	Entities engaged in the pursuit and dissemination of knowledge through research, education and training. (§13) This can include think tanks which are policy-oriented institutions, as long as they primarily perform research; while international associations of academic institutions are considered as NGO. (Note 2, p.10)	philanthropic foundation or an academic institution, but may apply relevant provisions of the WHO's policy and operational procedures on engagement with private sector entities, such as not accepting financial and in-kind contributions for use in the normative work. (§14)

Source: VENTURA and RACHED based on WHO. EB138 / 7. 8 January 2016.

Considering the close formal and informal relationship between the World Health Organisation and a great number of non-State actors, this chapter aims to understand how the WHO used to engage with them before FENSA. To understand why FENSA was proposed, negotiated and approved, without understanding the previous relationship between the Organisation and the four non-State actors involved seems impossible.

3.1 WHO Legislation regarding non-State Actors

The World Health Organisation has been a pioneer in addressing the issue of social participation in international organisations, going beyond the understanding of health as an individual right, and also including the communal and developmental dimensions. In the preamble of its Constitution, the Organisation guaranteed that 'informed opinion and active cooperation on the part of the public are of the utmost importance in the improvement of the health of the people' (WHO, 1948).

Moreover, the WHO Constitution not only mentions the role of public opinion and the active cooperation of citizens but also insists on the participation of non-governmental organisations in its bodies. For example, among the functions of the World Health Assembly (WHA), I highlight two:

> (g) to instruct the Board and the Director-General to bring to the attention of Members and of international organisations, governmental or nongovernmental, any matter with regard to health which the Health Assembly may consider appropriate;
> (h) to invite any organisation, international or national, governmental or non-governmental, which has responsibilities related to those of the Organization, to appoint representatives to participate, without right of vote, in its meetings or in those of the committees and conferences convened under its authority, on conditions prescribed by the Health Assembly; but in the case of national organisations, invitations shall be issued only with the consent of the Government concerned (WHO, 1948).

Additionally, article 71 establishes that the Organisation, concerning matters falling

within its competence, can make suitable arrangements for consultation and cooperation with international non-governmental organisations and, with the consent of the Government concerned, with national organisations, governmental or non-governmental (WHO, 1948).

Apart from the Constitution, relations between the WHO and the civil society were originally established at the first World Health Assembly in 1948, as it recognised that 'co-operation with professional and technical non-governmental organisations would be of value to WHO in many fields, and would assist WHO in many of the objectives envisaged by the Constitution' (WHO, 1948, p.82). The *working principles in relations with non-governmental organisations* were adjusted and expanded by the Third, Eleventh and Twenty-first World Health Assemblies (resolutions WHA1.130, WHA3.113, WHA11.14 and WHA21.28). Accordingly, the number of NGOs in official relations grew from 18 in 1948, to 206 at the beginning of 2016. These initial principles were mainly focused on the participation of NGOs at governing bodies' meetings rather than on programmatic issues.

Although since its creation the WHO recognises non-governmental organisations as important actors to address health challenges, it was from the late 1980s that the Organisation started to realise 'the complementarity of the resources they [NGOs] represent in the network of governments, peoples and WHO striving for health development (…) [and] the need to mobilize national and international non-governmental organisations for accelerated implementation of health-for-all strategies' (WHO, 1987, p.1). In 1987, the Executive Board, in light of article 71, recommended that the WHA adopt the 'revised version' of the Principles Governing Relations between the WHO and non-governmental organisations. This document then became the basic legal instrument for relations between them. The approved Resolution (40.25) decided that:

> The objectives of WHO's collaboration with NGOs are to promote the policies, strategies and programmes derived from the decisions of the Organisation's governing bodies; to collaborate with regard to various WHO programmes in jointly agreed activities to implement these strategies; and to play an appropriate role in ensuring the harmonising of inter-sectoral interests among the various sectoral bodies concerned in a country, regional or global setting (WHO, 1987).

Regarding the WHO's policies for engagement with non-State actors, seven documents were published between 1948 and 2010. Apart from the aforementioned *Working Principles of 1948* which were replaced by the Principles of 1987, there were the Regulations for Expert Advisory Panels and Committees - published in 1951 and replaced in 1982. It stated that 'organisations of the United Nations system, as well as non-governmental organisations in

official relations with WHO, may be invited to send representatives to expert committee meetings in which they are directly interested'. The purpose of the expert committee was to review and make technical recommendations to the Organisation on subjects of interest.

Moreover, in 1964, the *Regulations for Study and Scientific Groups, Collaborating Institutions and other Mechanisms of Collaboration* were published. The document regulates skilled advice on disciplines related to health and social development, and the direct support of global, interregional and regional technical cooperation programmes for national health development, given by individual, groups and institutions. It was amended once, in 2002.

In 1982, the thirty-fifth World Health Assembly approved the new regulations for expert advisory panels and committees in replacement of those adopted by the 4th WHA and amended by the 13th WHA. According to the regulations, an expert advisory panel might be established by the Director-General in any field and when required by the development of the Organisation's programme. Moreover, 'any person possessing qualifications and/or experience relevant and useful to the activities of the Organization in a field covered by an established expert advisory panel may be considered for appointment as a member of that panel after consultations with the national authorities concerned' (WHA, 1982, p.4).

In 2001, the Guidelines on Working with the Private Sector were established, and in 2010 the Policy on WHO engagement with global health partnerships and hosting arrangements was conceived.

To summarise, the table below shows all Resolutions and Guidelines which have historically coordinated the relationship between the WHO and non-State actors.

Year	Document	Will it be replaced by FENSA?
1948 (WHA1.130)	Working Principles in Relations with non-Governmental Organization	Amended in 1950, 1958 and 1968. Replaced in 1987.
1951 (WHA4.14)	Regulations for Expert Advisory Panels and Committees	Replaced in 1982
1964 (EB69.R21)	Regulations for Study and Scientific Groups, Collaborating Institutions and other Mechanisms of Collaboration	Amended in 2002 and shall be aligned with FENSA
1982 (WHA35.10)	Regulations for Expert Advisory Panels and Committees	Yes

1987 (WHA40.25)	Principles Governing Relations between the WHO and non-Governmental Organizations	Yes
2001 (EB107.20)	Guidelines on Working with the Private Sector to Achieve Health Outcomes	Yes
2010 (WHA63.10)	Policy on WHO Engagement with Global Health Partnerships and Hosting Arrangements	No, but shall be aligned with FENSA

This chapter was mainly based on the existing literature and documents from WHO Archives. The interviews conducted also provided some clarification when needed. The methodology used in this chapter is a content and discourse analysis; the aim is to give voice and meaning to the topic. Ten visits were made to the WHO Archives in Geneva and one visit to the United Nations Archives Office in New York. It is important to note that, according to WHO Archives access policy, archives are only accessible to researchers once the records are at least 20 years old. While in New York, forty documents regarding Global Health Foreign Policy and Resolutions adopted by the General Assembly were considered; in Geneva, one hundred and nine documents, with a ten-year timeline from 1987 to 1997 were analysed – those that contained at least one of these keywords: private sector, industries, universities, foundation, NGO, financial, technical collaboration, technical cooperation.

According to O'Leary (2014), there are three sorts of documents: Public Records, Personal Documents and Physical Evidence. As mentioned above, public records from the World Health Organisation and the United Nations formed the basis of this chapter. However, personal documents such as meeting notes and unpublished insights from individuals associated with non-State actors were also used. Some interviewees provided these documents. In view of valuable information about the concrete social, political and economic context of the analysed subject, all kinds of voices were sought and heard.

The next items will analyse the policies used to regulate the WHO's engagement with the four non-state actors embraced by FENSA: non-governmental organisations, the private sector, philanthropic foundations and academic institutions.

3.2 Non-governmental Organisations

As mentioned previously, engagement with NGOs derives from article 71 of the

WHO's Constitution - whereby the Organisation might make appropriate arrangements for consultation and cooperation with non-governmental organisations in carrying out its international health work. The relation was regulated by the *Principles Governing Relations between the World Health Organization and Nongovernmental Organisations,* last updated in 1987, which gave as its main objectives 'to promote the policies, strategies and programmes derived from the decisions of the Organisation's governing bodies; to collaborate with various WHO programmes in jointly agreed activities to implement these strategies; and to play an appropriate role in ensuring the harmonising of intersectoral interests among the various sectoral bodies concerned in a country, regional or global setting'.

According to the WHA40.25 Resolution (1987, p.1), the Organisation recognises 'only one category of formal relations, known as official relations (…) all other contacts, including working relations, are considered to be of an informal character'. For that reason, only entities in 'official relations' were allowed to participate in the meetings of the Governing Bodies, at least officially, and representing themselves. By participating in a GB meeting, an NGO in official relations 'shall be entitled to make a statement of an expository nature'. It is worth noting that official relationship status did not give NGOs the right to vote. The decision-making of the WHO has always been a prerogative of Member States, given the intergovernmental nature of the Organisation.

The decision about the type of relationship was made by the Standing Committee on Nongovernmental Organisations,[39] which recognised three levels of relations: informal contact, working relations, and formal relations. According to the last register before FENSA's approval, dating from January 2016, 206 NGOs were in official relations with the WHO, outlining a very heterogeneous group (WHO, 2016).

Informal relations consisted of 'exchanges of information and reciprocal participation in technical meetings' and could remain *ad hoc* as long as necessary without written agreement. When several specific joint activities were identified, collaboration could take a subsequent step by proceeding to a period (usually two years) of working relations. For this to occur, an exchange of letters was required, indicating details of the activities to be

[39] The Standing Committee on Nongovernmental Organisations used to make recommendations to the Board on the application for admission of nongovernmental organisations into official relations with WHO and was dissolved by the decision EB139(2) (2016), in follow-up to resolution WHA69.10 (2016) on the Framework of Engagement with Non-State Actors. Available at: https://www.who.int/about/collaborations-and-partnerships/who-s-engagement-with-non-state-actors/former-standing-committee-on-nongovernmental-organizations Accessed on 23/05/2019.

undertaken during the period. Additionally, an evaluation of the outcomes of the collaboration at the end of the joint activities was needed. Afterwards, the relation could result:

> in the continuation of the working relations for a further period; in an application for admission into official relations with WHO from an international NGO, for examination by the Executive Board, should there be a number of activities which might form the basis of a long-term and closer relationship with WHO; or in a decision that there is no scope for further contacts in the foreseeable future. (WHO, 1987, p.2)

Working and informal relations did not have to pass through the Executive Board. They previously required approval from the WHO Secretariat, which, however, could not guarantee the right to formal participation in the meetings of the Executive Board or the World Health Assembly. For formal recognition, as well as participation in decision-making bodies, the NGO would have to successfully complete a period of working relations and then apply for official relations. To be admitted into official relations, the interested NGO should: (*i*) present the main area of competence, which must be in line with WHO's purviews; (*ii*) not pursue commercial interests; and (*iii*) have activities which 'shall be relevant to and have a bearing on the implementation of the health-for-all strategies'. Every three years the collaboration should be reviewed by the Standing Committee on Nongovernmental Organisations.

The efficacy of this arrangement of relations, however, proved to be very limited - firstly because official relations were not applied to the WHO's regional and national offices, secondly because the rate of participation of these entities in the meetings of the Governing Bodies was less than 50% at the WHA and less than 30% at the Executive Council sessions. Lastly, and perhaps most importantly, because of the informal nature of relations between NGOs and the WHO, which were to be found in the greatest quantity (WHO, 2012).

During the interviews, I asked why the WHO did not adjust the 1987 principles instead of creating a new Framework. It was pointed out that the main issue at the WHO has always been the private sector; specifically, how under the umbrella of NGOs, they were able to have official relations with the WHO. Therefore, an update wouldn't be a solution by itself. Furthermore, interviewee 7, from the United Kingdom, affirmed that the discussions on the relationship between the Organisation and non-State actors opened a 'Pandora's box', as it 'became clear that it was a much more complex and complicated process'.

The relationship between the WHO and NGOs has been a controversial issue, although

not as much as its relationship with the private sector. On the one hand this was due to the requirements for entrance into official relations, which became a barrier that restricted the inclusion of those sections of civil society that are nationally-based or from lower-middle-income. Consequently, the process was unintendedly favouring big international NGOs to be admitted into official relations:

> the NGO shall normally be international in its structure and/or scope, and shall represent a substantial proportion of the persons globally organised for the purpose of participating in the particular field of interest in which it operates (…); shall have a constitution or similar basic document, an established headquarters, a directing or governing body, an administrative structure at various levels of action, and authority to speak for its members through its authorised representatives. Its members shall exercise voting rights in relation to its policies or action (…). In exceptional cases, a national organisation, whether or not affiliated to an international NGO, may be considered for admission into official relations, in consultation with and subject to the recommendations of the WHO Regional Director and the Member State involved. (WHO, 1987, p.3)

On the other hand, there were inadequate safeguards against conflicts of interest, which the interviews confirmed to be the principal concern of Member States. Foremostly, however, the rules failed to distinguish between public interest NGOs and business interest NGOs. When conducting the interviews, I could observe that the potential and veiled influence of the private sector was the main concern behind FENSA negotiations.

We should consider a letter from Dr Yuji Kawaguchi, Director of the *Division of Interagency Affairs* of the WHO Headquarters in Geneva, to the Assistant of the United Nations Secretary-General for External Relations in April 1998. It can be observed that since that time, the relationship with NGOs was an ongoing topic within the WHO:

> It was generally agreed that 'civil society' was composed of a number of elements, e.g. the associative type of organisation generally known as 'nongovernmental organisation', academia, religious groups, the media, foundations, as well as various sectors of the business world. (…) Please find attached, as requested, information regarding the current policies and practices of WHO in its relations with NGOs. I should also mention that WHO is currently involved in a process of reviewing its relations with NGOs outside the health sector.

Bearing in mind that NGOs have always been a key topic, even soon after updating the principles governing relations in 1987, the Organisation subsequently tried, in the early 2000s, to create a *civil society initiative*, as briefly mentioned in chapter 2. The aim was to clarify the different roles that civil society could have while working in collaboration with the WHO. In 2002, a review report of the ongoing policies and practices regarding civil society and non-governmental organisations was released. The report considered 'civil society organisations' as 'non-state, not-for-profit, voluntary organisations formed by people within

the social sphere of civil society' which 'cover a variety of organisational interests and forms, ranging from formal organisations registered with authorities to informal social movements coming together around a common cause'. It was highlighted how the borders were blurred, not only between state and non-State but also between market and non-market, due to excessive involvement of States and commercial enterprises. The report, therefore, pointed out that both private sector NGOs and public interest or citizen grouping NGOs were allowed to have official relations with the WHO under the same status of 'NGOs'.

The 2002 report listed, as general constraints for the relationship between the WHO and NGOs: gaps in communication and information, a lack of distinction between types of CSOs and NGOs along with insufficient safeguards over conflict of interests. Additionally, 'lengthy, onerous and rigid procedures', 'personalised linkages',[40] 'insufficient information on NGOs', 'uneven participation at governing bodies' and 'imbalance between North and South' were cited as specific problems of the official relations system. Finally, the constraints upon informal and working relations were also pointed out: lack of participation, lack of relevant guidelines and regional and country-level concerns. The latter was emphasised due to development aid actions which were 'increasingly being channelled through CSOs at the country level, with or without government consent, country office staff were also uncertain about circumstances under which they were allowed to work with CSOs directly or whether government endorsement was needed for all WHO collaboration with a national CSO' (WHO, 2002, p.17)

One of the primary arguments was that in July 2002, 189 non-governmental organisations were in official relations, and when analysing the previous four years, 'around 40% of these non-governmental organisations have attended the Health Assembly and 25% have attended Executive Board sessions. On average over that period, 16 non-governmental organisations made statements to each Health Assembly and 11 to each Executive Board session'. Moreover, the report revealed that the Organisation had more informal contacts and working relations, as 'an inventory of all interactions of the WHO at Geneva with non-governmental organisations revealed that 45% were with those in official relations and 55%

[40] "The linkage between the NGOs in official relations and WHO is between two individuals – the focal point in the NGO and the WHO designated technical officer. Therefore, the quality and endurance of the relationship can sometimes boil down to the personal commitment and rapport between the two individuals. This individual link can be broken during a turnover of WHO and NGO staff, leading to difficulties in re-establishing the relationship when new people take over" (CSI, 2002, p.15). Available at https://apps.who.int/iris/bitstream/handle/10665/67596/WHO_CSI_2002_WP6.pdf?sequence=1&isAllowed=y Accessed on 10/12/2019

were with those not in official relations. Regional and country offices report a similar pattern'.

The Civil Society Initiative, through the review report, then suggested that the WHO replace the 1987 Principles with a new policy which should involve a collaboration policy and an accreditation policy; the latter of which, in contrast with the official relations system, would not be conditional on working relations with the Secretariat.

After extensive debate on a new policy for relations between the WHO and non-governmental organisations, the 111th Session of Executive Board, in January 2003, decided to endorse the proposed policy which should replace the 1987 Principles:

> recognising the importance of civil society and its contributions to public health, and the growth in the numbers and influence of nongovernmental organisations active in health at global, regional and national levels; (…) noting that the existing Principles governing relations between the World Health Organization and nongovernmental organisations adopted by the Fortieth World Health Assembly in 1987 (resolution WHA40.25) have been reviewed; Noting the need to improve existing collaboration and dialogue with nongovernmental organisations, and to encourage new cooperative activities with such bodies.

The Resolution EB111.R14 also decided that the Director-General should establish 'suitable measures to implement the policy, including guidelines on the accreditation of, and collaboration with, non-governmental organisations'.

In April 2003, the 56th World Health Assembly declared that an improvement on dialogue and collaboration was needed, in response to the increase in both numbers and importance of non-governmental organisations within the WHO and the international arena. The report by the Director-General presented to the WHA, hence, pointed out the main findings and conclusion of the Civil Society Initiative review.

The *Policy for relations between the World Health Organization and Non-governmental Organisations* stated in its Introduction that:

> an organisation that is not established by a governmental entity or intergovernmental agreement shall be considered a nongovernmental organisation, including organisations that accept members designated by governmental authorities, provided that such membership does not interfere with the free expression of views of the organisation. For the purpose of this policy, nongovernmental organisations include a wide range of organisations, such as groups that represent consumers and patients, associations with humanitarian, developmental, scientific and/or professional goals and not-for-profit organisations that represent or are closely linked with commercial interests (WHA, 2003, p.5)

Moreover, the Accreditation Policy established the principles by which NGOs would be allowed to attend and participate in meetings of WHO governing bodies. To be eligible for accreditation to the World Health Assembly, the Executive Board and committees and

conferences convened under their authority, a non-governmental organisation should, amongst other stipulations, 'be non-profit in nature, and disclose information on its objectives, structure, membership of the executive body, field of activities and source of financing'. The privileges conferred to qualified non-governmental organisations included:

> (a) to appoint a representative to participate, without a right of vote, in governing body meetings and committees and conferences convened under their authority; (b) to make a statement of an expository nature at such meetings on agenda items of relevance to the non-governmental organisation, at the invitation of the Chairman; (c) to submit documents pertaining to such meetings, the nature and scope of distribution of which shall be determined by the Director-General (WHA, 2003, p.7).

The Collaboration Policy aimed to boost and simplify cooperative activities with non-governmental organisations, whether be they national, regional or international. Furthermore, collaboration with the WHO would be independent of the Accreditation Policy, and guided by four principles:

> (a) collaboration shall advance the objectives of WHO and be in conformity with policies adopted by the World Health Assembly; (b) collaboration shall be with a nongovernmental organisation that has a demonstrated competence in a field of activity related to the work of WHO; (c) collaboration shall be based on adequate knowledge of relevant characteristics of the nongovernmental organisation such as its objectives, structure, membership of executive body, field of activities and source of financing, so as to enable the Director-General or officials designated by the Director-General to assess the suitability of collaboration; (d) collaboration shall not compromise the independence and objectivity of WHO and shall be designed to avoid any conflicts of interests. (WHA, 2003, p.7)

Later, in November 2003, at the 113th Session of the Executive Board, it was declared that, due to insufficient time to consider the suggestions made, further review by the EB was required, and that the proposed Resolution be presented and discussed, once again, in the 57th WHA, in April 2004.

According to the article *Overhaul needed on rules on the WHO's relationship with NGOs* written by Sangeeta Shanshikant and published in the South-North Development Monitor (SUNS), No. 7290 on 19 January 2012,[41] the new policy had little success and remained 'in a coma, ignored and unimplemented'. Moreover, as already mentioned, interviewees 14, 19 and 20 affirmed that the proposal was shut down mainly by China, because 'they saw it as a liberal Western agenda to introduce non-State actors influencing the direction of WHO and the Member States should remain in the elite'. Correspondingly, interviewee 19, a former staff member who was the first responsible for elaborating the

[41] Available in: https://www.twn.my/title2/intellectual_property/info.service/2012/ipr.info.120103.htm Last access on 09/12/2019.

policies for the engagement with NGOs at the WHO, confirmed that some Member States historically have a fairly unfavourable position regarding the participation of non-governmental organisations, due to a strict perception of a central control of the State. China was cited as an example. The interviewee also confirmed that China was the main opponent to advance the reform on the relationship between the WHO and NGOs in the previous years before FENSA.

It can be observed that the relationship with NGOs has always been a major topic since the establishment of the WHO, both in its Constitution and with the first version of principles and guidelines launched at the first World Health Assembly. After minor amendments in 1950, 1958, 1968, they were completely replaced in 1987. However, the topic never remained overlooked, as was revealed in this chapter. This ambiguous relationship was then resurfaced as part of the WHO Reform, leading to the proposal and approval of FENSA in 2016, which will be analysed in detail in chapter 4.

3.3 Private Sector

In contrast with non-governmental organisations, the engagement with the private sector is not directly mentioned by the WHO's Constitution but is instead based on interpretations. It is worth noting that while the World Health Assembly adopted the NGOs guiding principles in 1987, the private sector principles were debated and, as they could not be agreed, were only noted by the 107th Session of the Executive Board in 2000 - not being approved or endorsed by the Member States.

In December 1999, the 105th Session of the Executive Board stressed how new policies and initiatives were being developed for collaboration with the public and private sectors, including foundations. It was asserted that:

> WHO is conscious of the potential of collaboration with the private sector at global, regional and country levels. The private sector has strong advantages that enable WHO to reach wider and to have a more significant impact on global public health. Thus far formal or informal partnerships have been established around drug and vaccine donations, donations in kind, pro-bono services, advocacy and communications, and financial support. (…) The Global Polio Eradication Initiative is an outstanding example of successful public-private sector collaboration between organisations of the United Nations system, Member States, foundations, nongovernmental organisations and the private sector. Rotary International, in particular, has contributed millions of volunteer work-hours, donations in-kind and advocacy efforts, along with financial support exceeding US$ 325 million, to the eradication of poliomyelitis. The recent commitment of De Beers to eradication of poliomyelitis has so far resulted in not only significant financial support but also advocacy activities ranging from its Chairman's calls to other business leaders, through active community engagement, to global media coverage. Given the

> imperative need to ensure that donations from the private sector are suitable, avoid conflicts of interest and provide clear health benefits, WHO revised its Guidelines on interaction with commercial enterprises in July 1999 for implementation on a trial basis. Consultations on these guidelines with governments and the private sector are being pursued.(EB, 2000, p.2)

A report by the Director-General Dr Gro Harlem Brundtland was presented at the EB105, asking for Member States to join forces with a variety of private sector partners from industries that did not traditionally work with the WHO as it could 'clearly enable WHO to have a broader and deeper impact on global public health'. The Global Alliance for Vaccines and Immunization (GAVI) was cited, for instance, as it had vast support from several public and private partners and also due to the WHO's 'lead role (…) which aims at saving children's lives and protecting people's health through the widespread use of safe vaccines'. Some literature indicates that the years of Dr Brundtland's administration (1998-2003) were the beginning of more WHO openness to the private sector, under the name of public-private partnerships.

The *Draft Policy on Extrabudgetary Resources* was also recommended by the Executive Board, emphasising a wider resource base, 'with more Member States contributing, and greater involvement of the public and private sectors'.

Regarding the guidelines on interaction with commercial entities, the Member States and non-governmental organisations in official relations with WHO were able to submit comments on the draft, which was also used alongside individual proposals for interaction with the private sector from previous years. The guidelines were, then, revised, taking into account the comments received, and past experience, and submitted to the 107th Session of the Executive Board in January 2000.

The goal of the guidelines were to 'help WHO staff to interact appropriately with commercial enterprises in order to achieve positive outcomes for health' and commercial entities were defined as those planned to make a profit for their owners. Moreover, the guidelines could be applied 'to a variety of other institutions, including State-run enterprises, associations representing commercial enterprises, foundations not at arm's length from their sponsors, and other not-for-profit organisations such as academic institutions' (EB, 2001, p.2) It can be observed that there was no mention of NGOs funded by the private sector.

According to the guidelines, the collaboration between the WHO and commercial enterprises was through 'participation with one or more commercial enterprises in alliances

and other relationships (sometimes with other public bodies, governments, nongovernmental organisations and foundations) to address specific health issues; exchange of information; product research and development; generation of cash and in-kind donations; advocacy for health' (EB, 2001).

Regarding conflicts of interest (the main concern during FENSA negotiations), it was stated that WHO Staff should always consider whether a relationship might involve a real or perceived conflict of interest, either for the staff member or for the work of the Organisation. No real or perceived definition of conflict of interest was assumed, in fact, an indefinite 'step-by-step evaluation of the commercial enterprise' was pointed out 'as the best way to identify potential areas of conflict of interest'. Relations with the tobacco or arms industries were advised to be avoided as well as indirect collaboration, 'particularly if arranged by a third party acting as an intermediary between WHO and a commercial enterprise' (EB, 2001, p.3).

Donations were one of the topics that raised more concern due to scandals surrounding the Organisation receiving illegal donations from the pharmaceutical industry. In 2007, for instance, the journalist Michael Day, in a report published by the BMJ, revealed that:

> Email correspondence passed to the BMJ seems to show that in June 2006 Benedetto Saraceno, the director of WHO's department of mental health and substance abuse, suggested that a patient organisation accept $10 000 (£5000; €7000) from GlaxoSmithKline (GSK) on WHO's behalf. The sum was then to be passed on to WHO—ostensibly with the intention of obscuring the origins of the donation. GSK withdrew its offer of funding when it learnt that acceptance was conditional on obscuring its origin. However, the email exchange indicates that other sums of money originating from drug companies may have already been channelled to WHO through patient groups (…). In the email dated 16 June 2006, Dr Saraceno thanks Mary Baker of the European Parkinson's Disease Association (EPDA), for raising the $10 000 "requested by the WHO." The money was to have funded a report on neurological diseases, including Parkinson's disease, for which GSK produces treatments. Dr Saraceno then seems to advise Mary Baker on how to get round the WHO's rules forbidding drug industry funding. "Unfortunately," he says, "WHO cannot receive funds from pharmaceutical industry. Our legal Office will reject the donation. WHO can only receive funds from Government agencies, NGOs, foundations and scientific institutions or professional organisations. Therefore, I suggest that this money should be given to EPDA and eventually EPDA can send the funds to WHO which will give an invoice (and acknowledge contribution) to EPDA, but not to GSK. (Day, 2007, p.338)

According to paragraph 15 of the WHO's guidelines on interactions with commercial enterprises, which deals with cash donations, funds may not be sought or accepted from commercial entities that have a direct profitable interest in the outcome of the project. Paragraph 16 then states that caution should be exercised even when the business has an

indirect interest.

Regarding Cash Donations, the guidelines stated that for meetings convened by the WHO, financial aid from commercial enterprise may not be accepted if 'it is specifically designated to support the participation of any or all of the invitees (including such invitees' travel and accommodation), regardless of whether such contribution would be provided directly to the participants or channelled through WHO'. When staff from the WHO participate in an external meeting, support from commercial enterprises for travel 'may be accepted if the company or trade association is also supporting the expenses of other participants at the meeting' and may not be accepted if a third party holds the external meeting.

It is important to highlight that, with regards to activities leading to the development of WHO guidelines or recommendations, financial donations should also not be accepted for financing staff salaries. Furthermore, paragraph 27 states that for reasons of transparency, contributions from commercial enterprises must be publicly acknowledged.

With regard to non-monetary contributions, in-kind donations, it is worth noting that pharmaceuticals should only be accepted under unbiased and justifiable criteria for the selection of recipient countries, communities or patients and if the drug donation is not 'of a promotional nature, either with regard to the company itself or by creating a demand for the drug which is not sustainable once the donation has ended' (EB, 2001, p.7).

Secondments, a topic that led to many confrontational discussions during FENSA negotiations, and one that will be analysed in chapter 4, used to be accepted from the private sector for a limited period, as long as the individual was not seconded from 'industries whose activities clearly conflict with WHO's mandate' or no conflict of interest existed between the person's proposed activities for the WHO and the activities for the employer company. Moreover, the guidelines highlighted that exceptional care should be taken when the secondment was from health-related enterprises.

Since the 1990s, when the private sector was raised as a remarkable source of financing and leadership in tackling diseases, its relationship with the WHO was seen as deceitful. Extra caution was therefore needed. Undoubtedly, the pharmaceutical industry and the food and beverage industries were mainly in the spotlight. For instance, in February 1998, a Memorandum from the FSF Director to the INA Director regarding WHO collaboration

with the private sector claimed that:

> A Food Safety Programme cannot function effectively without the collaboration of the food industry (i.e. primary procedures, processors, vendors/trade, food service industry). Our collaboration with the food industry started in the mid-80s. It has always been our policy not to collaborate with individual enterprises but with industry organisations. Two such organisations, the International Life Sciences Institute (ILSI) and the Industry Council for Development were given the status of NGOs in official relations with WHO. Collaboration with ILSI extends mainly to cosponsoring large regional and global food safety conferences while collaboration with ICD is more country-project-oriented with emphasis on development of training material and conducting training course.

Furthermore, in 1998, a Memorandum written by Dr Yuji Kawaguchi, *Director of the* Division of Interagency Affairs of WHO in Geneva stated that:

> The United Nations system, including WHO, is being urged, within the context of the movement in the United Nations and through the system, to intensify and consolidate collaboration with the private sector, for the benefit of Member States. This matter will be on the Agenda of the forthcoming Administrative Committee on Coordination (ACC), Geneva, 27-28 March 1998 and the item will be prepared by the Organisational Committee (OC/ACC) at its meeting, 6-9 March 1998, prior to ACC. I am therefore requesting that we obtain from your division the facts concerning WHO collaboration with commercial enterprises, and your views on this, if any.

In 1997, a fax correspondence to Dr Fritz Kaferstein, Director of Programme of Food Safety and Food Aid stated:

> Dear Fritz, thanks for the great news about your new arrangement. I had heard rumours but nothing specific. You and your associates must feel particularly good about this recognition since you know you earned it all the way – and with some risks taken about "political correctness". On the Business Week article why don't you write to the Personal Business editor, Edward C. Baig (Address) complimenting him on the article and pointing out that WHO has a major food safety programme which is supported by the global food and allied industries particularly through organisations like the ICD and ILSI.

Kaferstein answered:

> Dear Walter, thank you for the newspaper clipping. Why don't you write to the journal drawing their attention to the fact the WHO has issued Ten Golden Rules for Safe Food Preparation which may be obtained free of charge, from our office.

When it comes to Food and Beverage industry, companies have moved to the forefront of global health initiatives, especially those related to noncommunicable diseases. The International Food and Beverage Alliance (IFBA), which was interviewed for this thesis, consists of the 'leading global food and non-alcoholic beverage companies' aiming to 'empower consumers to eat balanced diets and live healthier lives'.[42] The IFBA includes Nestlé, PepsiCo, The Coca-Cola Company, McDonald's and others, and has been participating energetically in negotiations, taking part in ministerial meetings and chairing

[42] Available at: https://ifballiance.org/ . Last access on 20/12/2019

working groups. The concerns regarding this involvement should not be a surprise however, as central commercial interests collide with global health problems. The article *How Private Companies are Transforming the Global Public Health Agenda* (2011)[43] elucidates this conflict of interest:

> Soft-drink and snack companies make a living by reducing whole foods into easy-to-manufacture processed ones -- the kinds of foods that increase the risk of developing NCDs. To maintain their financial health, these firms need to sell more of their products in the very countries where NCD deaths are rising. With sales in developed countries fat, the industry now relies on increasing revenues in emerging markets to sustain future growth. Between 1982 and 2000, U.S. companies quadrupled their investments in overseas food processing companies, and sales of processed foods overseas grew from $39.2 billion to $150 billion. The average Mexican now consumes nearly 30 gallons of Coca-Cola drinks every year, more than the average American. Rates of NCDs have risen accordingly.

In 2012, the article *Is the Junk Food Industry Buying the WHO?*[44] was published, denouncing the WHO to be 'increasingly relying on what it calls 'partnerships' with industry, opting to enter into alliances with food and beverage companies rather than maintain strict neutrality'. In response, Margaret Chan made a statement[45]accusing the media of creating 'misinformation and confusion in the public health arena' and denying that the Organisation was receiving funds from the food and beverage industry to its work on noncommunicable diseases. The Director-General, while assuming that the private sector 'plays an important role along with other key stakeholders in taking action to improve health', assured that when working with the private sector, the Organisation 'takes all possible measures to ensure its work to develop policy and guidelines is protected from industry influence'. Moreover, Chan affirmed that the Organisation 'may engage with the private sector on occasion, but according to WHO policy, funds may not be sought or accepted from enterprises that have a direct commercial interest in the outcome of the project toward which they would be contributing (…) For this reason, the Organisation does not accept funding from the food and beverage manufacturers for work on NCD prevention and control'.

The pharmaceutical industry is the private sector most involved in global health initiatives and, accordingly, is in a dubious position as its main business is to sell brand medicines at high prices, especially given the competition from generic drugs. In this regard,

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[43] Available at: https://www.foreignaffairs.com/articles/2011-11-09/how-private-companies-are-transforming-global-public-health-agenda . Last access on 20/02/2020
[44] Available at https://www.motherjones.com/food/2012/11/junk-food-industry-buys-influence-global-level-too/. Last access on 20/12/2019
[45] Available at: https://www.who.int/mediacentre/news/statements/2012/nutrition_20121119/en/ Last access on 20/12/2019

K.M Gopakumar wrote an article in 2014 denouncing a set of leaked emails which showed that the Pharmaceutical Research and Manufacturers of America (PhRMA) industry association had planned a campaign against proposed pro-public health changes in South African patent law. Moreover, interviewee 5, from Brazil, explained that the patent issue was the main topic of the Uruguay Round trade negotiations between 1986 and 1994. What was disclosed was how powerful the pharmaceutical industry is, as it was considered the engine of negotiation on trade. The Trade-Related Aspects of Intellectual Property Rights (TRIPS) agreement[46] was seen as a 'big fail for the South countries' as they were not able to negotiate it energetically, especially small and poor countries that could not face the power of the pharmaceutical industry. As the health field is one of the largest budgets of any country, buying a fight with the pharmaceutical industry is, at least, imprudent. The interviewee then clarified that due to the AIDS crisis, precisely when South Africa, through compulsory licenses, authorised the imports of generic versions of patented medicines, Big Pharma companies sued the South African government, showing their thirst for profit.

According to Saslow (2009), pharmaceutical companies, threatened by what could be considered a weakening of patent protection, opposed the efforts of the South African government, arguing that it was violating international trade law, particularly the TRIPS Agreement. Therefore, lobbied by the pharmaceutical industry, United States government officials proposed bilateral trade sanctions in an attempt to pressure South Africa. AIDS activists, especially the civil society and NGOs, started a movement claiming that international law is flexible in cases of national emergency. It was clear that profit came above public interest, human rights and public health. The countries from the Global South took advantage of this increasing social movement to try to correct what they called a 'development deficit' in multilateral negotiations.

Interviewee 5 also explained that Southern countries started to push the WHO, arguing that as a United Nations agency with a mandate to defend the public interest and public

[46] The Agreement on Trade Related Intellectual Property Rights (TRIPS) was negotiated with other international trade agreements during the Uruguay Round trade negotiations of the GATT (General Agreement on Tariffs and Trade) from 1986 to 1994. As one of the World Trade Organization (WTO) agreements, it is totally binding for all WTO Member States. The TRIPS Agreement sets minimum standards in the field of intellectual property (IP) protection (such as copyrights, patents, and trademarks) that all WTO Member countries have to respect. To achieve this goal, WTO Members have to modify their intellectual property laws to make them consistent with the new WTO standards. For instance, the TRIPS Agreement states that all patents shall be available for at least 20 years from the filing date, whereas before TRIPS the patent term varied greatly among countries (7, 10, 17 or 20 years). All WTO Members have to incorporate this 20-year patent term in their own patent law. Available at: https://apps.who.int/medicinedocs/pdf/whozip18e/whozip18e.pdf Last access on 21/12/2019

health worldwide, the Organisation could not defend the interests of multinationals and corporate profit. Countries from the Global South, therefore, 'shifted a little of the topic by putting pressure on WHO to be a place where we could slightly mitigate the trade focus and move to the public interest focus and then we got an agenda, including the area of property intellectual, in favour of a pandemic crisis or emergency'.[47] At this time, according to the interviewee:

> there was a confrontational dialogue between the Southern and the developed countries, which in turn was under heavy pressure from the pharmaceutical lobby. This is home to the largest pharmaceutical group, Roche, so we were under pressure from everyone. England, the Nordics, Switzerland, United States. Not to mention that the pharmaceutical industry has a representation of our size, it has 20 members just to cover these forums dealing with issues with public repercussions and commercial interests.[48]

The interviewee also mentioned a 'scandal' that happened in 2005 at the WHO, when a final report was mistakenly distributed with tracking-changes from the head of the pharma's office in Geneva. 'It was a bit of a shame because it was clear that before being distributed to the members of the commission, the text had already passed through the pharma's mission to make the necessary modifications, ensuring that the report would not harm them'. This episode was seen as a 'symbolic moment' of the progressive capture of the WHO over the years by the private sector, especially regarding the patent topic, which was forbidden discussion.

One should also consider the potential conflict of interest from health policy experts who are supporting Pharma companies. To exemplify, in 2018, the director of the Margolis Center for Health Policy at Duke University was also part of the board of Johnson & Johnson. It is worth noting that as a board member of a for-profit healthcare company, the expert will have a fiduciary duty of not damaging when writing articles and speaking.

Not surprisingly, the relationship with the private sector was the crucial issue of FENSA negotiations, as much of this engagement has always been unregulated. While it's undeniable that the private sector plays a dominant role in health, careful consideration in policy and planning is required. It is precisely this function that FENSA is supposed to have.

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[47] In 2008 the sixty-first World Health Assembly adopted Resolution 61.21, which endorsed the Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property. This Global Strategy aims to improve the delivery of and access to health products and medical devices by effectively overcoming barriers to access.
[48] Translated from Portuguese.

3.4 Philanthropic Foundations

According to Gian Luca Burci (2004), philanthropic foundations, as well as the private sector, engage with the WHO based on interpretations of its Constitution. However, the relations with philanthropic foundations are different from those with the private sector, NGOs and academic institutions in that they are not based on any regulation or guidelines. One could observe, then, that although the financial contributions to the Organisation from philanthropic foundations have increasingly grown, it is the only category of non-State actor that receives no instruction.

One might observe how the relevance of philanthropic foundations to the WHO increased over the years; their first mention was during the First World Health Assembly in 1948. As the Member States were praising the Organisation's task of 'improving the health of the populations of the whole world (…) [what] indicates a new stage in international co-operation in the field of health services'. The URSS representative affirmed that:

> The present state of development of medical science is in contradiction to the basic organisation of medical aid for the population in most countries. Medicine, in its present state of development, has grown out of the private-practice system of treatment for payment, which is not available to the poorer sections of the population. Nor are the measures taken by the municipal authorities more effective, and still less **the activities of philanthropic organisations. All these measures, for the most part, are only pitiful palliatives, caricatures of a genuine public-health service.** (WHA, 1948, p.39 – *my emphasis*)

In 1951, philanthropic foundations were mentioned as potential sponsors for the first time but related to visual media activities in India.

The lack of suitable guidelines, nonetheless, was only one part of the problem, given the inadequacy of WHO policies on conflicts of interest and the need for more oversight of the numerous partnerships - a gap that FENSA is supposed to fill.

According to the WHO,[49] in 2012 the Organisation received financial contributions from 212 non-State actors, for a total amount of USD 417 million, representing 25.5% of the total income. Philanthropic foundations donated USD 310 million, representing 18.9% of the total budget. The Bill and Melinda Gates Foundation (BMGF) was the first private non-State contributor, the second-largest contributor of the WHO's entire budget, a total of 12.72% - second only to the US government.[50]

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[49] Available at: https://www.who.int/about/who_reform/governance/mapping-of-WHO-engagement-with-non-State-actors.pdf?ua=1 Last access on 17/12/2019

[50] Available at: http://open.who.int/2018-19/contributors . Last access on 17/12/2019.

Amidst the coronavirus crisis, President Donald Trump announced the withdrawal of the United States from World Health Organisation due to his criticisms of the agency's handling of the pandemic. The global health community was extremely concerned - not only because the departure of its biggest donor could affect the WHO's ability to respond to the ongoing outbreak as well to the future of the agency, but also because the Bill and Melinda Gates Foundation would become the top donor. The outstanding financial engagement of the BMGF is criticised as it potentially influences WHO's agenda, making the Organisation donor-driven instead of member-driven. However, Germany has become the current top donor, accounting for 12.18% of the WHO's budget, closely followed by the BMGF with 11.65%.

As already explained in chapter 2, specified voluntary contributions, which nowadays correspond to 74.82% of the WHO budget,[51]offer freedom to donors to choose programmes. For instance, 58.37% of BMGF's donations are allocated in the Polio eradication programme.[52] As a result, programmes' implementation by the WHO is more related to donors' demands than public health needs. In this regard, it is important to highlight that, according to the Guidelines on working with the private sector (2001), 'the overall amount of the funds raised should not be so large that the programme would become dependent on support from a single company, or group of commercial enterprises, for its continued operations. The level of dependency of the programme on such support shall be evaluated at regular intervals'. Given the Polio Programme and the Private Sector Guidelines statement, an excerpt of interview 5, with a Brazilian Ambassador, is enlightening:

> The Polio Programme is funded by the Gates Foundation, which is a very positive thing (....), but the way it was done reveals this lack of criteria (...) WHO was "free for all", someone with money used to arrive with a philanthropic assessment, beyond suspicion, Melinda Gates offered credibility (...) Finally, polio was eradicated in several countries, but the programme could not be deactivated because WHO was already using the money for other things and deactivating would be a thud; a lot of staff were paid with that money (...) As a parasite, [the BMGF] had fit into the WHO in such a way that it represented about 10-15% of the Organisation's annual budget. So when it came time to take it out, there was no way, WHO had become dependent (...) because the exit would disrupt several other projects in progress.[53]

In April 2017, one year after FENSA approval, a piece entitled *Meet the world's most powerful doctor: Bill Gates*[54] ironically stated that 'some billionaires are satisfied with

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[51] Ibid.
[52] Ibid.
[53] Interview made in Portuguese and translated by the author.
[54] Available at: https://www.politico.eu/article/bill-gates-who-most-powerful-doctor/ Last access on 17/12/2019

buying themselves an island. Bill Gates got a United Nations health agency in Geneva', going on to point out that Gates' priorities have become the WHO's. Therefore, 'rather than focusing on strengthening health care in poor countries — that would help contain future outbreaks like the Ebola epidemic — the agency spends a disproportionate amount of its resources on projects with the measurable outcomes Gates prefers, such as the effort to eradicate polio'.

To similar effect, in 2008, a New York Times article[55] denounced that the chief of the malaria programme criticised the growing control of malaria research by the Bill and Melinda Gates Foundation as it would be 'stifling a diversity of views among scientists and wiping out the health agency's policy-making function'.

One should also note that the Gates Foundation has been accused of having shares in pharmaceutical companies[56] and, therefore, having mutual financial interest with the makers of drugs, diagnostic tools, vaccines and more. Furthermore, in 2017, Civil Society representants sent an open letter to the Executive Board of the World Health Organisation reproving the official relations status granted to the Bill and Melinda Gates Foundation, as according to the United States Government's Securities and Exchange Commission, the Foundation's endowment has been disturbingly invested in many of the food, alcohol, and physical inactivity-related products that directly or indirectly cause harm to health. The Gates Foundation Trust's direct investments include:

> Coca-Cola regional company that operates in the Americas south of the U.S. ($466 million), Walmart ($837 million), the largest food retailer in the U.S. and a leading retailer of pharmaceutical drugs and alcoholic beverages, Walgreen-Boots Alliance ($280 million), a large multinational pharmaceutical drug retailer, and two of the world's largest TV companies (screen-time): Group Televisa ($433 million) and Liberty Global PLC ($221 million). In addition, approximately one-quarter of the Gates Foundation Trust assets are invested in Berkshire Hathaway Inc., a holding company that owns a US$17 billion share in the U.S.-based Coca-Cola company and US$29 billion interest in Kraft Heinz Inc., another of the world's ten largest food companies. These investments make the Gates Foundation a beneficiary of sales of several categories of products that are the subject of WHO standards and advice to governments related to nutrition and physical activity. (CIVIL SOCIETY OPEN LETTER, 2017)[57]

Notwithstanding accusations of setting the global health agenda in developing countries, the

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[55] Available at: https://www.nytimes.com/2008/02/17/world/americas/17iht-gates.4.10120087.html Last access on 17/12/2019

[56] In 2002, the Wall Street Journal showed the the Gates Foundation had purchased shares in nine big pharmaceutical companies

[57] Civil Society calls for Protection of WHO from Undue Influence. Available at https://iogt.org/open-letters/civil-society-calls-protection-undue-influence/ Last access on 17/12/2019

Gates Foundation's income sources, which as mentioned include food and beverage, pharmaceutical and healthcare industries, are increasing the fears of a conflict of interest at the World Health Organisation.

It seems that talking about philanthropic foundations' role in global health and consequently within the WHO amounts to talking about the Bill and Melinda Gates Foundation. In fact, as the literature review of the first chapter showed, while few articles are analysing philanthropic foundations in global health, there is a huge focus by scholars on the Gates Foundation's role in global health. However, interview 1 affirmed that people should not focus only on the BMGF; 'the Ted Turner Foundation is just as important. It had a 'secondment' at the highest level in WHO'. In this regard, in December 2015 the South-North Development Monitor (SUNS) exposed that the Gates Foundation and the United Nations Foundation seconded their staffers to top management positions at the World Health Organisation. The article also explained that the well-known UN Foundation is not a UN body but a philanthropy, registered in the United States by media entrepreneur Ted Turner.

Despite being an undeniably positive role of private philanthropy in global health and within the WHO (it was said by many interviewees that no one can afford what the Gates Foundation pays to WHO), more attention on the impacts and side effects of philanthropic engagement is essential. Youde (2018) brings our attention to how seriously philanthropic organisations should be taken, as they 'have the power to shape and alter the global political agenda – and can do so in ways distinct from other types of non-state actors'. This is especially true when it comes to the fragmentation of global governance, the lack of oversight and accountability tools, and the dominant practice of applying the commercial logic to the provision of public goods.

Researchers of International Relations need to look at the path of philanthropic foundations in the health scenario and perceive that, rather than merely trying to influence States' actions, philanthropic foundations are being directly involved in the decision-making processes. Youde (2018, p. 43) explains: 'wealth could provide a donor with power over other actors, allowing the donor to force a recipient to do something it would not otherwise do – the donor will only give a state money if that government agrees to certain policies'. This perspective is important when thinking about the North/South division during FENSA negotiations. Although an overall divergence was clear, some specific positions were hard to

understand. One should note, however, that philanthropic foundations commonly act at the level of low and middle-income countries. The possibility of powerful non-State actors being able to shape political and institutional processes, by preventing States from raising issues that would be prejudicial to them, is something that should be carefully analysed. However, it is also important to note that philanthropic organisations have had serious effects on scholars, due to huge financial support.

Therefore, philanthropy must be understood as a growing force that intersects influence, legitimacy, authority, and policymaking. When looking at the pharmaceutical treatments and new technologies focus, it is a far-fetched to argue that philanthropic organisations are unbiased actors. They are too powerful to be left unexplored.

3.5 Academic Institutions

According to the WHO website, the idea of using national institutions for international purposes started with the League of Nations, when national laboratories were entitled to be reference centres for the standardisation of biological products. Lately, the engagement with academic institutions was predicted in article 2 of the WHO's Constitution, similarly to nongovernmental organisations. 'To promote co-operation among scientific and professional groups which contribute to the advancement of health' is amongst the list of the Organisation's functions. In 1949, it was pointed out that research and the coordination of research were crucial functions of the Organisation and that priority should be given to research that directly relates to the programmes of the WHO.

Moreover, the second Health Assembly in 1949, while recognising that 'the development of planned programmes requires continuous application of research and investigation on many problems, the solution of which may be found essential for the diagnosis, treatment and prevention of disease, and for the promotion of positive health' (WHA, 1949, p.23), decided that the World Health Organisation should not consider the creation of international research institutions under its umbrella, but support the existing ones. The 69th Session of the Executive Board, in 1964, approved the *Regulations for Study and Scientific Groups, Collaborating Institutions and Other Mechanisms of Collaboration*, which were later revised and amended during the 105th EB, in 1999.

The Regulations highlighted that the knowledgeable support that the WHO needs should 'reflect high scientific and technical standards, the widest possible representation of

different branches of knowledge, and local experience and trends of thought throughout the world, and must cover a broad range of disciplines related to health and social development' (WHO, 2014, p. 131). Moreover, the Regulations stipulate the WHO Collaboration Centres (WHO CCs), institutions designed by the Director-General should become part of 'an international collaborative network set up by WHO in support of its programme at all levels'.

The WHO engages with academic institutions through the Collaboration Centres, mainly to gain expert advice and scientific or technical cooperation. In this regard,

> WHO gains access to top institutions worldwide and the institutional capacity to support its work. Similarly, institutions designated as WHO CC gain increased visibility and recognition by national authorities and greater attention from the public for the health issues on which they work. The centres also gain opportunities to work together (e.g. sharing objectives, exchanging information, pooling resources and developing technical cooperation), particularly at the international level; and opportunities to mobilize additional and sometimes important resources from funding partners. (WHO, 2018, p.6)

It is important to note that FENSA did not replace the relationship between the WHO and CCs. Therefore, academic institutions are the only non-State actors that can have official relations or be a collaborating centre, but they are mutually exclusive. Either the institution is a collaborating centre or has official relations under FENSA. Institutions with the capacity to fulfil functions related to the WHO's programme, as well as institutions of 'high scientific and technical standing having attained international recognition', may qualify for designation. The functions of WHO collaborating centres include:

> (a) collection, collation and dissemination of information; (b) standardisation of terminology and nomenclature, of technology, of diagnostic, therapeutic and prophylactic substances, and of methods and procedures; (c) development and application of appropriate technology; (d) provision of reference substances and other services; (e) participation in collaborative research developed under the Organisation's leadership, including the planning, conduct, monitoring and evaluation of research, as well as promotion of the application of the results of research; (f) training, including research training; and (g) the coordination of activities carried out by several institutions on a given subject" (WHO, 2014, p.134)

The Director-General makes the designation of a Collaboration Centre after consultation with the national government. It is an agreement with the head of the establishment to which the institution is attached or with the director of the institution, if it is independent. According to the WHO website,[58] the designation is 'independent of financial support being given to the institution by WHO. Grants may be made to any institution that is

[58] Available at: https://www.who.int/collaboratingcentres/cc_historical/en/index1.html Last access on 21/02/2020

able to perform a specific task connected with WHO's programme but this has no relevance to the eligibility or ineligibility of an institution for designation'.

Moreover, at least two years of collaboration in joint activities with the WHO is required. The collaboration is initially granted for four years, renewable for the same or shorter periods. As of 2017, the network of CCs consisted of over 800 academic and scientific institutions in over 80 countries 'supporting WHO programmes and priorities with time, expertise and funding'.[59]

The 2018 guidelines for WHO CCs clarify that institutions which might be qualified for designation comprise parts of universities, research institutes, hospitals or academies; parts of governments may also be eligible. Usually, the designation is limited to the specific department, division, laboratory, or another part that collaborates with the WHO. One must consider that 'eligible institutions can be public or private, but should not be of a commercial or profit-making nature' (WHO, 2018, p.6). In this regard, after FENSA approval, to guarantee the credibility, independence and objectivity of the work conducted by a Collaboration Centre, the WHO 'seeks to ensure that the interactions this institution may have with the private sector entities (…) conform to the requirements of the Framework of Engagement with NonState Actors (FENSA) adopted by the World Health Assembly in May 2016, in particular with regards to the management of conflicts of interest and other risks'.

It can be observed that the Member States, while concerned about the undue influence of the private sector, have always been silent regarding the engagement with academic institutions. However, it is worth noting that academic institutions can be influenced by private sector entities, making it impossible to recognise whether a corporation has had any undue influence on research. In 2016, for instance, a paper commissioned by the International Life Sciences Institute, financed by companies such as The Coca-Cola Company, Nestlé, McDonald's and PepsiCo, minimised the importance of regulating sugar intake. The professors who had authored the paper were quickly blamed for conflicts of interest.

Many countries have been experiencing austerity measures which directly impact social investments; while the government's funding for research has declined, academics need to pursue alternative funding sources. Given that there are no guidelines for how these

[59] Available at: https://www.who.int/docs/default-source/documents/about-us/factsheetwhocc2018.pdf?sfvrsn=8c7166ee_2 Last access on 12/12/2019

relationships should be conducted, all industry-funded research is likely to be distrusted.

3.5 Undue Influence of non-State actors at WHO

While it is almost impossible to accurately measure the influence of non-State actors in global health agenda, broadly speaking, and precisely at the WHO - the assumption that the private sector may have vested interests in influencing the WHO's work has proven to be true. Many companies that are active in global health initiatives come from a narrow range of industries, many of which are immensely criticised for their negative impact on public health. These private companies are accused of playing a double game - disrupting local communities while writing big cheques to allegedly help them. That's the reason why, when it comes to engagement with the private sector, special attention is needed, as profitable entities have tried to unduly influence the WHO's work and policy-making numerous times.

In 1975, for instance, the 28th World Health Assembly requested the Director-General to advise the Member States on 'the selection and procurement, at a reasonable cost, of essential drugs of established quality corresponding to their national health needs'. Therefore, in 1977, the WHO adopted the Model List of Essential Medicines (MLEM), which consisted of medicines of suitable quality and in adequate quantity, aiming to ensure the 'access of the whole population to essential drugs at a cost the country can afford',[60] as recognised by the resolution WHA31.32 (1978). However, in 1982, the Expert Committee on the Selection of Essential Drugs modified the description to 'those that satisfy the health care needs of the majority of the population; they should, therefore, be available at all times in adequate amounts and in the appropriate dosage forms' (WHO, 1983, p.9). This description was recognised and used until 1999, when the Committee decided to take into account the affordability concept from resolution WHA31.32, and defined that, 'essential drugs are those that satisfy the health care needs of the majority of the population; they should, therefore, be available at all times in adequate amounts and in the appropriate dosage forms, and at a price that individuals and the community can afford'.

It is worth noting that according to Fione Godlee (1994), the pharmaceutical industry was strongly opposed to the MLEM since the beginning, and in 1985, 'partly in protest at the essential drugs programme, the United States withheld its contributions to WHO's regular

[60] Essential Medicines and Health Products Information Portal. Available at: https://apps.who.int/medicinedocs/en/d/Js4875e/5.2.html . Accessed on 16/12/2019

budget. At that time the United States was home to 11 of the world's 18 largest drug companies'. Godlee also argued that the WHO was launched out of the discreet shelter of technical consensus into the political arena, 'being aggressively lobbied by industry on the one hand and pressure groups on the other' (Godlee, 1994, p.1491).

Hence, it is not a coincidence that the potential undue influence of big-Pharma was a contentious subject during FENSA negotiations. In this regard, interviewee 18, from a philanthropic foundation, confirmed that:

> access to medicines is a really significant part of this overall and one of the most significant dimensions that always gets charged and heated among the Member States at the World Health Assembly and then in New York when it comes up. And that it's one of the issues why the negotiations around FENSA were so contentious, because of the concern about undue influence that not certain pharmaceutical companies but those multinational pharmaceutical companies or other major private sector partners could have in how WHO did, for instance, the list of essential medicines or now the list of essential diagnostics. So, that was the most significant piece that they wanted to make sure it was protected.

Pharmaceutical industries, however, are not the only concern when it comes to undue influence. The baby food industry, especially infant formulas, is seen as a threat as it has been undermining breastfeeding and, therefore, fuelling the obesity epidemic. Lee (2009) claims that the debate over the International Code on the Marketing of Breast Milk Substitutes, which was adopted at the 34th WHA in 1981, was 'one of the most dramatic moments in the history of international health [as] the food industry lobbied furiously to prevent the adoption (….) with Nestlé seating its own attorney on the Guatemala delegation' (Lee, 2009, p. 88). Non-State actors trying to push the WHO through the Member States is not a new movement. Regarding the 1981 negotiations, Stanley Fink[61] wrote to the Secretary-General of the United Nations, Kurt Waldheim, to express 'outrage at the vote by the United States' Representative to the World Health Organisation in opposition to the proposed code of regulation for the marketing of infant formula'.

Until recently the breast-milk substitute industry was a concern, and this was reflected in FENSA negotiations; consequently, IBFAN was one of the most proactive NGOs, arguing that FENSA would make the ongoing work on preventing and addressing conflicts of interest at the country level even more challenging. To illustrate, IBFAN argued that in Botswana:

> a country that has comprehensively implemented the International Code and relevant WHA resolutions. Its MoH recently announced that appropriate action will be taken

[61] An American politic from the Democrat Party. In 1968, Fink was appointed as chief counsel to the Assembly's Committee on Mental Hygiene. He was a member of the New York State Assembly from 1969 to 1986, He was Majority Leader in 1977 and 1978; and Speaker from 1979 to 1986.

> against Professor Gabriel Anabwani for serving as the Executive Director of Baylor Children's Clinic, while at the same time being the Chairman of the Board of Nestle Nutrition Institute (NNI). A clear conflict of interest. The Professor also was a member of several MoH committees on public health and infant and young child feeding.[62]

Similarly, an analysis by Save the Children showed that the six companies (Nestlé, Danone, RB, Abbott, Friesland Campina and Kraft Heinz), which together own more than 50% of the industry's market share, failed to adhere to the International Code on the ground.

One must also consider that in 2019, the UK's Royal College of Paediatrics and Child Health decided to no longer accept financial contributions from the baby formula industry.[63] Moreover, also in 2019, the Indian Council for Medical Research (ICMR)[64] concluded that Nestlé sponsored a five-hospital study on infant milk substitutes and, therefore, violated India's Infant Milk Substitutes Acts. Both serve as recent examples of how the private sector can indirectly influence governments and local hospitals, among others.

The tobacco industry is another example of undue influence at the WHO and how non-State actors have been playing key roles. According to the Framework Convention on Tobacco Control (FCTC), 'the participation of civil society is essential in achieving the objective of the Convention and its protocols'. According to Roemer et al. (2011), the FCTC has its origins back in 1993, in a meeting at the UCLA Faculty Center where professors discussed how the WHO could apply its disused constitutional authority 'to promote the development and implementation of international law to advance global public health (…) Ruth Roemer suggested the enforcement of her ideas[65] to develop a specific international regulatory mechanism for tobacco control'. Simultaneously, confidential documents of tobacco companies were released, exposing their attempt to deliberately undermine the WHO's efforts to control tobacco use.

> The tobacco companies' own documents show that they viewed WHO, an international public health agency, as one of their foremost enemies. The documents show further that the tobacco companies instigated global strategies to discredit and impede WHO's ability to carry out its mission. The tobacco companies' campaign against WHO was rarely directed at the merits of the public health issues raised by

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[62] FENSA, not a "fence" to protect public health. Available at: https://www.ibfan-icdc.org/fensa-not-a-fence-to-protect-public-health/ Accessed on 16/12/2019.
[63] Why the UK's largest body of pediatricians will no longer take money from baby-formula companies. Available at: https://qz.com/1550656/why-the-uks-largest-body-of-pediatricians-will-no-longer-take-money-from-baby-formula-companies/ Accessed on 16/12/2019.
[64] Nestlé faces heat for sponsoring breastmilk substitute study in India. Available at: https://www.swissinfo.ch/eng/legal-limits_nestl%C3%A9-faces-heat-for-sponsoring-breastmilk-substitute-study-in-india/45201236 Accessed on 16/12/2019.
[65] Ruth Roemer was a Professor emeritus at UCLA School of Public Health and author of *Legislative Action to Combat the World Tobacco Epidemic.*

> tobacco use. Instead, the documents show that tobacco companies sought to divert attention from the public health issues, to reduce budgets for the scientific and policy activities carried out by WHO, to pit other UN agencies against WHO, to convince developing countries that WHO's tobacco control program was a "First World" agenda carried out at the expense of the developing world, to distort the results of important scientific studies on tobacco, and to discredit WHO as an institution. (WHO, 2000)

The research paper *Tobacco industry strategies to undermine the 8th World Conference on Tobacco or Health* exposed how tobacco companies hid their role by using external scientists and journalists, and even WHO staff as vehicles of influence. To illustrate, Paul Dietrich, a US attorney and the President of the Catholic University's Institute for International Health and Development (IIHD),[66] was appointed to the development committee of PAHO while at the same working alongside BAT and Philip Morris to develop a media programme aimed against the 8th World Conference on Tobacco or Health (WCToH). According to Muggli and Hurt (2003, p.196), 'Dietrich wrote articles and editorials attacking WHO's priorities and travelled around the world for key tobacco companies, criticising WHO's priorities to journalists and governments'.

As a consequence, the WHO sanctioned not only a strict policy of non-engagement with the tobacco industry and linked entities to it, but also adopted a policy on the non-recruitment of smokers or other tobacco users. Moreover, in 2003, the Framework Convention on Tobacco Control was adopted, and in 2005 came into force. Legally binding in 181 countries, the treaty includes provisions for lobbying, demand reduction, regulations, packaging and labelling, awareness, research and other areas for tobacco control. One should note, however, that China, Japan, Germany and the USA were called the 'big four' - the principal opponents of FCTC provisions, as a way to reduce its success and practical impact on the tobacco industry as they all had strong national tobacco interests.

According to Mamudu and Glantz (2009), tobacco companies provided written statements and oral testimony during the FCTC public hearings and worked directly and indirectly through country delegations and other third parties to influence and weaken the FCTC. 'During the negotiation, even directors of BAT as far away as Nigeria were in Geneva lobbying delegates. In addition, members of the industry were national delegates of (at least) China, Japan, Malawi, Russia and Turkey' (p.160).

Finally, yet importantly, the US Sugar industry and other sectors of the food industry

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[66] A non-profit body considering public health policy in developing nations.

lobbied strongly against the Global Strategy on Diet, Nutrition and Physical Exercise, which recommended reductions in fat, salt and sugar. The original recommendation was a 10% limit of free sugar per day, but the food industry and some governments accused the report of lacking scientific evidence. The Sugar Association even wrote to the DG, threatening to 'exercise every avenue available to expose the dubious nature' of the WHO's report. The final strategy was then presented as a non-binding document to promote dialogue. 'Due to direct or indirect pressure, WHO has chosen not to take a stand on anything other than education because of the huge amount of money at stake within the food industry'.[67]

Many interviewees mentioned representatives of the private sector being part of national delegations at WHO Governing Bodies' meetings. The most cited was the Ferrero Rocher part of the Italian delegation. In the same direction, a special report from Reuters accused the delegations from Mexico and the USA of bringing Coca-Cola and Kellogg's into the joint meeting between the WHO and the UN Food and Agricultural Organisation in 2011. It is clear, therefore, that NSAs can influence the WHO indirectly by working close to national governments.

The goal of this chapter was to elucidate the relationship between the WHO and the four non-State actors before FENSA, which was fairly blurred. Apart from philanthropic foundations, the NSAs were, to some extent, embraced by some guidelines which, however, were not comprehensively applied. Since FENSA doesn't cover potential indirect influence from NSAs through the Member States, it is worth emphasising the need for safeguards to preserve the WHO's reputation and trustworthiness, given the many examples of undue influence that already occurred.

[67] Derek Yach, executive Director of the Noncommunicable Diseases and Mental Health at WHO. Available at: http://www.albionmonitor.com/0405a/copyright/bushgutsobesity.html

CHAPTER FOUR: ANALYSING THE FRAMEWORK OF ENGAGEMENT WITH NON-STATE ACTORS

Even though international negotiations have historically been one of the most unavoidable processes in global politics, international relations researchers have been focusing much more on other topics, mainly security studies. The international relations research agenda leans towards the securitisation of several themes, including health.[68] Despite the awareness that powerful industry actors and civil society organisations have been incessantly seeking to influence legal rules, principles, practices and institutions, the global health research agenda scarcely approaches international negotiations. This fourth chapter aims to carry out an interdisciplinary analysis of the lengthy negotiation process of the framework of engagement with non-State actors and, thus, to embrace both international relations and global health perspectives.

Although there was no opposition among the Member States regarding the inevitability and necessity of more engagement with non-State actors, it took almost five years and several rounds of discussions and demanding negotiations to reach a consensus. It could be observed that the development of collaboration rules which are supposed to control the participation of non-State actors in the global health field, specifically through the WHO, occurred in a complex scenario of conflict of interests at different levels, embracing both the public and private sector.

The complexity of the negotiation lies in how the vast range of actors can interconnect in different ways as, for example, governmental actors can hold shares in private sector entities, support academic institutions or provide NGOs with funds for service delivery. This contributed to a range of competing interests during the negotiations.

While chapter two enlightened the proposals on global health governance that took place in the World Health Organisation in a historical perspective until 2012, when FENSA was proposed, this chapter aims to give voice and meaning to the FENSA negotiation process. The methodology used was primarily an exhaustive document analysis complemented by excerpts of interviews made and some pertinent existing literature.

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[68] The theoretical perspective formulated by the Copenhagen School maintains that security threats originate not only from the military sphere, but also from the political, economic, environmental and societal spheres.

4.1. FENSA Official Documents: How the Negotiation Process worked.

As previously discussed in the second chapter, FENSA's starting point is the burial of the idea of a Global Health Forum, requested by the WHA Resolution 64.2. A Special Session of the Executive Board in November 2011, therefore, requested the Director-General Dr. Margaret Chan, to further analyse proposals to promote engagement with other stakeholders. This engagement should be guided by the intergovernmental nature of the WHO's decision-making and the use of evidence to develop norms, standards, policies and strategies.

Later, in January 2012, the 130th Executive Board agreed that additional discussions regarding the WHO's engagement with other stakeholders were necessary, including different categories of non-governmental organisations and industry. At the 130th EB, the Secretariat proposed that the *Principles governing WHO relations with nongovernmental organisations* from 1987 should be reviewed and updated and should be taken into consideration: 'widening and improving the modalities for the participation of non-governmental organisations at regional and global governing body meetings; (…) updating practices and criteria for accreditation' (EB, 2012, p.3). Moreover, the report *Governance: Promoting engagement with other stakeholders and involvement with and oversight of partnerships* made by the Secretariat also proposed the development of 'a comprehensive policy framework to guide interaction with the private-for-profit sector, as well as not-for-profit philanthropic foundations' (EB, 2012, p.3).

The sixty-fifth World Health Assembly took place in Geneva between the 21st and 26th of May of 2012 and discussed, within the Committee A, the WHO reform. However, the requested policy regarding the WHO's engagement with other stakeholders was not submitted, even though the 9th paragraph of the Decisions and list of resolutions (A65/DIV/3, 2012) requested of the Director-General:

> (a) to present a draft policy paper on WHO's engagement with nongovernmental organisations to the Executive Board at its 132nd session in January 2013; (b) to present a draft policy paper on the relationships with private commercial entities to the Executive Board at its 133rd session in May 2013.

In October 2012, the WHO organised the first consultation with NGOs, led by Margaret Chan, and the main goal was to understand their perceptions of the WHO's engagement with non-governmental organisations. Sixty-three participants representing 44 non-governmental organisations attended the meeting on 18 October 2012 in Geneva, those

unable to attend could listen to the consultation via Webex.[69] In her welcome speech, Chan pointed out that:

> As part of efforts to strengthen governance, we were asked to prepare a draft paper on WHO's engagement with NGOs, for discussion during the January Executive Board. We are holding this consultation to gather your guidance and advice. We will be focusing, in particular, on a framework for ongoing consultation, collaboration, and accreditation. The deliberations of this consultation will be summarised and made available to Member States. (…) This is not an easy or an entirely straightforward assignment. (…) Some issues are still a little fuzzy. Some issues still make Member States a little nervous. I think we can all agree with the view of WHO's governing bodies, who have expressed a need to review and update the principles governing WHO's relations with NGOs. (…) I fully understand your concern about insufficient safeguards against conflicts of interest, a concern strongly voiced by our Member States. At the same time, the NGO community is not a uniform group of altruistic organisations. (…) Nothing is clearly black and white. (…) There are two final points (…) (that) are especially important, as they reflect the strong views of the Member States of this Organization. The first (…) while collaboration with multiple stakeholders, including NGOs, is essential, decision making remains the prerogative of governments. The intergovernmental nature of WHO's decision-making remains paramount. Second, WHO has been overextended and overstretched, which is one justification for reform. An overarching purpose of reform is to streamline WHO, to make it leaner, more flexible, and more responsive to rapidly changing health needs. Time and time again, our Member States have rejected proposals for reform that involve establishing new mechanisms or adding additional layers of complexity. In other words, my ability to respond to some of your requests may be limited by the explicit wishes of Member States. After all, they are the shareholders and owners of this Organization. (CHAN, 2012)

According to the report on the consultation, there was a consensus regarding the pillars of the new policy: consultation, collaboration, and accreditation to WHO governing bodies. The NGOs also identified the need to set out mechanisms to address the definition of NGO and civil society, conflict of interest, transparency and accountability. Regarding the concerns, the report pointed out that the NGOs asked for coherence between a new NGO policy and those for partnerships, private sector, and philanthropic entities and for ensuring that such new policies would be fully and adequately implemented. The definition of NGOs and civil society was a point of disagreement as some NGOs required a clear distinction between entities with commercial interests and links and those without. Given that no particular differentiation was made, at that time, amongst the non-State not-for-profit organisations with which the WHO engages:

> Differing views have been expressed on whether – and, if so, how – WHO should

[69] *Webex* online meetings and presentations, webinars, town halls, online courses and training and online presentations

> define the boundaries between the various constituencies of nongovernmental organisations and collaborate with the emerging subgroups. Some nongovernmental organisations are of the view that differentiation is unnecessary if full and public disclosure of information and interests is achieved. Any potential conflicts of interest would then be identified and tackled on a case-by-case basis in accordance with clear parameters and procedures (to be defined, as referred to in paragraph 16 above).Other nongovernmental organisations feel it is critical to differentiate between the constituencies of such organisations, particularly with regard to those with commercial interests or links. Even among these nongovernmental organisations, however, different views have been expressed on how then to treat the differentiated subgroups. Some would support housing commercially-linked nongovernmental organisations under WHO's policy on relationships with private commercial entities (currently in development). Others consider that commercial interests should be viewed in the context of WHO's specific functions. (WHO, 2013. p.5-6)

Conflict of interest was a significant discussion point for the NGOs that attended the consultation, especially considering the process of setting norms and standards. A Declaration of Interest (DoI) was suggested and an electronic platform like the Transparency Register used by the European Union proposed; it would provide information freely on all non-governmental organisations collaborating with the WHO, including the nature of collaboration, governance structure, sources of funding, and declarations of interest. Additionally, while some claimed that the same level of transparency and accountability should apply equally to all NGOs, others argued that real concern should be directed to NGOs with commercial interests. Yet, the scope of conflicts that could affect the WHO's integrity should be better defined, according to the NGOs' consultation report.

There was a consensus that the WHO should be more proactive in seeking interaction with NGOs, and that any general framework for collaboration should aim to guide the collaboration, while allowing some flexibility to take into consideration the countries' particularities, including the dynamics between civil society and government. A space was proposed, for NGOs to serve as a watchdog on how the WHO implements its policies. The problem of conflict of interests was once again discussed, as several NGOs pointed out that a separate policy should be developed to guide WHO interactions with not-for-profit philanthropic organisations, with appropriate safeguards against conflicts of interests. Finally, some NGOs highlighted that the differentiation between NGOs with commercial interests and links and those without should apply not only to collaboration but also to consultation and accreditation.

Regarding consultation, some NGOs advocated that entities should be involved in the planning and conceptualisation of discussions from the beginning. Also, to ease national level

consultations and NGO participation, an attempt to boost public voice was considered important. On the other hand, certain NGOs asked for an international level of multi-stakeholder consultations, and the Pandemic Influenza Preparedness (PIP) framework[70] was used as a reference. However, a consensus wasn't reached, as some NGOs argued that the WHO should not focus on one model. Conflict of interest, again, was a major concern. It was suggested that all names and affiliations should be made publicly available to ensure transparency regarding interests involved, particularly commercial interests. The funding of NGOs was considered a problematic issue as some NGOs representing patient groups get most of their funding from industry and others from governments. Finally, the rise of philanthropic actors and their impact and influence on NGOs and international multilateral organisations such as the WHO was also highlighted.

Accreditation to the WHO governing bodies was a topic of primary importance as it allows NGOs to engage with Member States. In this sense, it was proposed that accreditation to participate in WHO governing bodies should be de-linked from a period of working relations and be understood as an autonomous relationship based on the contribution that the non-governmental organisation could give to the WHO's governing bodies. It was suggested that the accreditation of non-governmental organisations should be limited to individual meetings of governing bodies or to a specific governing body or working group. The existing situation was that entities in official relations were able to participate without limit for the duration of the validity of that status. It would enhance transparency and improve the management of governing bodies' meetings by ensuring that the participation of relevant non-governmental organisations would enrich discussions.

Several suggestions were made to improve synergy, and some practices at the WHO governing body meetings, such as the requirement to submit statements 24 hours in advance, the practice of reviewing statements which on occasion may lead to a request being declined and permitting NGOs to speak only after Member States, were considered, by some NGOs, as an obstacle to effective exchanges between NGOs and Member States.

After the consultation in October 2012, a report by the Director-General was published in January 2013 and debated during the 132nd Executive Board. *Key issues for the*

[70] Developed by the Member States and adopted in 2011 by the 64th World Health Assembly, the Pandemic Influenza Preparedness (PIP) Framework brings together Member States, industry, other stakeholders and WHO to implement a global approach to *pandemic influenza preparedness* and response. Available at: https://www.who.int/influenza/pip/en/ Last access on 06/12/2019

development of a policy on engagement with nongovernmental organisations (WHO, EB 132/5 Add2, 2013) revealed that several crucial issues needed the guidance of Member States before a draft policy could be finalised. The following elements were supposed to be analysed and discussed:

> 1. how best to seek the views of nongovernmental organisations in the development of health policies and strategies (consultation); 2. how to improve the methods of working with non-governmental organisations on WHO activities and priorities across the three levels of WHO (collaboration); 3. how to improve the transparency and accountability of collaboration between WHO and non-governmental organisations; 4. how best to address engagement with different constituencies of nongovernmental organisations; 5. the desirability and feasibility of updating the practices and criteria, and of defining parameters for the participation of non-governmental organisations in the meetings of WHO's governing bodies (accreditation); 6. how best to proceed with the process of consultation for the development of WHO's policy of engagement with nongovernmental organisations, including the best means of harmonising this policy with the development of WHO's policy on relationships with private commercial entities. (WHO, 2013, p.1-2)

Moreover, according to the report, the WHO had no practical and organised tools to contemplate the ideas of non-governmental organisations on the development of health policies and strategies. Three mechanisms were then considered as important to strengthen the engagement and the consultative dimension: web-based or electronic platforms; public hearings; and a forum or formalised mechanism (i.e. a civil society mechanism). No-governmental organisations also identified several specific areas where collaboration with the WHO could potentially be strengthened, including 'action for large epidemics and civil strife, and other humanitarian action; transmission of advocacy efforts and information to country level; and dissemination of expertise and promotion of knowledge and best practices through expanded networks' (WHO, 2013, p.4). Lastly, the report requested that the Board deliver observations on:

> potential mechanisms for consultation with non-governmental organisations; methods to strengthen and widen collaboration between WHO and non-governmental organisations related to WHO's core functions, strategic priorities, and across the three levels of the Organization; mechanisms to improve transparency and accountability; approaches both to differentiation of nongovernmental organisations and to WHO's interaction with the different constituencies of such organisations; revisions to accreditation procedures for nongovernmental organisations. (WHO, 2013, P.7)

The decisions and list of resolutions of the EB 132nd session invited the Director-General to submit overarching principles but separate operational procedures for non-governmental organisations and private commercial entities. The EB also pointed out the need to keep reviewing the accreditation procedures for the WHO's governing bodies and to

include them in a draft to be presented in the 133rd EB, in May 2013. Finally, one public web-based consultation and two distinct consultations were demanded - one with Member States and NGOs and one with Member States and the private commercial sector.

In May 2013, a report by the Secretariat on the WHO governance reform was released to be analysed during the EB 133rd session and illustrated 'opinions expressed through governing body discussions and in consultations with the stakeholders'. The first consultation happened between the 6th and 24th March and was public web-based. It requested opinions on:

> the scope and range of non-State actors, how and whether they should be categorised; what benefits accrue to non-State actors from their relationship with WHO; what challenges are likely to arise in different contexts, including those related to non-State financing of WHO; what would constitute a set of overreaching principles to guide engagement, and what modalities are needed beyond such general principles to guide interaction in different circumstances.

Since the beginning of the negotiations, some issues have caused recurrent disagreements, e.g. conflict of interest, potential reputation damage due to engagement with particular actors and resources from non-State actors. Regarding the typology of non-State actors, the report pointed out that after the consultation a group strongly argued that the WHO should differentiate organisations purely devoted to public-interest issues from those linked with commercial concerns, while another group claimed that no differentiation was necessary.

To distinguish the different types of engagement was also a controversial topic, as some declared that 'any relationship with a commercial entity, even with adequate safeguards to prevent conflict of interest, can be seen as a benefit to the company concerned and a reputation risk to WHO' whereas others alleged that the key to avoiding commercial influence was full transparency of all interests, commercial or not. In this sense, some defended that groups whose activities have the potential to harm the public health, both in civil society and the private sector, should be excluded from any relationship with the WHO.

Funding from non-State actors only reached a consensus regarding prohibition of the WHO being sponsored for activities that influence the commercial interests of the donor. However, many were worried that any funding from non-State sources would distort or weaken the intergovernmental process of priority setting.

Regarding the overarching principles, four were proposed by the Secretariat, to apply to all interactions: the decision-making process should be exclusive responsibility of the

Member States; the development of norms, standards, policies and strategies should be based on evidence and protected from undue influence; the nature of the WHO's relations with non-State actors should be public; the management of conflicts of interest should apply to all aspects of WHO's work.

The Secretariat also identified six basic types of interaction: consultation, collaboration, financing, contractual, non-State actors in the WHO's governance and the WHO as part of the governance of non-State actors. In the report of May 2013, it was advocated that the rules of engagement should embrace the principles of 1987 between the WHO and NGOs, alongside the guidelines on interaction with commercial enterprises, as well as the WHO's processes concerning collaborating centres and policy relating to partnerships. After an agreement on the overall principles, the next step according to the Secretariat report (WHO, 2013, p.6) should be 'to review where there are already structures and systems in place that can form the basis of a more rigorous and comprehensive operational framework. These pieces will then be strengthened, refined or adjusted as necessary'.

Finally, regarding transparency and conflicts of interest, the Secretariat specified an 'architecture' for managing conflict of interest that would include a way of improving the transparency of interaction, a definition of what constitutes an institutional conflict of interest, tools for declaration of interest, and capacity and mechanisms to assess conflicts of interests. The definition proposed was 'a conflict of interest can be defined as a set of circumstances that creates a risk that judgment or actions regarding a primary interest will be unduly influenced by a secondary interest' (WHO, 2013, p.7). One must consider that the definition of conflict of interest changed during FENSA negotiations and this is different from the one specified in the final version of the Framework.

Considering the deliberations of the 133rd Executive Board, the Director-General was requested to move forward with the development of a framework on the WHO's engagement with non-State actors. The main focus should be on transparency, risk and conflict of interest. It was expected to be analysed by the Board at the 134th session in January 2014.

Between the 17th and 18th of October 2013, the first informal consultation with the Member States and non-State actors occurred at the WHO headquarters in Geneva, and was chaired by the Director-General, Margaret Chan. More than 320 representatives from

Member States and non-State actors participated in the consultation in person or via webcast. The goal wasn't to reach a consensus but to debate presented proposals for due diligence, management of risks (including conflicts of interest) and transparency to be submitted to the 134th Executive Board.

The consultation was divided into five parts: the welcome and meeting objectives; an introduction, where the Secretariat described the key issues related to engagement with non-State actors and presented an overview of the current relationship and the proposal for reform; proposed changes in due diligence, management of risk of engagement and transparency; enhancing engagement with non-State actors; and a conclusion and a look at the way forward.

Professor Thomas Zeltner, a public health expert who acted as Special Envoy, highlighted that above all the most outstanding problems were the lack of trust and clarity of the existing mechanisms of the WHO's engagement, inconsistency in the application of the rules, and the unsettled definition of roles, among others. Julio Mercado, the diplomat who chaired the FENSA negotiations from 2015 until its approval in 2016, also affirmed that 'most of the process was trying to understand the organisation, trying to know what the organisation was doing, to see how we have to change that'.

According to the report, the participants requested that the Secretariat propose a definition of non-State actors and launch a mapping of non-State actors who were engaging with the WHO at the time. It should also include a description of the types of engagements. The discussion paper used in the informal consultation in October 2013 pointed out that the already-agreed overreaching principles should apply to all non-State actors and the boundaries for the relationships. Moreover, it proposed to strengthen due diligence, strengthen the management of risk, including conflicts of interest, and increase transparency.

Regarding due diligence, it was proposed that the procedures should not only be expanded and reinforced but also applied to all sorts of engagement at all levels of the Organisation. According to the document, 'the revised procedure could also involve a public scrutiny phase where the public would be invited to draw attention to potential risks of engagement with a particular non-State actor that is being examined'. Similarly, it was proposed that a comprehensive risk management approach should apply to all the WHO's engagements at all levels and should be based on a clear definition of the risks. Concerning

transparency, an online transparency register was proposed, to provide basic information on the non-State actor with which the WHO engages and detail the nature of their interaction.

It was pointed out in the report that although private entities were not allowed to attend the sessions of the governing bodies, NGOs representing them could attend if they were in official relations. Two suggestions, therefore, were made by the NSAs and Member States. The first was to create an extra system specifically for the attendance of WHO governing body sessions. The second was to restructure and to update the official relations in order to allow the entrance of NGOs that cannot prove 'collaborative programmes with WHO' but which could offer contributions to governing bodies.

According to interviewee 14, from an NGO with official relations status and an attendee of this consultation, the meeting featured aggressive debate between some NGOs and the pharmaceutical industries. Afterwards, non-State actors were no longer invited to the negotiations.

With regards to the first informal consultation on the WHO's engagement with non-State actors, I only had access to the summary report, the comments on the discussion paper for the informal consultation and the comments written by two Member States, Chile and France, and seven NSAs. But, as previously mentioned, around 320 representatives of NSAs and Member States participated.

Three points are significant to this thesis. Firstly, the participants seemed to be concerned about the suggested examination of non-State actors before they engage with WHO and recommended that the level of due diligence should be tailored to the type of engagement. Secondly, they emphasised the need for different procedures for different types of non-State actors. Thirdly, there were multiple opinions about 'the various types of non-State actors; a typology of interactions with non-State actors; need and feasibility of differentiation, especially amongst the NGOs' (WHO, 2013).

Apart from proposing a definition of a non-State actor and developing a register of WHO engagements with NSAs, the Secretariat stepped forward by publishing participants' comments on the WHO website. At this juncture, it is crucial to emphasise that during the elaboration of this doctoral thesis, the WHO website was being restructured, which caused the loss of access to several previously-available documents. Additionally, several documents were removed from the WHO website without further explanation.

Regarding the comments written by the Member States, Mr Guy Fones, part of the permanent mission of Chile to UNOG, wrote that the WHO should prioritise the four pillars that were defining and guiding the management of the engagements. Three of them were proposed by the Secretariat: due diligence; management of risk, including conflict of interest, and transparency. The fourth pillar was proposed by Finland and strongly supported by Chile – it referred to the assessment of public health added value.

France reinforced the argument that the WHO should remain an intergovernmental organisation while aligning its commitment with the United Nations principles and guidelines for cooperation with the private sector. The country also advocated for applying the existing mechanisms and for Member States to conduct the WHO Reform process. Transparency was mentioned as the key element for collaboration with non-State actors as well as the concept of due diligence, seen as necessary to be implemented 'systematically'. Risk management, 'depending on their nature', was also cited as a crucial element in maintaining the integrity of the WHO whenever it could be translated into practical and efficient measures.

France also welcomed the idea of a transparency register that would be accessible on the Internet. It would provide details of all the non-State actors which were collaborating with the WHO, as well as the source and the destination of their fundings 'when appropriate'. Regarding the controversial topic of the differentiation of non-State actors, France advocated an 'inclusive definition which would encourage WHO's collaboration with a broad spectrum of non-state actors, in the exclusion of industries whose interest is fundamentally irreconcilable with public health purposes (tobacco, arms)' [71].

Furthermore, in response to the informal consultation, the European Alcohol Policy Alliance (EUROCARE) pointed out that the WHO should differentiate entities from economic operators as they 'should be treated similarly to the tobacco industry, and excluded from engagement with the WHO". EUROCARE also criticised the approach of categorising all external actors under 'the generic umbrella of "non-state actors"'. According to the organisation, 'while overreaching principles should govern all interaction with external actors, separate policies are needed to ensure clarity and transparency regarding the

[71] Translated from the orginal: "La France recommande une définition inclusive, de nature à favoriser la collaboration de l'OMS avec un large spectre d'acteurs no étatiques, à l'expection des industries dont l'intérêt est fondomentalement irréconciliable avec l'objectif de santé publique (tabac, arms)". Available at https://www.who.int/docs/default-source/documents/fensa/informal-consultations-who-nonstateactors-comments-france-oct2013.pdf?sfvrsn=e44e2e2d_2 Accessed on 09.12.2019

fundamental difference between NGOs and entities that represent or are linked to commercial entities'. Finally, EUROCARE requested that the WHO exclude the alcohol industry from FENSA.

In contrast, the International Food & Beverage Alliance (IFBA) advocated a homogeneous policy for all kinds of non-State actors and at all levels of the Organisation. Arguing that 'everyone has vested interests', the IFBA endorsed that a strengthened due diligence system should be applied to NGOs and that 'perceptions' should not surpass facts and positive results. In this sense, IFBA criticised the NGOs' preferred access to governing bodies and also warned that a 'hierarchy' of non-State actors with different roles and access to the WHO would jeopardise the work of the Organisation. Lastly, it was pointed out that when considering

> (…) opportunities for enhanced engagement in such areas as research and evidence generation, technical consultation, financing and advocacy and awareness raising, we urge you to ensure that WHO´s engagement policies are balanced, inclusive and conductive to effective cooperation and interaction with both private sector and NGOs. The policies should not imply or assume that conflict of interest concerns apply only and uniformly to the private sector; nor should they appear to give the private sector a lesser or subordinate role to NGOs. They should recognise the importance and legitimacy of the private sector's role and contributions, as recognised in the Political Declaration, and encourage them regardless of whether those involved are formally accredited to WHO or not.

In this direction, the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA) argue that every actor, even those without a commercial interest, has potential conflicts of interest, and also advocated that all non-State actors should have equal access. The IFPMA also claimed that a robust transparency policy should be applied similarly to all stakeholders: 'conflict of interest issues must be addressed in an open and transparent manner but should be not used as a reason to exclude any stakeholder who can positively contribute to improving health'. Finally, the IFBMA supported the maintenance of the 3-year collaboration plan and the adoption of a Transparency Register as used by the EU.

The NCD Alliance (NCDA) advocated for a more flexible accreditation system to admit the access of NGOs and other entities without official relations status to WHO governing bodies. Furthermore, in its written comments, the Alliance endorsed that the due diligence policy should be addressed according to the type of engagement and the kind of entity.

The main demand of the UK Centre for Tobacco and Alcohol Studies (UKCTAS) is to be found in paragraph 4 and states that 'WHO does not engage with industries that make

products that directly harm human health" and that should include the alcohol industry. Concerning the role of NSAs in funding WHO, the UKCTAS warned about the risks – e.g. dependency and distorting priorities – that could arise from WHO accepting funding from "individual entities [that] could represent a conflict of interest". UKCTAS also supported the WHO practice of excluding individuals working for the private sector from serving in guidelines development.

Finally, the comments written jointly by the Corporate Accountability International, the International Baby Food Action Network (IBFAN), the Medicus Mundis International Network (MMI) and Forum for Public Health emphasised not only the dangerous link between public health and commercial interests but also the WHO's engagement with philanthropic organisations. They underlined that when in the role of donors, these foundations 'have great power to influence WHO's directions and decisions through their financial leverage'. Moreover, their major concern was that FENSA, instead of improving WHO relations with non-State actors, would oppositely weaken WHO's position as the prime actor in public health. In this sense, the main suggestion was 'different engagement for different types of actors'.

After the consultation in October 2013, a first FENSA draft was presented by the Secretariat in January 2014, during the 134th session of the Executive Board. This moment allowed for more general considerations, such as 'Objectives, principles and boundaries', 'working definitions', 'strengthening the management of engagement', and the next steps which would include further consultations among the Member States to develop distinct policies, and operational procedures for the different non-State actors. Afterwards, it would be submitted to the Executive Board at its 135th session, in 2015.

As requested by the participants of the first consultation in October 2013, the paper *Mapping of WHO's engagement with non-State actors*[72] was presented at the Executive Board to offer an overview of WHO engagement with non-State actors. At that time, WHO was engaging with 729 non-State actors, including 298 nongovernmental organisations, 44 private sector entities, 24 philanthropic foundations and 363 academic institutions. It was pointed out, however, that 'although some areas of engagement can be illustrated with initial data, others are not documented in easily accessible databases, particularly those that are

[72] Available at: https://www.who.int/about/who_reform/governance/mapping-of-WHO-engagement-with-non-State-actors.pdf?ua=1 Last access on 06/12/2019

specific to one country, and too many informal collaborations at all levels of the Organization. The distinction between non-State and State actors can be difficult'. Regarding participation in Governing Bodies:

> Participation in Governing Bodies meetings is open to the 187 NGOs in official relations. In 2013, 55 NGOs with 275 delegates participated in the January Executive Board, 86 NGOs with 809 delegates in the World Health Assembly and 26 NGOs with 116 delegates in the May Executive Board. For previous years participation of NGOs in official relations at the World Health Assembly ranged from 33% to 41%and at the January Executive Board from 24% to 30%. Private sector entities do not participate in Governing Bodies other than their staff being members of delegations of business associations when these are NGOs in official relations. Philanthropic foundations and academic institutions do not regularly participate in Governing Bodies. Some of those entities have been invited to meetings on an ad hoc basis depending on the issues on the agenda. Participation in informal consultations is handled on a case-by-case basis. There is currently no central database documenting this participation.

The paper also detailed financial contributions from NSAs, which in 2012 corresponded to 25.5% of the total income; 4.8% was from NGOs, 1.5% from the private sector, 18.9% from philanthropic foundations and 0.2% from academic institutions. In-kind contributions were considered 'difficult to distinguish those resources provided by non-State actors to WHO from those resources used directly by the non-State actor in the context of its collaboration with WHO'. Moreover, the WHO seemed to have no documentation regarding human resources provided by NSAs, as it used to occur through 'stand-by agreements for emergencies and other established human resources mechanisms'. Finally, concerning advocacy, it was not 'thus far systematically documented (…) [and] no data are available on advocacy with the private sector, philanthropic foundations and academic institutions'.

The first version of FENSA also proposed, for immediate application, changes to the practices of implementing the policy regarding non-governmental organizations. For instance, non-governmental organisations wouldn't have to submit their statements for authorisation in advance anymore and the WHO should provide webpages for the posting of statements from NGOs in official relations for sessions of the World Health Assembly, the Executive Board and regional committees. Regarding transparency, the measures that should be promptly adopted were a designation of a head of each NGO's delegation and the indication of the organisational affiliation of all its delegates. Also, the access to the documentation submitted to the Board's Standing Committee on Nongovernmental Organizations, which was restricted, should be posted on the WHO website.

As requested by the 134 EB, on the 27th and 28th of March, the second informal

consultation on the draft framework, policies and operational procedures was held. Unlike the previous consultation, only the Member States took part. It was chaired by Professor Thomas Zeltner. The debate should guide the Secretariat to draft a FENSA proposal, to be submitted to the 67th WHA in May. Differently from the first consultation, it seems that written comments were not submitted; at the WHO website only the background document and the summary report are available. It is not possible, therefore, to track the Member States' positions in this specific moment, nor which countries were involved since the beginning of the negotiations. The summary report, however, indicated that 'nearly 200 Member States' representatives participated in person or virtually'.

One must consider that at this point, only the engagement with NGOs and the private sector was being discussed. The background document was, hence, divided into an overarching framework for engagement with non-State actors: WHO policy and operational procedures on engagement with non-governmental organisations; WHO policy and operational procedures on engagement with the private sector; WHO policy and operational procedures on the management of engagement with non-State actors. However, according to the summary report, there was a consensus among participants on two additional policies to address philanthropic foundations and academic institutions. To this effect, Member States requested that the Secretariat develop these policies and their operational procedures to result in one composite draft document.

In this regard, it is worth noting that interviewee 19, the first individual responsible for developing the new procedures of engagement with non-State actors at the WHO, affirmed that the initial idea was to have two landmarks, one for NGOs and one for the private sector and philanthropic sector:

> It's two logics, it's two different things, we can't mix, I said. And there were many NGOs in official relationship with WHO funded by the private sector. I said we could not keep that, that we had to have NGOs that are really people-oriented and not business-oriented. My position was very clear on that. And I think that at that time, neither the authorities, the Secretariat and many countries were in line with my position (…) And then the discussion started (…) [For me] we shouldn't mix the two relationship milestones. But then it changed the position of the Secretariat, I think by a lot of pressure from some Member States, who began to say that they preferred to have only one framework of relationship for all non-State actors. (…) Of Course, the Member States that have pushed the most in this direction are the member States that have more conservative and thematic positions on these governance issues: the United States, the UK, some countries – not all – of the European Union. We have many Member States that had a clear position that they could not restrict the space of insertion of the private sector (…) So, I think the first situation that was negative was when the Secretariat said we would not continue with both, that we would make a

unified proposal, responding to pressure from Member States.

At the beginning of May of 2014, a new draft of the framework was presented and debated during the 67th World Health Assembly. According to a report from the Intellectual Property Watch (non-profit independent news service which closely followed FENSA negotiations) 'some countries proposed to adopt the draft resolution on the framework, such as Finland, Canada, the United States and Australia, while others such as Pakistan and the UNASUR group considered that more discussion was needed'. Although South Africa was advocating that different actors play different roles, the country did not want to reopen the debate. Even though almost all the interviewees in this thesis stressed that Member States wanted to maintain the intergovernmental nature of the WHO during FENSA negotiations, according to the report, Thailand was supporting the presence of non-State actors at the negotiation table as it would be better than 'having them working behind the scenes'. The organised civil society which usually promotes side meetings to the Executive Board and the Health Assembly was concerned with the private sector as it could carry out activities incompatible with the WHO's purposes.

While FENSA was one of the most divisive topics of the 67WHA and it was being 'passionately discussed', as stated by a former public-interest NGO staff member, Melinda Gates made a speech at the opening of the Health Assembly highlighting that 'progress requires working with other government officials, not to mention the private sector, civil society, religious organisations, and community leaders'.[73] Moreover, as some Member States were pushing to adopt the framework during the Assembly, a working group was established. However, in the end, the framework was not adopted as controversial views over many key issues persisted.

Some interviewees explained that there was insufficient time to analyse and debate the document. Although it was dated 5th May, it was available on the web on the 9th of May, ten days before the World Health Assembly. In this sense, the WHA67 decision stressed the need for 'further consultations and discussions on issues including conflict of interest and relations with the private sector'. The Decision and List of Resolutions (WHO A67/DIV/3) stated that despite the progress made on the draft, further consultations and discussions were needed on some issues, specifically in relation to conflict of interest and relations with the private

[73] Available at: https://www.who.int/mediacentre/events/2014/Melinda-Gates_WHA-remarks.pdf?ua=1 Access on 16/12/2019

sector. Therefore, it was decided that the Member States should submit their detailed follow-up comments and questions to the Director-General in the next month (17 June 2014) and that the regional committees should discuss FENSA and submit a report on their considerations to the 68th World Health Assembly. Additionally, the Director-General was requested to prepare a 'comprehensive report' with the comments made by the Member States during the Health Assembly as well as the follow-up notes. The DG should also submit a paper to be discussed at the Executive Board in January 2015.

Comments written by Canada, France, United Kingdom, United States, Bolivia, Brazil, India, Mexico were available at the WHO website, however, it was not possible to see which other countries submitted their follow-up. Contrary to 2013, non-State actors didn't submit anything. It is worth noting that the WHO website was restructured and the individual comments submitted by the Member States in June 2014 after the WHA67 cannot be found on the WHO website anymore.

Canada commented on differentiation, conflict of interest, funding, secondments and evaluation. As well as the European Committee, the Canada Delegation position was to adopt FENSA, as it was presented in the WHA67, and propose an evaluation in two years to identify gaps. Moreover, the country supported 'a framework that applies to all NSAs, coupled with specific and uncomplicated policies and procedures for each group of NSAs (….) which will enable inclusive and effective treatment'.

France submitted its written comments on the 16th June of 2014 and it supported 'the adoption at the earliest opportunity of the framework of engagement with non-State actors'. The country described FENSA as 'crucial and essential' to WHO reform and believed it could be improved from the outcomes of practical application.

Regarding the WHO's operational capacity, France stated that FENSA would 'allow WHO to leverage its operational capacity by mobilising non-State actors to give practical effect to the strategies decreed by the governing bodies; the Organisation (….) might require the resources – whether in terms of expertise, financing or mobilisation – of non-State actors in order to take effective action'. This argument matches the interview made with a Norway representative (France did not answer my request for an interview for this thesis), for whom the main focus of developed countries (specifically the European group) was 'the practical aspects of a building system that we felt would effectively work and that would deliver

security without interfering with the efficiency and workability of the organisation'.

The non-distinction between the different types of non-State actors was one of the controversial topics of FENSA. In this regard, France supported a single framework with common rules and principles 'based around a classification of the different sorts of interactions rather than the different categories of actors' and detailed procedures according to the different categories of NSAs. However, to France, mechanisms to prevent conflicts of interest were more important than the categorisation of actors. Finally, France supported 'an inclusive definition (…) with the exception of those industries whose interests are fundamentally irreconcilable with the ends of public health (for example tobacco and arms)'.

Likewise, France, Canada and the United Kingdom wanted FENSA approved as soon as possible and supported the same framework for all NSAs. In its comments, the UK advocated a broad framework which should not be excessively strict as it would hinder rather than support the WHO's ability to deliver its mandate. This argument is not only in accordance with France and Canada's written comments but also to the interview made with the UK representative who alleged that Ebola crisis which took place during FENSA negotiations 'showed us that we needed an enabling framework and not a prohibitive one'.

Regarding transparency, the United Kingdom requested a clarification of the NSAs' engagement with the WHO, to include funding and purpose. The country also suggested improvements in potentially ambiguous phrases such as 'significant risk' and 'important and intentional cases'.

Secondments were also a contentious topic of FENSA. While France and Canada did not mention them, the UK stated that 'in the draft WHO policy and operational procedures on engagement with philanthropic foundations, the secondment policy is missing (…) we would encourage WHO to include secondment arrangements in the policy'. In this sense, it is essential to note that the FENSA-approved and final version excluded secondments from the private sector. The interviewee from the United Kingdom reaffirmed the country's support to secondments. 'The UK does not agree with WHO not accepting secondments from private sector: 'regrettable'. The overall position was in favour of bringing expertise from wherever. By forbidding secondments from the private sector, potential sources of expertise and networking might be lost. Secondments happen at the national level, but then it cannot happen at the WHO? Why?"

The United States was in favour of FENSA being in alignment with other United Nations' policies and practices such as UN Secretary-General Ban Ki-Moon's Five-Year Action Agenda (The future we want). Moreover, the US disagreed with the advocated definition as it was 'quite narrow [and] it does not reflect the wide concept of advocacy as influencing public policy and resource allocation decisions'. According to the country, FENSA should strengthen the benefits of engagement while treating the risks as *identified* risks. Regarding transparency, the US supported the online register of actors and requested more progress on that, including the types of data that would be collected, the frequency of updates, roles and responsibilities. Moreover, the country demanded clarification on how FENSA would be applied at the regional and country level.

It is important to note that many of the interviewees pointed out the US as a strong supporter of the private sector at the WHO. Therefore, regarding conflict of interest, the country stated that 'commercial interests are not the only interests through which conflicts can arise [and] conflict of interest should be uniform across all policies'. Additionally, the US suggested an adjustment in the opening paragraph on engagement with private sector entities to 'support and encourage positive engagement from the private sector'.

In contrast to the comments from the UK, the US, France and Canada, Bolivia wrote that although FENSA was a reasonable basis for establishing healthy relationships with non-State actors, 'the document still needs to refined before it can be adopted by States'.

The assertion that 'WHO does not engage with industries making products that directly harm human health, including specifically the tobacco or arms industries' (paragraph 6c, p. 3, 2014) was a point of contention. Bolivia advocated that the word 'directly' should be removed as it could be seen that the WHO could maintain relations with businesses which indirectly harm public health.

Bolivia also noted that private entities regularly work through non-governmental organisations and academic institutions. FENSA should, therefore, be clear that if a NSA is influenced by a private sector entity, it should be considered as private sector. Although paragraph 11 states that if controlled by a private entity, a philanthropic foundation will be considered private sector, Bolivia highlighted cases in which philanthropies had a stake in private entities, which were not addressed. Bolivia also pointed out the subjectively of paragraph 34 'when other non-State actors, such as nongovernmental organizations,

philanthropic foundations and academic institutions, receive funding from private sector entities, they will not automatically be considered as being themselves private sector entities, unless the level and modalities of funding are such that the non-State actor can no longer be considered as independent of the funding private sector entities.' Finally, while paragraph 37 stated that 'the Secretariat distinguishes non-State actors on the basis of their nature, objectives, governance, independence, and membership, not necessarily on the basis of their legal status or funding', Bolivia's position was the opposite - funding is the key element for defining the nature of a non-State actor as main elements are limited and conditioned by the source of funds. India adopted the same position in paragraph 37.

During my interviews, it was evident that NGOs were pushing for a differentiation among NSAs considering the different levels of conflict of interest. In this regard, Bolivia argued that 'while some risks may be common to all the actors, it is also evident that relations with some specific actors entail greater risk. Relations with nongovernmental organisations, philanthropic foundations, and academic institutions should perhaps be differentiated from the risk posed by relations with private entities'. Bolivia also requested how and who would define what an indirect interest is, given the assertion 'Caution should be exercised in accepting financing from private sector entities that have even an indirect interest in the outcome of the project' of paragraph 11c of the draft Policy and Operational Procedure on Engagement with Private Sector Entities.

Concerning paragraph 19: 'WHO does not accept in principle secondments from private sector entities', Bolivia argued that the Member States rejected the topic in the previous draft. Finally, regarding funding, contributions, and donations from the private sector, Bolivia's position was that they should be through the Organisation's general budget and not conditional on any activity in particular. The country also requested further information on Public-Private-Partnerships and multi-stakeholder initiatives. This information was also requested by Brazil and India, who wanted to know which public-private partnerships and multi-stakeholder initiatives the WHO was engaging with and what the budget was.

Brazil and India started their comments on the FENSA Draft requesting all questions, comments, suggestions raised by the Member States during the discussions of the drafting group sessions, and the WHA 2014 NSA Committee A, in addition to all documents and

policies relevant to FENSA debate. Brazil also requested the number of seconded personnel from non-State actors to the Organisation and to indicate who seconded them.

Alongside Bolivia, Brazil pointed out the need for the distinction of non-State actors concerning funding sources and also the specific risks associated with engagement with each type of them. Moreover, Bolivia and Brazil supported information requests on the origins of funding of NGOs. Brazil also demanded the removal of paragraphs which allowed secondments from NGOs, from the private sector and academic institutions. At the end of the document, Brazil stated that it 'considers that secondment of personnel from non-State actors is not appropriate because it can risk WHO's integrity and reputation.' The deletion of the paragraph on contributions from the private sector for financing staff salaries was also demanded. Again, like Bolivia, Brazil advocated that any input from private sector entities should be made only to the regular budget. India took the same position.

Paragraph 36 of Draft WHO Policy and Operational Procedures on Engagement with Private Sector Entities specified that 'technical collaboration with the private sector is welcomed if potential risks of engagement are managed or mitigated, provided that the normative work of WHO is protected from any undue influence and there is no interference with WHO's advisory function to Member States'. Brazil asked for specification of which types of technical collaboration would be allowed and the risks that could arise from each practice. The country requested the same for technical collaboration from philanthropic foundations.

Regarding paragraph 15 of the Draft WHO Policy and Operational Procedures on Engagement with Philanthropic Foundations, 'contributions received from philanthropic foundations are listed in the financial report and audited financial statements of WHO as well as the Programme budget web portal and the WHO register of non-State actors', Brazil argued that it would be necessary to inform, in financial reports, the programs or activities that received funds from philanthropic foundations. Finally, Brazil suggested that the Secretariat should put in brackets points that Member States have already expressed restrictions during debates that took place before and during the 67th WHA.

Like Brazil, India asked for complete information on secondments from NSAs. India also asked for details of all financial and in-kind contributions made by non-state actors in the previous five years, specifying the name of NSA, amounts contributed, and the specific

destination (project/programme/activity). Finally, the country requested the existing practice and experience of the WHO in dealing with conflict of interests.

Similar to Bolivia, regarding paragraph 6 on industries that generate products that directly harm human health, India asked for a list of which these were, apart from tobacco and arms. According to the interviews, India was trying to mention the food and beverage industries precisely. Moreover, India pointed out the contradiction between paragraph 34 and 37; while paragraph 34 stated that an entity would not be re-categorised as a private sector entity, paragraph 37 stated that the attribution of an NSA could change over time.

An alignment between the so-called public-interest NGOs and India's comments is evident. A distinction between a real and perceived conflict of interests, and between an individual and institutional conflict of interest were encouraged by both. In this direction, India's position on the different types of NSAs was that the risk of engagement with some categories is higher than with others: 'It is important to acknowledge that WHO's engagement with the private sector/businesses associations poses a much greater risk particularly where the private sector has a commercial or financial interest at stake'. Furthermore, India advocated that NGOs which were not in official relations should not 'be denied the opportunity to participate in governing board meetings and to observe WHO proceedings. Thus, it would be useful for WHO to distinguish between formal collaboration (which will require official relations) and accreditation at least with regard to NGOs'. Some interviewees, such as 7, 9, 20 and 21, affirmed that some NGOs had written statements for India.

Like Brazil, India's position was against secondments from non-State actors as they 'may undermine the independence and integrity of WHO (…) may also provide access to critical information (…). In our view, if WHO needs personnel for a particular activity, it should employ such personnel rather than rely on secondments'. Regarding philanthropic foundations, India was against inviting them to participate in the financing dialogue, given the lack of flexibility of their contributions. As already discussed in chapter two, the donor-driven programme priority setting is seen as one of the main problems of WHO, as it has been replacing the Member States' collective priority setting.

Comments submitted by Mexico reveal a more neutral position. While the alignment between Canada, France, United Kingdom and the United States is clear, as well as that

between Brazil, Bolivia and India, Mexico did not comment on polemical topics such as industries that indirectly harm human health or distinction among non-State actors due to different levels of conflict of interest. For instance, Mexico did not advocate against secondments, like the other developing countries, but just asked for more precise references regarding the role of seconded staff and the budget involved.

The regional offices also submitted their follow-up comments after the WHA67, however they were not available at the WHO website. *Information on regional committee debates* - a document that was part of the provisional agenda of the 136th Session of the Executive Board, pointed out that the African Region stated that although transparency of FENSA process should be imperative, there was a lack of clarity 'in the process and criteria regarding due diligence and related procedures'. The African Region also pointed out the earmarking of funds from private sector non-State actors, as well as the use of such funds for the payment of staff salaries. Also mentioned in the report were worries about the influence of non-State actors on the WHO's normative and standard-setting work along with strong reservations regarding staff secondments from the private sector.

The African Region agreed that the WHO should not engage with the tobacco and arms industries, highlighting that 'a number of Member States considered that this restriction should be extended to other sectors, including notably the alcohol, food and beverage industries'. Finally, the recommendations made by AFRO were: (a) representatives should further consult at country level (…); (b) the revised framework should provide a clear policy on how the WHO will manage conflicts of interest and define its due diligence processes; (c) the revised framework should better reflect the role and function of academic institutions'.

The Regional Committee for the Americas (PAHO - the Pan American Health Organisation) considered that the framework presented at 67WHA 'lacked detail regarding the criteria that non-State actors must meet in order to be classified in each category and the way in which each group could engage with WHO. At the same time, Member States cautioned against the adoption of an overly prescriptive framework that might not allow sufficient flexibility'. Numerous Member States from the PAHO were advocating that any interaction with actors whose activities or products were harmful to health, and any secondment of personnel from the private sector should be expressly prohibited. One should note that within the PAHO, the collaboration must have been troublesome as the Member

States of the regional office had very different perspectives at the WHO Headquarters. Moreover, it was highlighted that non-governmental organisations and philanthropic and academic institutions that received funding from for-profit private companies should be specified. Finally, it was pointed out that PAHO experience in interacting with non-State actors, including with the pharmaceutical industry, could be shared with the WHO Secretariat.

While secondments were causing controversy, the Regional Committee for South-East Asia (SEARO) noted that there were no secondments to the WHO from the private sector and requested that the report and recommendations of the Inter-sessional Meeting held in August 2014 should be taken into consideration; hence, no secondments from non-State actors should take place in WHO.

The Regional Committee for Europe (EURO) 'strongly urge adoption of the Framework of engagement with non-State actors at the Sixty-eighth World Health Assembly in 2015'. Although recognising that improvements on management of conflicts of interest and process and timetable for evaluation were needed, EURO Member States advised firmly against 'trying to perfect every detail, preferring instead to begin work, trusting in the wisdom of the governing bodies to oversee the operation of the framework in practice and continue to improve it'. Although interviewee 10, from the European Union, affirmed that the EU Member States did not reach a consensus, the States interviewed, the UK, Norway and Germany, had very similar positions, including being against 'line-by-line' negotiation.

The Regional Committee for the Eastern Mediterranean Office (EMRO) reinforced the need for comprehensive guidelines for WHO interaction with non-State actors and pointed out the following areas for improvement: management of conflicts of interest; clarification of boundaries, especially with the private sector and business associations; definition of actors; acceptance of donations of pharmaceutical products; and technology transfers.

The Regional Committee for the Western Pacific (WPRO) argued that 'WHO should be able to engage with the private sector in its commercial capacity to advance the research and development of new medical products' and suggested that the Framework should establish the concept of competitive neutrality.

Lastly, it was pointed out that in a regional meeting of the PAHO, the establishment of an office to oversee FENSA implementation was suggested. The office would not only

‘exercise a watchdog function but also play a facilitating role in promoting engagement and actively support WHO programmes in their efforts to reach out to non-State actors, including the private sector. Mechanisms for receiving funds from private sector entities should be aligned with national health sector strategies’ (EB, 2014, p.4).

In December 2014, the Secretariat released a report to be discussed at the 136th Executive Board of January 2015. It presented the comments and the follow-up observations made by the Member States during and after the 67th World Health Assembly. It can be observed that conflict of interest and how it could be efficiently managed had been a topic of central concern since the beginning. Process and criteria of due diligence were also cited.

As mentioned in chapter 3, financial resources from the private sector have always been a polemical issue within the WHO. Therefore, according to the report, ‘Member States stressed that WHO should accept financial resources from private sector entities only if potential conflicts of interest are ruled out and if this engagement does not compromise WHO’s integrity and reputation’ (EB, 2014, p.2). Regarding secondments, some Member States proposed that the WHO should not allow secondments from any non-State actors, while others pursued to exclude only secondments from the private sector. Moreover, some suggested that NGOs, philanthropic foundations and academic institutions not ‘at arm’s length’ from private sector entities should also be considered as private sector entities and that the WHO should consider adding the definition of “international business associations” as a subcategory of “private sector entities”.

In relation to entities with which the WHO should not engage, some Member States were advocating that the non-engagement with tobacco and arms industries should be extended to alcohol, food and beverage industries. Besides, some suggested that the involvement of the private sector should be open to Member States’ examination and that Member States should be involved in due diligence.

It was pointed out that it was not clear if FENSA would also be applied to partnerships nor how conflicts of interest should be managed in such partnerships. An improvement of the concept of ‘non-State actor’ was also suggested, as it should include entities falling outside the definition, such as public-private partnerships and multistakeholder initiatives. The concept of ‘competitive neutrality’ was also suggested as a way of safeguarding interaction with entities that are subject to market forces, so that they would not confer undue

competitive advantages. Medicine donations, safeguarding of the WHO's name and emblem, assessment of the framework and the role of academic institutions were mentioned in the report.

The second part of the report contained the Secretariat's proposals to address the issues raised by Member States. Regarding conflicts of interest, a section on the management of institutional conflict of interest and other risks of engagement was added to the framework. 'The new section defines conflict of interest, both in general and in the institutional context. For the WHO, the most important institutional conflicts of interest arise in situations where the economic interests of private sector entities are in conflict with the Organisation's interests, its independence and impartiality in setting norms and standards'. The report also clarified that the rules for engagement with private sector entities were more detailed and more restrictive than the rules for other non-State actors aiming to preserve the WHO's integrity when accepting financial contributions from the private sector. It was also proposed by the Secretariat that the WHO should not accept secondments from any NSA. Moreover:

> any non-State actor clearly influenced by private sector entities will be considered as a private sector entity. Thus, engagement with such entities will be circumscribed by the policy on engagement with private sector entities with its more stringent rules. If a non-State actor is clearly independent from private sector entities, but still receives funding from such entities, the individual engagement will be examined to determine if the provisions of the private sector policy should be applied. Funding from such a non-State actor would for instant not be acceptable for normative work linked to the interest of those private sector entities that provide funding to them. Evidence provided by such non-State actors would be considered as potentially influenced, while funding for, or other collaborations on, an implementation project in the area of expertise of this non-State actor could be acceptable. (EB, 2014, p.5)

The Secretariat declared that Member States were consensual in keeping the system of official relations, instead of replacing it by another accreditation system.

Furthermore, the broad interpretation that has always been given to the term 'non-governmental organisations' was recognised, which had allowed business associations and philanthropic foundations to have official relations with the WHO. The draft, therefore, 'proposes to increase transparency by narrowing the definition of nongovernmental organisations compared with past practice, while still allowing international business associations and philanthropic foundations to be accepted as non-State actors in official relations'. However, entities considered by the WHO as private sector entities, and which do not represent a business sector, would not be suitable for admission into official relations.

It is worth noting that FENSA should be applied to engagement with all non-State

actors, not only to those in official relations, different to the 1987 Principles which were applied only to NGOs in official relations. Regarding the non-engagement with the tobacco and arms industries, it was moved into a new paragraph on engagement with particular industries, and other industries affecting health. While prohibiting any engagement was not proposed, the WHO should apply particular caution when engaging with them.

The clause on competitive neutrality was added to the private sector policy, and the policy on engagement with academic institutions should be applied, combined with the Regulations for Study and Scientific Groups, Collaborating Institutions and Other Mechanisms of Collaboration. Finally, an item requiring systematic monitoring of the implementation of the framework was added. Furthermore, the implementation of the framework should be periodically evaluated, and it was proposed that the first evaluation and revision of FENSA should be made at the Seventieth World Health Assembly in 2017. The 70WHA report on FENSA stated that after the adoption, regional committees were discussing the implementation of the Framework and the PAHO had already decided to adopt and implement during the 55th Directing Council of the WHO and the PAHO. The WHO register of non-State actors and the electronic workflow were also mentioned as advancements in implementation. Moreover, a guide for staff and a handbook for non-State actors were being finalised at the time and should be 'regularly updated in the light of the experience gained in the implementation of the Framework and will be made available on the WHO website' (WHA, 2017, p.3) Finally, a set of criteria and principles for secondments from NGOs, philanthropic foundations and academic institutions was also prepared.

Based on the comments of those consultations, the Secretariat drafted a third version of the FENSA for the 136th EB in January 2015. The EB symbolises a turning point in the negotiation process as it was decided that FENSA would be moved to an open-ended intergovernmental meeting (OEIM) to discuss 'textual proposals submitted by Member States and, where applicable, regional economic integration organisations'. The goal was to adopt them at the 68WHA in May. Therefore, a drafting group was created, and Argentina was appointed by Margaret Chan to chair the discussions. FENSA discussion then shifted from the Secretariat to a called Member-States' phase. The EB136 decisions and list of resolutions included a 'non-exhaustive list of issues which seem to need more work amongst Member States'. The issues cited were:

> conflict of interest (including individual conflict of interest); criteria of due diligence and process of risk management; transparency; secondments and provision of personnel; role of private sector (acceptance of funds, pooling mechanism, evidence generation and advocacy); engagement with particular industries; criteria for attribution to type of non-State actors, including criteria applied to classify some nongovernmental organisations as international business associations; in which kind of meetings can non-State actors participate; use of funds provided by non-State actors to support the salary of WHO staff; official relations (some aspects); policy, norms and standard setting; applicability of the framework to all levels of the Organization and all 6 regions; general principles that guide collaboration; definition of terms ("arm's length", "resources", etc); support to policy making at national level. (EB, 2015, p.3)

The open-ended intergovernmental meeting took place in Geneva from 30 March to 1 April 2015 and was chaired by Dr. Andrea Carbone from Argentina. At the meeting, the draft was reviewed, taking into account the proposals submitted by the Member States for amendments, additions or deletions. The product of the open-ended intergovernmental meeting was a reviewed version of FENSA, reflecting discussions at the meeting. The Director-General reported the outcomes to the 68th World Health Assembly.

The topics that the open-ended intergovernmental meeting could not reach a consensus upon were: resources, management of conflict of interest, conflict of interest, due diligence and risk assessment, risk management, transparency, and secondments. (WHO, 2015).[74]

Before the 68th WHA, a report on the financial and administrative implications for the Secretariat regarding FENSA was released. The Framework was part of the Leadership and Governance programme area, and its adoption was seen as a tool to 'provide a solid basis for the ongoing strengthening of due diligence and risk assessment'. The cost required for FENSA implementation and activities for the period 2014-2019 was estimated to be $10,508,800. Of which $8,238,300 would be for staff and $2,270,500 for activities. While the costs were incurred at the WHO headquarters in Geneva, it was argued that the implementation of the framework would impact 'work processes at all three levels of the Organization'. It can also be observed in the report that FENSA could not be implemented by existing staff and it would 'increase the team conducting due diligence and managing interaction with non-State actors from four full-time professional staff members to five'.

Three draft versions were considered at the 68th World Health Assembly between the 18th and 26th of May 2015. At that time, a consensus was reached in many parts, including introduction, rationale, principles, benefits of engagement, risks of engagement, non-State

[74] Framework of engagement with non-State actors, Report by the Director-General. Available at: http://apps.who.int/gb/ebwha/pdf_files/WHA68/A68_5-en.pdf?ua=1 Last access on 02/01/2020.

actors, and types of interaction.

According to interviewee 2, 'many meetings took place in the Programme, Budget and Administration Committee (PBAC), to which we had no access and for which there are no reports. There are, for example, no verbatim or even summary PBAC reports giving any information about MS' positions. More importantly perhaps, throughout the six years, since the official start of the Reform, there had been many meetings behind closed doors as well as many drafting or working groups during EBs and WHAs'. At the 68th WHA, the disagreement between the Member States was echoed as no consensus was reached and FENSA, once again, was left to be considered for adoption at the 69th WHA.

It is worth noting that during the 68WHA, non-State actors, precisely the NGOs, were more active as many reports and articles were written in the margins of the meeting. In this sense, the controversy surrounding FENSA seemed not only to be among Member States but also between different NGOs, something that is expressed in their official statements made at the 68th WHA. According to the Third World Network,[75] Health Action International (HAI) advocated that the WHO should exercise particular caution when engaging with industries affecting human health or affected by WHOs norms and standards. HAI was furthermore asking that FENSA should clearly define the industries with which caution should be taken. The International Baby Food Action Network (IBFAN) argued that the FENSA draft reasserted old channels of undue influence as, instead of reviewing the constitutionality of recognising business-interest associations as 'NGOs', it proposed their comprehensive admission – the same of philanthropies too. IBFAN also pointed out the inadequate concept of conflicts of interest. Medicus Mundi International and the People's Health Movement called the FENSA draft 'obscure and complex', which would not be able to prevent improper influence.

Given the impasse, a resolution was adopted and it was requested that the WHO convene 'as soon as possible and no later than October 2015, an open-ended intergovernmental meeting to finalize the draft framework of engagement with non-state actors on the basis of progress made' during the Health Assembly. The resolution also asked the DG 'to develop a register for non-State actors' in time for the 69th WHA. Consequently, further OEIGMs were held. The open-ended intergovernmental group met twice officially in

[75] WHO: Work on non-State actors engagement framework to continue. Available at: https://www.twn.my/title2/health.info/2015/hi150512.htm Last access on 02/01/2020

2015, from the 8th to the 10th of July and from the 7th to the 9th of December, as well as for informal consultations for nine days in September and October 2015. The third and last meeting took place from the 25th to the 27th of April 2016.

In October 2015, a non-paper of the *Implication of Implementation the Framework of Engagement with non-State actors* was released by the Secretariat for consideration at the informal meeting of Member States on 19th to the 23rd of October. It was argued that while FENSA would put the relationship between the WHO and non-State actors 'on a more solid basis and strengthen the management of risks of engagement', the Framework, as it was drafted, could also lead to an 'unintentional restriction of WHO's engagement with non-State actors'. The non-paper was divided into two sections: Intended Consequences of FENSA Implementation and Risks of Unintended Consequences of FENSA Implementation.

The paper highlighted the proposal of establishing an oversight function of the Executive Board through its PBAC. Moreover, the Executive Board Standing Committee on NGOs would be abolished, and its functions transferred to the PBAC. Regarding the financial and human resource costs, the paper stated that a significant part of the additional workload should happen at the country level. It also detailed seven risks regarding FENSA implementation, including a systematic overload of the clearance system: 'if all engagements from a minor engagement with a small NGO (…) to a major financial contribution have to go through the full system and the same process'. Moreover, transparency beyond a certain level could 'conflict with legal undertakings entered into by WHO with regards to accessing or disclosing certain information'. Also cited were: applying the full FENSA system during emergencies, and conflict of interest with individuals, such as experts from universities, that might have links to non-State actors.

The paper also mentioned more than seven risks from proposed but not agreed provisions of FENSA. The first one was a ceiling for earmarked contributions which would 'deter non-state contributors from making such contribution and have important resource mobilisation implication'. Regarding experts associated to non-State actors, 'WHO could not perform its work on preparing norm and standards if no experts connected to a non-State actor could be involved, since a large part of the expert knowledge WHO need is outside of state actors'. Moreover, it was argued that 'an extensive interpretation of the non-engagement with the arms industry could lead to important missed opportunities, such as engagement

with the IT sector on e-health on e-health and m-health, since most of companies operating in this field have either close ties with defence industry or have developed expertise, branches and subsidiaries in this area'. Due diligence and risk assessment were mentioned as potential risks as they 'may put at stake WHO's reputation and may encourage non-State actors to press charges against WHO'. The exclusion of secondments and an eventual separate accreditation procedure were also cited.

As a response, 44 public-interest civil society networks signed an open letter[76] to Margaret Chan arguing that 'the non-paper prepared by the Secretariat (…) provides no constructive contribution to the new Member-State-led process' and questioning 'the motives behind such a paper as it comes in the middle of the negotiations'. The organisations expressed their concern as the paper could 'undermine further strengthening of a FENSA and prevent it becoming a truly robust framework as the paper lists the potential 'unintended consequences' often in an exaggerated manner, as assumptions, without providing empirical evidence to back up these claims'. Finally, they requested that Secretariat support a 'constructive finalisation' of FENSA, which should include forceful provisions to avoid undue influence from the private sector, as well as corporate philanthropies, considering that the WHO's concern to secure funding should not 'collide with the WHO constitutional mandate, a conflict of interest that global public health cannot afford'.

Given the report of the open-ended intergovernmental meeting and of the Programme, Budget and Administration Committee of the Executive Board, it was decided in the 138th Session of the Executive Board to have a final session from the 25th to the 27th April 2016 of the open-ended intergovernmental meeting, in order to submit a consensus text of FENSA to the 69th World Health Assembly. Moreover, in March 2016, a report from the External Auditor was released, on the implication for the WHO of the implementation of FENSA. As the Member States didn't reach a consensus:

> the Executive Board adopted the decision, among others, to request the Secretariat to prepare an objective and balanced analysis of the implications for WHO of implementing the framework, with inputs from headquarters and the regional and country offices. The purpose of the paper was to provide an overview of the possible implications of the implementation of FENSA, describing its impact and effects from a policy, financial and human resource perspective at all levels of WHO. In order to ensure a balanced and objective report to Member States, the assistance of the External Auditor was sought on the aspects of validating and commenting on the

[76] Civil Society Letter of Concern on FENSA 'non-paper'. Available at: http://www.babymilkaction.org/wp-content/uploads/2015/10/NGOs_Chan_67.pdf Last access on 02/01/2020

> replies to a questionnaire, as well as commenting on and enhancing the detailed matrix of analysis of the implications for WHO of the implementation of FENSA, and thereafter writing a final report on the matter. Hence, this report contains the results of the independent assessment conducted by the External Auditor (WHO, 2016, p.4)

The report was based on a questionnaire given to the six regional offices, 17 country offices and seven groups at the WHO. While there was a shared view that FENSA could result in positive opportunities, risks were pointed out that would need to be efficiently managed and avoided. According to the report, the critical areas of FENSA were due diligence and risk assessment procedures, transparency and accountability, the registering of non-State actors, conflict of interest, and oversight of engagement. Additionally, applicability to emergencies, due diligence and risk assessment procedures, and the receipt and provision of resources were topics that required improvement.

According to the report, in 2015, NGOs had the highest percentage of NSAs engaging with the WHO, within the three levels of the Organisation, corresponding to 40% of the total NSAs. The academic institutions followed them, with 32%, then the private sector entities with 21%, and the philanthropic institutions counted as the lowest, with 7%. It should be noted that the methodology used did not prevent double counting in instances where different departments, regional offices or country offices engaged with the same NSA. Furthermore, all kinds of engagements, from one particular participation in a meeting to a vast resource contribution, were considered as one engagement. Regarding the kind of engagement, according to the report, 'participation' was the main one for all categories of NSAs, corresponding to 38%. This was followed by technical collaboration (34%), advocacy (13%), evidence (10%) and resources (5%). The report then showed engagement in emergencies. While NGOs still accounted for the highest volume of engagements with 46%, philanthropic foundations shift from the last to the second-highest level of engagement, followed by the private sector and academic institutions.

While highlighting the importance of FENSA, the report also pointed out the improvements needed with regards to the 'clarity of the framework itself and the acknowledgement that specific policies and guidance must be crafted'. Another concern confirmed later during the interviews was that process proposed by FENSA could prove burdensome and delay engagements.

Other noteworthy point was the required adoption of rigid measures so that 'all

engagements by all offices and at all levels of the Organization abide by the framework. As provided for in the draft framework, non-compliance by an NSA can have consequences after due process, including a reminder, a warning, a cease and desist letter, or other measures.' Furthermore, that clarity should be apparent in the detailed operational guidelines and procedures:

> The adoption of the overarching framework and the resulting operational guidelines and processes should streamline activities and simplify accreditation of actors. It is only when transitioning from the existing system to the proposed framework and operational processes that changes in the volume of transactions will be noted. The system should operate much more smoothly and efficiently once it is in place and all staff and NSAs become accustomed to how it functions.

Regarding due diligence and risk assessment procedures, according to the report, it was mainly a matter of priority, 'a system that is quick and easy, but does not assure safeguards for the interests of WHO; or a system that is rigid and firm, protecting the reputation and integrity of the Organization, though requiring time and resources to perfect and institutionalize the system through tried and tested operational procedures'. It was also noted that given no structured and systematic monitoring and documentation process for engagements with NSAs existed, FENSA would offer 'a single, unified system and transparent policy for all types of engagements with NSAs across the Organization'. Moreover, FENSA guidelines should offer proper and necessary controls to manage the risk of policy override as 'on the basis of lessons learned from past engagements with NSAs, WHO may reconsider the adoption of alternative control processes for voluminous, recurring and less risky engagements'.

Finally, the report highlighted that discussions on FENSA have been going on for years, 'a long, arduous and costly' policy development which 'has barely taken off, at least in the form of a formal framework from which specific policies can emanate'. It was then recommended that a decision on its implementation should be made at the 69th World Health Assembly. It was reminded that the WHO was engaging with NSAs for years, without an overall formal framework being applied consistently and uniformly across all levels of the Organisation, thus relentlessly taking the risk of compromising its mandate of providing global leadership in public health.

As demanded, the final session of the open-ended intergovernmental meeting (OEIGM) on the draft framework of engagement with non-State actors took place in Geneva from the 25th to the 27th April 2016. One day before, on the 24th of April, the Secretariat

presented additional information on the 'Cost implication for WHO of the implementation of FENSA'. On 25th April, the Civil Society Statement *Save the World Health Organisation from the undue influence of corporations and corporate linked entities* was released. The public interest civil society organisations called the participants of the meeting to ensure that the framework would not fall below the existing safeguards that prevent undue influence from the private sector. The topics stressed were: the acceptance of financial resources from the private sector to support salaries of WHO staff; the allowance of groups that are primarily of a commercial or profit-making nature to establish official relations with the WHO, and to participate in meetings of governing bodies; the wrong conceptualisation of conflict of interest; the failiure to apply FENSA in the case of humanitarian emergencies; the use of FENSA as a fund-raising strategy.

Based on the outcome of the OEIGMs, the 69th WHA adopted FENSA in May 2016. It is the first arrangement to manage the relationship between a United Nations organisation and non-governmental actors. Although broadly celebrated by the Member States after four years of discussions, some non-State actors were, and remain, more uncertain about the framework. Chapters five and six will outline the perspective of some selected Member States and some non-State actors.

4.2 Progress in FENSA Negotiations: Tracking Changes.

Between the first version of FENSA (2014) and the approved one (May 2016), several drafts and reports were released. To examine the changes in the document, eight versions will be considered in this part. I decided to exclude the first draft that was presented to the 134th session of the Executive Board (January 2014), because, as I already mentioned, it was a basic version divided into three parts: Objectives, Principles and Boundaries; Working Definitions; and Strengthening Management of Engagement. Since May 2014, FENSA included an overarching framework and four separate policies and operational procedures on engagement with non-governmental organisations, private sector entities, philanthropic foundations and academic institutions. In this topic, the findings will be detailed and discussed afterwards, alongside the interviews in the last chapter (seven).

One could observe that the structure of FENSA followed the same pattern from December 2014 to May 2016, only with the topic Implementation added in April 2016.

Version 1 A67/6 05.05.2014	Version 2 EB 136/5 15.12.2014	Version 3 A68/5 01.05. 2015	Version 4 WHA68.9 26.05 2015	Version 5 FENSA/ OEIGM 27.12.2015	Version 6 FENSA/ OEIGM 07.04.2016	Final Version WHA69.10 28.05 2016
Rationale, paragraphs 1, 2,3 and 4	Introductio n paragraph 1 Rationale paragraphs 2-5	Introduction paragraph 1 Rationale paragraphs 2,3,4 and 5	Introductio n paragraph 1 Rationale paragraphs 2,3,4 and 5 *Paragraph 4 deleted	Introduction paragraph 1 Rationale paragraphs 2,3,4 and 5 *Paragraph 4 deleted	Introduction paragraph 1 Rationale paragraphs 2,3,4 and 5 *Paragraph 4 deleted	Introduction paragraph 1 Rationale paragraphs 2,3 and 4
Principles Paragraph 5	Principles Paragraph 6	Principles Paragraph 6	Principles Paragraph 6	Principles Paragraph 6	Principles Paragraph 6	Principles Paragraph 5 (A to H)
Boundaries Paragraph 6	Benefits of engagemen t Paragraph 7	Benefits of engagement Paragraph 7	Benefits of engagemen t Paragraph 7	Benefits of engagement Paragraph 7 *Item a deleted	Benefits of engagement Paragraph 7 *Item a deleted	Benefits of engagement Paragraph 6 (A to E)
Actors Paragraphs 7 – 12	Risks of Engagemen t Paragraph 8	Risks of Engagement Paragraph 8	Risks of Engagemen t Paragraph 8	Risks of Engagement Paragraph 8	Risks of Engagement Paragraph 8	Risks of Engagement Paragraph 8 (A to G)
Types of Interaction Paragraphs 13 – 20	Non-State Actors Paragraphs 9 – 14	Non-State Actors Paragraphs 9 – 14	Non-State Actors Paragraphs 9 – 14	Non-State Actors Paragraphs 9 – 14	Non-State Actors Paragraphs 9 – 14	Non-State Actors Paragraphs 8 – 13
Benefits and risks of engagemen t Paragraphs 21 – 24	Types of Interaction Paragraphs 15 – 21	Types of Interaction Paragraphs 15 – 21	Types of Interaction Paragraphs 15 – 21	Types of Interaction Paragraphs 15 – 21	Types of Interaction Paragraphs 15 – 21	Types of Interaction Paragraphs 14 – 20
Due Diligence, Risk Assessment and Risk Manageme nt Paragraphs 25 – 28	Manageme nt of Conflict of Interest and other risks of engagemen t Paragraphs 22 – 43	Management of Conflict of Interest and other risks of engagement Paragraphs 22 – 43	Manageme nt of Conflict of Interest and other risks of engagemen t Paragraphs 22 – 43 *Paragraph s 42 and 43 deleted	Management of Conflict of Interest and other risks of engagement Paragraphs 22 – 43 *Paragraphs 42 and 43 deleted	Management of Conflict of Interest and other risks of engagement Paragraphs 22 – 41	Management of Conflict of Interest and other risks of engagement Paragraphs 21 – 43

Transparency Paragraphs 29 and 30	Specific Provisions Paragraphs 44-46	Specific Provisions Paragraphs 44 – 46	Specific Provisions Paragraphs 44 – 46	Specific Provisions Paragraphs 44 – 46 *44bis added	Specific Provisions Paragraphs 44 – 46 *44bis added	Specific Provisions Paragraphs 44 – 47
Policy, Norms and Standard Setting Paragraph 31	Relation of the Framework to WHO's other Policies Paragraphs 47-48	Relation of the Framework to WHO's other Policies Paragraphs 47-48	Relation of the Framework to WHO's other Policies Paragraphs 47 and 48	Relation of the Framework to WHO's other Policies Paragraphs 47-48	Relation of the Framework to WHO's other Policies Paragraphs 47-48	Relation of the Framework to WHO's other Policies Paragraphs 48-49
Association with WHO's name and emblem Paragraph 32	Official Relations Paragraphs 49 to 64	Official Relations Paragraphs 49 to 64	Official Relations Paragraphs 49 to 64	Official Relations Paragraphs 49 to 64	Official Relations Paragraphs 49 to 64	Official Relations Paragraphs 50 to 66
Relation of the framework and the 4 specific policies Paragraph 33 and 34	Oversight of the Engagement Paragraphs 65 – 66	Oversight of the Engagement Paragraphs 65 – 66	Oversight of the Engagement Paragraphs 65 – 66	Oversight of the Engagement Paragraphs 65 – 66	Oversight of the Engagement Paragraphs 65 – 66 *64bis added (Accreditation of NGOs)	Oversight of the Engagement Paragraphs 67 – 68
Relation to other WHO Policies Paragraphs 35 and 36	Non-Compliance with this Framework Paragraphs 67 -69	Non-Compliance with this Framework Paragraphs 67 -69	Non-Compliance with this Framework Paragraphs 67 - 69	Non-Compliance with this Framework Paragraphs 67 - 69	Non-Compliance with this Framework Paragraphs 67 - 69	Non-Compliance with this Framework Paragraphs 69 - 71
Process of Management of Engagement Paragraphs 37 – 42	Monitoring and Evaluation of the Framework Paragraphs 70 and 71	Monitoring and Evaluation of the Framework Paragraphs 70 and 71	Monitoring and Evaluation of the Framework Paragraphs 70 and 71 *Paragraph 72 proposed	Monitoring and Evaluation of the Framework Paragraphs 70 and 71 *Alternative Paragraph 72 deleted	Implementation (added)	Implementation Paragraphs 72 and 73

Terms of Reference of the Committee on NSA of the EB Paragraphs 43 – 47					Monitoring and Evaluation of the Framework Paragraphs 70 and 71 *Alternative Paragraph 72 deleted	Monitoring and Evaluation of the Framework Paragraphs 74 and 75
Official Relations Paragraphs 48 – 63						
Oversight of Engagement Paragraphs 64 – 66						

Considering that it would be useless and exhausting to point out every single change that occurred through the negotiation process, as many language adjustments were requested, the focus will be on the content of FENSA, especially relating to the controversial points.

An introduction for the framework, paragraph 1, was added in version 2 and remained the same until the approved version. The four paragraphs (2 to 5) of the Rationale became three (2 to 4) but remained almost the same. Paragraphs 3 and 4 (version 1) or 4 and 5 (other versions) were merged into one. Regarding the overarching principles of the WHO's engagement with non-State actors, five were cited in version 1: a) demonstrate a clear benefit to public health; b) respect the intergovernmental nature of the WHO; c) support and enhance the scientific and evidence-based approach that underpins the WHO's work; d) be actively managed so as to reduce and mitigate any form of risk to the WHO (including conflict of interest); e) be conducted on the basis of transparency, openness, inclusiveness, accountability, integrity and mutual respect. In version 2, point B was complemented by the phrase '(…) where the decision-making by WHO's governing bodies is the exclusive prerogative of Member States'. Moreover, two other points were added: 'protect WHO's processes in setting norms and standards from any undue influence' and 'avoid compromising WHO's integrity, independence, credibility and reputation'. Version 4, presented at the 69th WHA, proposed to add to point A '(…) conform with the WHO's

Constitution, mandate and general programme of work'. The final version of FENSA establish eight guiding principles:

> WHO's engagement with non-State actors is guided by the following overarching principles. Any engagement must: (a) demonstrate a clear benefit to public health; (b) conform with WHO's Constitution, mandate and general programme of work (c) respect the intergovernmental nature of WHO and the decision-making authority of Member States as set out in the WHO's Constitution; (d) support and enhance, without compromising, the scientific and evidence-based approach that underpins WHO's work; (e) protect WHO from any undue influence, in particular on the processes in setting and applying policies, norms and standards; (f) not compromise WHO's integrity, independence, credibility and reputation; (g) be effectively managed, including by, where possible avoiding conflict of interest and other forms of risks to WHO; (h) be conducted on the basis of transparency, openness, inclusiveness, accountability, integrity and mutual respect. (WHO, 2016, p.5)

The topic 'Boundaries', of version 1, which included four points, was reallocated within the Framework. The topic 'Benefits of Engagement' was initially alongside 'Risks of Engagement' (Version 1, paragraph 21 to 24) but, since version 2, became one single topic with one paragraph. The text of Benefits of Engagement changed slightly from the version 1 until version 3:

> WHO's engagement with non-State actors can bring important benefits to global public health and to the Organization itself. For this reason, WHO engages extensively with non-State actors. Engagements range from major, longer-term collaborations to smaller, briefer interactions. Some engagements focus on the benefits that non-State actors can bring to the work of WHO, whereas others focus either on (i) the influence that WHO can have on non-State actors to enhance their impact on global public health or to influence the social, economic and environmental determinants of health or on (ii) enabling WHO to fulfil its directing and coordinating role in global health. (WHA, 2015, p.3)

Then, the version presented to the 68th WHA had a more far-reaching text:

> WHO's engagement with non-State actors can bring important benefits to global public health and to the Organization itself in fulfilment of its constitutional principles and objectives, including its directing and coordinating role in global health. Engagements range from major, longer-term collaborations to smaller, briefer interactions. Benefits arising from such engagement can also include: a) (DELETED) b) the contribution of non-State actors to the work of WHO c) the influence that WHO can have on non-State actors to enhance their impact on global public health or to influence the social, economic and environmental determinants of health d) the influence that WHO can have on non-State actors' compliance with WHO's policies, norms and standards e) the additional resources non-State actors can contribute to WHO's work f) the wider dissemination of and adherence by non-State actors to WHO's policies, norms and standards (WHA, 2015, p.5)

It was also suggested to add a point G, stating that 'non-State actors engaging with WHO [fully implement or more readily conform with] WHO public health policies [norms and standards], including in their own activities in the areas of food safety, chemical safety, ethical promotion of medicinal drug products, tobacco control and others.]'. In the final

version, point G was not added, and the benefits remained those presented in May 2015.

Regarding the Risks of Engagement, initially these were considered: undue or improper influence, a negative impact on WHO's reputation and credibility and misuse by a non-State actor for its interest. Moreover, a paragraph (24 in version 1) detailed the concept of conflict of interest, initially considered 'a set of circumstances in which professional judgment or actions regarding a primary interest (WHO's work) may be unduly influenced by a secondary interest (a vested interest in the outcome of WHO's work in given area). This secondary interest may affect or may reasonably be seen to affect the independence and objectivity of WHO's work. A conflict of interest can be individual or institutional and can be based on a commercial or financial or any other interest'. From version 2 to version 6, the paragraph remained virtually unchanged by naming the risks and moving the concept of conflict of interest to another part of the framework. In this sense:

> WHO's engagement with non-State actors can involve risks which need to be avoided or mitigated in accordance with WHO's risk management framework. Major risks relate to the occurrence of the following: (a) conflicts of interest; (b) undue or improper influence exercised by a non-State actor on WHO's work, especially in, but not limited to, normative and standard-setting activities; (c) a negative impact on WHO's reputation and credibility; (d) the collaboration being primarily used to serve the interests of the non-State actor concerned with limited benefits for WHO and public health; (e) the collaboration conferring an endorsement of the non-State actor's name, brand, product or activity; (f) the whitewashing of a non-State actor's image through an association with WHO; (g) a competitive advantage for a non-State actor. (WHA, 2015, p.4)

The final and approved version of FENSA changed the beginning to 'risks which need to be effectively managed and, where appropriate, avoided' while preserved the seven risks recognised since December 2014.

Regarding non-State actors embraced by the Framework, version 1 recognised: non-governmental organisations, private sector entities, international business associations, philanthropic foundations, and academic institutions. From version 3 (May 2015) until the approved FENSA, international business associations were placed as part of the private sector. One must note that the description of all NSAs remained almost intact, apart from international business associations which were first described as entities and then as private sector entities. Footnotes were added, explaining what an entity 'at arm's length' is and including think tanks, which are policy-oriented institutions, as academic institutions were added.

The types of interaction of non-State actors from the first until the final version

included: participation, resources, evidence, advocacy and technical collaboration. The paragraph about participation remained almost untouched. The phrase 'there are no limits imposed on non-State actors' participation at such meetings' concerning consultations and other meetings was added in version 2 but then removed in version 4, presented at the 68th WHA. About resources, pro-bono work was accepted in version 1 but withdrawn since version 2. Moreover, the last Intergovernmental Meeting Group from April 2016 requested to add a footnote enlightening that 'free provision of services' would not include secondments, which are covered in another paragraph of FENSA. Technical collaboration initially included 'support to policy-making at the national level', but it was removed.

Evidence was the only topic that suffered a substantial change. Version 1 to 3 established that evidence 'includes gathering and generation of information and management of knowledge and research'. The text started being amended at the 68WHA and ended up as:

> For the purposes of this framework, evidence refers to inputs based on up-to-date information, knowledge on technical issues, and consideration of scientific facts, independently analysed by WHO. Evidence generation by WHO includes information gathering, analysis, generation of information and the management of knowledge and research. Non-State actors may provide their up-to-date information and knowledge on technical issues, and share their experience with WHO, as appropriate, subject to the provisions of this framework, its four specific policies and operational procedures, and other applicable WHO rules, policies and procedures. Such contribution should be made publicly available, as appropriate, wherever possible. Scientific evidence generated should be made publicly available. (WHO, 2016, p. 9)

In version 1, conflict of interest was part of the 'Benefits and Risks of Engagement' section, while 'Due Diligence, Risk Assessment and Risk Management' were one other topic. Since version 2 it all became part of one division called *Management of Conflict of Interest and other risks of Engagement.* One should note that the definition of conflict of interest gave rise to many criticisms, especially from public-interested NGOs. Since version 2 (EB136/5, December 2014), conflict of interest was more detailed, as in version 1 only one paragraph (24) specified the definition and, afterwards, four or five paragraphs presented the concept and its relations. Therefore, paragraph 23 of version 2 defined conflict of interest as:

> [arising] in circumstances where a secondary interest (a vested interest in the outcome of WHO's work in a given area) unduly influences, or may reasonably be perceived to unduly influence the independence or objectivity of professional judgement or actions regarding a primary interest (WHO's work). The existence of conflict of interest does not mean that improper action has occurred, but rather that the risk of such improper action occurring exists

The definition of conflict of interest in version 3 had a language change; it was added that a

conflict of interest arises in circumstances where there is potential for a secondary interest and that 'conflicts of interest are not only financial but can take other forms as well'. It was also requested that a footnote be added to paragraph 23 regarding individual conflicts of interest: 'Individual conflicts of interests within WHO are those involving experts, regardless of their label, and staff members; these will be addressed in accordance with the policies listed under paragraph 48 of the present framework'. This definition was maintained in the final version, and the footnote became one paragraph (23).

Another noteworthy change related to an institutional conflict of interest. In version 2, paragraph 26 stated that 'for WHO, the most important institutional conflicts of interest arise in situations where the economic interests of private sector entities are in conflict with WHO's interests, especially the Organization's independence and impartiality in setting norms and standards' (EB, 2014, p.15). According to document A68/5 from 1st May 2015, no consensus was reached in this paragraph, therefore it was proposed to add financial interests to the excerpt and to change private sector entities to 'non-State actors addressed under this framework'. However, some Member States requested that 'in particular private sector entities' should be added. Some Member States even suggested deleting the paragraph and others to add footnotes referring to the norms and standards and evidence gathering. Another proposal was to add the footnote 'being aware that economic interest is the important institutional conflict of interest, nonetheless other forms of conflicts of interest should also be taken into consideration, to protect WHO's integrity as a UN specialized agency (see paragraph 67)]'.

The Chairperson proposed: 'for WHO the most important institutional conflicts of interest arise in situations where the economic, commercial or financial interests of non-State actors, in particular private sector entities, are in conflict with WHO's public health and constitutional mandate and interests'. Nevertheless, in final version, the text is 'For WHO, the potential risk of institutional conflicts of interest could be the highest in situations where the interest of non-State actors, in particular economic, commercial or financial, are in conflict with WHO's public health policies, constitutional mandate and interests, in particular the Organization's independence and impartiality in setting policies, norms and standards' (WHO, 2016, p. 10).

Paragraphs with regards to Due Diligence had minor changes between version 2 and

FENSA final text. In the Document EB136/5, paragraph 28 stated that:

> before engaging with any non-State actor, WHO, in order to preserve its integrity, conducts due diligence. This refers to the steps taken by WHO to find and verify information on a non-State actor and to reach a basic understanding of its profile. While due diligence refers to the nature of the non-State actor concerned, risk assessment refers to the assessment of a specific proposed engagement with that non-State actor. (EB, 2014, p.11)

While some Member States proposed only minor language adjustments, such as to add risk assessment in the first line: '(…) conducts due diligence and risk assessment' and 'to find and verify all relevant information'; a complete change was also proposed:

> Before engaging with any non-State actors, given the potential benefits for [both parties]/[public health] from such engagement, WHO needs to conduct due diligence, in order to preserve its integrity. This refers to the steps taken by WHO to find and verify information on a non-State actor and to reach a [basic]/[meticulous/definite]/ [clear] understanding of its profile. A risk assessment on a proposed engagement is conducted in addition to the due diligence. This involves the assessment of risks associated with the engagement with a non-State actor, in particular the risks described in paragraph 8.

In May 2015, the Member States reached a consensus and the final text is:

> Before engaging with any non-State actor, WHO, in order to preserve its integrity, conducts due diligence and risk assessment. **Due diligence** refers to the steps taken by WHO to find and verify relevant information on a non-State actor and to reach a clear understanding of its profile. While due diligence refers to the nature of the non-State actor concerned, **risk assessment** refers to the assessment of a specific proposed engagement with that non-State actor.

With regards to the paragraph that defines which are the principal functions of due diligence, initially, five points were mentioned:

> a) clarify the interest of the actor in engaging with WHO and what they expect in return; b) establish the "business card" of the entity (general screening); c) determine status, area of activities, governance, sources of funding, constitution, statutes and by-laws, affiliation; d) define main elements describing the history of the entity: human and labour issues, environment ethical and business issues, reputation and image as well as the financial stability and the examined entity; e) identify "red lines" such as activities that are incompatible with WHO's work and mandate (including specifically activities by the tobacco and arms industries) (WHA, 2014, p. 6)

It was required both by the Member States and the Chairperson to separate the bullet A into two: 'clarify the nature and objectives of the entity proposed to engage with WHO' and 'clarify the interest of the entity in engaging with WHO and what they expect in return'. Moreover, while version 1 and version 2 proposed to identify 'red lines', which would be activities irreconcilable with the WHO's work and mandate (e.g. links to the tobacco and arms industries), version 2 added the excerpt 'or that require the Organization to exercise particular caution when engaging with the entity (e.g. links to other industries affecting

human health or affected by WHO's norms and standards)'. Among the suggested amendments, there was a request to delete the expression 'red lines' and 'links to', so the bullet point would be 'activities that are incompatible with WHO's work and mandate (the tobacco and arms industries)' and to isolate the phrase 'particular caution' in another point. Some suggested that this last phrase should be deleted. Another request was to delete the reference to the tobacco and arms industries or to change the text to 'identify activities of the entity that may require the Organization to consider setting more narrow parameters for the engagement, or that are affected by WHO's norms and standards'.

Version 4, the one discussed at the 68th WHA, included a text proposed by the Chair: 'Identify if the nature or activities of a NSA are incompatible with WHO/s work and mandate (e.g. links to be tobacco and arms industries) or if they require the Organization to exercise particular caution when engaging with the entity (e.g. links to other industries affecting human health or affected by WHO/s norms and standards (FOOTNOTE As described in paragraph 44)". The consensus was reached only in November 2015 during the intergovernmental meeting, and the final version is "identify if paragraph 44 or 45 should be applied'.[77]

The paragraph concerning risk assessment was initially developed in version 2: 'Risks are the expression of the likelihood and potential impact of an event that would affect the Organisation's ability to achieve its objectives. A risk assessment on a proposed engagement is conducted in parallel to due diligence. This involves the assessment of risks associated with an engagement with a non-State actor, in particular the risks described in paragraph 8'.[78] In May 2015, during the 68th WHA (version 3), it was suggested to delete the paragraph or replace it with 'while due diligence refers to the nature of the non-State actor concerned, risk assessment refers to the assessment of a specific proposed engagement with that non-State actor'. The Chairperson proposed to keep the paragraph by just changing 'a risk assessment on a proposed engagement is conducted in addition to due diligence' instead of 'is conducted in parallel to due diligence'. In the final version the paragraph kept the text suggested by the Chairperson in 2015, just adding in '(…) and is to be conducted without prejudice to the type of non-State actor' at the end.

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[77] Paragraphs 44 and 45 are part of specific provisions, which refers to no-go relations and those where particular caution should be exercised.
[78] Paragraph 8 in version 2 is the one that lists the risks of engagement.

Version 2 from December 4 included four paragraphs regarding risk management, although the draft discussed during the last open-ended intergovernmental meeting, in April 2016, had the four paragraphs highlighted as agreed during the negotiations; the final version includes three paragraphs. Regarding the concept of Risk Management, the paragraph had minor changes in an explanatory way. It went from 'the Secretaries decides' to 'the Secretariat decides explicitly and justifiably'. While it is clear that most of the changes were more focused on clarification, or providing explanatory additions, the Chairperson suggest adding that risk management 'is a management decision taken by the unit engaging with the non-State actor, subject to the oversight of the Programme, Budget and Administration Committee and the Independent Expert Oversight Advisory Committee in accordance with paragraphs 22 and 66 and the transparency for Member States in accordance with paragraph 38'. It is worth reiterating that FENSA is also seen as a tool for Member States to oversee the Secretariat's actions regarding engagement with non-State actors.

The paragraph regarding the unit responsible for performing due diligence and risk assessment was attached to the previous paragraph, on the concept of risk management. Moreover, until April 2016, an Engagement Coordination Group was idealised as 'a Secretariat group appointed by the Director-General that includes representation from regional offices'. (EB, 2014, P. 17). While the Member States required a more descriptive and detailed text, until April 2016 the paragraph had undergone only the requested linguistic adjustments. However, it was profoundly changed in the final version. It was altered from:

> The Engagement Coordination Group reviews proposals of engagement referred to it by directors and recommends engagement, continuation of engagement, engagement with measures to mitigate risks, non-engagement or disengagement from an existing or planned engagement with non-State actors. In cases where the Regional Director or Assistant-General disagrees with this recommendation, the final decision rests with the Director-General. (A/FENSA/OEIGM/5, 2016, p.15)

To:

> A dedicated secretariat mechanism reviews proposals of engagement referred to it and recommends engagement, continuation of engagement, engagement with measures to mitigate risks, non engagement or disengagement from an existing or planned engagement with non-State actors. The Director-General, working with the Regional Directors, ensures coherence and consistency in implementation and interpretation of this Framework across all levels of the Organization (FENSA, 2016, p.12)

It is worth noting that transparency was a topic widely mentioned as controversial during the interviews. In version 2 (December 2014), transparency included five paragraphs while the final version includes seven. Document EB 136/5 stated that 'WHO's interaction

with non-State actors is managed transparently. WHO provides the governing bodies with annual reports on its engagement with non-State actors and makes publicly available basic information on the non-State actors it engages with and the individual engagements concerned'. Some suggested adding the work of the Engagement Coordination Group into the annual reports, but in the end, as the Coordination Group was not established, the text is 'WHO's interaction with non-State actors is managed transparently. WHO provides an annual report to the governing bodies on its engagement with non-State actors, including summary information on due diligence, risk assessment and risk management undertaken by the Secretariat. WHO also makes publicly available appropriate information on its engagement with non-State actors' (FENSA, 2016, p.12).

Paragraph 38 on the register of non-State actors changed a lot. The main suggestion was that 'the register will be finished in March 2016 and can be consulted and updated in an on-going fashion, including its preliminary versions'. However, in 2019, three years after the proposed deadline, the online register was not fully implemented yet. Some also proposed to add that 'due diligence and risk assessment reports, as well as decisions on engagement-related options listed in paragraph 33, will be made available to the Member States'. The Chairperson proposed the footnote 'information on financial contributions received from non-State actors is documented in this register and the Programme Budget web portal', which was accepted as the footnote in the final version.

The responsibility of non-State actors engaging with the WHO to provide information on their organisation was improved through the negotiation process and became a separate paragraph. It was also suggested to add a paragraph 'The due diligence reports, including the decisions related to risk assessment and risk management, including decisions to refuse to engage, will be made available to Member States and relevant information shall be made publicly available'. While the Member States proposed the text 'due diligence and risk assessment reports, as well as decisions on engagement-related options listed in paragraph 33, will be made available to Member States', the Chair suggested:

> In addition to the publicly available information, Member States have electronic access to a summary report on due diligence of non-State actor, and risk assessments and risk management on engagement. [Further details of the information used by the Secretariat to manage such engagement, can be made available for Member States to consult, upon request and as far as legally feasible.] Furthermore Member States can search for such information concerning cases considered by the engagement coordination group.

The text is similar to the final version. Moreover, the two paragraphs about 'Policy, norms and standard-setting' were deleted from version 3 onwards.

Unquestionably, the 'Specific Provisions' which comprise engagement with particular industries and secondments were among the most controversial topics of the FENSA negotiation process. The notorious paragraph 44 in version 2 was 'WHO does not engage with the tobacco or arms industries. In addition, WHO will exercise particular caution when engaging with other industries affecting human health or affected by WHO's norms and standards'. During the 68WHA paragraph 44 changed to 'WHO does not engage with the tobacco or arms industries' It was proposed to add 'and its affiliates'. A supplementary paragraph was even considered, but no consensus was reached.

After issue-specific consultations that took place in September 2015, and informal consultations held in October 2015 conducted by the Chair of the intergovernmental meeting, FENSA draft (version 5) reached a consensus by stating that:

> 44. WHO does not engage with the tobacco industry or non-State actors that work to further the interests of the tobacco industry. WHO also does not engage with the arms industry. Engagement where particular caution should be exercised; 44bis[79] WHO will exercise particular caution, especially while conducting due diligence, risk assessment and risk management, when engaging with private sector entities and other non-State actors whose policies or activities are negatively affecting human health and are not in line with WHO's policies, norms and standards, in particular those related to noncommunicable diseases and their determinants.

Secondments were another topic perceived to have caused disagreements between the Member States during the interviews. Therefore, while paragraph 46 of the Document EB136/5 stated 'WHO does not accept secondments from non-State actors', Member States proposed two alternative texts in May 2015: 'WHO does not accept secondments from private sector entities. Secondments from other types of non-State actors shall be accepted, in accordance with WHA67/7', or, 'WHO can accept secondments from non-State actors for technical work or implementation of WHO's programmes and policies and emergency response'. In the draft discussed during the 68WHA, it can be observed that the Chair proposed that the WHO should not accept secondments from non-State actors. The last intergovernmental meeting was still discussing secondments, and the final version (paragraph 47) forbids secondments only from private sector entities.

Regarding Official Relations, the main paragraph was kept from the first to the last, approved version, assuring that it is 'a privilege that the Executive Board may grant to

[79] Paragraph 45 in the FENSA final version.

nongovernmental organisations, international business associations and philanthropic foundations that have[80] a sustained and systematic engagement in the interest of the Organization'.

The topic 'Procedure for admitting and reviewing organizations in official relations' remained practically the same throughout the negotiation process. In the document (version 3) presented and discussed during the 68th World Health Assembly, it was suggested to add the topic 'Accreditation of NGOs'. The Chair suggested removing the topic while others suggested to move it to the specific policies and procedures on engagement with NGOs. In the final version, the topic was deleted, and paragraph 53 was added, affirming that:

> For nongovernmental organizations working on global health issues, sustained and systematic engagement could include research and active advocacy around WHO meetings and WHO's policies, norms and standards. Official relations may be considered for such nongovernmental organizations based on at least three years of their activities and future work plan on research and advocacy on global public health issues (FENSA, 2016, p. 16)

Regarding the Oversight of Engagement, the establishment of a Committee on non-State actors was proposed as a subcommittee of the Executive Board in order to offer some control to the Member States. A Senior Management Committee was also suggested as a Secretariat committee, appointed by the Director-General, which should include representation from regional offices. Both proposals were quickly forgotten as it was decided that the Programme, Budget and Administration Committee should take the responsibility. Therefore, the outcome draft of the open-ended intergovernmental meeting indicated, on 1st May 2015, that 'the Executive Board, through its Programme, Budget and Administration Committee, oversees the implementation of WHO's policy on engagement with non-State actors, proposes revisions to the framework and can grant the privileges of official relations to international nongovernmental organisations, philanthropic foundations and international business associations'. The text reached consensus and remained the same until the final and approved version.

Finally, the topics 'Non-compliance with this Framework' and 'Monitoring and Evaluation of the Framework' had minor language and clarification adjustments during the negotiation. The topic on Implementation was added for deliberations of the last open-ended intergovernmental meeting.

Initially, the Policy and Operational Procedures on Engagement with

[80] Final version: "that have had and continue to have".

Nongovernmental Organisations highlighted the contributions of NGOs in paragraph 1. While not reaching a consensus among the Member States, in the draft discussed during the 68th WHA, the Chair advocated keeping the paragraph, but it was deleted. Regarding participation, in version 1, the draft stated that:

> WHO can hold consultations with nongovernmental organisations in the preparation of policies. Consultations can be electronic or in person, and may take the form of hearings at which nongovernmental organisations can present their views. The format of such consultations is decided on a case-by-case basis either by the governing body at the session at which a hearing or consultation is mandated or in other cases by the Secretariat.

After the 68WHA, the paragraph was deleted, and a consensus was reached in three paragraphs that should constitute the topic 'Participation by nongovernmental organisations in WHO meetings'. The text changed from 'WHO can invite non-governmental organisations to participate in other WHO meetings' to 'WHO can invite NGOs to participate in consultations, hearings or other meetings in accordance with paragraph 16 of the Overarching Framework' and a new paragraph was added and remained the same until the approved version.

> The nature of participation of nongovernmental organisations depends on the type of meeting concerned. The format, modalities, and the participation of nongovernmental organisations in consultations, hearings, and other meetings is decided on a case-by-case basis by the WHO governing bodies or by the Secretariat. Participation and inputs received from nongovernmental organisations shall be made publicly available, wherever possible. Nongovernmental organisations do not take part in any decision making process of the Organization.

Within the topic 'Involvement of the Secretariat in meetings organised by nongovernmental organisations', the subtopic 'Operational Procedures' had its title changed to 'Specific policies and operational procedures.'

Regarding Resources, in version 1 (May 2014) the WHO was allowed to accept 'funds, personnel and in-kind contributions'. After the 68WHA debate, the Chair suggested keeping the text but adding a footnote to personnel, stating that 'Contribution of personnel are only acceptable for short term assignments that do not involve normative work and if potential risks are managed in accordance with this framework'. In October 2015, the Chair proposed a new text that was kept in the final version: 'WHO can accept financial and in-kind contributions from nongovernmental organisations as long as such contributions fall within WHO's General Programme of Work, do not create conflicts of interest, are managed in accordance with the framework, and comply with other relevant regulations, rules and policies of WHO'.

The intergovernmental meeting in October also proposed a new paragraph about the conditions for accepting contributions (whether in cash or in kind). The paragraph on the WHO providing resources to NGOs for implementation of work was developed in a more explanatory way, and the paragraph about acceptance of resources from NGOs added, in April 2016, that this should also be in accordance with 'WHO's guidelines for medicine donations and WHO's guidelines for health care equipment donations'.

It has already been mentioned that secondments were a controversial topic of FENSA negotiations. The draft presented by the Secretariat on 5th May 2014 (version 1) included a paragraph on secondments from NGOs, which was withdrawn in the draft developed in December 2014; that was discussed at the 136th Session of the Executive Board, in January 2015. The paragraph on Evidence, which until the 68WHA was 'nongovernmental organisations can provide up-to-date information and knowledge on technical issues, and share their experience and engage with WHO in the following: generation of evidence, knowledge management, scientific reviews, information gathering and research' underwent some adjustments and ended up as:

> Nongovernmental organisations may provide their up-to-date information and knowledge on technical issues, and share their experience with WHO, as appropriate, subject to the provisions of the overarching framework, and this specific policy and operational procedures, and other applicable WHO rules, policies and procedures. Such contribution should be made publicly available, as appropriate, wherever possible. Scientific evidence generated should be made publicly available.

Advocacy is a topic that grew from two paragraphs to four in the final version. While the first paragraph on advocacy remained the same, the second paragraph stated that 'WHO favours independent monitoring functions and therefore engages with nongovernmental organisations working in this field'. In the intergovernmental meeting of October 2015, it was suggested to change the excerpt to 'WHO encourages critical engagement and therefore engages in this constructive spirit with non-State actors' or 'WHO recognises the usefulness of an independent monitoring function provided by some NGOs in the field' or 'WHO engages with NGOs which provide an independent monitoring function'. However, the suggestion accepted was actually to delete the text. Moreover, a third paragraph on NGOs being encouraged to 'implement and advocate for the implementation of WHO's norms and standards' was suggested.

Technical collaboration from NGOs was the only topic that could not reach consensus until the final version of FENSA. The first text of the paragraph was 'The Secretariat is

encouraged to undertake technical collaboration with nongovernmental organisations, provided that it is in the interests of the Organization and managed in accordance with the framework for engagement with non-State actors'. The text proposed by the Chair after the Informal Consultations of 2015 was 'Technical collaboration [ADD FOOTNOTE: as defined in the overarching framework] with NGOs is encouraged. This collaboration must be in the interest of WHO, and managed in accordance with this framework to protect WHO, and in particular, its normative work, from any undue influence and to ensure there is no interference with WHO's advisory function to member states', but this wasn't accepted by all Member States. In the final version, the paragraph solely suffered language adjustments.

Similarly to the Policy and Operational Procedure on Engagement with NGOs, the specific provision for the engagement with the private sector also stressed initially the role played by private sector entities in health. After, during 68WHA, the following text was proposed: 'this policy applies to private sector firms, international business associations, academic institutions and philanthropic foundations not at arm's length with the private sector and other not-for-profit organisations, which are not qualified as NGOs under the overarching framework on the engagement of non-State actors'. However, after the debates of the intergovernmental meeting in September 2015, the paragraph was deleted. Moreover, the draft from 15th December 2014 (version 2) added a paragraph stating that 'In engaging with private sector entities, WHO will aim to operate on a competitively neutral basis' which was requested, by some Member States, to be deleted, but remained in the final version. At the last intergovernmental meeting, in April 2016, it was suggested to add a paragraph declaring that:

> When establishing relationships with private sector entities, it should be borne in mind that WHO's activities affect the commercial sector in broader ways, through for example, its public health guidance, its recommendations on regulatory standards, or other work that might influence product costs, market demand, or profitability of specific goods and services. Such activities include setting of norms for quality, safety, and efficacy of pharmaceuticals and related promotional practices, dissemination of information on pharmaceuticals; provision of guidelines for diagnostics and treatment or advice that might affect the market for individual products and product categories; establishment of chemical safety standards; and formulation of nutritional guidelines.

The final and approved version of FENSA, while keeping three initial explanatory paragraphs, removed, from the text proposed in April 2016, the passage that starts at 'such activities include' until the end. It withdrew any straight reference to pharmaceuticals and nutrition and thus to the pharmaceutical and to the food and beverage industries.

Like the policy for NGOs, the topic of 'Participation' grew from two paragraphs to three, and the text was adjusted from 'WHO can invite private sector entities to participate in other WHO meetings' to 'WHO can invite private sector entities to participate in consultations, hearings or other meetings in accordance with paragraph 16 of the Overarching Framework'. It is worth noting that despite all the effort of public-interest NGOs to distinguish how NGOs and the private sector participates at the WHO, in the final version, both NSAs have the same procedures for participation. Regarding the subtopic of 'Participation', 'Specific policies and operational procedures', the text of paragraph 8 changed from 'WHO does not cosponsor meetings organised by specific private sector entities' to 'WHO does not cosponsor meetings organised wholly or partly by private sector entities'. All other paragraphs of the subtopic remained the same from version 1 until the approval.

Accepting resources from the private sector was another polemical point during the debates both inside and outside the negotiation rooms. Many paragraphs related to this took time to achieve consensus among the Member States. For instance, in version 1 (May 2014), the first paragraph on Resources (paragraph 11) included three subparagraphs, then the draft resolution presented and debated during the 68WHA (version 3) added more two subparagraphs, and the final and approved version has four. Firstly, one should note that the word 'funds' changed to 'financial contributions'. In this sense, the text of subparagraph A was improved from 'funds may be accepted from private sector entities whose business is unrelated to that of WHO, provided they are not engaged in any activity that is incompatible with WHO's work' to 'financial contributions may be accepted from private sector entities whose business is unrelated to that of WHO, provided they are not engaged in any activity or have close ties with any entity that is incompatible with WHO's mandate and work'. While subparagraphs D and E were suggested without reaching consensus, the Chair advocated to delete both.

> (d) WHO shall not receive financial resources from private sector entities as well as non-state actors with links to private sector entities whose activities [or advocacy] are undermining the mandate of WHO as stated in its Constitution. (e) The WHO should establish ceiling in the voluntary contribution from non-state actors. Any contribution beyond that amount should go to the core voluntary fund which gives enough freedom to the Secretariat to allocate resources to underfunded programmes. The Member States assessed contributions should be allocated to the programmes that are underfunded under voluntary contribution.

None of the paragraphs is in the final version, which added one subparagraph with the

following text: ‘The provisions set out in paragraph shall be without prejudice to specific mechanisms, such as the PIP Framework, set up by the Health Assembly that involve the receipt and pooling of resources’. India was the main actor pushing for ceilings to funds from the private sector.

The paragraph that establishes the conditions upon which financial and in kind contributions from private sector entities to WHO programmes can be accepted reached consensus in the early stages of negotiations, therefore, there are no changes from version 1 to the final framework. Although not reaching consensus until April 2016, paragraph 13 (in version 1 only, paragraph14 in other versions) stated that:

> The Director-General can set up mechanisms for pooling contributions from multiple sources, if the mechanisms are designed in such a manner as to avoid any perceived influence from the contributors on WHO’s work; if the mechanism is open to all interested contributors; and if the mechanism is subject to the conditions in paragraph 12 above and transparency is achieved through the WHO register of non-State actors and the Programme budget web portal.

In the last intergovernmental meeting, of April 2016, some suggestions were made, in the final version, however, the paragraph was withdrawn.

The paragraph which recognised that ‘any acceptance of financial, personnel or in-kind contribution from private sector entities shall be managed in accordance with this framework and based on a signed agreement’ was initially proposed to add a footnote to ‘personnel’: ‘Contribution of personnel are only acceptable for short term assignments that do not involve normative work and if potential risks are managed in accordance with this framework’. However, the consensus reached was to change to ‘acceptance of resources’. The paragraph on private sector entities using the results of the WHO’s work for commercial purposes had minor language corrections.

Concerning secondments, the first version of FENSA presented to the 67th World Health Assembly stated that ‘WHO does not accept in principle secondments from private sector entities’. Although many Member States were against this exclusion as will be later considered, the paragraph was quickly deleted as it became part of the overarching framework. Furthermore, paragraphs concerning donations of medicines and other health technologies, financial contributions for clinical trial, contributions for WHO meetings, contributions for WHO staff participating in external meetings, contributions for publications, and cost recovery, did not raise intense debates. Let us consider the topic ‘Contributions for financing staff salaries’, whose text indicated that ‘Funds designated to

support the salary of specific staff members or posts (including short-term consultants) may not be accepted from private sector entities if they could give rise to a real or perceived conflict of interest in relation to WHO's work'. While some suggested removing the words 'if they could give…', the entire paragraph was deleted.

With regards to Evidence, version 1 included the two following paragraphs:

> 31. WHO can only collaborate with private sector entities in the generation of evidence, in knowledge management, in information gathering and in research when potential conflicts of interest are managed in accordance with this framework and the collaboration is transparent. 32. Individuals working for interested private sector entities are excluded from participating in advisory groups; however, expert groups need to be able, where appropriate, to conduct hearings with such individuals in order to access their knowledge.

The text of paragraph 31 was substituted with 'Private sector entities may provide their up-to-date information and knowledge on technical issues, and share their experience with WHO, as appropriate, subject to the provisions of the overarching framework, and this specific policy and operational procedures, and other applicable WHO rules, policies and procedures. Such contribution should be made publicly available, as appropriate, wherever possible. Scientific evidence generated should be made publicly available'. On the other hand, paragraph 32 could not be agreed upon and some Member States requested its removal or a change to 'Individuals working for interested private sector entities are excluded from participating in expert groups; however, expert groups need to be able, where appropriate, to conduct hearings with such individuals in order to access their knowledge'. It was also suggested to add a third paragraph stating that 'If information gathering is done in the preparation of the development of norms and standards, private sector entities can only be involved in the form of hearings'. The final and approved version, however, maintained only the aforementioned consensual text of paragraph 31.

While paragraphs about advocacy had only language adjustments, technical collaboration with the private sector figured as a controversial topic. The text initially proposed was 'Technical collaboration with the private sector is welcomed if potential risks of engagement are managed or mitigated and provided that the normative work of WHO is protected from any undue influence and there is no interference with WHO's advisory function to Member States'. In the FENSA draft presented to the 68WHA, the Chair proposal was 'technical collaboration with the private sector is welcomed provided that it is in the interests of the Organization and managed in accordance with this framework and in

particular provided that the normative work of WHO is protected from any undue influence and there is no interference with WHO's advisory function to Member States', but no consensus was reached. In the December 2015 meeting, the Chair proposed another option - 'Technical collaboration [ADD FOOTNOTE: as defined in overarching framework paragraph 21] with private sector entities is encouraged. This collaboration must be in the interest of WHO, and managed in accordance with this framework to protect WHO, and in particular, its normative work, from any undue influence and to ensure there is no interference with WHO's advisory function to Member States', which was accepted.

Finally, about product development, the initial text was:

> WHO collaborates with private sector entities in the development of health-related technology, either by conducting research and development on their products and supporting transfers and licensing of technology or by licensing its intellectual property to such enterprises. Collaborative research and development, technology transfer and licensing should, as a general rule, be undertaken only if WHO and the entity concerned have concluded an agreement cleared by the Office of the Legal Counsel that ensures that the final product will ultimately be made widely available and accessible, including to the public sector of low- and middle-income countries at a preferential price. If such an agreement is concluded, financing may be accepted from the private sector entity for a clinical trial arranged by WHO on the product in question, as contractual commitments obtained from the entity in the public interest outweigh any potential conflict of interest in accepting the financial contribution. These contributions should be distinguished from the acceptance of contributions for a clinical trial arranged by WHO on a proprietary product as described in paragraph 23.

There were disagreements regarding whether to use the word affordable and if 'public sector' and 'at a preferential price' should be in the text. An alternative language was proposed by the Chair but could not be agreed amongst the Member States, and they a consensus was only reached in the last intergovernmental meeting in April 2016:

> WHO may collaborate with private sector entities in the research and development of health related technologies that contribute to increasing access to quality, safe, efficacious and affordable medical products. Collaborative research and development should, as a general rule, be undertaken only if WHO and the private sector entity have concluded an agreement which ensures that the final product will ultimately be widely available, including to the public sector of developing countries at a preferential price. If such an agreement is concluded, financing may be accepted from the private sector entity for a trial arranged by WHO on the product in question, on the basis that contractual commitments obtained from the private sector entity outweigh any potential conflict of interest in accepting such financing. (FENSA, 2016, p.29)

The Policy and Operational Procedures on Engagement with Philanthropic Foundations underlined initially 'the significant contributions to global health in general and to WHO's work in particular in many areas ranging from innovation to capacity-building to

service delivery'. The text was kept until the 68WHA, and although the Chair recommended keeping the paragraph, it was deleted after the intergovernmental meeting of September 2015. Similarly to the policy for NGOs and the private sector, the topic of Participation grew from two to three paragraphs and the text was adjusted from 'WHO can invite philanthropic foundations to participate in other WHO meetings' to 'WHO can invite philanthropic foundations to participate in consultations, hearings or other meetings in accordance with paragraph 16 of the Overarching Framework'.

The first paragraph about resources changed from accepting 'funds, personnel and in-kind contributions' to 'financial and in-kind contributions'. At the intergovernmental meeting of September 2015, it was suggested to add a footnote to 'personnel' stating that 'contribution of personnel are only acceptable for short term assignments that do not involve normative work and if potential risks are managed in accordance with this framework', even though, it was later deleted. The paragraph about Evidence was changed in a sense, to clarify the text, as it initially detailed that 'philanthropic foundations can provide up-to-date information and knowledge on technical issues, and share their experience and engage with WHO in the generation of evidence, in knowledge management, in scientific reviews, in information gathering in research' and in the approved version it states that:

> Philanthropic foundations may provide their up-to-date information and knowledge on technical issues, and share their experience with WHO, as appropriate, subject to the provisions of the overarching framework, and this specific policy and operational procedures, and other applicable WHO rules, policies and procedures. Such contribution should be made publicly available, as appropriate, wherever possible. Scientific evidence generated should be made publicly available

One should note that mentions of the generation of evidence, knowledge management, scientific reviews, information gathering and research were withdrawn from the paragraph.

Regarding advocacy, although previous FENSA drafts indicate that a consensus was reached, the version presented to the last open-ended intergovernmental meeting of April 2016 had two further paragraphs:

> 18bis WHO encourages Philanthropic foundations to implement and advocate for the implementation of WHO's policies, norms and standards. WHO engages in dialogue with Philanthropic foundations in order to promote the implementation of WHO's policies, norms and standards. (ADD FOOTNOTE: Philanthropic foundations working with WHO will be expected to conform to WHO's public health policies in areas such as food safety, chemical safety, ethical promotion of medicinal drug products, tobacco control, noncommunicable diseases, as well as health and safety at work) 18ter Philanthropic foundations can only collaborate with WHO in advocacy for the implementation of WHO policies norms or standards if they commit themselves to implement these policies, norms or standards in their entirety. No partial or selective implementation is acceptable

Finally, the paragraph on Technical Collaboration has, in the final version, more detailed text, which was proposed during the informal consultation of September 2015.

Following the pattern, the paragraph that addressed the contributions of academic institutions to global health was removed, and the paragraph on participation also changed from 'WHO can invite academic institutions to participate in other WHO meetings' to 'WHO can invite academic institutions to participate in consultations, hearings or other meetings in accordance with paragraph 16 of the Overarching Framework'. With regards to Resources, part of the text of the paragraph on the WHO providing resources to academic institutions was withdrawn: 'Grants are normally provided on the basis of review and recommendations by a group of external convened by WHO. If no such review mechanism is followed, WHO's Contract Review Committee should be consulted. The provision of financial resources for a project organised or coordinated by WHO is subject to WHO's procurement rules'.

Like the policy for NGOs, the draft presented by the Secretariat on 5th May 2014 (version 1) included the topic 'Seconded Personnel', stating that 'secondments from academic institutions are acceptable, provided that a) there is no conflict of interest'. The whole paragraph was withdrawn in the draft developed in December 2014. The paragraph about Evidence had a similar path to the one concerning the relation with philanthropic foundations - it was changed into a clearer text. With regards to 'Advocacy', the topic initially included only one paragraph and ended with three. One should note that the excerpt 'WHO favours independent monitoring functions and therefore engages with academic institutions working in this field', of the first paragraph on advocacy, was removed.

Finally, when it comes to 'Technical Collaboration', it is worth noting that the four specific policies ended up with the same paragraph which changed from 'The Secretariat is encouraged to undertake technical collaboration with academic institutions, provided that it is in the interests of the Organization and managed in accordance with the framework for engagement with non-State actors' to:

> WHO may engage with academic institutions as defined in overarching framework paragraph 20. Technical collaboration with academic institutions is encouraged. This collaboration must be in the interest of WHO, and managed in accordance with the overarching framework and this policy to protect WHO, and in particular, its normative work, from any undue influence or conflict of interest and to ensure there is no interference with WHO's advisory function to Member States.

When tracking changes between these documents specifically, it can be noted that there were almost no changes in the operational procedures. Perhaps the major change on the

way NSAs can engage with the WHO was the withdrawal of the possibility to support policy-making at the national level. The document changed more in a way of improving the structure, the explanation of polemical concepts – such as conflict of interests – and the development of safeguards.

4.3 The Position of the Member States According to the Documents

While I previously compared several versions of the FENSA, aiming to track the most significant changes of the document, in this part of the chapter, I will look at the textual proposals submitted by the Member States after the 136th Session of the Executive Board. As already clarified in the Introduction, the Member States were selected given their participation, which was considered based on official documents, media reports and interviews. Initially, the Member States from the Global North which were more active, considering documents and media reports were: Canada, France, Norway, United Kingdom and the United States; from the Global South they were: Bolivia, Brazil, India, Mexico and Zambia. However, all research has its limitations and researchers should not try to deny such limitations. Five representatives from those countries agreed to be interviewed for this thesis but the other five Member States remained essential to this analysis. In order to avoid a deadlock, I decided to consider the written comments from the Member States, which were initially selected but denied the request for an interview. Therefore, the proposals submitted by Canada, France, United Kingdom, United States, Norway, Germany, India, Bolivia, Brazil, Zambia, Mexico, Argentina and Egypt were taken into consideration.

4.3.1 Canada

According to the methodology chosen, Canada was one of the most active Member States during the negotiations. Three emails were sent requesting an interview for this thesis, but the answer was that the Ambassador was travelling. Even though I explained that I would be conducting interviews for the next eight months, the answer was ‘unfortunately our current Health officers were not involved in the negotiations and are not well placed to speak on the issues’. Therefore, the position taken by Canada during FENSA negotiations will be analysed, taking into consideration the available documents, media reports and interviewees who may have mentioned the Canadian participation. The primary source used, however, is a non-paper with the textual proposal submitted by the Member States on the draft of FENSA which was presented and discussed during the EB136.

The first comment made by Canada was in relation to paragraph 16 on Participation sustaining that the country was 'satisfied with the Framework's current policies regarding non-State actors participation in WHO meetings' but stressed that it was important that the WHO should remain open 'to the views of all interested parties during hearings and consultations'. Concerning paragraph 27 on due diligence and risk assessment, Canada was also satisfied, but pointed out that the practices outlined in the Framework could be more refined 'to include existing WHO structures, such as the Office of Compliance, Risk Management, and Ethics, and should be amended to protect against individual conflicts of interest'. About due diligence detailed in paragraph 29, Canada advocated that while non-State actors should not be able to directly fund the salaries of WHO staff, they could 'contribute funds to a pooled human resources fund, or contribute to a programme, then have their contributions spent as the programme area deemed appropriate'.

Considering the general comments presented in the section 'Management of conflict of interest, and other risks of engagement', Canada agreed that it required the WHO to 'equip itself with the right tools to transparently manage its engagement with non-State actors. In our view, the proposed registry and disclosure policies as demonstrated at PBAC will assure transparency of the Organisation's engagements'. Regarding the controversial paragraph 44, which stated that the WHO does not engage with the tobacco or arms industries, Canada, while recognising the importance of excluding engagement with the tobacco and arms industries, asserted that it 'would not like to see any further limitations formalised. Canada trusts the WHO to use sound judgement to engage appropriately with actors from different sectors while respecting the provisions of the Framework; we also understand that these provisions should be closely monitored and modified as necessary to ensure the organisation's protection from undue influence'.

Concerning the section 'Official Relations', Canada submitted general comments affirming that it was pleased with the procedures delineated in the Framework. Whereas consultations and hearings should be open to a comprehensive variety of actors, 'WHO should remain vigilant and judicious in selecting the NSAs to which it confers the privileges of official relations. We appreciate that organisations in official relations will be reviewed every three years and that they are required to provide yearly reports on progress made in implementing the plan of collaboration that will be published in the register of NSAs'.

Canada did not submit any comment about the Policy and Operational Procedures on Engagement with Nongovernmental Organisations, Philanthropic Foundations or Academic Institutions. The country made just one observation on the specific engagement with the private sector, precisely on the section about resources, claiming that it was satisfied that the conditions for resources from private sector entities providers had the 'necessary safeguards to protect against undue influence'. Therefore, 'respecting the principles of fairness and inclusivity, private sector actors should be able to contribute funds like other non-State actors, as long as there is a clear policy that ensures that WHO staff are void from any obligation to donors and that they remain neutral and unbiased'.

Finally, Canada's general comments on the draft of the framework of engagement with non-State actors, presented and discussed during the EB136, were that FENSA should not contain policies and regulations that would limit the WHO's ability to engage with the necessary non-State actors. The country also advocated that the Framework should be adopted 'on a trial basis' to check which practices would be more effective and then to improve policies throughout the implementation. Moreover, Canada underlined that the Framework should be applied 'consistently' across all levels of the Organisation and all regions. Regarding the controversial issue of secondments, Canada argued that, while recognising that the WHO and Member States benefit from the work of personnel from non-State actors, the FENSA should clarify the cases in which the WHO could accept personnel from NSAs and also suggested that these individuals should be required to complete a declaration of interests with the Office of Risk Management, Compliance and Ethics, as should staff and external experts.

While encouraging the FENSA to be 'as inclusive as possible', Canada claimed that, given that the attribution of a non-State actor to any one of the four categories may change over time, 'the criteria to inform and the mechanism responsible for decisions regarding the categorisation of non-State actors be made explicit (…). This addition should include instructions on the process for evaluating non-State actor classifications and should specify the frequency at which these evaluations should take place'. Lastly, regarding the private sector, Canada requested that the same robust criteria required for private sector actors to collaborate for the generation of evidence should be applied to all non-State actor; 'it is possible that NGOs, philanthropic organisations and academic institutions have vested

competing interests and these risks must be mitigated diligently and fairly'.

4.3.2 United Kingdom

The United Kingdom was another country selected, considering the chosen methodology. The positions taken by the UK during the FENSA negotiations will be analysed considering the available documents, media reports and an interview conducted on the 6th of December of 2018; this will be further discussed in chapters 5 and 7. At the moment, the leading source is the non-paper with the textual proposal submitted by the Member States on the draft of FENSA in February 2015, in which the United Kingdom made 26 comments, only behind India, Bolivia and the United States.

The UK initially remarked that the excerpt 'The functions of the WHO, as set out in Article 2 of its Constitution, include: (…) to establish and maintain effective collaboration with diverse organisations' was a critical point to the country as it provides a constitutional basis for proactive engagement with non-State actors. In paragraph 7 (benefits of engagement), the UK once more underlined the importance of an extensive engagement with NSAs. The United Kingdom also made some language observations which do not need to be specified.

Paragraph 7 details the WHO's involvement in meetings organised by a non-State actor and the UK suggested an additional provision for Member State-sponsored events which are co-sponsored by an NSA. Regarding paragraph 24 on conflict of interests, the UK suggested a more precise understanding of what an institutional conflict of interest would be and what elements should be covered by non-institutional conflict of interest. Moreover, because paragraph 26 stated that 'For WHO the most important institutional conflicts of interest arise in situations where the economic interests of private sector entities are in conflict with WHO's interests, especially the Organisation's independence and impartiality in setting norms and standards', the UK required a 'strong rationale' for just the private sector being mentioned in the paragraph. Paragraph 30 establishes the main functions of due diligence; in this regard, the UK argued that topic D of paragraph 30, which stated: 'identify "red lines" such as: activities that are incompatible with WHO's work and mandate (e.g. links to the tobacco and arms industries) or that require the Organization to exercise particular caution when engaging with the entity (e.g. links to other industries affecting human health or affected by WHO's norms and standards)', the use of the expression 'links to' was

obstructive as it could potentially include a very broad range of entities, ‘some of whom may have a positive role to play in global health’. The UK, on the whole, supported the principle ‘but the language needs to be tightened’.

The United Kingdom also expressed its support of the establishment of an engagement coordination group and a non-State actor register. Regarding the controversial secondments, the UK suggested deleting the paragraph that forbids secondments from non-State actors and argued that ‘WHO should accept secondments from non-State actors but based on the robust due diligence and risk management processes set out in this framework’. The last comment of the United Kingdom on the overarching framework was on the topic ‘Relation of the framework to WHO’s other policies’. Given that paragraph 48 asserts that the FENSA would apply for the management of risks of the WHO’s engagement in partnerships, the UK affirmed that it was concerned about the practical implications of hosted partnerships and special programme operations.

With regards to the Policy and Operational Procedures on Engagement with Nongovernmental Organisations, the United Kingdom commented equivalently on paragraph 6, about the participation of the WHO in meetings organised by nongovernmental organisations, on paragraph 16 , about NGOs being encouraged to disseminate the WHO’s policies, guidelines, norms and standards and on paragraph 31 about the generation of evidence. On the whole, the UK pointed out that the language ‘should be consistent with the other non-State actors' policies’. Furthermore, the UK enquired as to the reason why paragraph 6 on participation in meetings organised by a private sector entity had the excerpt ‘as long as the integrity, independence and reputation of the Organization are preserved’ added.

When it comes to Resources, the UK criticised that, differently from the NGO policy, there was no provision for personnel contributions from the private sector. Paragraph 26 is part of the topic Contributions for WHO meetings and states that ‘WHO receptions and similar functions shall not be paid for by private sector entities’. In this regard, the UK was advocating for a more flexible approach as ‘against an agreed and robust set of criteria, a private sector entity could host and/or part fund events/meetings’.

The UK did not provide further notes on the specific policies for philanthropic foundations and academic institutions. Overall, it can be noted that the United Kingdom was

seeking the same treatment for all NSAs and broader engagement with all kinds of non-State actors in order to strengthen the WHO's role in the global health landscape. This perspective was also observed during the interview. Therefore, in the general comments on FENSA, the country declared that:

> We believe that it is impossible for WHO to fulfil its convening role, if it is unable to engage with all actors who are able to contribute to the global health agenda (…)Secondly, we believe it is vital that the policy be a platform for a proactive engagement with all actors that have a legitimate and positive role to play in advancing public health for all. So it should enable more engagement, not less. (….) While we agree that there is a need, in some instances, for non-State actors to be treated differently, we want to see a focus on commonalities within the Framework, with a clear rationale where difference is necessary. In the current draft there remain a number of areas where the rationale for such differences is unclear

To conclude, the United Kingdom highlighted that the country could not accept a prohibition on all secondments from non-State actors; this affirmation was also made in the interview.

4.3.3 France

Despite having made significant interventions, as shown by documents, France was not highly mentioned in media reports nor in preliminary interviews. I have tried to contact different individuals who were involved in FENSA negotiations but with no answer. Similar to Canada, the comments submitted by France in February 2015, to be discussed in the open-ended intergovernmental meeting from 30th March to 1st April 2015 will be taken into consideration in the analysis of results provided in chapter 7.

Already in paragraph 1, France advocated to specifically list where the framework would apply: headquarters, regional offices and country offices, as well as hosted partnerships and entities set up under the WHO. The country also pointed out some language issues, mainly due to translations that ended up having different meanings. Regarding the subparagraph B 'Consultations', part of paragraph 16 about non-State actors' participation in meetings organised by the WHO, France proposed some edits in order to have a less ambiguous text. The country also criticised the passage 'there are no limits imposed on non-State actors' participation at such meetings', arguing that this could not be categorically stated, given that occasionally the Member States can decide 'to meet alone, among themselves, for intermediate consultations outside meetings of the governing bodies'.

In relation to the section 'Management of Conflict of Interest, and other risks of engagement', France proposed to change the phrase 'Risks of engagement need to be managed and communicated coherently throughout the Organization' to 'Risks of

engagement need to be managed and communicated coherently in each of the three levels of the Organization and throughout the Organization'. France made many suggestions to edit text without modifying the substance. For instance, in paragraph 36 on risk management, France suggested that 'a precise definition of the 'risk management framework' referred to here would be very helpful'. Furthermore, the country pointed out that the concept of 'WHO's interests' was not precisely defined as the concept 'seems to vary slightly depending on the paragraph of the text (…) it would, therefore, be preferable to provide a clear definition in the future glossary and then to ensure concordance with paragraph 23 which identifies the 'primary interests' (of WHO) exclusively with WHO's work.'

Paragraph 38 details the register of non-State actors as 'an internet-based, publicly available electronic tool used by the Secretariat to document and coordinate engagement with non-State actors' and France suggested converting part of the paragraph into a new one 'Non-State actors engaging with WHO are required to provide information on their organisation. This information includes: name, legal status, objective, governance structure, composition of main decision-making bodies, assets, annual income and funding sources, main relevant affiliations, webpage and one or more focal points for WHO contacts'. Regarding the contentious paragraph 44, France affirmed that 'the important thing is to have a clear and fixed definition of the excluded sectors, leaving no room for multiple interpretations that would have to be decided upon on a case-by-case basis'.

Finally, France recommended that the Secretariat should develop, by way of a glossary or terminological annexe, a series of fixed definitions that should facilitate the interpretation of the framework. The country also highlighted that FENSA draft contained contradictory, or 'not entirely consistent definitions' in numerous paragraphs.

4.3.4 United States

As would be expected, the United States had a protagonistic role during the FENSA negotiations. The country was the one from the Global North that made more proposals on FENSA draft of the EB136, second only to India. In order to analyse the US position on FENSA alongside the interviews and media report, this chapter will detail the written comments submitted by the country in February 2015.

The first comment was regarding paragraph 5, part of the 'Rationale'. The US proposed to add that due diligence and transparency measures would be applicable to all non-

State actors. Then, in paragraph 6, which determined the overarching principles of engagement, it was suggested to add a bullet point, asserting that any engagement should conform with the WHO's mandate and work programme. The country also proposed to change the sub-section title Risks of Engagement to Management of Engagement. Therefore, with regard to paragraph 8 on the topic, it was suggested to change the phrase 'engagement with non-State actors can involve risks which need to avoided or mitigated' to 'engagement with non-States actors should involve the management of risks'.

One should note that the US asked to delete 'entities not 'at arm's length' from their commercial sponsors' as well as the footnote explaining what an 'entity at arm's length' actually is from paragraph 11, which establishes what should be considered private sector. According to paragraph 14, the overarching framework and the respective specific policy on engagement should apply to each NSA, while due diligence would determine 'if a non-State actor is subject to the influence of private sector entities such that the non-State actor has to be considered itself a private sector entity'. The United States, however, proposed a new wording: 'For all non-State actors, the overarching framework and the respective specific policy on engagement apply. WHO will determine through its due diligence if a non-State actor does not meet the criteria above and take appropriate action, with opportunity for the non-State actor in question to have opportunity to both provide further information and to seek information on the WHO assessment.' The country also proposed a new paragraph including public-private partnerships, highlighting that 'WHO's engagement with public-private partnerships should not be prohibited or restricted solely on the basis of a business model which includes multiple types of non-State actors'. The United States also recommended talking about risks and benefits, instead of just risks.

Regarding the section 'conflict of interest', the US asked to delete from paragraph 23 the excerpt '(conflict of interest) may reasonably be perceived to unduly influence' and to add that conflicts of interest are not always financial. The country also suggested to withdraw the definition of institutional conflict of interest from paragraph 24 and its subsequent mention in paragraph 25. Finally, the total deletion of paragraph 26 was recommended: 'For WHO the most important institutional conflicts of interest arise in situations where the economic interests of private sector entities are in conflict with WHO's interests, especially the Organisation's independence and impartiality in setting norms and standards'.

The country also made comments about all paragraphs included in the section 'Due diligence and risk assessment'. For instance, the US suggested adding the following passage to paragraph 28: 'A benefit/risk assessment on a proposed engagement is conducted in parallel to due diligence. This involves the assessment of risks associated with an engagement with a non-State actor, in particular the risks described in paragraph 8'. Additionally, to change 'public' for 'legal' in paragraph 29, which stated that due diligence would not only review the information provided by the non-State actor, but search for information about the entity from other sources. Paragraph 30, on functions of due diligence, was also mentioned. The country suggested that the fourth bullet point on 'red lines' be changed from 'that require the Organization to exercise particular caution when engaging with the entity (e.g. links to other industries affecting human health or affected by WHO's norms and standards)' to 'identify activities of the entity that may require the Organization to consider setting more narrow parameters for the engagement, or that are affected by WHO's norms and standards'. In paragraph 31, the United States recommended the removal of the passage that allowed the Secretariat to categorise each non-State based on 'its nature, objectives, governance, funding, independence and membership'. Finally, it asked to delete paragraph 32, about risks.

As will be discussed in the next chapters, paragraph 44 was central to the United States, as affirmed by interviewee 7. The country, hence, requested the deletion of the passage 'WHO will exercise particular caution when engaging with other industries affecting human health or affected by WHO's norms and standards'. The country also sought the removal of paragraph 46 which was forbidding secondments from non-State actors and pointed out that the section 'Procedure for admitting and reviewing organizations in official relations' lacked mechanisms for discussion with a non-State actor, in the case of disagreement on the determination of eligibility. The last comment on the overarching principles was suggesting the addition of a passage to paragraph 71 on FENSA implementation and evaluation, both concerning results relating to the protection of the organisation from conflicts of interest. The US position was clearly towards facilitating 'meaningful engagement with non-State actors to shared global health goals'.

With regards to the Policy and Operational Procedures on Engagement with Nongovernmental Organisations, the United States started suggesting two new paragraphs to

complement paragraph 1. One to state that the engagement with NGOs at the institutional level should be distinguished from the collaboration with individual experts working for non-governmental organisations, and the other to suggest that when engaging with non-governmental organisations, the WHO should operate on a competitively neutral basis. The country also proposed that in paragraph 14, about NGOs being able to engage with the WHO in the generation of evidence, knowledge management and others, it should be added that this collaboration should take place 'when potential conflicts of interest are managed in accordance with this framework, and the collaboration is transparent'.

The specific policy for the private sector can be considered to be of great importance to the United States as the country made several recommendations, starting at paragraph 1, suggesting some improvements. For instance, that the engagement between the WHO and the private sector would maximize the positive contribution and advance efforts to reduce significant health risks. As recommended for NGOs, a new paragraph on engagement with the private sector at the institutional level should distinguish it from the collaboration with individual experts. Regarding paragraphs 8 and 9, about meetings organised by the private sector, the US commented that the paragraphs 'should not be restrictive in comparison to other policy frameworks such as CODEX where WHO cosponsors workshops parallel with CODEX meetings'. As for paragraph 12, on the acceptance of resources from private sector, the US suggested to switch 'Funds may not be sought or accepted from private sector entities that have (…) a direct commercial interest in the outcome of the project toward which they would be contributing' to '(…) direct effects on profits or competitive advantage (…)'.

Concerning the conditions under which financial and in kind contributions from the private sector could be accepted, the United States made three observations. The first one was on the passage '(c) the proportion of funding of any activity coming from the private sector cannot be such that the programme's continuation would become dependent on this support'. The country stressed that more explanation was required, as 'not only Pandemic Influenza Preparedness, but also many NTD programs, are highly reliant on industry contributions for their success'. The second was on the passage '(e) the contributor may not use the results of WHO's work for commercial purposes or use the fact of its contribution in its promotional material'. The US argued that whilst it understood the need to protect the WHO's brand from being used for commercial purposes, 'public profiling of partnerships are important, both for

building momentum and additional contributions (…) Too restrictive interpretation of this language could lead to loss of effectiveness of WHO as a global convener on global health matters from NCDs to pandemic preparedness'. The third observation was made on '(g) the acceptance of the contribution does not offer the contributor any possibility for advising, influencing, participating in being in command of the management or implementation of operational activities'. Although the United States agreed that the private sector should not be involved in advising, influencing or leading the management of operational activities, excluding their participation could result in loss of 'valuable additional resources and expertise in a given project or even emergency response situation'.

Paragraph 24 states that 'For meetings convened by WHO, a contribution from a private sector entity may not be accepted if it is designated to support the participation of specific invitees (including such invitees' travel and accommodation), regardless of whether such contribution would be provided directly to the participants or channelled through WHO'. The United States suggested to complement this with 'WHO can accept such financial contributions, only if the meeting would not take place without WHO's involvement or if WHO's involvement is necessary in order to ensure that the work is undertaken in conformity with internationally accepted technical and ethical standards and guidelines'.

The USA suggested an entire change in paragraphs 31 and 34, about evidence and advocacy, respectively. The new texts would be:

> Paragraph 31 - Private sector entities can provide up-to-date information and knowledge on technical issues, and share their experience and engage with WHO in the generation of evidence, knowledge management, scientific reviews, information gathering and research, when potential conflicts of interest are managed in accordance with this framework and the collaboration is transparent.
> Paragraph 34 - WHO may collaborate with private sector entities to advocate for the implementation of a WHO norm or standard if the entity commits to implement the subject norms and standards in their entirety.

Regarding the paragraph on technical collaboration, the passage 'technical collaboration with the private sector is welcomed if potential risks of engagement are managed or mitigated and provided that the normative work of WHO is protected from any undue influence and there is no interference with WHO's advisory function to Member States' should be replaced by 'technical collaboration with the private sector is welcomed provided that it is in the interests of the Organization and managed in accordance with the framework for engagement with non-State actors'.

Lastly, it is worth noting that the United States highlighted that the country 'applauds innovative solutions to global health challenges like the recent Pandemic Influenza Preparedness Framework, which includes provisions for the industry to provide financial support to WHO for the functioning of the Global Influenza Surveillance and Response System. We wish to ensure that nothing in this framework would impede such collaboration now or in the future'.

On the specific policies for Philanthropic Foundations and Academic Institutions, the United States made the same overall observations made about NGOs. The country then ended with a note arguing that the WHO should align and harmonise its institutional and individual policies concerning conflict of interest. It was also pointed out the 'undue emphasis on financial interests of the private sector implies that potential financial conflict of interest of private entities are somehow more important than any type of conflict of interest of any other type of-non-State actors'. During the negotiations, the country advocated that financial and non-financial conflict of interest should be managed consistently across all types of non-State actors.

4.3.5 Norway

Norway was not among the first selected countries to be analysed as, according to the documents, the country made fewer interventions than the UK, US, France, Canada and Finland. However, after analysing the media reports and also some exploratory interviews, Norway was pointed out as an essential country during FENSA negotiations.

Norway made four suggestions on FENSA draft, as requested in the 136th Session of the Executive Board. The first one was related to the Section 'Engagement: rationale, principles, benefits and risks'. The country highlighted the importance of preserving the balance between 'the safeguards to protect WHO against undue influence on the one hand, and the need for WHO to fulfil its leadership role and to foster the use of non-state actors' resources on the other'. Regarding Due Diligence, Norway stated that the final framework should maintain the possibility for non-State actors to earmark financial contributions 'as appropriate' as well as for the WHO to use part of such contributions on staff salaries, 'provided that the contributions fall within the priorities and activities reflected in any adopted programme budget and when all relevant safeguards in the framework has been applied'.

Paragraph 44 was also mentioned by Norway. While fully supporting the non-engagement of the WHO with the tobacco or arms industries, the country affirmed that when mentioning particular caution with other industries, the Framework had provided 'sufficient safeguards concerning potential engagement with other industries and would not want to see any additional industries or sectors specified, keeping in mind that the purpose of the framework should be for the WHO to manage risk rather than attempting to eliminate it'.

Norway also emphasised the importance of coherence amongst all the six regions and the three levels of the organisation, therefore, the final framework should apply across the whole organisation. This point was significantly cited during interviews.

4.3.6. India

India was the country that made the most comments on FENSA draft used here, and it was also referred to as a very active Member State by both media and interviewees. Given this protagonistic role, we tried to reach any representative from India several times and through different approaches: writing to the Indian Embassy in Geneva, writing to names indicated by other interviewees, writing to diplomats whose names were on WHO documents. Nonetheless, we never received any kind of answer.

The first amended proposed by India was for the 1st paragraph, the excerpt 'this overarching framework and four specific policies shall govern WHO's all types of engagement with non-State actors including alliance or collaboration or partnership irrespective of any existing policies' should be added. For paragraph 2, apart from a language adjustment, the main proposal was to delete '*WHO engages with non-State actors in the advancement and protection of public health* in order to foster the use of non-State actors' resources (including knowledge, expertise, commodities, personnel and finances) in favour of public health and to encourage non-State actors to improve their own activities to protect and promote public health'. On paragraph 5, it was suggested to add '*WHO needs simultaneously to strengthen its* framework for engagement to avoid, or where unavoidable appropriately managed of the associated potential risks'.

Paragraph 6 defined the principles of engagement and, for India, engagements should not compromise the scientific and evidence-based approach. Hence, instead of 'protect WHO from any undue influence', the text should be 'protect WHO from any undue influence in particular the process of evidence and information gathering, in elaborating regulatory

frameworks and treaties, setting norms and standards, as well as policy implementation'. Similarly, subparagraph F should change from 'be actively managed so as to mitigate any form of risk to WHO (including conflicts of interest)' to 'actively avoid, or where unavoidable, appropriately manage both actual and perceived conflict of interest as well as to mitigate any other form of risk to WHO'.

Regarding the risks of engagement, India suggested two amendments. The first was to add 'evidence and information gathering' among the issues that could be unduly influenced. The second was to include integrity and independence in the text 'a negative impact on WHO's reputation and credibility'.

To the section 'Non-State Actors', India proposed to add the following text in paragraph 10 about NGOs:

> The membership, governing or advisory bodies of the NGO shall not include private sector entities, individuals working for the private sector entities, philanthropic foundations or academic institutions which are not at arm's length from the private sector entities including individuals working for such academic institutions or philanthropic foundations (…)Private commercial or profit-making nature is assessed not only on the basis of the document of incorporation but also from its activities, governance structure, source of finance etc. NGOs shall not receive more than 30% of their financial resources from the private sector entities, philanthropic foundations or academic institutions which are not at arm's length from the private sector entities.

In the paragraph about private sector entities, India recommended adjusting the footnote about an entity being 'at arm's length' from another entity to not only being influenced in its decisions but also objectives and activities. Regarding philanthropic foundations, it was required to add that they should be independent of any private sector entity, not only in their governance and decision-making but also in their objectives, programs and activities. Moreover 'their programs and activities shall not further the commercial interest of the donor/donors'. For academic institutions, the following text was proposed:

> (Academic institutions are entities engaged in the pursuit and dissemination of knowledge through research, education and training) as part of an university or public funded institutions. Academic institutions established by the private sector or the presence of private sector in the administration including governing and academic bodies would be treated as private sector entities. Further if an academic institution receives more than 30 % of their total revenue from private sector entities or any funding from private sector in the area where it seeks engagement with WHO would be considered as private sector.

The country also proposed to delete from paragraph 14 the excerpt 'if the decision-making processes of a non-State actor remain independent of the private sector influence, WHO can decide to consider the entity as a nongovernmental organisation, a philanthropic

foundation or an academic institution, but may apply relevant provisions of the private sector policy, such as not accepting funding for normative work'. Instead, the passage 'to ensure consistency and certainty, if in its due diligence, the non-State actor fulfils one or more of the following criteria, such an entity shall be categorised as a private sector entity' should be added. Four bullet points were also recommended:

> • Private sector entities including international business associations; philanthropic foundations and academic institutions not at arm's length from the private sector entities, are present in the membership or governing bodies or advisory bodies of the non-State actor.
> • More than 30% of the non-State actor's revenue or funding is from private sector entities including international business associations; philanthropic foundations and academic institutions not at arm's length with the private sector entities.
> • The activities and publications of the non-State actor to find out whether it promotes the interest of private sector entities against public health goals.
> • The key office bearers of the non-State actor have significant past and present connections with private sector entities.

On types of interaction, India proposed to highlight that the framework should apply to any existing or future collaborations and partnership, both hosted and external. Additionally, the phrase about no limits to non-State actors' participation at WHO meetings should be replaced by 'participation of non-State actors in Consultations are subject to the corresponding mandate from the Governing Bodies and in absence of such mandate the consultation shall be carried out on web-based platform and inputs received from non-State actors shall be made publicly available'. The country also suggested a new subparagraph defining that 'Meetings of Bodies for setting Norms, Standards and Policies: private sector entities, as well as non-State actors with links to private sector entities, shall not be allowed to attend or participate in any WHO meetings including expert committee meetings or intergovernmental negotiations, involved in the formulation or setting of policies, norms, standards or guidelines'.

The country was against allowing personnel as a form of resource and of NSAs being allowed to support policymaking at the national level as an activity of technical collaboration. On paragraph 19 about evidence, it suggested adding 'utmost care should be taken to ensure that gathering, analyses and generation of information and the management of knowledge and research is free from the conflict of interest. The Secretariat should always make available the evidence gathered with the cooperation of non-state actors for independent verification'.

Concerning conflict of interest, India suggested starting paragraph 22 with

'Avoiding and if unavoidable appropriately managing (…)'. The same passage was recommended to paragraph 23, which should also add three types of conflict of interest: individual, institutional and conflicting interest. A new paragraph was proposed, defining that an individual conflict of interest 'occurs when an individual who is a consultant or expert engaged or commissioned by WHO, influences the decisions of WHO at the cost of its integrity, independence and objectivity of WHO'. Besides, some examples were given of situations in which an individual conflict of interest could happen.

The country asked to remove 'all institutions have multiple interests, which means that in engaging with non-State actors WHO is often faced with a combination of converging and conflicting interests' from paragraph 24. The proposed new text was:

> An *institutional conflict of interest* is a situation where WHO's primary interest *as articulated in its Constitution* may be influenced or compromised by an individual or individuals acting on behalf of WHO the conflicting interest of a non-State actor in a way that affects, or may reasonably be perceived to affect, the independence, *integrity* and objectivity of WHO's *constitutional functions and work mentioned in the General Programme of Work.*

For India, paragraph 25 and 26 should be deleted and replaced by:

> In addition to individual and institutional conflict of interests, of important concern are situations of conflicting interests where the commercial interests of private sector entities including international business associations or other non-State actors not at arm's length from the private sector entities are in conflict with WHO's constitutional mandate and affect the Organisation's independence and impartiality in evidence and information gathering, setting norms and standards and policy implementation. A conflicting interest can occur *inter alia* in the following circumstances: (a) Private sector entities influences or is perceived to influence WHO, in pursuance of direct or indirect commercial interest, and thereby compromising the objectivity, independence and integrity of WHO; (b) The likelihood of private sector entities using its engagement with WHO to further its commercial interests; (c) Potential or real conflict or divergence of objectives, interest or activities of private sector entities and the public health goals or mandate of WHO as per its Constitution, decisions or resolutions of the governing Bodies.

Given that paragraph 30 defines the primary function of due diligence, India proposed two extra functions 'clarify the nature and objectives of the entity proposed to engage with WHO' and 'examine whether the entity complies with the norms, standards, guideline, strategies or action plans established by WHO or whether its activities undermine any of WHO's norms, standards, guideline, strategies or action plans established by WHO'. Furthermore, the excerpt 'due diligence reports including the risk assessment report shall be made available in public domain for independent verification and scrutiny' was supposed to be added to paragraph 31. Paragraph 34 established a unit responsible for due diligence and

risk assessment. For India, it should be a specialised central unit, and the recommendations regarding risk management should be made public, along with the reasons.

In paragraph 44, India suggested that the WHO should not engage with the tobacco and arms industries, nor with 'organisations having any direct or indirect affiliation with these industries'. Additionally the WHO should set up 'a mechanism of screening and identification of such organisations' and, "when engaging with other industries affecting human health or affected by WHO's norms and standards such as food and beverages, alcohol, infant formula, WHO will exercise particular caution and WHO's engagement will be strictly limited to assisting such industries to comply with WHO's norms and standards or guideline or policy'. On the topic of secondments, the country only suggested changing 'WHO does not accept' to 'WHO shall not accept'.

Regarding official relations, specifically the paragraph 53 on NSAs being invited to participate in the WHO's governing bodies, it was recommended to add the passage 'when making the statement, international business associations and philanthropic foundations should declare their interest, particularly commercial interest, in the item'. Furthermore, the country suggested a new paragraph establishing norms for the accreditation of NGOs to governing bodies:

> To be eligible for accreditation to the Health Assembly, Executive Board and committees and conferences convened under their authority, a nongovernmental organisation shall: (a) have aims and purposes consistent with WHO's Constitution and in conformity with the policies of the Organization as well as resolutions and decisions adopted by the Executive Board and the World Health Assembly; (b) demonstrate competence in a field of activity related to the work of WHO; (c) have membership and/or activities that are international in scope; (d) be non-profit and public interest in nature, and in its activities and advocacy; (e) have an established structure, a constitutive act, and accountability mechanisms; (f) for a membership organisation, have the authority to speak for its members and have a representative structure; The Membership should not contain private sector entities, individuals associated with private sector entities or philanthropic foundations and academic institutions not at arm's length with private sector. ; (g) have existed formally for at least three years as of date of receipt of the application by WHO; (h) disclose information on its objectives, structure, membership of executive body, field of activities and source of financing, and, where applicable, its status with other entities of the United Nations system; (i) agree to provide WHO regularly with updated information as well as to inform WHO of any changes with respect to its status as « non-governmental organisation » as soon such changes take place.

India proposed a report from the Independent Oversight Committee Advisory Committee every two years on engagement with non-State actors as part of the surveillance of FENSA implementation. Moreover, it exemplified situations which should be considered non-compliance with the framework, such as: activities that go against the WHO's mandate,

decisions and resolutions of the Governing Bodies; actions or activities that negatively affect the independence, integrity, reputation or credibility of WHO; and activities of the non-State actor after the establishment of engagement lead to actual and perceived conflict of interest. For India, the implementation should be evaluated every two years after the adoption. Finally, a new paragraph was suggested, containing steps to be followed 'for the effective implementation' of FENSA. It included a review of the existing list of non-State actors in official relations as well as their categorisation, a review of the WHO's existing external and hosted partnerships and collaborations, among others.

To analyse the comments made by India in the four specific policies, we will first point out the suggestions for NGOs, philanthropic foundations and academic institutions, which were more similar, and then the policy for the private sector. One should note that India was against the WHO accepting personnel as a form of resource from all NSAs. When it comes to participation, India recommended that all inputs should be publicly available. However, for philanthropic foundations, the country added that all information about the participation of philanthropies should be available, as well as presentation and oral or written submission. Regarding contributions and donations, the country suggested that the source of contributions from NGOs and philanthropic foundation should be disclosed.

Concerning 'Evidence', India highlighted that for NGOs 'utmost care should be taken to ensure that gathering, analyses and generation of information and the management of knowledge and research is free from the conflict of interest'. While for philanthropic foundation and academic institutions, any decision on evidence should only be taken 'after proper risk assessment, including the actual or perceived conflict of interest. This risk assessment report shall be made public'. Lastly, for technical collaboration from NGOs, the following amendment to paragraph 17 was proposed: 'the collaboration for product development shall be based on the delinking principle to ensure innovation and access to the developed product at affordable cost". The suggestion for academic institutions was similar.

One can observe that, principally, India and the United States polarised the debate on the participation of the private sector. Thus, regarding participation, India recommended that all information related in consultation, hearing or any other meeting at the WHO should be made public. Moreover, the private sector should only be allowed to participate after a 'proper risk assessment, including the actual or perceived conflict of interest' and the WHO

should not cosponsor meetings organised by the private sector. With regard to resources, India advocated that the WHO should not accept funds from ‘food and beverages, or alcohol, or infant formula industry for its work in NCD or WHO shall not accept resources from pharmaceutical industry for implementation of quality and safety standards of medical products’ and should not also accept financial resources from the private sector as specified voluntary contribution. The country also suggested that no project except product development and clinical trials should be implemented with more than 50% of the financial resources from the private sector, and that activities leading to the production of WHO guidelines or recommendations should not also receive funds from business entities. Paragraph 14 on pooling contributions from multiple sources was requested to be deleted and a suggested addition to paragraph 19 was that anonymous donations should not be accepted under any circumstances. Moreover, a received donation which was subsequently discovered to be non-compliant with FENSA should be returned to the donor.

India also proposed three new subparagraphs to paragraph 22 on product development, ‘(c) The clinical trial data shall be made available for public, (d) The clinical trial follows the ethical standards laid down in the Helsinki Protocol, (e) The final product shall be made accessible to the needy people’. A new sub-section ‘Donations for preparation of guidelines or recommendations’ was also recommended, and it should establish that ‘financing may not be accepted from commercial enterprises for activities leading to the production of WHO guidelines or recommendations’. As a final point on resources, India was against the WHO accepting contributions from the private sector to support the salary of staff, including short-term consultancy.

On ‘Evidence’, India was against the WHO collaborating with private sector entities in the generation of evidence, in knowledge management, in information gathering and research. On ‘Advocacy’, the country suggested changing ‘Private sector entities can only collaborate with WHO in advocacy for the implementation of a WHO norm or standard’ to ‘Private sector entities can only collaborate with WHO for the technical assistance for the implementation of a WHO norm or standard’. Regarding paragraph 36 on technical collaboration, India did not agree with the WHO collaborating with the private sector for the implementation of norms and capacity building; an exception could be made for providing technical assistance to the private sector to implement WHO norms.

Regarding product development, India proposed the excerpt '(Collaborative research and development, technology transfer and licensing should, as a general rule, be undertaken) only if WHO and the entity concerned have concluded an agreement cleared by the Office of the Legal Counsel that ensures that the final product will ultimately be made widely available and accessible, at affordable prices'.

Overall, according to documents and interviews, India was the leading country advocating for public-interest NGOs and the primary opponent to the private sector.

4.3.7 Bolivia

As already explained, this thesis initially proposed a North-South division hypothesis. Therefore, Member States from the Global North and the Global South were selected. Bolivia was one of the most active Member States, according to the available documentation. Three emails were sent to different individuals who were involved in FENSA negotiations, to request an interview. While one did not answer, others denied the request due to a change of position. Like Canada, France and India, the positions taken by Bolivia will be analysed considering the available documents, media reports and interviewees who may have cited its participation. The main source, however, will be the non-paper on the draft of FENSA which was presented and discussed during the EB136. Bolivia was the third country that made more contributions to this document, only behind India and the United States.

The first comment was on paragraph 2 of the section 'Engagement: rationale, principles, benefits and risks'. The country suggested to deleted the excerpt 'WHO can only fulfil its leadership role in global health and its mandate if the Organization proactively engages with Member States, other international organisations and non-State actors' and rewrite it as 'WHO engages with non-State actors as appropriate to fulfil its constitutional mandate'. The country also suggested some amendments regarding language in order to elucidate the text.

Paragraph 6 establishes the overarching principles to guide the engagement between the WHO and non-State actors, and Bolivia proposed to change 'support and enhance the scientific and evidence-based approach' to 'not compromise the scientific and evidence-based approach'. Moreover, it suggested adding 'evidence and information gathering and implementation' to the subparagraph that mentions which processes should be protected from undue influence. Subparagraph F was suggested to be changed from 'be actively managed so

as to mitigate any form of risk to WHO (including conflicts of interest)' to 'actively avoid, or where unavoidable, appropriately manage both actual and perceived conflict of interest as well as to mitigate any form of risk to WHO'. Finally, the country suggested the addition of an eighth paragraph stating that any engagement should not divert from its public health mandate.

Bolivia suggested adding, among the risks, that engagement with non-State actors could bring about a negative impact on integrity, independence and the public health mandate of the WHO, besides the risks to the Organisation's reputation and credibility, which were already predicted.

Regarding the non-State actors embraced by FENSA, Bolivia made comments on philanthropic foundations and academic institutions. Paragraph 12 defined that philanthropic foundations should be clearly independent from any private sector entity in their governance and decision-making; the country advocated to also add objectives, programs and activities, and to state that 'their programs and activities shall not further the commercial interest of the donor/donors'. Paragraph 13 recognised academic institutions as entities 'engaged in the pursuit and dissemination of knowledge through research, education and training'. Bolivia suggested to add the passage 'academic institutions established by the private sector or the presence of private sector in the administration including governing and academic bodies would be treated as private sector entities'.

In the section 'Types of Interaction', Bolivia recommended adding a new paragraph on participation stating that 'participation of non-State actors in WHO bodies dealing with formulation or setting of policies, norms or standards, frameworks, strategies, plan of action, guidelines, toolkits, strategies etc. such as expert committee meetings or intergovernmental negotiations, shall not be allowed unless Members States decide otherwise to include non-State actors participation'. The country also suggested removing personnel as a form of resource and the support to policymaking at the national level as a form of technical collaboration. Moreover, it was also requested to complement paragraph 19 on evidence with 'evidence gathered with the cooperation of non-state shall be available for independent verification'.

Regarding due diligence, approached in paragraph 31 - Bolivia proposed that due diligence reports, including the risk assessment, should be made available in public domain.

For Bolivia, the section ‘Policy, norms and standard-setting’ should be deleted from the document. The country’s general comment on ‘Management of Conflict of Interest and other Risks of Engagement’ was that a comprehensive Conflict of Interest policy should be developed but without suggestions about the subject.

Regarding the infamous paragraph 44, Bolivia suggested that in the passage ‘WHO will exercise particular caution when engaging with other industries affecting human health or affected by WHO’s norms and standards’, the excerpt ‘in particular aiming to get compliance with WHO’s public health mandate, norms, standards, guideline or policy’ should be added. Bolivia also advocated that in case of conflict with other policies, FENSA should prevail. Moreover, international business associations and philanthropic foundations should not be granted ‘official relations’ status and a set of rules for accreditation of NGOs should be developed.

On the specific policy for non-governmental organisations draft, Bolivia proposed that all input of NGOs provided during consultation or hearing should be made public, and also suggested to remove personnel as a resource accepted by the WHO. Furthermore, while paragraph 10 guaranteed that due to transparency ‘contributions and donations from nongovernmental organisations must be publicly acknowledged by WHO in accordance with its policies and practices’, Bolivia also recommended to add that ‘the contributing NGO shall disclose the source of its contribution and the Secretariat shall make this information publicly available’.

With regard to the policy and operational procedure for the private sector, Bolivia advocated removing paragraph 3 on the WHO operating in a competitively neutral basis and including non-State actors with links to private sector entities as part of the private sector. Since paragraph 5 established that private sector entities could be invited to participate in other WHO meetings, Bolivia recommended adding that they should only be invited ‘if there is a mandate from the governing bodies and if those meetings are not involved in the formulation or setting of policies, norms, standards or guidelines. In the absence of such mandate, applicable rules, policies and procedures of the organization shall apply’.

The country also proposed a new paragraph, establishing that information concerning participation of private sector entities as well as non-State actors with links to private sector entities ‘in consultation or hearing or any other WHO meeting including inputs of the private

sector entities as well as non-State actors with links to private sector entities in such meetings such as presentation or oral or written submission shall be made publicly available'. This was the same suggestion made by India.

Bolivia then recommended that paragraph 8 should only define that the WHO does not cosponsor meetings organised by private sector entities (the paragraph, however, talks about specific private sector entities) and the rest of the text should be deleted.

Regarding 'Resources', Bolivia suggested adding a subparagraph D to paragraph 12 on the risks associated with the acceptance of resources from private sector entities. The text proposed was: 'WHO shall not receive financial resources from private sector entities as well as non-State actors with links to private sector entities whose activities or advocacy are undermining the mandate of WHO as stated in its Constitution or decisions and resolutions of governing bodies'. The country also recommended two new paragraphs for the session, one stating that anonymous donations should not be accepted and one declaring that 'any donation received by WHO which is subsequently discovered to be noncompliant with this Framework shall be returned to the donor'. India also proposed both texts in the same style.

Paragraph 22, about financial contributions for clinical trials, had many changes recommended. For instance, Bolivia asked to delete subparagraphs B and C:

> (b) the research is conducted at WHO's request and potential conflicts of interest are managed; (c) WHO only accepts such financial contributions, if the research would not take place without WHO's involvement or if WHO's involvement is necessary in order to ensure that the research is undertaken in conformity with internationally accepted technical and ethical standards and guidelines.

Instead to add three different subparagraphs:

> (b) the clinical trial data shall be made available for public scrutiny; (c) the clinical trial follows the ethical standards laid down in the Helsinki Protocol (d) the final product shall be made accessible accessible and affordable to the patients, in particular in developing countries.

Bolivia was against contributions for financing staff salaries and therefore suggested the following text for paragraph 29: 'WHO shall not accept contributions from private sector entities to support the salary of staff including short-term consultancy'. Finally, paragraph 38, on product development, as previously mentioned, took time to achieve consensus. Bolivia was amongst the countries who asked that final products should be widely accessible at affordable prices.

Regarding the specific policies for philanthropic foundations, Bolivia initially suggested that they should not take part, through consultations, in the preparation of policies.

In general it can be observed that the suggestions for philanthropic foundations were similar to those made to private sector entities. For instance, in paragraph 6 on operational procedures, Bolivia suggested adding the excerpt 'any decision with regard to the participation of WHO staff in the meeting can be done only after proper risk assessment including the actual or perceived conflict of interest. This risk assessment report shall be made public' and to delete personnel from paragraph 7, which establishes funds accepted by the WHO. The main focus of the country concerned risk assessment and transparency.

The WHO Policy and Operational Procedures on Engagement with Academic Institutions had five amendments suggested by Bolivia. The country recommended deleting the possibility of academic institutions taking part in the preparation of policies and instead proposed that the WHO could hold consultations if there is a mandate from the governing bodies. The country also highlighted the importance of publicising the inputs received from academic institutions regarding their participation in WHO meetings. Similar to the other three non-State actors, Bolivia asked to remove personnel from paragraph 8, that defines which kind of resources are accepted by the WHO. Paragraph 16, stating 'intellectual property arising from collaborations with academic institutions is regulated by the agreement with the academic institution. This should be addressed in consultation with the Office of the Legal Counsel' was suggested to have the passage 'addressed by the Legal Counsel' removed and replaced by 'WHO shall ensure that the intellectual property arising from collaboration with academic institutions are freely accessible for further research and development or studies as well as other non-commercial uses'.

As a final point, Bolivia proposed to add the following excerpt to paragraph 19 on scientific collaborations: '(In case of collaboration for product development collaborative research and development, technology transfer and licensing should, as a general rule, be undertaken) only if WHO and the entity concerned have concluded an agreement cleared by the Office of the Legal Counsel that ensures that the final product will ultimately be made widely accessible at affordable prices'. This was the same text suggested by India.

4.3.8 Zambia

Zambia was included in the selected countries due to written comments from official documents, media reports and exploratory interviews. The Zambian position will be further analysed in chapters 5 and 7, analysing the available documents, media reports and the

interview conducted on the 24th of July of 2019. In this session, the textual proposals submitted by the country on the draft of FENSA in February 2015 will also be detailed.

Zambia suggested a footnote for paragraph 22 on steps required to manage conflict of interest and other risks of engagement stating that 'The framework is designed to regulate institutional engagements; its implementation is closely coordinated with the implementation of other organisational policies regulating conflict of interest in respect of individuals (see paragraph 48)'. The country argued that conflicts of interest at the institutional level are usually defined as conflict of financial interests. The draft was, therefore, overlooking 'the possibility of non-State actors' bias due to their non-financial interests – like strongly held personal or professional beliefs, declared policy positions, personal relationships (even adversarial), or the desire for individual or organisational recognition or advancement'.

Zambia criticised the word 'may' in paragraph 23; 'A conflict of interest arises in circumstances where a secondary interest unduly influences, or may reasonably be perceived to unduly influence' and stressed that undue or improper influence exercised on the WHO's work was one of the most significant risks of engagement. Accordingly, conflict of interest represents a potential for, and not the occurrence of, undue influence. Yet on the issue of conflict of interest, Zambia suggested the deletion of paragraph 26,[81] arguing that it was wrongly implied that financial conflict of interest of the private sector is more important than the financial conflict of interest of other non-State actors. The framework was, therefore, creating 'a clear bias against the private sector'. The country suggested a new text for paragraph 24 on institutional conflict of interest:

> The quality, independence and objectivity of the WHO's work are all primary interests of the WHO, which should not be unduly influenced by the competing interests of any non-State actors. Thus, the draft does not clearly distinguish institutional conflict of interest from conflict of interest generally. Nor should it. Institutional conflict of interest are equated with financial conflict of interest – an improperly narrow scope for this framework. The framework must instead address financial and non-financial conflict of interest, at institutional and individual levels.

Concerning paragraph 30 about due diligence, for Zambia, the bullet point 'identify 'red lines' such as activities that are incompatible with WHO's work and mandate (e.g. links to the tobacco and arms industries) or that require the Organization to exercise particular caution when engaging with the entity (e.g. links to other industries affecting human health or

[81] For WHO the most important institutional conflicts of interest arise in situations where the economic interests of private sector entities are in conflict with WHO's interests, especially the Organization's independence and impartiality in setting norms and standards

affected by WHO's norms and standards)' was incompatible with paragraph 44. The country argued that barring the engagement with any entity with links to the tobacco industry would 'for example, bar the WHO from engaging with anyone connected to the current effort to produce Ebola and other vaccines more quickly by growing them in tobacco leaves'. Moreover, the country claimed that the phrase 'Industries affecting human health or affected by WHO's norms and standards' was too broad and applying such particular caution to any entity with links to these industries could be arbitrarily applied in order to exclude some entities. Zambia, then, asked to delete the 4th bullet point.

Zambia also argued that, according to paragraph 34, since the Secretariat could collect supplementary information on non-State actors from sources which are not necessarily reliable or neutral, NSAs should be allowed to review and respond to the information on which risk assessments, recommendations and risk management decisions are based.

The general comment on the section 'Management of Conflict of Interest and other risks of engagement' made by Zambia was 'quality, independence and objectivity of the WHO's work are all primary interests of the WHO, which should not be unduly influenced by the competing interests of any non-State actor'. The country also pointed out that the draft did not clearly distinguish institutional conflict of interest from conflict of interest generally and that FENSA should address financial and non-financial conflict of interest, at institutional and individual levels. Regarding the well-known paragraph 44, Zambia argued that 'particular caution' was neither defined nor limited and, consequently, could be interpreted and applied differently at different levels of the WHO - 'eliminating the inclusiveness and predictability intended by the framework, and needlessly denying WHO access to appropriate input from qualified non-State actors'.

Regarding the four specific policies, Zambia commented on non-governmental organisations' possibility to cooperate in the generation of evidence and technical collaboration by arguing that 'managing risks of engagement with consistent diligence and transparency requires that the provisions in this paragraph be identical across each type of non-State actors'. In paragraph 31 about evidence from private sector entities, the country advocated that 'Private sector entities do not inherently present risks for the WHO by their participation in scientific reviews on any and every subject. Indeed, the private sector may well have the most authoritative expertise on some issues. There is no justification for this

paragraph's sweeping exclusion of private sector entities from any collaborating on any type of scientific review'.

Paragraph 32 stated that 'Individuals working for interested private sector entities are excluded from participating in advisory groups; however, expert groups need to be able, where appropriate, to conduct hearings with such individuals in order to access their knowledge'. For Zambia, it was not clear why advocacy groups and expert groups should not benefit 'from the full participation of appropriate professionals' given that any risk should be managed through the transparent application of FENSA, instead of 'random exclusion of even highly qualified professionals'. Finally, regarding advocacy from the private sector, Zambia argued that other non-State actors were not subject the conditionality of only being able to collaborate in advocacy 'if they commit themselves to implement these norms and standards in their entirety'. Therefore, 'these conditions set the bar for private sector engagement impassably high. In so doing, the provision creates an unfairly broad argument to exclude a private sector entity, contradicting the spirit that Member States seek to capture in this framework'.

On the specific policy for philanthropic foundations and academic institutions, Zambia only requested identical appliance of provisions across all non-State actors. The country noted that the paragraphs dealing with technical collaboration were 'redundant and unnecessarily confusing' as there was no need to state that 'collaboration must be in the interests of the WHO (….) Any collaboration managed in accordance with the framework will necessarily be in the interests of the Organization'.

4.3.9 Brazil

Brazil was chosen due to participation in official documents and presence in media reports but, above all, because it was widely mentioned in the interviews. Almost all interviewees pointed to Brazil as one of the essential Member States during FENSA negotiations, as the country acted as the leader of the Global South. Two interviews were conducted with different Brazilian diplomats and they will be further analysed in chapters 5 and 7, combined with the written comments which will be now presented.

The first comment from Brazil was regarding subparagraph B of paragraph 6, which establishes the overarching principles of the engagement with non-State actors. The country suggested deleting 'by WHO's governing bodies' from the text 'respect the

intergovernmental nature of WHO, where the decision-making by WHO's governing bodies is the exclusive prerogative of Member States'. Therefore, to Brazil, all the decision-making in the WHO should be carried out by Member States.

Paragraph 16, on the types of meetings organised by WHO in which NSAs were allowed to participate, Brazil recommended removing the section 'there are no limits imposed on non-State actors' participation at such meetings'. Instead, the text would read 'the format of such other meetings/consultations and the participation of non-state actors is decided on a case-by-case basis either by the governing body at the session at which it is mandated or in other cases by the Secretariat'.

On conflict of interest, Brazil suggested that, in paragraph 26, 'conflict with the promotion of public health among the situations where the most critical institutional conflicts may arise', should be added. The country also recommended the withdrawal of paragraph 43, which stated that 'references elsewhere in this framework to the norms and standard-setting process and normative work concern the second type of activity'. Regarding paragraph 44, Brazil requested to add that the WHO should exercise particular care 'especially while conducting due diligence and risk assessment analyses' when engaging with industries affecting human health. Similar to Bolivia and India, Brazil was opposed to granting official relations to international business associations and philanthropic foundations. Instead, it suggested that they would be granted 'observer' status.

With regards to the specific policies, Brazil suggested a new paragraph in the section 'Resources from nongovernmental organisations', asserting that they should be 'invited to participate in the financing dialogue, which is designed to improve the alignment, predictability, flexibility and transparency of WHO's funding and to reduce budgetary vulnerability'. The country also proposed to change paragraph 14, about evidence, to the following text: 'WHO can only collaborate with non-governmental organizations in the generation of evidence, in knowledge management, in information gathering and in research when potential conflicts of interest are managed in accordance with this framework and the collaboration is transparent'.

When it comes to the private sector, Brazil alleged that paragraph 29, which allowed contributions to financing staff salary, should be deleted. Moreover, the country requested that in the text concerning product development, the final product should be affordable.

Regarding the policy and operational procedures for philanthropic foundations and academic institutions, Brazil was against accepting personnel as a form of resource accepted by WHO. The country also suggested changing the paragraphs about evidence to 'WHO can only collaborate with philanthropic foundations/academic institutions in the generation of evidence, in knowledge management, in information gathering and in research when potential conflicts of interest are managed in accordance with this framework and the collaboration is transparent'.

One can observe the convergence between positions advocated by Brazil, India and Bolivia, which strengthens the hypothesis of a North/South division during the FENSA negotiation process.

4.3.10 Argentina

Although not providing considerable comments on FENSA draft in February 2015 nor being mentioned much in media reports, since the beginning of the 'Member States' phase of the negotiations, Argentina is singled out to be the Chair by Margaret Chan. In this chapter, the primary source to analyse the positions taken by Argentina will be the non-paper on the draft of FENSA, which was presented and discussed during the EB136; in chapter 7 it will be combined with the interview with a diplomat who chaired the discussions, along with media reports and relevant mentions by other interviewees.

The first comment made by Argentina was regarding paragraph 22, on the steps required to manage conflict of interest and other risks of engagement. The country proposed two options for the paragraph, the first was that due diligence would be audited by a group of twelve representatives of Member States, called the Group, which would be composed of two representatives from each Regional Office. The Group would also review risk assessments. The second option would be, instead of the establishment of the Group, the Member States would conduct due diligence and risk assessment through the open-ended group.

Concerning due diligence and risk assessment, Argentina suggested that the responsibility for conducting them should be of technical specialised units or of Member States through the open-ended group. The country also recommended the withdrawal of paragraphs 34, 35 and 36, all included in the risk management section. Paragraph 38 on 'Transparency' stated that 'The WHO register of non-State actors is an Internet-based, publicly available electronic tool used by the Secretariat to document and coordinate

engagement with non-State actors'. Argentina suggested that it should be a tool used by the Secretariat and the Member States.

While paragraph 39 recognised that the Secretariat possessed responsibility to decide on an engagement with a non-State actor, Argentina recommended that 'the open-ended group with the advice of the technical units' should decide. Regarding paragraph 44, it was suggested to change 'WHO will exercise particular caution when engaging' to 'WHO will exercise particular caution during the process of due diligence, risk assessment and management of risks'. Argentina did not provide explicit comments on the specific policies but affirmed that 'in the draft WHO policies and operational procedures on engagement with nongovernmental organisations, private sector entities, philanthropic foundations and academic institutions, all references to the possibility of WHO's accepting secondments from the aforementioned non-State actors should be deleted'.

CHAPTER FIVE: ANALYSING INTERVIEWS; WHAT WERE THE MEMBER STATES' POSITIONS ON FENSA NEGOTIATION?

This chapter aims to scrutinise interviews with individuals from nine Member States who were involved in the FENSA negotiations at any point. As already explained, the Member States were initially selected by considering their participation according to official documents, and by bearing in mind the hypothesis of a cleavage between the North and South at the World Health Organisation. However, after preliminary interviews and emails requesting participation, the selected countries were the United States, the United Kingdom, Norway, Germany, Brazil, Argentina, Egypt and Zambia. The European Union was also selected, as many European countries were pointed out to be very vocal and, often, seeking a coalition among them.

As advocated by Merton & Kendall (1946) and Morse & Field (1995), a Semi-Structured Interview (SSI) aims to gather personal perspectives from individuals regarding a particular situation. According to the same authors, the SSI demands a reasonably detailed interview guide and may be used when there is proper objective knowledge about the phenomenon which will be analysed, but where the subjective knowledge is lacking. To analyse the SSIs conducted, the most usual way is to compare participants' responses, considering they were all asked the same questions in almost the same order. The data collected is, therefore, comparable. The interviews conducted were divided into two parts, first aiming to deepen knowledge about the Member States' expectations regarding FENSA, and then to clarify the Member State's position on the controversial topics of the negotiation. Apart from the United Kingdom, whose interviewee did not allow recording, all interviews were recorded and transcribed.

While this chapter will summarise the Member States' perspectives on FENSA without further analysis, Chapter 7 will combine the interviews and the document analysis, leading to the final results of this thesis.

5.1 What is the Official Position Regarding the Framework of Engagement with on-State actors (FENSA)?

To Brazil, FENSA is an essential and unprecedented milestone within the United Nations system for regulating the relationship between the Secretariat and non-State actors in the broad sense, civil society and the private sector. According to interviewee 4, in the global public health scenario, there is meaningful participation of philanthropic entities which do

not necessarily or strictly fit within the categories of civil society, non-governmental organisation or the private sector. Therefore, it is of utmost importance to have clear, transparent and objective rules. Considering the 2030 Agenda for Sustainable Development, of which one of the driving ideas is precisely to reinforce global partnerships including with civil society and the private sector, Brazil believes in dialogue and partnerships. However, rules, along with updated and revised practices, are needed. Interviewee 4 affirmed, 'as I understand it, [the Brazilian participation was] very present, very active and in this line of preserving the legitimacy of WHO, minimising or eliminating the possibilities/opportunities for conflict of interest'.[82] The country believes that the WHO needs to increase not only the level but the quality of health worldwide. To achieve this, non-State actors have to collaborate. The focus, therefore, should be on a research-based relationship, founded on technical advice, and without undue interference from economic agents or of another nature.

Egypt was officially supportive of FENSA due to the awareness of non-State actors' increasing role in the global public health domain. Moreover, according to the interviewee, the documents that previously regulated the engagement between the World Health Organisation and the non-State actors, the Principles of 1987, were not specific and comprehensive enough, according to the Egyptian interviewee.

For Germany, the main goal during the negotiations was to strengthen the WHO vis-à-vis other global actors. In other words, 'WHO has to engage' while keeping transparency and safeguarding the reputation of the Organisation. According to the interviewee, the country was trying to avoid a bureaucratic tiger that would deny the WHO the possibility to enter into an appropriate engagement with non-State actors. If FENSA were to establish an onerous bureaucratic regime, then Germany would have been against it.

One must consider that, according to the interviewee from the European Union (EU), whenever a topic comes up with the World Health Organisation, the EU tries to coordinate a position, and this can only be done by consensus. If there is no unanimity, the EU cannot have a position and the Member States should participate in their national capacity. This happened during FENSA negotiations. The European Union, therefore, only supported FENSA when it was agreed, and currently 'consistently support its full implementation across all of the WHO'. The interviewee admitted, however, that 'the EU is very supportive

[82] Interview conducted in Portuguese and translated by the author.

of WHO even if we are critical sometimes, (…) and we always try to reach a coordinated position on any topic. If we cannot, this is a very good predictor that whether the WHO Member States discusses there will not be in agreement, it will be difficult. So FENSA was a very good example of that. Migration is another one'.

For Norway, a framework to more carefully regulate the interaction between the WHO and the private sector and NSAs, in general, was necessary. Accordingly, the country advocated that FENSA should introduce necessary safeguards, but without interfering with the efficiency and workability of the WHO. According to the Norwegian interviewee:

> as everyone else, we shared the starting point that there is an inherent risk to interact with the private sector, particularly some sectors such as food and drinks' industry. At the same time, other sectors at WHO are very dependent on interacting close to the private sector, particularly with regards to NGOs in crisis-related, the response in humanitarian work, vaccines development, and some development areas where NSAs play crucial roles and WHO really needs to work in all seamlessly with that type of actor.

For the United Kingdom, FENSA was seen as an essential tool for WHO operation and engagement with non-State actors. However, during the negotiations, the UK was concerned that all engagements could stop until FENSA was approved, which would be a significant risk to the Organisation.

The United States of America described themselves as 'strong supporters of FENSA' as the Framework would be an important achievement for the WHO to be able to 'work effectively with all categories of non-State actors', especially civil society and the private sector, the main focus of US delegation during the negotiations. The interviewee argued that 'FENSA is important both to protect WHO, write the kind of rules of the road, but also it should be helping to enable engagement and to kind of promote and faster engagement as much as protect the organisation. So it should have a dual function really'.

Zambia's position 'was based on principles' and on the fact that the WHO was struggling financially and, consequently, allowing undue influence. According to the interviewee, the WHO has a coordinating role and, to advance in health care, should bring every player to the table rather than distance them. The WHO, therefore, should engage more with more non-State actors, but the Member States are those who should develop the guidelines. The interviewee, hence, affirmed that:

> We should guide the organisation (…) because what we were seeing was that the organisation was just following the money. Where they were putting money, is where the organisation went. It wasn't following the agenda that was being set by the countries; it was more following the agendas of who was putting money on the table,

> whatever if it was a country or business (…) [if] a country X would want to influence what's happening in country Y in the South, X could use WHO by putting money into WHO to go and influence what's happening in country Y. So they'll put in 200 million and then send your people into WHO, when those people go to country Y, country Y view those people as the experts coming from WHO, when it's actually X country experts.

Argentina was chosen as the chair of FENSA negotiations, and although supporting the framework since the beginning until the end, the interviewee affirmed that it 'was a total nightmare. At the very beginning, some Member States wanted to have a co-Chair (…), and I did not want, I thought that having a co-Chair would be hard for the process. (…) I assumed all the responsibility, but in the end, I was exhausted, I was hoping to have a co-chair because I could share every single meeting that we had on FENSA. So for me, it was completely exhausting'. Moreover, according to the diplomat, the Member States 'didn't know exactly what [they] were doing at the very beginning' and underestimated 'how deep one issue had to go because we wanted to have something useful (…) every time we met with a naive thinking that in three hours we're going to finish the document and we were almost two years in sessions and from the very beginning, from the first session, we thought with one session we would cover everything'.

The interviewee also explained that most of the long process was trying to understand the WHO, but at the very beginning, part of the Secretariat was reluctant because the Member States were scrutinising their actions. Overall, Argentina believes that the WHO is 'a very strong [organisation] with excellent professionals, people who work very consciously, very devoted and committed to the work. After the FENSA process, my view of the organisation was much better'. The former chair stated that although being happy and supportive of FENSA, 'we are not talking of the final document, that is why we have this evaluation process to know if it is working or not. So I am not totally, completely committed to that document, because it was decided [that] if we did something that at that time we thought it was good and now by implementing it, we realise that it is wrong or harming, or whatever, we have to be open when it is not working, to change'.

5.2 What Was the Nature of the Debate About Replacing the 1987 Principles with FENSA?

As already pointed out in Chapter 3, FENSA replaced the Principles Governing Relations between the World Health Organisation and Nongovernmental Organisations (1987) and the Guidelines on Working with the Private Sector to Achieve Health Outcomes

(2001). The interviewed individuals from Member States were asked how this replacement occurred, if the States were consulted and involved, and if they were in favour of it.

According to the Brazilian perspective, given the higher level of participation by civil society, the private sector and new actors from the late 1980s through the 1990s, which permeated the entire multilateralism system, an update in the normative framework for the WHO was needed. The interviewee highlighted that the last update had happened in the late 1980s, in a still bipolar Cold War scenario, which no longer reflected the needs and characteristics of the current system. Moreover, the Brazilian representative argued that the previous definition of non-governmental organisations was excessively flexible and caused many debates, because it used to include other forms of non-State actors instead of being limited to the strict sense of a non-governmental organisation. As the WHO became increasingly and frequently more related to non-State actors who would not, strictly speaking, be non-governmental organisations, it was necessary to update the normative legal framework for the relationship. To illustrate, one can observe that although the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA) classifies itself as an *international business association,* it was in official relations with the WHO before FENSA under this broad concept of a NGO.

Interviewee 4 also reiterated that the backdrop of the negotiations was the issue of funding, due to the large proportion of the budget that relied on voluntary contribution. It was also mentioned that the WHO has normative functions that could directly impact on highly profitable economic activities. The funding issue, alongside the normative functions, creates the perfect scenario for opportunities of conflict of interest to arise. The pharmaceutical industry was used to illustrate the argument. This context would be an additional reason for having a ‘clear, transparent, consensual framework to guide the Secretariat on how to relate in such cases and to avoid or minimize the risk of conflict of interest’. Finally, Brazil at that time was in favour of the replacement and perceived itself as among the main actors of the negotiations that ended up with FENSA approved. Other interviewees confirmed this protagonistic role.

For Egypt, the replacement of the documents by FENSA was ‘some sort of agreement among all the negotiating countries that we need new documents’ considering that the previous rules didn’t reflect the current reality which involves diversified actors playing a

very significant role. Consequently, the Principles of 1987 did not reflect the 'comprehensive and complex environment that the WHO is working right now'.

As mentioned above, the representative did not participate in the negotiations, given that the European Union countries did not have a coordinating position. Similarly, the interviewee from Norway did not know how the discussions on the replacement of the two documents by FENSA were conducted.

The diplomat from Germany explained that it all started with some Member States, including Germany, arguing that the WHO should have the opportunity to engage with all relevant actors in order to be able to coordinate and lead them. However, the German idea was not the Member States negotiating everything, 'line by line', which is what happened in the end. The interviewee also assured that it was only during the negotiations that became clear that FENSA would replace something, but it was not the initial goal, 'we did not start off by saying we need to replace something, but only through all the exercise we realised we already have something and that has to be replaced by FENSA. So there was no vote, but there were lengthy debates on that'.

Disagreeing with the German perspective, the United Kingdom declared that the replacement was part of the process, given that the WHO recognised that the 1987 principles were mostly outdated, and not enough to provide proper support to WHO in the 21st century. The UK interviewee explained that the origin of FENSA was some Member States' concern about WHO relations with the Private Sector, although it was not only this. Moreover, the WHO itself felt that a better policy was needed as the Secretariat was having problems explaining all the decisions taken. However, for the United Kingdom, a 'Pandora's box was opened as became clear that it was a much more complex and complicated process'. The interviewee pointed out that FENSA firstly started just with NGOs but then 'became clear that the main problem was not the NGOs but the private sector'.

The United States representative defined the discussion on the replacement of the existing documents by FENSA as 'a mess', which 'we did not expect, I do not think anyone expected it to be so big when it started, to be honest'. The interviewee explained that the broad context was the WHO Reform proposed by the former Director-General Margaret Chan. Consequently, several small reforms were also happening, on budgeting processes and transparency, and on priority setting. The interviewee then highlighted that a 'number of

those successes (…) happened because we, the US and Brazil could work together and I think as you can imagine, we are often on the opposite sides, especially historically'.

The interviewee also clarified that the private sector principles debated in 2001 were not agreed, but only 'noted by the Board and not approved or endorsed'. Thus, the discussions were regarding civil society and the private sector. Afterwards, some Member States proposed to also include the academia and philanthropies, mainly due to issues related to the Bill and Melinda Gates Foundation, given that its role as a large funder of the WHO was seen by many as 'an undemocratic situation where one funder who is not accountable to anyone, is driving a lot'. The interviewee assured that the initial idea of FENSA was to be the replacement or update of the 1987 principles and the guidelines for the private sector. However, it was not supposed to be a Member States' negotiation, it was meant to be an update process from the Secretariat, which would be informed and approved by the Member States.

When the interviewee from Zambia started to become involved with FENSA negotiations, it was already in the Member States phase. The Zambian perception is that the replacement of the existing documents by FENSA was a Member States move, because they perceived that:

> the organisation was being hijacked by a few entities and a few countries that were trying to influence (…) So we found problems with it because the documents were in place, but these things were going on (…) So the Member States started initiatives to try to correct the problems that were being faced because we found the Organisation malfunctioning. For example, if Bill Gates thinks we should work on devices, all of a sudden there was a big program. (…) The structure of the organisation was following the money".

Argentina answered that the principles 'were good and worked for a long time, but they were not enough, they were very general, they were very open, and the Member States wanted something more specific, more clear procedures'. Therefore, there was a consensus among the negotiating countries that they needed to protect the reputation of the WHO. With this in mind, FENSA was proposed.

5.3 Which Coalitions Could Be Observed During FENSA Negotiations?

This research started with the North-South cleavage hypothesis, based on Nitsan Chorev's book 'The WHO between the North and the South' (2012). Chorev (2012) focuses on the strategic practices organised by WHO governing bodies to balance the demands of nations from the Global North and South, once called developed and developing countries.

Therefore, the first hypothesis of this thesis is 'the North/South conflict that characterises WHO's evolution was reflected in FENSA negotiations, with the conformation of two groups of negotiators: developed and developing countries'.

The Brazilian interviewee explained that in negotiations both at the WHO and within the multilateral system as a whole, formal coordination processes do exist. In the specific case of the WHO, there are the so-called 'regional groups'. Brazil usually participates as part of the 'Americas' group, however, depending on the topics, a formation of other coalitions occurs, 'sometimes more transversal [the coalitions], but it is very variable and very dynamic even within the same negotiation. There are times when, in the beginning, you participate in some informal groups, informal conversations about certain topics (…), sometimes you switch groups, sometimes you do not maintain that coordination for others. So this is all very variable'. However, regarding FENSA negotiation specifically, interviewee 4 reported that 'there was an attempt to articulate with developing countries (…). And the other members too, they organised themselves into a European Group, African Group'.

One must consider the explanation given by interviewee 4, a Brazilian Ambassador who brought to FENSA negotiations the TRIPs agreement, negotiated at the World Trade Organisation (WTO) between 1984 and 1994:

> The issue of pharmaceutical patents was a defeat for the south at TRIPS negotiations(...) The pharmaceutical industry is so powerful that it was considered the drive of the negotiations (...) After that, a bitterness remained within developing countries, because we felt the defeat, that we were unable to negotiate properly, because many small countries were couldn't afford to "confront" the power of the pharmaceutical industry. Health is a central area and one of the largest budgets in any country. If you pick a fight with the pharmaceutical industry, the country would be weakened, especially if it is a country in Africa, not very rich. (...) As soon as the result came out, the "big octopus" was not very visible, it was a technical negotiation, only diplomats or lawyers in the commercial area who were understanding. But a few years later, and somehow linked to HIV/AIDS epidemic, the interrelation between the patent and the cost of the medicine became more visible than politically sensitive for everyone (...), because it was profit above public interest, human rights and health (...) [the rich countries] managed to create very strong and politically active NGOs, so the topic was highlighted on the agenda. With that, the whole issue of the influence of big companies and conflict of interests regarding public interest became a social movement (...), evidently the WHO became a bit involved because as an entity of the United Nations with a mandate to defend the public interest at the world level, obviously it was expected that it could not protect the interests of multinationals and corporate profits. WHO had to be sensitive. So, the South shift the claim to WHO and we started pushing so WHO could be place where we could slightly mitigate the focus on trade and focus on public interest.

The Brazilian Ambassador also explained that several confrontational dialogues between developing and developed countries occurred due to pressures from pharmaceutical lobby:

'so we suffered pressure from England, the Nordics, Switzerland, the United States and the pharmaceutical industry have a representation [at WHO] of the size of ours with 20 members, just to cover these forums dealing with issues with public repercussions and commercial interests'. Another argument presented was that health increasingly became one of the major areas of technical cooperation, and many poor countries rely on health aids from huge donors such as Norway, Sweden - influential countries within the WHO. These external dynamics, therefore, should also be considered when analysing the establishment of coalitions:

> If you go to WHO you will see that governance is not very multilateral. There are some countries that are politically active, for instance, from the South, there are Brazil, Argentina, South Africa, which are also active in trade negotiations. Then, you have, disproportionately, many countries from the Global North where, in general, there are the headquarters of large pharmaceutical companies, such as United States, England, Switzerland, Germany, Japan, Norway…, or they are home for pharmaceutical industries or they have scientific research capacity in the medical field, or they are important donors to poor southern countries. So, in reality, the debate takes place between around 40 countries, it is more or less the governance of WHO.

From Egypt's perspective, there were two main groups among the negotiating countries with a clear division. The first group was inclined to accept engagements with non-State actors but with enough precautions to prevent undue influence on the work of the Organisation. While the second group, although agreeing to avoid undue influence, believed that necessary criteria and necessary precautions were lacking. In this regard, the interviewee asserted that:

> So basically I can say (…) that the developed countries (…) have well established civil society and well-established environment for the work of non-state actors and non-State actors present a very significant partner in the implementation of the domestic policies. So they are already aware of the dynamics (…) that would make such engagement on the domestic level very easy. I think that this group was that group that didn't want to put any obstacles whatsoever in front of engagement between WHO and NSAs. While the developing countries from another side were agreeing basically that non-State actors have a very significant role to play, but we want to make sure that WHO is an intergovernmental organisation and is not going to be affected or unduly influenced by NSAs. But this idea was related to the rules of the private sector (…), so if we are going to have an engagement with the private sector, we need to make sure that the WHO was not going to be negatively affected.

When asked if it was a strict division and whether it permeated all topics of FENSA negotiations, the Egypt representative's reply was unequivocal: 'yes, it was a strict division and pretty clear'.

Although there are always coalitions of Member States within the negotiations at WHO, for Germany, unlike Egypt, FENSA was very comprehensive and, consequently, there were different notions and diverging views but 'there was no clear cut'. According to

interviewee 8, there are more important variables which are based on history and the national definition of democracy:

> I guess if you have nationally concept where you engage a lot with non-State actors and where this is seen as a principle or pillar of democracy, then you obviously start from somewhere else, then if you have a system where that doesn't exist. So I think there I would see the divide, whether that's north and south, I wouldn't know because they are enough south countries who have exact exactly the same history and have democracies where voices from non-State actors are consulted and heard. (…) In the EU there are some Member States who are very clear about where WHO's engagement with non-State actors should stop. And I think they are clearer than many countries from Latin America. So no, I think there is no clear cut. (…) I think that some Member States were more outspoken than others, so we expect that they are representing blocks, but sometimes that's not the case.

When asked to explain the dynamics of the coalitions established during FENSA negotiations, the German interviewee pointed out that Argentina played an important role and was supported by Latin American countries; in contrast the African group was not very coordinated. Moreover, while India and Brazil had strong involvement with the South network, the European countries were, as usual, coordinating their positions. It is important to note, however, that according to the European Union representative, the EU did not reach a consensus.

The German interviewee assured that coalitions depended on the specific item that was being discussed and this division was 'part of a show'. To illustrate, Latin America could not be seen as one homogenous bloc due to diverging views of the Member States who compete with each other. Another alliance mentioned was between Cuba and Iran.

The European Union interviewee does not agree with the idea of a North/South division; 'maybe it was in the past but it is not now'. The argument was that the BRICS would be seeking their agenda and that in many areas such as human rights, the European Union and South America 'are right much on the same page'. Thus, the alliances change depending on the paragraph.

For Norway, it is relevant to note that there was a general position in broader issues, and then some countries had specific issues they used to care more about. For the interviewee, in FENSA negotiations, the Member States were broadly divided into two groups. One group of countries which were 'sceptical towards the solutions that were gradually emerging with thorough procedures to be applied without exemptions or any sort leeway'. This group would broadly be the European countries, Canada, Australia and the United States. On the other hand, a group of countries was 'wedded to the notion of having a

waterproof legal system with extensive mechanisms for control, including a role for the Member States in overseeing even individual cases'. This second group was formed by Brazil (seen by the Norwegian representative as the key one) and was supported by countries from the GRULAC (Group of Latin America and Caribbean Countries).

When asked about a division between the Global North and the Global South, the interviewee from Norway said that perhaps 'it is a little bit too simplistic as of generalisations inevitably are, but certainly, I think the FENSA discussion very well brought out the general divides whistle in differences of an overall approach to the organisation'. Additionally, it was pointed out that a country's experience on how the WHO operated in their own country was an important variable. Thus, the second group would have a more critical view, considering that most of the western countries do not have WHO offices or actions in their countries. The Norwegian critical perspective, however, was that the other group failed to take into account the enormous volume of interactions that the WHO had with non-State actors and risked the mandate to an unworkable system that could compromise the ability of the Organisation to operate.

For the United Kingdom, 'polarisation fairly dominated the negotiations', and the western countries were mostly the European countries, except Russia, Canada and the United States. In contrast, Global South countries were India, Pakistan, North Africa, Egypt, Brazil, Central/Latin America, Cuba, Nigeria. Like Germany, the UK interviewee confirmed that there was not a clear African position as they split. Moreover, it was pointed out that some individuals were very active solely, and not as a bloc, like Ghana and Zambia. Furthermore, given that the European Union presidency changes every six months, different countries were more active depending on the date of the meeting. The interviewee, however, assured that although agreeing with the EU, the United Kingdom had its positions and speeches.

For the United States, the cleavage between the North and the South came out in some points 'absolutely'. According to the interviewee, 'broadly speaking there was an alignment of interests I think between the WEOG[83] countries on the one hand and sort of India, Latin America and Africa, on the other hand'. However, it was pointed out that, in contrast with the United Nations headquarters in New York, where alliances are very static and do not ever shift, at the WHO the coalitions usually shift.

[83] The Western European and Others Group (WEOG) is one of five unofficial Regional Groups in the United Nations that act as voting blocs and negotiation forums

The interviewee from the United States highlighted the role played by India, Bangladesh ('to a certain extent'), the African Group, and Brazil as dominant negotiators from the developing countries. On the North side, the US and the European Union were mentioned. To illustrate the less than strict division, the interviewee argued that the Americas worked together as a bloc, with support from Argentina, Colombia, Canada, i.e. developed and developing countries.

Zambia explained that coalitions are always formed, not just in FENSA, but in any negotiating table at the United Nations or the WHO. To illustrate, the interviewee pointed out that the European Union always negotiate as the European Union, even though each country may have 'little spikes of what they are interested in'. Another coalition that was mentioned was that between Russia, Cuba, Iran, and Venezuela who are 'always kind of working together' and also Africa that always negotiates together: 'we only stick joint positions because we have strength in numbers'.

Regarding the division between North and South, the interviewee from Zambia clearly assured that:

> There was a clear difference between what the developing countries wanted and what developed countries wanted. It was very clear because (…) if you look at this structure and start thinking, we never give a lot of money, we don't give an amount of funding to the WHO from the developing world. What we wanted as developing countries, for example, on the issue financing we wanted to increase our assessed contribution but the Western world blocked up because they're the ones who benefit from the earmarked funding. They're the ones with the staff going into WHO, they're the ones who are directing what WHO should do with your money. So, you know, we have differences there.

Although assuming the difference of position between North and South, the Zambian interviewee guaranteed it was not very rigid. It is significant to highlight that the interviewee was very critical about different treatments of the North and the South at the WHO: 'the South didn't get much at all, they didn't get the jobs, they didn't get positions (…) and yet the organisation was mostly working in the South. Everything that WHO does, it does in the South. You do not see WHO Europe doing anything (…), because the European countries do what they want and not what the WHO says'.

Still regarding the coalitions, the Zambian interviewee mentioned the BRICS and the eastern countries, specifically Southeast Asia, even though neither were seen as powerful or united groups. In the end, the interviewee admitted a division along developed and developing countries lines, as the African position was similar to South America and a bit

similar to East Asia ‘because there are a lot of resemblances with them, which do not happen with Europe or North America’.

Without mentioning any country specifically, Argentina just confirmed that FENSA negotiations divided the Member States between those who wanted more engagement and those who wanted less engagement. In this sense, according to the interview, ‘for Argentina, it was clear that we needed to have more interactions with different organisations’. When asked about a North/South division, the interviewee sidestepped by saying that ‘this North/ South issue is always present, but we try to avoid that’. However, in the end, they assumed the different positions taken by ‘those countries with more money for organisations or those who host NGOs or the private sector who was interested in having something more relaxed. And those countries with less private sector who wanted a more strict framework. I cannot deny that there was that kind of division’.

5.4 How Was the Involvement of Non-State Actors Perceived During FENSA Negotiations? Did They Try to Influence the Outcomes?

Interviewee 5, from Brazil, clarified that the WHO was suffering a progressive capture over the years by the private sector, what the Zambian interviewee referred to as a ‘hijack’. However, the private sector exercised its influence on the Organisation through developed countries ‘because they treat the interests of multinationals as a national interest’. On the other hand, there was an alignment between diplomats from developing countries and the organised civil society of rich countries:

> We, negotiators from developing countries, did not have allies in companies nor in countries with clear positions towards national interest. Nobody says it, but that's what Trump today verbalizes: America first. That is, whoever has strength/power, imposes their perspective/position although trying to disguise it as a global interest, but basically it is not. So who we had to support us? Organised groups from developed countries, which had structure, resources from other sources and did not depend on private sector companies. Therefore they could confront powerful companies. Moreover, civil society in developed countries had access to international media and managed to publish an article in the New York Times, in the Guardian. And we joined these movements as a way of counterbalancing our lack of negotiating power. They sometimes helped us in many positions that we were advocating because issues can be very technical, negotiators from poor countries are more unprepared and insecure. They managed to give us access to renowned professors from major American universities, so we wrote with them or held seminars presenting a perspective to defy a purely commercial vision (...) As a diplomat, if you don't have real power, you have to find alliances, find people that will listen to you and take you seriously.

For Egypt, all categories of non-State actor followed the FENSA process meticulously. Considering that all negotiations happened behind closed doors, NSAs tried to influence,

through the Member States, the Capitals or countries' missions in Geneva. It was the only way for them to put their points of view on the negotiation table. However, the interviewee argued that this was expected behaviour, as FENSA has the potential to impact NSAs' work directly. Some non-State actors, e.g. the Bill and Melinda Gates Foundation, donate millions of dollars to the global public health arena. Consequently:

> (…) we took on board as well because this affected our negotiating positions. Not in a negative way, but in a positive way because we stressed when we had these non-State actors trying to influence the capitals of governments, we working in our points of views that we want to perceive them reflected in the documents because of this, because they started to lobby and they started to try to influence the negotiating process.

Notwithstanding this attempt to influence FENSA negotiations, The Egyptian representative argued that this is normal in multilateral negotiations, and that 'in FENSA process, my personal judgement is that even with all the complexities that were surrounding the negotiating process, we managed to have a strong document that if properly implemented in WHO, it will protect WHO from any negative or undue influence'.

Although they could not assure it, the European Union interviewee did believe that non-State actors could have influenced 'at least in the initial stages, in the design phases'. When asked if non-State actors were trying to influence FENSA negotiations through the Member States, Norway argued that although it is a natural suspicion, it could not be confirmed.

On the other hand, the United Kingdom's perspective was that 'powerful non-State actors were lobbying for their own demands' during FENSA negotiations through the Member States as there were around 25 diplomats who were very active in health topics, 'probably because they get lobby from some companies'. Although the interviewee did not mention any NSA in particular, they affirmed that some NGOs in Geneva were writing the speech for developing countries 'like a script of what they should argue'. For the UK representative, this happened due to capacity issues and close work relations. In this same direction, the interviewee said that many probably thought that the private sector was influencing the UK, but 'this close relationship is a government policy. No one is going to write what we are going to say'.

The United States confirmed that several NSAs were very actively following the FENSA and cited as example IBFAN, the Third-World Network, the South Centre, and the NCD Alliance. Moreover, the interviewee claimed that the Third-World Network and South

Centre were ‘very close with India and helping to feed some of their thoughts in and their approaches in’. For the North American interviewee, some groups of NSAs wanted a ‘blacklist’ that would include not only tobacco and firearms but also alcohol, food and beverage companies and some other companies, such as Big Pharma. Hence, there were a lot of debate and coalitions regarding this issue, which included some of the ‘most active NGOs’ such as IBFAN and the Third-World-Network. These discussions relate to paragraph 44 of the FENSA document and will be further analysed in this chapter.

Additionally, the interviewee from the U.S believes that in the first phase of FENSA negotiations when the non-State actors were more involved, they were not very strategic ‘because they were coming at it very aggressively from their side. And once we went to the Member State portion of the negotiations, it went back to the normal, diplomatic way. And then they still provided input. They would meet with us outside of the room (…) we would meet with everyone, and it was very helpful’. IFBAN and IFPMA were explicitly mentioned.

For Zambia, the NSAs were undoubtedly trying to influence FENSA negotiation behind the scenes as they would be alarmed by the new rules. Although assertively declaring that FENSA was strictly a Member States agenda and that non-State actors were not allowed to participate, the interviewee, similarly to the Egyptian interviewee, affirmed that non-State actors were trying to influence through the Capitals. Moreover, the Zambian representative also confirmed that this happens in every resolution: ‘the non-state actors feel threatened or want to influence Member States position because they have no space at the table’. As NSAs are never allowed in the negotiation room, they try to exert influence through national governments. As an example, the interviewee said that in the western countries, the pharmaceutical industry probably thought they were under threat, therefore they were possibly influencing their governments, which perchance buckled as ‘they cannot shoot themselves in the foot, and nobody is putting things that destroy your industry and your interests’. Thus, non-State actors can influence the agenda and the negotiations at the United Nations in any resolution including FENSA, they never did it by sitting at the negotiation table or standing at the corridors. They have to act through the Member States.

Regarding how non-State actors were acting among themselves, the interviewee from Zambia assured that as the private sector and NGOs have more to lose, and the decisions of the WHO affect them greatly, they were more active and more organised, because:

> they [philanthropic foundations] have the money anyway, so you follow that and you engage with them (…) if you don't want money from philanthropic organisations, do they lose anything? No. If you don't want to engage with academic institutions, do they lose anything? No. But the private sector and NGO was found to lose a lot from the engagement with the organization. So those two yes indeed were the most interested in this negotiation and process.

Not only for FENSA, but in many negotiations, NGOs are usually more organised as a group to work together, while the private sector, even within the same group, is not synchronised. However, there is a big split within NGOs as they see each other as competitors. For Zambia, the NSAs must be better coordinated because 'it is difficult to listen and to work with one entity; therefore, the more fragmented they are, the more their voice is not strong;.

For Argentina, as the chair of the negotiations:

> I was always open and I received anyone who wanted to see me, I had four maybe five meetings with different private sectors, maybe one NGO that was concerned about what we were doing. But to be honest, I never felt pressured or influences in some way to do one thing or another. (…) And I'm not saying that they were not worried and they were not always around, (…) but, I never received direct pressure, I just received some comments.

The interviewee, however, assured that NSAs did not try to influence the negotiations behind the scenes.

5.4.1. With Which Non-State Actor Did the Member State Have Closest Relations During the FENSA Negotiation?

As already mentioned, Brazil confirmed having had close relations with civil society from developed countries and cited some NGOs such as the Quaker United Nations Office, PAX and the South Center.

Egypt used to have informal meetings with the so-called watchdog organisations which, according to the interviewee, although they 'do not have the capacity or the aptitude to engage on the same level like, for example, Bill and Melinda Gates, a philanthropic foundation that has a very significant role right now in engaging with WHO, they were keen to follow the process very carefully'. In these meetings, the NSAs used to underline the problems they saw in the text. The interviewee, however, assured that the country did not adopt these watchdog organisations' views 100%, because 'at the end of the day, they represent a non-state actor and we are representing governments. Governments usually have their own views while they might hear the voice of non-state actors'. Moreover, the Egyptian representative highlighted that various non-State actors were interested in FENSA negotiations and were coordinating particularly with developed countries how the framework

could impact their work. ‘But as a developing country, I think our basic engagement was with these watchdog organisations’.

Regarding the allegation that non-State actors were trying to influence the Member States in their capitals, Egypt affirmed that ‘[I] used to regularly feedback our Ministry of Health back in Cairo and I'm sure they used to communicate with domestic non-state actors, I'm not really familiar with the outcomes of such kind of consultations, but the Ministry of Health used to support all the views that our mission had in the negotiating process’. The interviewee also mentioned that the United States contacted the Egyptian Ministry of Health at the level of capital to make sure their views were well known to the team in charge of FENSA. These views, however, ‘were somehow not all in agreement with views taken by a developing country in Geneva’.

Germany assumed close relationships with all non-State actors, and not only those related to health or global health topics, since ‘anybody who is affected by German politics has to be consulted’. Therefore, the German government comprehensively engages with non-State actors through consultation, recommendations, among others. According to the interviewee, ‘that's part of the German overall policy line, we are in favour of hearing the voices of civil society as well as academia, as well as the private sector as well as potentially the elderly, vulnerable groups, they are all part of our democracy model’. For this reason, Germany does not distinguish different sectors, although being aware they have specific interests.

According to the European Union, the bloc does not have ‘any favourites’ and usually accepts requests for meetings no matter who is making the request. The interviewee said that before one World Health Assembly, the EU organised a meeting and invited civil society based in Geneva, including NGOs, industry and foundations. The EU asked the WHO for a list of non-State actors that could be invited, so that the EU member states could hear their views before finalising their positions. The WHO, however, did not provide the information.

The United Kingdom interviewee affirmed to have spoken to many NGOs and institutions that were influencing Member States’ positions, without explicitly mentioning anyone. Interviewee 7 stressed that this is how diplomacy works, ‘we spoke to them, informal conversations outside the negotiations table, in small groups to try to make progress outside the room’.

The United States admitted to have always been interested in meeting all interested stakeholders. During the FENSA negotiation process, the government individuals met with public-interested NGOs such as the Third-World Network and the NCD Alliance and also with IFPMA and IFBA, part of the private sector. It is important to note, however, that the IFBA does not have official relations with the WHO. Regarding the Bill and Melinda Gates Foundation, the interviewee said the US and the Foundation:

> (…) kept each other informed, but I would say they were less engaged in FENSA. Their attitude throughout it was that this is a Member State decision and that they'll abide by whatever the Member States said. And I think that was actually a helpful position that they took because they already have kind of conspiratorial feelings toward that. So, it was good that they took a hands-off and supportive approach (…) But we also worked very hard to make sure that FENSA wouldn't break them. And I'll be honest (…) I remember one conversation with my Brazilian counterpart at that time, we wanted to increase the transparency, increase the pressure on them, but we don't want to kill the goose that lays the golden egg. Because we can't, none of us can afford to pay to the money that Gates pays to WHO.

Zambia claimed to be home to all non-State actors at the domestic level, but these non-State actors do not play key roles in the UN as they are more focused on local issues. The interviewee explained that the huge non-State actors, such as the Bill and Melinda Gates Foundations, are 'active on our ground'. Therefore, the country does not have NSAs to request how Zambian diplomats should negotiate. Therefore, Zambia's positions on FENSA were based only on '[their] principles of a truthful and responsive Organisation'.

As the chair of the Member States negotiation phase, Argentina confirmed that it talked 'mainly to the private sector and one NGO'. The interviewee, however, explained that most of the time, NSAs were requesting information. Regarding the private sector, interviewee 13 affirmed that 'we would not see that they were very well briefed or very well and prepared to see me. (…) They had some general ideas, and they wanted more information'. When asked about the Bill and Melinda Gates Foundation's involvement in the FENSA process given their massive donations, the interviewee assumed that the Foundation was following closely, but 'I assume that they acted through the national delegates. Probably they have contact with their own delegates or delegates from different countries (…) So, they have sent their representatives from the countries, or different countries to come to the negotiation through the delegations. That is totally fine'. The interviewee also stressed that no non-State actor tried to influence the process through the Chair.

5.5 Which Issues of FENSA Were Seen As Of Particular Concern?

For Brazil, the critical point during FENSA negotiations was the relationship between the WHO and the private sector, as it was a diffuse relationship, due to the lack of clarity exhibited by the Principles of 1987, which raised doubts if industries were also embraced as business-oriented NGOs were in official relations with WHO. Therefore, the establishment of rules that would cover the relationship with the private sector was the most important and most sensitive topic, according to the interviewee, because it was the point with the most room for conflicts of interest, undue interference, and manipulation of the WHO Agenda for purposes beyond its objectives or the interests of the Member States. The Brazilian representative also mentioned another important element, not only for Brazil but also for the Latin American countries - the adherence to FENSA rules by the three levels of the World Health Organisation, namely, at the global level (the headquarters in Geneva) and at WHO regional offices and country offices.

For Egypt, the fundamental issue was conflict of interest: 'WHO is the international organisation responsible for putting the norms and standards for global public health. If we open the door for any non-State actor to influence this process, then we have undermined the work of WHO'. This principle, therefore, should be reflected through the FENSA document for any engagement. To enable this, safeguards and precautions against conflict of interest might be implemented. Thus, just the same as Brazil, the Egyptian interviewee asserted that the conflict of interest was a concerning topic when considering the private sector.

For the European Union, despite not being part of the negations, the different categories of actor was a point of concern, as the focus was relying more on the idea of risk avoidance rather than risk management. 'I see no problems inviting industry into a meeting, as long as everybody knows this is an industry. You have to listen to what they are saying with the filter, knowing where they are coming from'.

Germany pointed out that paragraph 44 'WHO does not engage with the tobacco industry or non-State actors that work to further the interests of the tobacco industry. WHO also does not engage with the arms industry' was controversial; this was confirmed by the United States' interviewee. Moreover, the German interviewee also mentioned the conceptual discussion on undue influence, different interests, groups and:

> this major diversion in between the Member States as some of them wanted to enable engagement but safeguards WHO reputation and WHO independence. Others didn't

> want engagement, they wanted to cut engagement. So that was a heavy debate. And I think there was also a debate, but that was at the very start, whether there should be one framework for everything or whether there should be different approaches to the different types of non-State actors.

To Norway, the broad capacity for implementation, the effectiveness, and the cost of FENSA were the most important, as was the impact on the WHO's ability to operate, in particular in a health crisis context: 'finding a type of arrangement that provided increased security against undue influence by non-state actors, but at the same time did not hinder WHO's interaction with the kind of non-state actors we wanted the organisation to be even more able to interact with'. Lastly, the interviewee pointed to the application of FENSA in regional offices, highlighting PAHO.

For the United States, paragraph 44 was 'the biggest thing' as 'there was a lot of concern in Washington that some countries would push for an expanded blacklist of companies. And some even did actually saying at certain points, like pharmaceuticals should be on that list or something because of their market behaviour (…) we pushed back very hard on as it would just be too crippling for the organisation'. The interviewee also mentioned the specific policies of the four non-State actors. In this regard, 'we fought very hard for the information coming in [to] be treated the same. Basically, the text in the four policies should be the same for the information coming in'. The interviewee also argued that although agreeing that the Expert Committee and the Secretariat should be clear-eyed and unbiased about the information, 'if it's coming from industry or from the civil society or from advocacy groups (…) they have to be aware that's coming from that point of view, but we wanted all the information treated the same, we don't want a front door for the good information to come in and the back door for the bad information. Information is just information'. The country advocated that the Member States should trust that the WHO's experts would sort the right and useful information.

Zambia wanted a functional organisation:

> Meaning that if we do pass the resolution, that resolution should be implemented, at least 90, 80, 70% should be implemented. We wanted an organisation that was leading health and leading health in the modern era was not speaking to the 1948 agenda. The world has changed. We need an organisation that could be responsive and we're trying to go into partnership. In the new era, you can't move forward without partnerships.

The interviewee highlighted, however, that although the engagement was seen as essential to implement the resolutions, it should be pursued and done 'with caution, with integrity,

engage not with special interests'.

For Argentina, the main concern was having a balance between 'trying to regulate the engagement, but not to stop people, not to complicate. So we wanted transparency'. According to the interviewee, the WHO is a "huge bureaucracy", hence, it is difficult to get information, especially for those Member States with limited resources. Argentina, therefore, as the Chair of the negotiations 'wanted to promote a more transparent process'.

5.5.1 Distinction Between the Different Types of Non-State Actors

Brazil was in favour of differentiating the non-State actors, and its most significant concern was with the private sector. According to interviewee 5, the country also had some reservations with philanthropies, since the Gates Foundation, by acting like a 'parasite' had attached itself to the WHO, representing about 10-15% of the Organisation's annual budget and making the WHO dependent, even concerning other projects - not only those financed by the Foundation. The Brazilian interviewee admitted to having a bit of concern with the academic sector as it is very government-related and receives a lot of money typically from companies. They had no significant worries with NGOs.

For Egypt, the idea of separating the different types of non-States actors was raised at the beginning of the negotiations, but the Member States opted to have an overarching framework to be fully applied to the four categories of non-State actors. However, taking into account that each non-State actor has its own domain of work as well as its own dynamics of interacting with the WHO, and its own, separate interests, it was decided to have separate documents for each NSA. The interviewee pointed out that apart from the four specified groups of non-state actors, Egypt sought to insert think tanks as the country sees them as players with a very significant role as well as being funded by the private sector or philanthropic foundations. 'So we were keen to have reference to think tanks to make sure that if these think-tanks are reflecting in their academic studies a specific point of view, then we should be careful when there is engagement with think-tanks that are supported by the private sector or a philanthropic foundation'.

For Germany, this topic was polarised into 'who is the good one, who is the bad one'. According to the interviewee, the Member States were taking positions in light of their culture of engaging with non-State actors domestically, therefore the focus was not only in the interests of the private sector, as for other countries civil society groups would be more

challenging. This argument is in line with the Zambian interviewee, who pointed out that NGOs are domestically problematic. Germany's point of view, given internal politics, is that nobody comes free of any interest: 'nobody - apart from democratically elected representatives who represent the people -, neither civil society nor academia, nor private sector, nor foundations. So from that point of view, they are all one group vis-à-vis the non-State actors (…) So that notion to argue that the private sector is always coming with commercial interests while others come with the right interests I think that is not real'. Germany, consequently, was advocating for the same standards for all NSAs.

Norway confirmed that the distinction between the categories of NSAs was an issue that indeed provoked much debate during the negotiations and 'we spent an entire day on two paragraphs of that (...) I think we ended up with a fairly rational result on that in the end. Certainly, one that we could live with'. The interviewee explained that the WHO needs to work very closely with research and academic institutions given its role as a leading normative organisation. Therefore, if the Member States decided to limit the WHO's ability to work with institutions that are privately funded, it would be a problem as 'quite a lot of the best academic institutions of the world are privately funded'. The same argument was used for the development of vaccines, and to conclude affirming that 'there is simply no way of avoiding interaction with private entities. You have to take that into account. There has to be a pragmatic balance, and you have to interact with things as they actually exist. Rather than we would have ideally liked them to be'.

For the United Kingdom, the WHO should be able to engage with any relevant organisations. They were also concerned about the parity between NSAs because if the Member States decided to have different rules, they would need good reasons to justify. Therefore, a common framework should apply to everyone, and it was essential to be clear that there was parity in the requirements. The interviewee asserted that there was a clear division between delegations that wanted different requirements for each NSAs and those who wanted parity and advocated that the WHO should be able to engage with any organisation as long as they had compelling reasons for that. 'Sometimes you need to talk to bad guys to do good things'. Moreover, the British interviewee clarified that while the western group wanted a more homogeneous framework, India wanted clear differentiation between NSAs.

For the United States, the distinction between the different types of non-State actors 'was another big fight that we have spent a lot of energy on'. The interviewee explained that some countries (without mentioning any in particular) were trying to set out 'even clearer distinctions' while the US wanted 'to protect public-private partnerships and not to penalise different entities'. Although 'personally agreeing' that there are different risks among non-State actors and assuming that the power asymmetry is real, 'it is not practical, it is not realistic'. Therefore:

> What we tried to do with FENSA and with the four policies was to keep the symmetry where it made sense, like on the information, but to allow differences. So for example, we did allow the exclusion of private sector representatives from expert committees (…). So we did recognize that there needed to be places where the private sector was treated differently, but we just tried to look at each of those particular scenarios and situations on their merits and not on whether is it just private sector.

Zambia confirmed the contentious debate among the Member States regarding non-State actors being treated differently, 'I remember there were some publications, kind of social media from India who always wanted to demonise private sector'. Zambia, however, did not agree with the idea of treating non-State actors differently because, domestically, the country has more problems with NGOs. The interviewee went on to clarify:

> only the Western world does not have problem with NGOs because they finance NGOs, they give NGOs the agenda of what they should do, and most of them are working in the developing countries (…) So, we have had problems sometimes with NGOs on the country level because they push an agenda that is of other interests (…) we found them (NGOs) to be just as problematic, even more problematic because you have no accountability mechanisms that we can monitor.

The Zambian interviewee also argued that while the debate was guided by the argument that the private sector is only driven by profit interest, 'from our perspective, we knew that NGOs were also driven by money. They use the money of the agenda that they push; they do not push the agenda of the need. They may use the needs on the ground to get space in your country. But what they do is deeply guided by who is giving them money and they're not accountable'.

Argentina confirmed that some countries wanted to put Food and Beverage industries in the same no-go list as arms and tobacco. The country, however, was against it and wanted something more general, instead of having a list of prohibited sectors, to have four policies 'with the main characteristics to separate the four categories'. According to the interviewee, Brazil proposed to have the differences among the categories, but it was before the Member States phase of the negotiation.

5.5.2 Secondments

Given that a seconded individual turns into regular staff, even though the releasing entity keeps the responsibility to pay remuneration, secondments raised fears of potential conflicts of interest during FENSA negotiations. To this regard, in December 2015, the Third World Network criticised secondments from philanthropic foundations, specifically the Bill & Melinda Gates Foundation and the United Nations Foundation, to 'top management positions at the World Health Organization'.

According to a leaked document released by Baby Milk Action in December 2015,[84] there were nine secondments from NGOs, philanthropic foundations and academic institutions in 2015. The document also revealed that between 2012 and 2015, the WHO did not have secondment from a private sector entity. The final version of FENSA, however, only prohibited secondments from private sector entities.

Interviewee 5, from Brazil, while arguing that secondments from the private sector indeed represent a 'ridiculous quantity', the number is small but the influence is not:

> Things are done indirectly, subtly. So it is fair to say that in numerical terms, private sector has never been so important. But anyway it was important to block them, even though blocking would not prevent their influence as they have other ways of influencing. They take part in all projects of any disease, promote workshops, seminars, informative material.

Nevertheless, it is worth pointing out that the private sector can finance secondments through programmes. The interviewee gave, as an example, the Junior Professional Officer Programme, which annually seconds approximately 120 individuals from Member States. Hence, pharmaceutical industries finance Sweden, Denmark, and other developed countries, which, in turn, sponsor young people who stay for a year or two:

> [young professionals seconded at WHO] already know everyone, they already know the opportunities that will open, it is a totally biased system to integrate labour. (…) and it is a way they [private sector] have to keep feeding the staff with new people, with their people. And when it is claimed why there are no Brazilians there, it is because Brazil has no money and does not finance these young interns.

Zambia had a similar argument towards internships at the WHO and how different developed and developing countries were treated on this topic.

Germany was against this decision as 'there should not be any secondments that seemed naive and odd, and although this forbiddance was not its viewpoint, the country

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[84] Available at: http://www.babymilkaction.org/wp-content/uploads/2015/12/FENSA-secondment-table-9-Dec.pdf Accessed on 28/11/2019

accepted in the spirit of compromise'. Interviewee 8 argued that Germany was, and still is, favourable to secondments from all non-State actors. However, 'obviously we would not be in favour of having a thousand staff members being seconded, and one would have to ensure that there is no undue influence when it especially comes to norms and standards-setting from non-State actors'. To illustrate, the interviewee affirmed that:

> During the negotiations, it became clear that the Gates Foundation was seconding one or two staff members to the Polio eradication initiative, which is a program under WHO. And that was then seen as a major scandal while also there the Gates Foundation has invested billions of dollars into the polio eradication initiative. It seems strange then not to allow seconding someone to the organisation if they are not writing norms and standards. So we believe it's possible to handle these potential conflicts of interests.

The United Kingdom was supportive of secondments and did not agree with the FENSA final version of not accepting secondments from the private sector. The interviewee described it as a regrettable decision. The country's broad position was of bringing expertise 'from wherever they are, by forbidding secondments from the private sector, a potential source of expertise and network can be lost'. Finally, the interviewee posed the question that if secondments happen at the national level, why could they not happen at the WHO?

For Zambia, like Brazil, the secondments were problematic because the WHO was only accepting many secondments from the Western countries, from academic institutions, from philanthropic organisations, 'even from governments (…) and secondment was based on who can finance it. And that's not fair; you know that in this world not everybody has money'. To illustrate, the interviewee talked about the internship programme at WHO:

> [the internship programme] was problematic, because WHO never found resources, which they could if they wanted to find resources that would pay for the interns when they come to do their internship in WHO. But, our people in the South don't have the capacity and money to come and live in Geneva. So they never could come and do internships and because they don't have that experience in WHO and in the UN, when they apply for jobs they never get accepted because (…). If you went to WHO the interns you found were only from the west. I think WHO is a little bit opening up and is offering a little bit of payment for the interns and is also trying to make it a little bit more universal, so interns come from everywhere.

The interviewee also explained that another problem with secondments at the WHO was that people would switch immediately from a seconded position into being full staff, which was clearly in unfair competition with qualified people outside the organisation. Zambia suggested a gap between the secondment and the job and proposed a two year gap before the seconded person could be considered for a position as staff in the WHO. For the Zambian interviewee, the issue with secondment was mostly to do with fairness.

Additionally, seconded staff may allow donors to influence the organisation and, consequently, influence other countries.

Zambia, however, did not agree with the FENSA final version which banned only secondments from the private sector: 'When I was in WHO there was not nonsense like that, everybody wants to be treated the same. So as I said, whether they came from governments, they came from any other non-State actor, they were putting money into WHO as earmarked funds, that money came with human beings as secondments'. The interviewee ended by asserting that secondments in the WHO were unfair and a way to elevate people with their own agenda and interests, which were not the same as all Member States. 'WHO must work on what Member States vote to do and not what a country or an NSA alone wants'.

Argentina highlighted that 'a long debate, mainly around transparency' regarding secondments took place during the negotiations. The interviewee explained that it all started when the Member States requested a list of the seconded organisations of the Secretariat and 'realised that they did not have a list of the organisations. So we started to request information (…), and then we discovered some secondments from the private sector in the organisation (…) then we decided we wanted a clear policy of this. But during FENSA negotiation we decided that would deserve another process'.

In this regard, it is important to note that the FENSA final version, in paragraph 3, demanded of the Director-General:

> to develop, in consultation with Member States, a set of criteria and principles for secondments to WHO from nongovernmental organisations, philanthropic foundations and academic institutions and to submit the criteria and principles for the consideration of and establishment by, as appropriate, the Seventieth World Health Assembly, through the Executive Board, taking into account, among others, the following identified issues: (a) specific technical expertise needed and exclusion of managerial and/or sensitive positions; (b) the promotion of equitable geographical distribution; (c) transparency and clarity around positions sought, including public announcements; (d) secondments are temporary in nature, not exceeding two years."

The Director-General, in fact, presented at the Executive Board 142, in January 2018, a report on 'Criteria and principles for secondments from nongovernmental organisations, philanthropic foundations and academic institutions'.

5.5.3 Emergency Crisis

As analysed in Chapter 2, the World Health Organisation was hugely criticised during the Ebola outbreak. In this regard, it is important to note that FENSA negotiations were

happening for a while, alongside the epidemic. During some interviews, the topic of Ebola emerged as a variable which could have influenced the positions of the Member States.

For Germany, even though Ebola didn't play a significant role, it, in fact, influenced how the WHO should engage with non-State actors in cases of emergencies. In the end, the solution was that in an emergency, the WHO has to act and use all the support it could get. Practically, it means that FENSA should not be a deterrent for the WHO to engage in crises as 'in a case of emergency you do not have time to a lengthy process'. The interviewee also mentioned that even though there was some controversy about this emergency clause, there was an overall consensus that the main focus regarding the engagement with non-State actors was the normative and standard settings, which are not linked to health emergencies.

Crisis response, however, was a topic that made Norway 'seriously considered blocking it (FENSA)'. For the interviewee, the Ebola outbreak revealed quite serious shortcomings in how the WHO used to operate in a health crisis context and, therefore, the sort of changes needed in its methods for working with emergency situations also extended to the general humanitarian work. The Norwegian interviewee explained that the previous system required the WHO to do 'a sort of eight-week procedure every time they were going to talk to an NGO in the field', which seemed incompatible with the required speed of operation and field flexibility. The country, therefore, was advocating for a language that would create an opt-out for an emergency context that would enable the WHO not to apply FENSA in a crisis response operation. Thus, it was 'an absolute precondition for delivering FENSA (…), this was kind of a complete red line for many countries'.

For the United Kingdom, the Ebola crisis was essential in showing that the Member States should seek an enabling framework instead of a prohibitive one: 'when Ebola started, this entire tension shift as it could be seen that it was not Western position but the reality'.

According to the United States, elaborating an emergency response took much effort and required separate negotiation. The interviewee pointed out that the main opponent for more flexibility on FENSA in cases of emergency was Iran, along with 'a few, very few countries supporting so that they were not alone'.

> (…) in fact, what I should also do is put Switzerland and a little bit UK on the spot in that emergency negotiation as well. They were for it, but they were for an extreme version. So, they were making a deal impossible because they were not interested in giving Iran any kind of assurances. So what Iran was kind of asking, for example, was some basic notification from WHO that the flexibilities around FENSA were going to be used in X response that's in the region or something like that. And I think

> we got to something fairly like that with very flexible implementation instructions that basically leaving it to the discretion of the DG how to do that. But the Swiss and a few of the other Europeans at first didn't want to have any of that, they wanted just a full carve-out with no caveats. So that's the main challenge, actually, bringing them together. And I think it was Norway actually in Switzerland in particular.

Interviewee 9, however, did not mention Norway, which, according to media reports and to the Norwegian interviewee itself, was the leading country on the issue. The topic was so contentious that the former DG Margaret Chan had to return to Geneva earlier from the Paris climate negotiations to try to help broker a deal. 'It was super crazy and very difficult because we wanted to make sure that in emergency situations, the paperwork could come later'. Given that the WHO was hugely criticised during the Ebola outbreak, the interviewee argued that 'we did not want FENSA, one good thing, to create unintended consequences in future emergencies'. The interviewee also explained that the United States and South Africa were leading the subgroup, which was discussing the emergency crisis as both countries had led the Ebola special session negotiations on the health emergencies work.

For Zambia, the Ebola outbreak did influence FENSA debate and the Member States' positions. Zambia was leading the African states, and they 'were not very happy with the response, the speed of the response, the nature of the response. We are also not very happy that they use some of the response to do things like testing vaccines that are not proven to be effective at all, just because it is an emergency situation'.

The interviewee reiterated that when people are dying, no one is able to see if help is coming from the private sector, if ethics are going to be followed or not. Therefore:

> When you want to come up with a new product in medicine, it goes through a lot of rigorous processes, but because of the emergency, you throw away all those ethics for the name of trying to save lives. But for us, we know that in this world there are many governments that have done experiments with other people. And I can't remove Ebola from that topic. It's possible that an amount of experiments were done with our people, using the Ebola outbreak as an excuse. So yes, it did influence FENSA negotiation for the emergencies and shipped the discussions. But we were stuck between the devil and the deep blue sea.

Thus, for Zambia the guidelines should not be flexible in an emergency context as 'they [the rules] should be solid, emergencies come and go'. In the end, the Western countries were:

> trying to make us back them on certain positions so that we can solve [the deadlock], because we were crying that we needed these emergencies to be addressed, but you have to be flexible with this, otherwise, we will not have any way to help in an emergency (….) There is no way it can follow the regular process of FENSA because it is cumbersome, it is long, and you need a response very quickly. So how do we do that? So they used that to push the agenda. But overall, it was like I said, it was a fleet situation, too tricky things going on at the same time. So it was very difficult. Ideally, we would love, we would have loved that negotiation with FENSA to place

> without the outbreak but it was there so it did influence, unfortunately.

Argentina occupied a definite position on the 'emergencies' topic, which resulted in discussions and disagreements between the Member States. According to the interviewee, 'we wanted FENSA to be applied, but we wanted flexibility. For us, it was not possible just to say if there is an emergency that will not apply at all. But we wanted some flexibility, some reasonable flexibility, because when you have to respond to an emergency, then you cannot go through the process, that's clear'. The Chair of negotiations stressed that while some Member States were not delighted with the flexibility, others wanted to suspend FENSA at all during an emergency, 'but for us, that was very risky. So we negotiated some balance. I think, in the end, we managed to find a flexible solution for emergencies'.

Paragraph 72 of FENSA states that 'when responding to acute public health events described in the International Health Regulations (2005) or other emergencies with health consequences', the Director-General must act in accordance with both the WHO Constitution and FENSA, however, 'may exercise flexibility as might be needed in the application of the procedures of this framework in those responses, when he/she deems necessary, in accordance with WHO's responsibilities as health cluster lead, and the need to engage quickly and broadly with non-State actors for coordination, scale-up and service delivery'.

5.5.4 PAHO and Regional Offices

When conducting the document analysis, the Pan America Health Organisation (PAHO) was not perceived as an important topic; however, during the interviews, it could be observed that the PAHO was a 'thorn in one's side', especially for the European countries.

Interviewee 5, from Brazil, confirmed the contention surrounding the PAHO and said that Europe wanted to control it from Geneva.

> PAHO is our domain, we are in charge, we did not want a straitjacket (…) PAHO and the regional governments have great permeability and we are beyond the central control from Geneva. (…) This is another tension between the centralised control by WHO of its regional arms and the regional arms not wanting to be controlled by the "mothership". Because in our region, we want Latin American standards and a certain regional protectionism, we don't want the Nordics to have the same influence they have in Geneva. So that tension did exist.

Egypt confirmed that 'European countries had a concern that they might be buying FENSA and (…) and PAHO might not do the same. They were seeking some sort of a guarantee that this document is going to be applied to all regional offices, including PAHO'.

For Germany, the PAHO was part of the starting point as 'whatever we decide here

[WHO Headquarters] should also apply to PAHO, clearly'. The interviewee argued that the Europeans were concerned that the Latin American countries, that were so outspoken in negotiating FENSA, could not have the Framework applied to the entire region. So, the German perspective was that FENSA should either apply to all or nobody. It was an unequivocal position as, according to the interviewee, some Member States were only focusing on headquarters and 'for us that was unacceptable because WHO is one organisation, so if we set up rules for WHO then they apply to the entire organisation'.

Zambia agreed that the PAHO became an issue during the negotiations, as almost all the Member States wanted the FENSA to be applicable at all levels and in all regions:

> We actually find the whole PAHO policy to be kind of double standards. We don't like it. It's only the people at PAHO who like that - it's not only the FENSA resolution, it's every resolution. If we design something in Geneva, it doesn't get automatically implemented in PAHO. Somehow PAHO has the seed to do it again or say we can do it or not. So why should they have that flexibility when all of us do not? Because it was kind of a hypocritical for the PAHO Member States to come and push a lot of things there when they not even are going to implement in the region. Or even take very strong positions there when they knew that may not be applicable and they can change it.

The interviewee also reiterated that all WHO regional offices have autonomy, and they could also make their own decisions, but instead they were all following FENSA.

Argentina also confirmed that, given the PAHO is older than the WHO, with different conditions when compared to the other regional offices, 'PAHO always feels that they deserve different treatments'. Moreover, as already affirmed by the Brazilian interviewee, the PAHO works effortlessly with the region, therefore 'in many policies that WHO decides in Geneva, PAHO thinks differently. Mostly because for PAHO, the region works together'. Regarding FENSA negotiations:

> at the very beginning, we are that region, we knew that this problem existed. So we invite invited PAHO to participate in the negotiation. We invited all the regions, but we invited specially PAHO. And PAHO said, "maybe later, now you work in Geneva, then we see what we do here in our region". And that was uncomfortable because the Member States from our region were being very active. (…) and it's very difficult to say, okay, we're going to approve something that would be good for Geneva, but we don't know if it's going to be good for PAHO. Then, PAHO finally started to participate in the conversations because we insisted them to come. They started to meet us, the Member States of the region, to do some analysis, some papers and discussions that they were very useful (…) And finally, when we approved the document in Geneva, PAHO was the first region that started to apply FENSA. In the beginning, they tried to approve something different, something adapted to the region, but our commitment in Geneva was that all regions would apply the same way, that no regions have the right to change FENSA. And it was actually the first region after the approval that started to apply.

In order to hear a counterargument, I contacted PAHO three times (12/06/2019,

02/07/2019 and 17/07/2019), without response. According to the document CD55/8, discussed during the 68th Session of the Regional Committee of WHO for the Americas in September 2016, four months after FENSA approval, due to the PAHO's independent legal status:

> once FENSA was adopted by the World Health Assembly (WHA), it would not automatically apply to PAHO until such time as PAHO Member States expressly approved and adopted it through PAHO's Governing Bodies (…) Having considered the implications for PAHO to implement FENSA, PAHO Member States at the 69th WHA in May 2016 committed to adopt FENSA through PAHO Governing Bodies in a manner that respects PAHO's independent legal status as an international organisation. Accordingly, PAHO Member States understood that certain accommodations and adjustments to FENSA would be required, but that these would not affect the substantive provisions of FENSA or prevent coherent and consistent global application. The required accommodations relate to matters of PAHO Constitution, e.g., oversight by PAHO Governing Bodies and decision-making authority resting with PAHOs Director. These are imperative, as PAHO must retain responsibility over those activities for which it has legal and fiduciary obligations, such as its engagement with non-State actors, i.e., the same way that PAHO independently enters into agreements with State actors, PAHO must retain authority to review, analyse, and make its own decisions on this Organisation's interactions with non-State actors. PAHO's Secretariat will work closely with WHO's Secretariat in the implementation of FENSA. (…) PAHO Member States should note that the FENSA document adopted by the 69th WHA also modified WHO's process for granting nongovernmental organisations (NGOs) the status of "Official Relations". It is therefore proposed that PAHO Member States follow similar procedures for granting NGOs "Official Relations" with PAHO. (PAHO, 2016, p.2-3)

In the end, the PAHO was the first regional office to adopt and implement the Framework.

5.5.5 Industries Affecting Human Health

During the preliminary interviews, it was noted that paragraph 44 had raised many controversial perspectives during FENSA negotiations. In the initial version of the Framework, paragraph 44 was 'WHO does not engage with the tobacco or arms industries. In addition, WHO will exercise particular caution when engaging with other industries affecting human health or affected by WHO's norms and standards'. In the approved version, Paragraph 44 states that 'WHO does not engage with the tobacco industry or non-State actors that work to further the interests of the tobacco industry. WHO also does not engage with the arms industry'. Moreover, paragraph 45 added 'WHO will exercise particular caution, especially while conducting due diligence, risk assessment and risk management, when engaging with private sector entities and other non-State actors whose policies or activities are negatively affecting human health and are not in line with WHO's policies, norms and standards, in particular, those related to non-communicable diseases and their determinant'.

Egypt reiterated that India proposed, in the fragment 'industries that direct or indirect

harm the human health', that there should be an explicit clarification of which industries were being referred to. Egypt and Iran supported the proposal. The interviewee argued that these countries wanted an explicit reference to Food and Beverage companies. However, some developed countries, specifically the United States and the United Kingdom, objected, since 'they have domestic interest that they do not want to harm, from another part, they argued that if we do so, then we are sending a negative message to these non-state actors. And this negative message might tempter or impede the WHO's role in trying to influence the standards and rule of non-state actors industries'.

Nevertheless, Egypt believes that as paragraph 45 was inserted, it became clear that some NSAs might have a negative impact on WHO. 'To me, even if we are not explicitly referring to these companies, the current formulation as used in paragraph 45 reflects the reality and stick precautions to make sure that these companies are not engaging with WHO'.

For the United States, paragraph 44 was 'the key paragraph (…) which resulted in a lot of discussion and a lot of coalitions relating to the non-State actors themselves. I think some groups wanted not only the blacklist for tobacco and firearms but to extend it to alcohol, food and beverage companies and some other companies, even Pharma'. For the North American interviewee, it was problematic because, although there are problems related to Big Pharma, the WHO obviously has to work with them:

> Anyway, and that was a very fundamental part of the debate. And we as the US and others who agreed with us, we're successful in saying, we should, the blacklist should stay the same: tobacco and firearms because there's no, for those two industries there's no other side of the coin. Both of those industries exist only to harm humans, and so there's no benefit for WHO to work with them. But the other industries are all much more nuanced and all play different, much different roles in all of our communities. I mean, everybody has to eat and drink and everybody doesn't have to drink alcohol, but a lot of people choose to. So how do you work with? It's just kind of working effectively.

Interviewee 9 also pointed out that many discussions surrounding paragraph 44 took place with the African group as they were engaging a lot with some NGOs, such as IBFAN and the Third-World-Network.

For the United States, the WHO should meet with 'Nike or Adidas when working with physical activity' and also 'with Coca-Cola and Nestlé to talk about reformulation'. The interviewee then affirmed that 'a lot of countries, mostly the WEOG countries supported us in terms of having a difference between tobacco and arms, which is the no-go area and, and the other industries affecting human health'. However, they pointed out that Norway wanted

‘much more restrictions on the health effecting industries then than ultimately went there’. Finally, the US interviewee also called attention to the discussion over the language that should be used in paragraph 44 – explicitly whether it should be softer or harder. In the end, ‘particular caution while engaging’ was negotiated and the Member States ended up agreeing on the exact wording.

For Zambia, paragraph 44 represented a fight between two positions from different groups headed by the United States and India with their corresponding allies. The interviewee, however, assured the country was neutral on this topic and saw sense in both sides:

> Why do I say so? The arms industry is definitely, we don't see anything good that comes out of arms. Not only in health, but in everything. […] But then, for example, India wanted to frame the industries that affect human health, […] when you also look at it from the American perspective, everything affects health. There is no industry that doesn't affect health. So when you say arms industries that affect human health, then you're just saying everyone as well. So I think we'd use that as the counter-argument, which they did and it makes sense.

According to Argentina, while some Member States wanted a list of industries that should have restricted engagement with the WHO, ‘for the US, it was very difficult to deal with that’. The interviewee affirmed that, in the end, the Member States managed to find a balance for paragraph 44; ‘the US was happy with that, other members were happy with that. Maybe it is not the best solution (…), but we just tried to cover every position. I do not remember exactly paragraph 44, but I do remember that was the maximum possibility that had to approve and the USA would be happy with that’. Interviewee 13 stressed that although the US ‘covered the food industry very strong’, they were not alone in the controversy about paragraph 44 ‘they were maybe leading that position, but they were not alone’. The interviewee concluded by stating that Argentina was not in favour of the restrictive list.

5.6 Can FENSA be Seen as a Tool to Address the WHO’s Underfunding Crisis?

To Brazil, FENSA precisely helps to shed light to non-State actors’ contributions, to increase transparency, in order to keep the donations aligned with the WHO’s purposes, objectives and its mandate. Interviewee 4, however, affirmed that one needs to exercise a great deal of realism, as in the short and indeed medium term, there is no Member State in a position or willing to cover this funding from non-State sources. ‘I see neither political nor financial conditions to cover this gap’.

For Egypt, if the WHO was in a good financial state, Member States might not have

negotiated FENSA.

> WHO has been facing a chronic financial problem in relation to its funds. You have the assessed contributions from one side and you have the voluntary contributions from one side. More than 80% of the biennial budget of WHO came from voluntary contributions, while the remaining part comes from the assessed contributions. So this is not enough to support the work of WHO in the field and you are aware that we have three levels of work in WHO, we have the headquarters in Geneva, then we have the regional offices and we have the country offices. And right now there is really increasing emergency demanding crises that require the attention of WHO. And this really aggravated the financial crisis of WHO.

According to the interviewee, as a result, developed countries wanted to use the engagement with non-State actors, particularly with philanthropic foundations and the private sector, to try to alleviate the WHO's financial crisis. While not having a problem with this, 'we needed from our side as developing countries to take into account that this might undue influence the work of WHO'.

For the Egyptian interviewee, the main challenge during the negotiations was to have enough principles to address conflicts of interest and norms for risk management and risk assessment. In this regard, there were two main points of view; 'one side wanted the engagement to alleviate the financial crisis of the WHO, even if this comes in contradiction with the mandate of WHO. It was something we totally refused as developing countries, and we did not object to the engagement as long as the work of WHO will not be defeated'. Without explicitly mentioning anyone, the interviewee affirmed that the financial crisis was one of the reasons behind the pressure that some countries have exerted to allow more engagement with non-State actors.

For Germany the criticism that FENSA would open the door for private funding to the WHO is 'nonsense because there is private funding in quotation marks already'. In this regard, the interviewee affirmed that the Gates Foundation, Rotary and other non-State actors provide funding to the WHO or to specific programmess, and these programmess might, to some extent, be heavily dependent on those resources, 'to argue that only FENSA now allows that money to come in is not true because it was possible before'. The interviewee did not agree that this was one of the critical concerns for the Members States during FENSA negotiations.

For Norway, that was a fanciful notion as FENSA was contrarily creating a regime that would reduce the organisation's ability to bring significant resources to the field. However, 'if you have a framework in place that strengthens WHO's reputation with regard to having a

sort of clean and credible relation to nonstate actors that might, in the long run, prove image organisation, hence its attractiveness as a funding option'.

For the United States, 'hopefully [WHO] can use the tools in FENSA that are provided to set up other funding mechanisms, whether it is voluntary funds or what you have to be able to collect resources and address those issues'. According to the interviewee, as long as the essential functions (the normative function, the technical work and the policy-making work) are protected from undue influence, the WHO should be able to use FENSA to address some of the funding gaps. Moreover, 'the US government would also support that as a general matter, as the largest funder to WHO, we are always sort of officially encouraging WHO to broaden their donor base'.

For Zambia, funding was one of the issues, as the Member States started feeling that few entities deviated the whole functioning of the organisation.

5.7 Is the FENSA Enough to Address the Initially-Proposed WHO Challenges?

For Germany, it is not yet possible to say for certain, as the FENSA still needs to be evaluated. Thus, the interviewee asserted that one crucial point was to make sure that the FENSA would not establish a non-usable regime. The German diplomat also affirmed that an 'interesting part about FENSA' was that the Framework was heavily negotiated, line by line, for long periods, 'every single word as if it was a war in between member states'. However, once it is adopted, nobody cares anymore.

For Zambia, FENSA is just the start. According to the interviewee, the Member States developed a document to improve the relations of the organisation with non-State actors, however, 'I do not think that is a very very good document that all of us now closed and go home and think something will happen very well'. Interviewee 12 also pointed out that FENSA is not only just the starting document, but, as the negotiations took many years and it was not an easy process, 'in the end, most of us were very keen just to get the work done. Even when you look at the actual document, we had to compromise, most almost all of us had to compromise so we could close the negotiations. Because time was running out'. The interviewee also argued that without approving FENSA, the organisation was frozen, 'could not function, could not really work because we were waiting for the position. So you know, if that goes on for three, four years, you know, the impact of that is to paralyze the institution. So everybody was very keen to have this engagement and discussion and negotiation closed'.

For Zambia, the only positive element of FENSA was that the Member States were able to come up with a starting document.

For Argentina, the WHO was revolutionising the multilateral system with FENSA as it was a totally a new process. ‘We did not have precedence to use, so we knew every time we met that we were creating something totally new, out of the blue, something necessary, something that we need to cover, but something completely new’. The country chaired the Member States’ phase of the negotiations and argued that the MS managed to cover everything and although not being sure if FENSA ‘is an excellent document or the perfect document, it was a positive document at that time. We decided what we wanted, and we said all the time that we would not close the door for change’. The interviewee, however, highlighted the importance of the evaluation process, as during the negotiations the focus was to approve the text. Afterwards, the implementation could start, to finally be able to see whether it is working or not. The former chair concluded assuring that if the FENSA needs to change, the Member States will change.

5.8 Is FENSA a Model to be Applied to Other UN Agencies?

Even if FENSA raised different perspectives, the only certain thing is that it sets a precedent, as it is the first comprehensive regulatory framework within the United Nations system that covers all types of interaction with non-State actors. Considering that a semi-structured interview allows the researcher to approach other subjects as they arise during the interview, the idea of FENSA being a template that could be applied in other UN agencies was not mentioned to all interviewees. However, among those to whom it was mentioned, it remained controversial whether FENSA could be a blueprint for future regulatory frameworks.

To Brazil, the general idea could indeed be applied, especially when it came to relations based on more transparency and opportunities for the Member States to see how these relationships would unfold. Interviewee 4 pointed out that the 2030 Development Agenda placed the private sector as one of the partners in implementing sustainable development goals alongside civil society, which is universal recognition of the role of the private sector not only in the WHO but generally in all UN agencies. Therefore, as the relations with non-State actors are becoming universal through the multilateral organisations, ‘the basic and conductive idea of FENSA is an idea that deserves to be explored within the

United Nations', especially in a broad spectrum context of a crisis in agencies' budgets, which demands additional resources. To conclude, the Brazilian representative asserted that 'this discussion is very pertinent not only to the WHO, at least I understand that the FENSA main idea is indeed replicable, or should be examined to be replicated in various United Nations bodies'.

Along the same lines, Egypt considers that the FENSA represents a 'sort of a model or a template' which other organisations could build on: 'I believe that this document is really a very strong document that could be actually used as a template or a model to govern the engagement between other UN organisations and non-State actors'.

For Germany, conversely, FENSA was a cumbersome exercise and should not be recommended for all international organisations as it was 'to some extent (…) frustrating, long, heavy, (…) and at some stages too politicised'.

The United States' opinion was a midpoint between the two aforementioned perspectives. For the interviewee, FENSA could not be seen as a blueprint yet, 'but hopefully in the future, if we accomplish it, it could be okay'. The interviewee argued that the WHO could indeed be a trailblazer within the UN system because if FENSA were fully implemented, then it would be a unique tool to actually protect, communicate, and encourage engagement as in the multilateral system either you have very little engagement at all or basically no rules. However, they concluded that "I think I would say no for right now".

For Argentina, FENSA 'absolutely' can be used as a model, although the interviewee was not sure if would apply directly as every organisation has a different nature, 'but at least when other organisations start working with that kind of framework, they will have as a precedent what WHO did. And they can use it or not, but at least they can use it as reference'. Interviewee 14 strongly believes that other international organisations will have to start dealing with NSAs at some point, and explained that the WHO was the first one due to its normative work. In this sense, the interviewee explained:

> We need to protect the normative work from the influence on non-State actors. But, the point is NSAs are there and we need to work them more and more. The United Nations needs to work with them more and more. So it's not a matter of engaging or not, it's a matter of regulating. (…) And for those who used to think or say that having a framework like this in WHO would prevent country offices to work with non-State actors, for country offices was difficult to engage with non-State actors sometimes because before [FENSA], if they think the work was risky, they would prefer not to engage because they didn't want to take the risks. So actually we wanted to give people working in the countries with NGOs and private sector, clear norms, clear procedure to engage without any risk, without taking personal risks.

5.7 Does Final and Approved FENSA Text Embrace the Position of Some Member States More than Others?

Brazil believes that its positions were considered in the final version of the FENSA. While interviewee 5 saw FENSA as ‘a victory’, interviewee 4 suggested that the parameter to judge is the consensus reached and even if any element in Brazil's assessment had not been addressed, the interviewee however did not mention to which element he was referring, the main interests were contemplated. However, for interviewee 4, FENSA was a bit inclined to the Global North perspectives ‘but not too much’.

For Egypt, on the other hand, the FENSA approved version isn’t inclined towards the views of any group of countries; it is a well-proportioned document. Although at the end of the negotiations, the interviewee was concerned due to the implementation, ‘at the end of the day I believe we got a balanced document that has taken on board all the views of the negotiating countries. Of course, this is the logical outcome of any intergovernmental and multilateral negotiation (…) I think there was a consensus that if we want to know exactly whether FENSA was going to be a success or not, we need to follow the implementation closely’.

It is worth noting that the European Union, the United Kingdom and Brazil highlighted that not many Member States participated in FENSA negotiations. Therefore, the European Union argued that instead of thinking in a Cold War division, one should consider that some States are better negotiators than others. Furthermore, if a document is one-sided, it could be a consequence of the dynamics in the room, where some diplomats are better prepared.

In Germany’s opinion, nobody would have supported FENSA in the end if some Member States had had more success in the negotiations:

> Not everybody got what they wanted. We started with an overall goal and then you obviously have to set compromises, but if you're too far away from your goals and the other one gain all, then you don't approve the whole thing. So, no, I think it's, it's really a compromised version. I wouldn't see anybody who, I think there was a success that this was, that in the end it was successfully adopted. But I wouldn't say that there's anybody who was completely happy and anybody who was completely upset otherwise.

To similar effect, the United Kingdom declared that there were no ‘winners’ in the FENSA negotiations and that ‘success in any negotiation is if everyone is a little unhappy’.

For Norway, ‘the basic tenor of the solutions came mostly from those who wrote the original proposals’. Nevertheless, the interviewee believes that FENSA outcomes probably

looked ‘a good deal more like what about Brazil like-minded proposals than with what we [Norway] have proposed’. However, for the interviewee, everything lies in the implementation.

For the United States, in the end ‘there was a strong sense of accomplishment that we really did provide a major contribution to how WHO could be governed in an effective way’ and the final version treads a balanced path between protection and engagement.

In contrast, Zambia believes that some States had their inputs in the final version and were happier, because ‘even when we negotiate in the spirit of giving a tick, there are superpowers, big entities that are so adamant, so strong that they do not want to move from the position’. Accordingly, the interviewee explained as Zambia did not have specific interests, and after negotiating for ‘hours, days and years’ without success, some countries started asking themselves ‘are we going to die if this all goes through? Can we live with it? Of course, if it is not worse than what is already there, we may be willing just to let go so that we can agree’.

> So definitely some countries did have the acquisitions much more embraced. For us, in the Third World, we were fighting for principles. We had no specific special interests. So we could tolerate a lot of things that may be set by some countries, but generally, those countries then would celebrate. But, on the road, the universal feeling was that we wanted to conclude the negotiation and end them.

For Zambia, the feeling that powerful countries are achieving specific victories is recurrent and present not only in FENSA negotiations but in any resolution that the Member States have ever negotiated. In addition to that, ‘while some countries meet their demands, some countries can live with the trash that comes up’.

The Chair of the negotiations, Argentina, believes that ‘it is difficult to say that in general terms if we lose or we win. Maybe in some parts of the document I have to join the consensus against my own feelings and some other parts of the documents is the other way around’. The interviewee concluded by arguing that FENSA was a consensus document and the outcome was good for the organisation.

CHAPTER SIX: THE PERSPECTIVES OF NON-STATE ACTORS ABOUT FENSA

When analysing FENSA, it is essential to understand the role that non-State actors played in the negotiation process, because although decision-making at the WHO resides in the hands of Member States, NSAs can influence political processes in the Organisation, as it was revealed in chapter 3. This chapter, hence, aims to understand the involvement of non-State actors the during FENSA negotiations, as well as explore their perspectives on the framework.

According to Ruhlamn (2015) not only do 'NSAs have a number of alternative strategies for impacting global governance' but 'states and bureaucracies have not always resisted their inclusion'. Despite official participation in the WHO, meetings and hearings[85] are the most recognised tool to impact the health policy agenda, NSAs can also indirectly influence international negotiations by doing consultations or holding bilateral meetings with States entitled to vote in WHO governing bodies, or by taking part in national delegations. Non-State actors can also pressure governments at the national level, where they can make their power felt more effectively. This relation is of central importance due to its potential impact in global governance; as Matthews (1997) reminds us, NSAs' 'easy reach behind other states' borders forces governments to consider domestic public opinion in countries with which they are dealing, even on matters that governments have traditionally handled strictly between themselves'. Not to mention that non-State actors can count with the global media and also 'lobby their own governments to pressure leaders in developing countries, creating a circle of influence'. (Matthews, 1997, p.55).

Building coalitions with other NSAs can also add pressure to particular demands. Therefore, while the range of roles and methods of participation for non-State actors have expanded, as well as their ability to exercise some authority in the global health agenda, different non-State actors play different roles even amongst the same category. It is worth noting, however, that at least when it comes to health, there is much heterogeneity inside transnational actors, especially within the private sector. In this regard, an interviewee from

[85] NSAs can make statements, and also have the right to submit a statement in the forefront of a WHO meeting and to submit a memorandum to the WHO's Director General, who chooses the nature and scope of its circulation.

the UN Foundation affirmed: ‘it is not unanimous (…) one has to avoid a perception that non-State actors will want or civil society will want one side and private sector will want the other because there is a lot of heterogeneity and viewpoints inside non-State actors’ different domains’.

This chapter, while describing the opinions and behaviours of NSAs regarding the FENSA negotiation process, will also check the evidence gathered through Member States’ interviews and document analysis. Thus, guided by the key-question ‘what views, role and influence NSAs had in the negotiations?’, five semi-structured interviews were conducted with representatives of non-State actors. Written statements were also taken into consideration. We tried to reach at least two representatives from each category of NSA, and the only group that was not considered in this thesis is that of academic institutions as no institute accepted or answered our interview request; it is also the group that seems to have had the least interest in the FENSA process, according to the interviewees. Moreover, as already expounded in Chapter 3, the WHO still engages with academic institutions through Collaboration Centres and the *Regulations for Study and Scientific Groups, Collaborating Institutions and Other Mechanisms of Collaboration* was not replaced by FENSA.

The selected NSAs are Medicus Mundi International (MMI), the International Federation of Pharmaceutical Manufacturers & Associations (IFPMA), the International Food & Beverage Alliance (IFBA), the United Nations Foundation (UN Foundation) and the Bill and Melinda Gates Foundation (BMGF). The interviews were based on purposive sampling, a common technique in qualitative research which aims to identify and to select ‘individuals or groups of individuals that are especially knowledgeable about or experienced with a phenomenon of interest. In addition to knowledge and experience, is the importance of availability and willingness to participate, and the ability to communicate experiences and opinions in an articulate, expressive, and reflective manner’ (Palinkas et al., 2015, p.2).

It is essential to mention that many meetings took place to discuss FENSA in the Programme, Budget and Administration Committee, to which no NSAs has access, even those in official relations with WHO, and for which there are no reports. Therefore, Interviewee 1, a former staff of a public-interest NGO, argues that ‘through the six years, since the official start of the Reform, there had been many meetings behind the closed doors as well as many drafting or working groups during Executive Boards and World Health

Assemblies. We had no access to these, and there are no reports. Transparency was badly lacking in these crucial negotiations' (Participant 1, personal communication, August 31st 2018). When FENSA was being negotiated, only NGOs could have official relations with the WHO, given the principles of 1987. Therefore, it is understandable that amongst all the NSAs embraced by the framework, NGOs and some private sector entities had the most significant participation, as one must consider that, before FENSA, there was no differentiation between business-interest NGOs and public-interest NGOs.

This chapter is divided into five parts. The first four parts correspond to each non-State actor and their corresponding documents, official or not, as well as any relevant information gathered from preliminary interviews and exchange of emails. Then, the last part will describe the interviews made with representatives of 5 NSAs.

6.1. Non-Governmental Organisations

When this project started, given the scarcity of reports about the FENSA negotiations process, especially from within academia, informal contact was made with some individuals who were directly or indirectly involved in the WHO reform. This unstructured informal contact is generally conducted as a preliminary step in the research process. It is entirely informal and not controlled by a specific set of detailed questions. Instead, the interviewer is guided by a pre-defined list of issues. Aware of that, a former staff of a public-interest NGO affirmed that the main concern for them were issues related to conflicts of interest, as they believed that the FENSA document had never clarified satisfactorily what conflicts of interest are. The Organisation, according to this first source, was only focusing on conflicts of interest between actors, rather than within a person or institution.

In this direction, in 2016 a PowerPoint presentation made by a consultant from the International Baby Food Association Network (IBFAN) criticised the non-compliance of the WHO's decision in 2014 that stressed the need for 'further consultations and discussions… [including] on issues including conflicts of interest and relations with the private sector'. The public-interest NGOs accused the FENSA of proposing 'a flawed conflicts-of-interest concept', failing, therefore, to state that conflicts of interest are conflicts within a person or institution, and not between actors. It was also pointed out that the Conflict of Interest

section in FENSA had some gaps, like no reference to whistle-blower protection,[86] no reference for the revolving door[87] and no reference to the leadership's duty to 'create an organisational culture in which dealing with conflict of interest matters can be freely discussed and raised'. Hence, 'the poor conceptualisation of the Conflict of Interest (…) was one of the keep points through which our NGO tried to make the MS see that the policy was flawed'. (Interviewee 1, personal communication, August 31 2018).

Furthermore, it was said that prior to the WHO Reform, the *Principles Governing Relations with Nongovernmental Organisations* had never been properly implemented. Therefore, the reform regarding non-State actors could have improved it, instead of proposing a new policy, which, in their view, can potentially open Official Relations status to 'precisely those interests against which the original policy tried to protect WHO and its policy-making spaces'.

To this effect, Gupta and Lhotská (2015) wrote the article 'A fox building a chicken coop? World Health Organization Reform: Health for All, or more corporate influence?'. They argued that NGOs were complaining about the unification of all actors under the term 'non-State actors' (NSA) and that a clear distinction between public-interest and business-interest actors was needed. This point seems to be one of the major concerns of the public interest NGOs. According to a personal document from a consultant of IBFAN, even after the 2014-15 discussion, the FENSA draft kept 'blurring lines between public-interest actors and corporations and business – interest actors'. The main argument was that placing social movements, academia, business associations, public-private partnerships and philanthropies under the term non-State actor would be a 'Trojan horse' to bring powerful economic interests into WHO. In an informal conversation about the non-distinction between the different types of non-State actors, it was said that 'WHO's Secretariat was manipulative to not distinguish non-state actors (…), in my opinion, this was a move that may have been

[86] You're a whistleblower if you're a worker and you report certain types of wrongdoing. This will usually be something you've seen at work - though not always. The wrongdoing you disclose must be in the public interest. This means it must affect others, for example the general public. As a whistleblower you're protected by law - you should not be treated unfairly or lose your job because you 'blow the whistle'. You can raise your concern at any time about an incident that happened in the past, is happening now, or you believe will happen in the near future. Description available at: https://www.gov.uk/whistleblowing . Last access on 18/12/2019.

[87] The term 'revolving door' refers to the movement of high-level employees from public sector jobs to private sector jobs, and vice versa. The idea is that there is a revolving door between the two sectors as many legislators and regulators become lobbyists and consultants for the industries they once regulated and some private industry heads or lobbyists receive government appointments that relate to their former private posts. Available at: https://www.investopedia.com/terms/r/revolving-door.asp Last access on 18/12/2019

requested by transnational corporations, and possible venture philanthropies' (Participant 2, personal communication, September 4th 2018).

One should note that, almost three years after FENSA approval, in January 2019, the civil society meeting ahead of the WHO EB144 promoted by the Geneva Global Health Hub (G2H2) was still discussing the inadequacy of the term non-State actor used in FENSA.

Gupta and Lhotská (2015) criticised that instead of re-examining the constitutionality of accrediting business-interest associations as NGOs, FENSA was proposing their indiscriminating admission; the same for philanthropies. It was also pointed out that legitimising the access of business-interest associations to WHO governing bodies would consequently legitimise new channels of inadequate business influence, including through staff secondment, pro-bono work, participation in meetings and 'support' to policymaking. One must consider, however, that in the final version of the FENSA, secondments from the private sector were forbidden.

Germany was mentioned as a country that 'lobbied against the idea that venture philanthropies should not be allowed to second staff, because they have in the meantime signed a Memory of Understanding with the Gates Foundation that there would be staff exchanges between the German Development Agency' (Participant 2, personal communication, September 4th 2018).

Interviewee 2 also questioned the fact that FENSA-related material was classified under the 20-year protection clause for documents.[88] Moreover, it was revealed that Professor Thomas Zeltner, acting as special envoy on the relationship with NSA, was asked to contact the World Economic Forum[89] on their expectations regarding the WHO Reform Process but then, the WHO refused access to the detail report, both to the Member States and the general public.

It was widely mentioned that secondments were a controversial point of the negotiation process as it raised concerns of conflict of interest, the improper influence of an

[88] According to the WHO Archives Access Policy: In most cases, external researchers may access archival records once the records are 20 years old, according to the dates of individual documents consulted or, in the case of a file, the date of the most recent document in the file, unless an exception is granted by the Director-General's Office. The term "external researchers" includes academic researchers (both professors and students) and other members of the public. (Available at: https://www.who.int/archives/about/AccessPolicy.pdf?ua=1 . Accessed: 18/03/2019)

[89] Established in 1971, it is an International Organization for Public-Private Cooperation that "engages the foremost political, business, cultural and other leaders of society to shape global, regional and industry agendas". (Available at: https://www.weforum.org/about/world-economic-forum. Last accessed on 18/12/2019)

NSA on the WHO's work, and potential endorsement of the NSA's name, views or activity. According to interviewee 2, during the negotiations, the Ted Turner Foundation had a secondment at the highest level in the WHO and 'he or she was among other also busy advising to displace the NGO Policy with FENSA that opened up the gates to private sector NSAs and philanthropic NSAs' (Participant 2, personal communication, September 18th 2018).

The Official Relation policy was another major issue for public-interest NGOs. For instance, paragraph 49 of the FENSA draft stated that 'official relations is a privilege that the Executive Board may grant to (…), international business associations … [whose] aims and activities … shall be in conformity with the spirit, purposes and principles of WHO's Constitution' was widely criticised. It was seen as highly problematic because it would promote a 'wholesale admission of business-interest associations and philanthropies' to the governing bodies and, consequently, shift the WHO's agenda and work to corporate and private donors' interest. Participation, provision of resources, evidence creation and advocacy, were all seen as at high risk of 'undue industry influence', therefore:

> we hoped Member States would understand and act upon. However, most MS did not pay much attention to incorporation of this new OR policy within FENSA and to the fact that it was to replace, without any debate the *Principles Governing Relations with Nongovernmental Organizations*. To them this new OR policy was a part not directly related to the workings of WHO, only to the procedural issue of who can come to the WHO governance meetings. They failed to understand (or did not want to understand) how important the "old" principles had been to safeguard against entities with commercial interests entering the Official relations status. (Participant 1, personal communication, August 31st 2018)

It is essential to highlight that business associations were removed, and are not considered an NSA in the FENSA final version.

Due diligence and risk management were seen as having poorly-conceived concepts. According to the IBFAN presentation, 'there is a need to better distinguish between actors and to determine how to arrive at appropriate assessment and regulation of interactions'.

IBFAN seemed to be one of the most active NGOs during FENSA negotiation; to them, at the beginning of 2016, the year that FENSA was approved, the WHO still needed to 'evaluate the process, clarify concepts, obtain missing evidence, and [carry out] an in-depth review of the adequacy of existing relevant WHO policies'.

After the approval, Professor Judith Richter wrote that 'WHO's leadership ignored repeated requests of WHO Member States to provide guidance on conflict of interest issues.

Ignored were warning that the WHO-NSA relations policy contains a misleading conceptualisation of conflict of interest'.[90] Moreover, Richter accused the WHO of not providing appropriate public debate about the possibility of corporate lobby associations, and mega-sponsoring foundations have official relations with the WHO. To illustrate, she argues that the Bill and Melinda Gates Foundation was one of the first organisations to benefit from the new rules as it gained official relation status in January 2017. She also evoked the speech of the Vice President of the Rockefeller Philanthropy Advisors, Heather Grady, during the UN General Assembly hearings on the Post-2015 Agenda in May 2015: 'We do not want to be just another 'non-state actor', one not even mentioned within the Major Groups. And we see recognition in the High-Level Political Forum and Global Partnership for Effective Development Cooperation processes as positive steps forward in this regard. (…) First, the UN and governments must open your arms and create a more enabling environment for philanthropy, domestically and across borders'. (Grady, 2015, p.2)

Considering all sources used in this thesis: interviews, media reports, official and personal documents, NGOs, represented by civil society organisations, represented the NSA which have expressed the most concern during FENSA negotiations. Although recognising that the Framework resulted in some improvements compared with the previous norms and practices, CSOs remain worried about transparency and oversight mechanisms, risk assessment and management, and classification and evaluation of non-State actors' commercial interests. CSOs, therefore, kept pushing and inspecting the WHO for FENSA implementation. The Geneva Global Health Hub, for instance, has been organising and hosting civil society meetings ahead of Governing Bodies meetings to discuss WHO governance and reform, in which FENSA is a regularly-discussed topic.

6.2 Private Sector

As no initial informal contact was made with the Private Sector, this section will be based on the available documents, including statements submitted during FENSA negotiations.

The International Federation of Pharmaceutical Manufacturers & Associations (IFPMA) sees itself as the 'voice of the biopharmaceutical innovation and health progress

[90] WHO redefines conflicts of interest and opens floodgates to undue influences. Available at: https://mezis.de/downloads/6523 (Last accessed 07/03/2020)

around the world'. Differently from NGOs which were very critical about FENSA, IFPMA called for more significant and effective collaboration through embracing partnership approaches as being critical to future global health progress, as well as advocated the role of the private sector and the need to engage in 'whatever partnerships are open to us, in whatever way we can, to achieve our goal'. In this sense, in the statement IFPMA comments on Discussion Paper on the WHO's engagement with non-State actors, the Federation advocates that:

> every actor has a potential conflict of interest. An overall principle (…) lies in the management of conflicts of interest (…). IFPMA believes transparency is a cardinal element in recognizing and dealing with such potential conflicts. Transparency can be achieved through a robust policy applying equally to all stakeholders. Conflict of interest issues must be addressed in an open and transparent manner but should not be used as a reason to exclude any stakeholders who can positively contribute to improving health.

While NGOs were sharply criticising the possibility of official relations with for-profit institutions, IPFMA's opinion was that all non-State actors should have equal access and that participation should be open to all actors sharing the WHO's vision and mission.

In May 2016, during the World Health Assembly, IFPMA published a note on its website[91] welcoming the 'efforts to design a framework allowing WHO to fulfil its leadership role in global health and its mandate by engaging with a varied set of actors, while managing any perceived or actual conflict of interest'. Moreover, IFPMA claimed that FENSA would give 'an equitable voice to a community of public and private organisations whose shared goal is to make this world healthier'.

The Federation, however, argued that while the FENSA should ensure that interactions continue to grow, the draft framework 'still appears to be restrictive in a number of areas that could hamper non-State actors in their ability to fully contribute to global health outcomes'. Again, IPFMA advocated for the equitable application of the provisions of the framework across different categories of non-state actors. Regarding conflict of interests, the solution proposed was 'where conflicts of interests may arise, whether commercial or not, it is appropriate that these are managed in a robust, clear, transparent and equitable manner with all non-state actors. We call for transparent engagement with all non-state actors and accountability by all'. IFPMA suggested that the FENSA should be stress-tested against

[91] WHA 69, Item 11.3 Framework of engagement with non-State actors. Available at: https://www.ifpma.org/resource-centre/wha-69-11-3-framework-of-engagement-with-non-state-actors/

existing best practice in the WHO's interactions with non-State actors so that NSAs could witness its impact on important implementation work. Moreover, it was recommended that Member States consider a periodic review of the framework to ensure its relevance and to amend it as necessary if it becomes a barrier, rather than a facilitator to the WHO achieving its objectives. Finally, IFPMA welcomed the flexibilities introduced, such as a phased approach to mitigate unintended consequences, and for emergency situations.

The International Food & Beverage Alliance (IFBA)[92] is another important actor from the private sector. In 2011, when the discussions about engaging with NSAs were in their initial stages at the WHO, IFBA wrote to the Director-General Margaret Chan, affirming that 'non-communicable diseases and childhood obesity are major public health problems that require multi-stakeholder solutions. As a member of the private sector, we firmly believe that the food industry has a role to play as part of the solution, and have committed our time, expertise and resources to do our part'. IFBA claims to be working with the WHO to achieve the UN Sustainable Development Goals, especially the achievement of Zero Hunger, Good Health and Well-Being, Partnerships for the Goals. The companies have been focusing on promoting how partnerships could help to deliver a more significant impact on people's health and well-being. On the Nestlé website, for instance, the WHO is among the list of 'main relationships' and it is also declared that, from engaging with diverse stakeholders and by working together, 'we maximise what can be achieved. These stakeholders include multilateral agencies, international organisations, governments, academia, nongovernmental organisations (NGOs) and industry bodies'.[93] FENSA embraces all these actors.

In 2015, a journalist from The Times of India, Rema Nagarajan,[94] denounced the undue influence of IFBA at the World Health Organisation. According to her, a leaked mail referred to alliance representatives having several 'outreach meetings' on FENSA with the missions of the US, the UK, Canada and Latvia (which held the European Union presidency at that time) in Geneva. The report exposed that the Secretary-General of IFBA thanked the Food and Consumer Products of Canada (FCPC) and the Grocery Manufacturers Association (GMA), from the US, 'for helping to drive home what would be an acceptable outcome for

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[92] IFBA is a group of eleven companies (Coca-Cola, Ferrero, General Mills, Grupo Bimbo, Kellogg's, Mars, McDonald's, Mondelez International, Nestlé, PepsiCo and Unilever) that defines itself as group that 'shares a common goal of helping people around the world achieve balanced diets and healthy, active lifestyles'.
[93] Available at: https://www.nestle.com/csv/what-is-csv/partnerships-alliances Last access on 28/12/2019.
[94] Available at: https://timesofindia.indiatimes.com/india/How-food-beverage-giants-influence-WHO-rules/articleshow/47378845.cms

the alliance in the tussle to the frame rules for WHO's engagement with the private sector'. Moreover, the mail declared that the WEOG group was fully aligned 'on a position that is essentially equivalent to ours (…) [and] while the WEOG would actively work for the framework to be adopted, it will not accept any document that excludes the food and beverage industry from the framework'. Yet, according to the report, 'helpful outreach was also conducted by IFBA members, associates and partner organisations in a number of capitals which included several emerging economies and developing countries in Africa and the Asia Pacific'. Concerning this allegation, an interviewee from Nestlé voiced that indeed the US Government held meetings with non-State actors, precisely the private sector, to hear their opinions before the FENSA negotiations in Geneva.

In this sense, one must consider that the FENSA final version did not include Food and Beverage industries directly in the controversial paragraph 44 (regarding the engagement with specific industries that negatively affect public health). Moreover, as it was pointed out in chapter 5, when asked if FENSA represented a response to the lobbying of powerful actors, especially in the private sector and philanthropic foundations, interviewee 7 from the United Kingdom said: 'probably yes, there were very active diplomats, more or less 25, in health topics, probably because they get lobby from some companies'.

In October 2013, during the consultation on the WHO's engagement with non-State actors, the IFBA asserted to have been working 'closely' with the WHO since 2002 through resources and expertise, and sustained the importance of partnerships:

> as multisectoral actions and collaborative partnerships represent one of the most cost-effective ways to address public health challenges (…) [and] by including the private sector you are able to add valuable perspectives; help achieve scale; open the possibility of innovative finance mechanisms where public institutions are able to leverage private capital; provide leadership to encourage others to participate; and bring together different skill sets that can deliver a better and more effective outcome.

IFBA also claimed to work in collaboration with governments and NGOs by offering 'product innovation, consumer understanding and communication, R&D expertise, supply chain expertise and the potential positive influence on small and medium enterprises'. Regarding FENSA specifically, the Alliance welcomed the effort made by the WHO to develop 'a clear policy for the engagement of all non-State actors and the management of these relationships in a way that can harness the knowledge, expertise and resources non-State actors can contribute to advance the goals of public health while safeguarding WHO and public health from undue influence and reputational risks'. Moreover, by using Margaret

Chan's argument that 'everyone has vested interests', IFBA supported the idea that the WHO's engagement policy should be inclusive, rather than an approach of categorisation and exclusion of particular stakeholders. The FENSA, therefore, should be applied 'systematically and uniformly to all kinds of non-State actors and at all levels of the Organization'. Finally, the statement recognised and respected the decision-making as being an exclusive entitlement of Member States as 'it is not our role to set or define policy. Rather, we believe our role is to help inform the development of policy, as evidenced by our past engagements with WHO and Member States, and to implement such policies'.

Inclusiveness, then, was a word used extensively by the private sector. The IFBA's main argument, along with IFPMA, was that the FENSA should be applied equally to all non-State actors, as the key point should not be with whom to engage, but rather whether an engagement is in the best interest of global health policy. When arguing against the 'exclusion' or different treatment for any 'for-profit' stakeholder, the IFBA noted that numerous NGOs were aligned with, or funded by, the private sector. Therefore, their exclusion would not only be ignoring the complex health scenario and the significant role of public-private partnerships and the donor community but also attempting 'to arbitrarily categorize or classify or create a 'hierarchy' of non-State actors, each with special roles and differing access to WHO based on a pre-determined view of the value of an organization with the goal of exclusion, will inevitably work to the detriment of the organization'.

In May 2016, when the FENSA was approved, the IBFA made a statement to welcome the adoption of the Framework, as the new rules of the WHO's engagement with NSAs included the private sector, and it stated that it was looking forward to 'building on the work already underway and to additional opportunities for engagement' (IFBA, 2016).

6.3 Philanthropic Foundations

As already explained in chapter 3, talking about health and philanthropic foundations seems to equate to talking about the Bill and Melinda Gates Foundation and its controversial role at the WHO and overall field of health. Two points, however, should be noted.

Firstly, the Gates Foundation seems to have distanced itself from FENSA negotiations, at least directly. There are no reports, statements or comments available that related to the Framework, and the interview with its representative was brief and vague. Although being one of the largest donors to the WHO, the Gates Foundation apparently did not show much

interest in a Framework that directly benefits it, as for the first time the Foundation found itself in official relations with the WHO. In this sense, the interviewee assured that the Foundation did not engage in negotiations 'because of the perceptions and these perceptions are false. So all we could do is act responsibly (…) Of course, we were there, but we were not engaging in it. We were present at the EB and the WHA when it was discussed. But we in no way engaged in any advocacy effort to try to shape it'.

Secondly, one should note that in contrast with the BMGF, the UN Foundation followed the negotiations. On the UN Foundation Blog,[95] Kate Dodson argues in her statement that civil society groups 'keep governments honest, advocate for patients, deliver services through community connections, and serve the most marginalised and remote populations (…) Moreover, civil society groups can leverage their own expertise to inform government policy'. The Foundation also warned that the FENSA, while needing to avoid conflicts of interest, should not become a wall to keep out the private sector, but to be a 'guardrail to facilitate collaboration with appropriate boundaries'.

It is worth noting that the Bill and Melinda Gates Foundation is a significant funder of the UN Foundation. In 2015, Adams and Martens published 'Fit for whose purpose? Private funding and corporate influence in the United Nations' and affirmed that a large share of the UN Foundation's revenues came from the Bill & Melinda Gates Foundation. 'Between 1999 and 2014 Gates gave US$231 million in grants to the UN Foundation, mainly for projects in the areas of health and agriculture' (Adams and Martens, p.23).

Philanthropic Foundations are seen by many as a tool to open up the WHO to the business sector, however they are supposed to do precisely the opposite, to sensitise businesses for public interests. Nevertheless, the philanthropic foundations' extreme dependence on private funding, combined with its complicated governance structure and lack of accountability and transparency leave little space for the effective oversight of financial contributions.

6.4 Academic Institutions

FENSA defines academic institutions as 'entities engaged in the pursuit and dissemination of knowledge through research, education and training'. As previously

[95] A New Era of Partnership at WHO. Available at: https://unfoundation.org/blog/post/a-new-era-of-partnership-at-who/

mentioned, individuals from academic institutions were not questioned, firstly due to the non-response to interview requests and also due to their diminished interest in the FENSA process. Moreover, academic institutions were excluded from official relations because, otherwise, they would be privileged over the other three groups of NSAs, as they would already have the possibility to gain the status of a WHO collaborating centre, one which is reserved for academic institutions only.

One should consider that Professor Ilona Kickbusch, director of the Geneva Graduate Institute's Global Health Centre, was mentioned as having played 'more of a role in the development of FENSA, and certainly now propagate the idea of aligning the health agenda with the Sustainable Development Goals (SDGs), which includes under the SDG 17 closer, 'partnership engagement'. This aligning is totally high on the agenda, and this Institute is likely to form the health diplomates for this endeavour' (Interviewee 2, personal communication, September 18th 2018). I tried to contact Professor Kickbusch four times, but she never responded.

Kickbusch argues in her article 'A new governance space for health' that given the post-2015 Sustainable Development Goals, the United Nations was leading towards a major question of global governance. Moreover, it is pointed out that public health must deal with 'Big Food, Big Soda, and Big Alcohol' given that the global health industry represents more than an eighth of global economic flows. It is essential, therefore, that:

> global health governance institutions firmly establish processes to link actors within and between sectors and define firewalls and conflict of interest strategies. The collective problem solving required in the global public health domain requires these controversial actors to be involved but without a commonly agreed rule-based system for including non-state actors in global governance institutions, it is difficult to subject these powerful organizations – large corporations, foundations and NGOs – to critical analysis. (Kickbusch, 2015, p.3)

During the informal consultations, NGOs and private sector entities actively participated, while only a few academic institutions and philanthropic foundations took part. The UK Centre for Tobacco and Alcohol Studies (UKCTAS) is a research centre that includes thirteen University teams and joined in the consultations of 2013. UKCTAS suggested that paragraph 44 'WHO does not engage with industries that make products that directly harm human health, such as tobacco or arms' should be extended to the alcohol industry. Regarding the participation of non-State actors at the WHO, it was argued that:

> Of the six broad categories of interactions described between WHO and non-State actors, there are five for which it is unambiguously inappropriate for the

> Organisation to engage with individuals, organisations and companies whose interests starkly diverge from those of public health: namely Collaboration, Financing, Contractual, Non-State actors in WHO's governance, and WHO as part of the governance of non-State actors. Any such interaction would threaten to introduce inappropriate influence over priorities and policy and expose WHO to very high levels of reputational risk. Current policies and practices clearly preclude such interactions with the tobacco industry, and we see the case for the extension of these principles and practices to the alcohol industry as equally compelling.

It can be observed, through document analysis and also by checking the reports of the watchdog organisations that were following the negotiations, that academic institutions were a minor concern for the Member States. However, as already mentioned, in addition to NGOs and philanthropic foundations, academic institutions can be controlled by the private sector, leading to conflict of interests. This relationship should not, therefore, be neglected.

6.5. Analysing Interviews

Even though NGOs in official relations are allowed to make statements during the governing bodies meetings, pursuing a broader and more in-depth understanding of non-State actors' perspectives on FENSA, five semi-structured interviews were conducted. They will not only allow for the cross-checking of statements made by the different NSAs, but also deliver a triangulation of data regarding the hypotheses on their influence through the Member States.

6.5.1 What Kind of Non-State Actor did the Interviewee Consider Their Institution to be and What Kind of Engagement does it have with WHO?

Medicus Mundi International (MMI) describes itself as an international non-governmental organisation and an academic network, 'a network of networks'. It represents national networks working on international health in many countries in Europe, such as Switzerland, Spain, Germany, Belgium, Netherlands, the UK, and actors across Africa too. The interviewee described the NGO's mission as health for all, universal access to health and health equity. Regarding the relationship with the WHO, given that MMI has existed for 55 years and has been in a close working relationship with the Organisation throughout, the interviewee explained that 'Medicus Mundi has been always standing for comprehensive primary health care and being a constructive partner in making collaboration happen'.

The International Federation of Pharmaceutical Manufacturers & Associations (IFPMA) labels itself as an international business association, 'which would probably be the same as saying private sector. I think it's the same kind of recognition'. The interviewee also highlighted the wide-ranging activities that the Federation conducts with the WHO under the

status of official relations:

> we have a vaccines committee; we have a global health committee which covers things like non-communicable diseases, universal health coverage. We also have antimicrobial resistance. We have an African engagement committee; we have a *regulatory in the science* committee. So basically we have a lot of different areas in which our organization interacts with WHO. So it's a very broad picture. I mean, I think some of the biggest pieces of our interaction with WHO would be things like the pandemic influence preparedness program, where many of our manufacturers are involved in contributing towards that framework, you have the PQ contribution as a prequalification contributions towards the WHO which again, our companies are involved in this; you have work on non-communicable diseases, so we involve with the WHO, we're part of the global coordination mechanism. So we're one of the partners on that, which is a multistakeholder dialogue or multi-stakeholder platform for addressing prevention and control of NCDs. You have neglected tropical diseases. So you know, we have worked with WHO on the NTDs, tuberculosis, mainly in terms of giving sort of industry expertise towards some of the technical matters. But I mean, it can also be just contributions in terms of financial income contributions towards certain events or workshops that the WHO might be organising. (…) We have an essential medicines list, we have a task force, this also takes part in consultations with WHO (…). I mean it's so varied. I am only just giving you a small flavour of how many different ways that we interact with WHO.

It is imperative to highlight that although the 1987 Principles specified that 'WHO recognises only one category of formal relations, known as official relations, with those NGOs which meet the criteria described in the Principles', it can be observed that the official relations could be extended to NGOs representing private sector entities. It contradicts the most accepted definitions of NGOs, which are that they should be of a non-profit nature. The FENSA, therefore, can be seen as a starting point for a clearer distinction between NGOs and the private sector.

The International Food and Beverage Alliance (IFBA) described itself as a business organisation. Even though IFBA does not have official relations with the WHO, they maintain a so-called relationship of dialogue that includes 'meetings on different issues, it includes participation in consultations, hearings, etc. And then I think there are some elements that we could describe as collaboration, so technical collaboration, for example, on phasing out industrial trans-fats or working on salt reduction'.

One must consider that according to the Guidelines on interaction with commercial enterprises to achieve health outcomes, in order to improve health outcomes:

> WHO regularly interacts with commercial enterprises in various ways, including: participation with one or more commercial enterprises in alliances and other relationships (sometimes with other public bodies, governments, non-governmental organisations and foundations) to address specific health issues; exchange of information; product research and development aimed at improving health; generation of cash and in-kind donations to WHO; advocacy for health (WHO,, 2001. p.2).

However, as they are internal guidelines and not regulations , the relationship between the WHO and the private sector before FENSA was blurred.

The Bill and Melinda Gates Foundation (BMGF) considers itself to be private philanthropy and describes its engagement with the WHO as ‘certainly a funder’.

The UN Foundation is classified as a foundation ‘because one of our jobs as a public charity is to provide grant support to the United Nations in various agencies, including WHO. So, we are a grantmaker to WHO, that's why they classify us as a Foundation, and that's kind of where our focal points administratively rest inside WHO, through their foundations' team’. The Foundation, however, works with the WHO in ‘a range of other ways, although we're not called a civil society actor, we do a lot of work with civil society, and that's how we got involved with the civil society task team’. Accordingly, for the interviewee, the work of the UN Foundation is more similar to the work that an NGO does due to their operating work. That means that the foundation not only gives out grants, but also: ‘[does] our own work; we do our own coalition work, our own communications work, our own policy work, our own advocacy work, et cetera. But for WHO purposes, they classify us as a foundation because of that grant-making dynamic that we have with them’. It is worth noting that the UN Foundation has been in official relations with the WHO since approval at the Executive Board meeting in January 2019, under FENSA rules.

6.5.2 Official Position Regarding FENSA

When asked what position MMI took towards FENSA, the interviewee answered ‘non-State actors do not have to approve it or not, right? Member States that have approved it. The position for Medicus Mundi International is to not to reject it, but to watch it critically’. Moreover, from MMI’s perspective, FENSA should protect against conflict of interests, and the aim of health for all should be facilitated through the Framework, ‘so that would be a fence towards actors that are seen as not legitimate working towards public health and that it will be open to actors that would be more contributing to the public interests, the public good approach WHO ought to have’. The interviewee also pointed to ‘a whole grey area in-between’ the debates about conflict of interests, perceived benefits and how to deal with that issue.

For IFPMA, ‘it was very painful to get to having FENSA be adopted and finalised (…) we understand the need for FENSA, and of course, there are many industries and sectors

where we understand that WHO has to be quite careful about its engagement'. The interviewee believes that IFPMA would welcome FENSA if the implementation were to be pragmatic, as the framework is seen as 'an enabling mechanism for private sector engagement, depending of course, who the private sector is'. However, according to the interviewee, 'FENSA seems to be often used as an excuse or reason by some parts of WHO to slow down in the process of working with the private sector because they're not sure about how to work with the private sector'.

It was also argued that the pharmaceutical industry has many solutions for global health challenges, and that it is already involved with the WHO in many different ways, such as bringing industry expertise. Finally, for the interviewee:

> as long as they (WHO) see FENSA as an enabling mechanism where they manage the risk in a pragmatic way but still use it in a way to enable meaningful engagement and meaningful work, find meaningful areas of collaboration with our sector, then it can be a very good mechanism. But I think that the issue has been for too long now (….), it's true that there's not a lot of clarity on how to consistently implement the framework. So that confusion inside of WHO then makes it very difficult to find a dynamic path forward for working together. So I think that FENSA sometimes is more creating a bit of confusion for some parts of WHO who don't know how to implement it. In that way that it was happening, it's actually becoming a problem rather than an enabler.

IFBA supported the adoption of FENSA at the time, and even though did not participate in the negotiation, the Alliance was aware that there were a lot of complex discussions with the Member States. The interviewee understands that conflicts of interest need to be addressed and managed, 'and so if the WHO requires a formal framework for doing that, then we would support it. Particularly because I think, the spirit of FENSA was to enable dialogue and where possible increase collaboration with non-State actors'. As well as IFPMA, the interviewee argued that the framework should be a tool to facilitate engagement while managing conflicts of interest, instead of being an obstacle to engagement.

The Gates Foundation interviewee was quite vague in all their answers and argued that the Foundation did not have a position, but 'welcomed the clarity that it [FENSA] was attempting to bring and we did not engage deeply into the process, but we welcomed it'.

The UN Foundation describes itself as 'believers in FENSA'. For the interviewee, FENSA is a crucial instrument for ensuring that conflicts of interest are managed and mitigated, and to avoid undue influence at the World Health Organisation, especially when it comes to normative and technical functions. It was highlighted, however, that FENSA should not constrain the WHO's ability to be an 'effective, smart and strategic partner with non-State

actors'. The interviewee believes that the WHO should maximize its partnership with non-State actors. Therefore, 'our position is that there is plenty of room to manoeuvre, for smart, effective, strategic partnerships for WHO with non-State actors, even inside the framework of FENSA'.

6.5.3 How Was the Behaviour of the Member States Perceived? Were Coalitions Formed? Did Meetings Between NSAs and Member States Happen During the FENSA Process?

For Medicus Mundi, the Member States were divided 'a bit along the lines of the G77 and the Global North but with some mix positions in there'. According to the interviewee, Brazil and the Latin American countries were the most vocal against the framework because they perceived that it would undermine the role of the State and the legitimacy of the Member States' governance in the WHO. India, another vocal Member State in during the negotiations, was seen as 'relatively supportive and in a kind of a middle position'. On the other hand, some European countries and the United States were pushing for the Framework, 'but some with caution'. To sum up, the interviewee asserted that:

> China was somehow withdrawn from the debate and (…) the UK and the US have always been making the case, (WHO) should be open to other actors as well because in the end it was about the role of big financers in WHO, the role of the Gates Foundation in collaboration with WHO that was at stake. The Gates Foundation and other financers. (…) Countries like Germany and Norway have also been pushing for it, but in a very regulatory, moderated way: WHO should change, should work with other actors, but we should indeed ensure that the Member States remain in the driving seat and that the public interest is being served. Eventually, I think some Member States agreed because FENSA became a bit of a headache process. Got stuck after several years and this more technocratic approach to managing risks, to mitigate risks, also announcing that it would not put a heavy financial burden on WHO made all countries accept it eventually in 2016.

Considering the Member States with a more private sector-focused approach, IFPMA mentioned the United States was 'of course' the most vocal Member State in terms of advocating for pragmatic implementation, specifically in a way that makes the most out of public-private sector expertise.

Moreover, 'Zambia was another country that at the time quite surprisingly for an African Member State was very vocal but in a positive way as well for us'. The interviewee also mentioned Japan and Germany (the latter only more recently) as in favour of a supportive framework for engagement with the private sector, and Finland 'probably on the other side'. Brazil and India were also mentioned as being very vocal against the private sector and in ensuring avoidance of conflict of interests.

Regarding a North/South coalition, IFPMA's interviewee confirmed that:

> in general, it was that, for sure. And what was really surprising about Zambia was that it is like an outlier. But I think that it very depends on the individual health attaché at the Geneva level. Because if they are very vocal, if they have a particular position, if they are very influential in Geneva, then that can also impact how the country is perceived. So, at the time, Zambia had a health attaché who was quite vocal, quite engaged, involved in FENSA. So I guess sometimes you have situations where it's not clearly North/South, it can depend on the individual. (…) But in WHO, if you look at all Member States, there used to be more coalitions, more groupings. Now it's not so much.

When it comes to close relations, the IFPMA 'tend to kind of communicate quite a bit with the United States and some of the European Union Member States as well, traditionally the UK'. The interviewee also explained that, traditionally and politically, the countries that have big pharmaceutical industries were obviously the Member States that we tried to know better. So for example, Germany, Switzerland, the UK, US, Denmark (…), this is a political-economic thing where you have countries where that is a big part of their economy is that industry. And you see that playing out in WHO of course. I mean you see that in all the geopolitical discussions'.

The IFBA's interviewee pointed out different perspectives between the Member States, of which, countries such as the G77 wanted 'quite a restrictive type of framework' and others, namely in the WEOG group, wanted a more flexible arrangement. 'At the time we issued a position paper or a statement in support of FENSA, (…) But we did not advocate specifically with the Member States'. Regarding countries with close relations, the IFBA affirmed that it took the view that 'we should support FENSA as an organisation, we did not have a much more specific point of view. So I don't think that we engaged more closely with any Member State'.

The Gates Foundation declared that it didn't have exceptional relations with any of the Member States, nevertheless it 'consults a lot with the UK, increasingly with Germany, sometimes Norway, Sweden, but not formal agreements, it is simply often like-minded donors will have conversations'. When asked if the BMGF met with the Member States during negotiations, the interviewee denied this, saying that it 'does not make sense'. Finally, regarding trying to find a common position with the US government, the interviewee said that this didn't occur. In this regard, the interviewee from the United States said 'our relationship with the Gates Foundation is close when our interests align', and, regarding the FENSA process 'I would say we kept each other informed, but I would say they were less

engaged. Their attitude throughout it was that this is a Member State decision and that they would abide by whatever the Member States said. And I think that was actually a helpful position because they already have kind of conspiratorial feelings towards them'.

For the UN Foundation, coalitions and Member States coming together around aligned positions occurs a lot in governance matters at the UN, including in the WHO. The interviewee affirmed that while various of those coalitions were reasonably loose, others became 'kind of more formal negotiating blocks'. However, it was pointed out that:

> some of those [coalitions] changed over time as the politics of certain countries changed. You can imagine if a new prime minister or political party came into power that had a different kind of policy posture around engagement, around the role of civil society or the role of the private sector in any kind of policy formulation process, they might then exhibit that differently in terms of their posture at WHO, or in regard to FENSA negotiation. So some of that did change over time. I don't think it was static for the kind of five years in the lead up to the adoption of FENSA. But I think one of the reasons why it took so long was because of these different positions and kind of groups of Members States suggesting either a much more enhanced and flexible way for WHO to engage with non-State actors versus those who were suggesting a much more constrained mode of engagement for WHO and non-State actors.

In 2015, Margaret Chan asked a few Member States to start working together to unblock some of the impasses. Together with the IFBA, the UN Foundation representative affirmed that the G77 countries were 'more apt to want a constrained, a more conservative approach', while those representing some countries in Europe and North America were advocating a more open relationship. Besides, the interviewee declared that even though FENSA has been approved, these positions, especially on the role of the private sector and to a certain extent the role of civil society, are a highly political issue in some countries. Therefore, it still plays out at the WHO. 'I mean it plays out in the Executive Board meeting in January; it plays out in New York in UN conversations; it plays out every year through the World Health Assembly. (…) The US, especially, and others as well, are much more in support of a significant role for the private sector. And others negotiating on behalf of a range of countries are more apt to want a measured approach to the role of the private sector'.

When it comes to the relationship between the UN Foundation and Member States, the interviewee argued that the Foundation works directly with the Member States to support other governments and countries on immunisation or malaria prevention, for example. The Foundation also receives grants from several governments. It was highlighted, however, that none is related to the governance of the WHO.

6.5.4 How Was the Role of NSAs Perceived During the FENSA Negotiation Process?

Medicus Mundi' interviewee explained that in 2011 and 2012, the WHO was quite open to 'a more differentiated approach', therefore, NSAs worked in a loose coalition to try to influence the FENSA. NGOs were clearly against a single benchmark because the WHO should provide a differentiation between the actors. The interviewee affirmed, however, that 'under pressure by some Member States probably to have a more open framework (…) given the pressure by donors and Member States, and this is always informal, they shifted the debate'. Regarding the behaviour of non-State actors, the interviewee explained that until 2013 the debate was 'quite aggressive between the NGOs and pharmaceutical industry representatives about who are the good guys, who are the bad guys, who were public-interest NGOs, who were the business-interested NGOs. I didn't find that constructive, but WHO afterwards changed the governance process'. Therefore, after 2013, the non-State actors were not directly invited anymore, but separately meetings were arranged: 'we were in contact with the FENSA office still, but they have closed a little bit the gates'.

The IFPMA considers itself to have been 'heavily involved' with FENSA negotiations and mentioned a consultation for the non-State actors 'to sort of voice our concerns around how to ensure that FENSA was worded in a way to be an enabling mechanism to be something that encouraged engagement (…) I remember it felt as if at the time there was a good opportunity to input into the development of the framework'. Regarding the performance of NSAs, the interviewee explained that 'some of the NGOs were being very vocal on the same, (…) which is about the conflicts of interest and being very concerned that the private sector could be influential in a way that is not appropriate to the workings of WHO'. The Third World Network, MSF and IBFAN were mentioned as part of this group of NGOs. Moreover, interviewee 15 confirmed that there was 'a fairly kind of broad coalition of interests amongst these NGOs that is quite solid and quite consistent'.

When asked if IFPMA sought to establish coalitions among the private sector, the interviewee pointed out the heterogeneity of the private sector:

> You have pharmaceutical, you have the alcohol industry, you have food and beverage, you have tobacco and arms. We know that's a complete no-go for WHO. But even if you look at food and beverage, alcohol, these are industries that we as pharmaceutical we don't want to be associated with (…) because we don't see ourselves in the same light at all. We're creating treatment, solutions, cures, that help to prolong life, to enable better health outcomes (…), it's a completely different part of the private sector. So you see that it's difficult to form a coalition of the private sector because you have very different objectives, different things that we work on.

> So I think in optically and then within WHO be very complicated and not necessarily a good thing for us, for example, to associate with other parts of the private sector.

It was also argued that the private sector became quite isolated in the FENSA negotiation, because, although some Member States have shared some of the private sector's views on the Framework, 'at the end of the day, the likelihood of philanthropic or NGOs or academia agreeing with you on common language is very difficult. I think we are kind of a bit on our own in some ways'. To finalise, the interviewee admitted that FENSA was an important topic, maybe one of the biggest, as IFPMA needed to ensure that the language of FENSA came out balanced, as it was significant for the pharmaceutical sector:

> You imagine that if the language came out to be very prohibitive, that would be big problems for us in terms of how you engage with WHO and not just for us, for WHO as well, to be honest. So, I think it shouldn't be underestimated at the time it was really, it was huge (…) we felt that it was really important to ensure the best outcome possible for FENSA because it had implications not just for WHO, but implications for potentially the whole UN system.

For IFBA, FENSA negotiation was a Member State-driven process, therefore, any request that non-State actors could have carried out would have, by necessity, been addressed to the Member States. Hence, regarding non-State actors trying to influence the negotiations through the Member States, the interviewed affirmed that there 'was quite some activity'. While some organisations in the private sector were concerned that FENSA could be used to impede meaningful engagement, organisations within the civil society were concerned that FENSA would open the gates to collaborations with the private sector that would entail conflict of interest. In this respect, 'there was a fair bit of advocacy towards the Member States to either have a tougher or a more pragmatic approach'.

The Bill and Melinda Gates Foundation argued that they 'stayed pretty much out of all of that negotiation', but 'certainly we believe very strongly in a vibrant civil society. So we would have expected that the NGOs would have been mobilised, but we did not in any way engage in that'. When asked if the Foundation exchanged views with the other non-State actors during the negotiations, the interviewed assumed that cannot 'speak for my entire organisation, but I do not recall any specific engagement with any other non-State actors'.

6.5.5 Sensitive Contents of the FENSA

As previously detailed in this chapter, some points of FENSA raised concerns from NSAs, specifically conflict of interest, secondments, and the distinction between non-State actors with commercial interests. The interviewees were firstly asked which topics of FENSA

were, from their perspective, more sensitive. After, if the polemical topics perceived from documents and reports were not mentioned, they were directly questioned.

For Medicus Mundi International, the most sensitive issue was conflict of interest, precisely, what is a perceived or real conflict of interest? Given that a conflict of interest implies that commercial or economic interests are being blurred with the public interest, which, then, could lead to organisations indirectly influencing policymaking or norm-setting by the WHO, the interviewee believes that 'it is all about how tight or how open you set what a conflict of interest is'. To illustrate, the interviewee argued:

> Before (FENSA) it was only about individual conflict of interests, and now it's also about institutional conflict of interest. (….) The NCD Alliance, which is one of the biggest non-communicable diseases, it's an NGO Alliance that also has patient groups (…) part of it is taken by the American Heart Federation or the Diabetes Federation, they receive money from the pharmaceutical industry. So (the money goes) from the pharmaceutical industry to the Patient Federation to the NCD Alliance. NCD Alliance applies for FENSA and FENSA says it's all okay with the NCD Alliance, it does not have any conflict of interest. And we say if you would trace it down, there might be indirectly something that might influence how agendas are being shaped.

Moreover, the interviewee explained that, according to the Director for Partnerships and Non-State Actors at the World Health Organisation, Gaudez Silberschmidt, non-State actors did need FENSA to indirectly influence the WHO, as they could direct themselves to the Member States. To exemplify this argument, it was explained as follows. In the debates about guidelines for the amount of sugar, Italy lobbied against it, to lower the norm, as there were individuals from Ferrero Rocher in the Italian Mission making the statements. Silberschmidt, therefore, argued that for the NGOs, if FENSA did not exist, private sector entities would work directly via national missions. The interviewee affirmed that the main argument of the WHO was that with FENSA, at least, that it would be a more open process.

The differentiation between the types of non-State actors was also mentioned by Medicus Mundi. According to interviewee 14, the WHO should be more careful regarding the topic, and question to be considered would be: 'Who do these groups really represent?'. The interviewee then expanded upon the democratic deficit of non-States actors:

> If the Gates Foundation is on the table and they're paying so much to WHO to become the second biggest donor after the US, who do they represent? You could also say, do the US really represents its citizens? Well, but at least you can either hold them accountable through the democratic process and you could ask questions in Congress, et cetera. But with the Gates Foundation, same with an NGO in a sense, right? (…) the main debate is that organisations need to be accountable, they need to be transparent, but you hear much less about actual representation. What is their agency, who was actually there on the table? (…) So, in the end, it's a political

> question about how countries want to organise multilateral global health governance and how are other actors represented in the decision making and who has allowed you to meet a role in that decision making or not?

The MMI interviewee then recalled that some NGOs were also objecting about the term 'non-State actors'. It is worth noting that, before 2014, the debate surrounded NGOs and the private sector. Afterwards, it became a non-state topic.

The interviewee also mentioned engagement with particular industries, in paragraph 44, but pointed out that, in the end, industries do not directly influence the WHO but use other channels, however, he did not mention would be these channels would be. Finally, regarding secondments, the interviewee only affirmed that might be a sensitive matter.

The IFPMA mentioned 'a long discussion' regarding perceived conflict of interest versus actual conflict of interest.[96] 'Perceived does not mean that it is going to be a conflict of interests; it just means that there might be. Again, it is all down to the interpretation of how you choose to use that framework for your organisation if is a risk management approach or a risk aversion'. Regarding secondment, the interviewee declared that:

> secondments from the private sector were perhaps more acceptable once upon a time, way back. But one thing that we were surprised about with the FENSA adoption was that a secondment from private sector was completely no-go, like completely forbidden. And I think it's one of those things where you have to consider, is that a very clever idea? Not necessarily. If you're lacking expertise in WHO, technical expertise and you refuse to have secondment from private sector, then you have a gap. You have a knowledge gap.

For the IFBA, the language regarding the types of non-State actors was 'particularly sensitive', and the Member States were looking at it with an additional degree of caution as 'there are inevitably some grey areas and some difficulties around that'. However, for the interviewee, FENSA is a framework for all non-State actors that has distinct subsections and specific rules for the different non-State actors, therefore, 'whether you have one framework and four sections or four different frameworks, it does not really make a difference'.

Regarding a different treatment for the different categories, the interviewee affirmed that common rules were needed, but that 'you need some specific rules for different types of non-State actors as the conflict of interest issues that might arise in respect of a not-for-profit NGO might well be different to the conflict of interest issues that may arise in relations with

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[96] According to the World Health Organisation, an actual conflict of interest arises when a vested interest has the potential to unduly influence official or agency judgement/action through the monetary or material benefits it confers on the official or agency. A perceived conflict of interest arises when a vested interest has the potential to unduly influence official or agency judgement/action through the non-monetary or non-material influences it exerts on the official or agency.

a business organisation. So, there is a case for some additional specific provisions in addition to a basic horizontal framework'. To conclude, the interviewee mentioned the concept of perceived conflict of interest and argued that 'personally, I have never understood how that should be applied because my perception is necessarily subjective, so it is quite complex to apply that concept in relation to the notion of conflict of interest'.

The Bill and Melinda Gates Foundation mentioned conflicts of interest, which, according to the interviewee, need to be managed. 'We would certainly be very concerned about any potential conflicts of interest, whether real or imaginary. But we believe very strongly that conflicts and potential conflicts of interests can be managed'. When asked about secondments, the interviewee affirmed that the Gates Foundation did not 'have a view' on the topic. Once asked if the Foundation used to second people to the WHO, the answer was 'I'm not sure we would call it a secondment, but we certainly did provide staff support on the polio program'.

The UN Foundation believes the role of the private sector was, and continues to be, the most contentious topic of FENSA negotiations, especially when it comes to access to medicines and essential diagnostics and donations to the WHO. The interviewee also mentioned the way in which non-State actors can engage in the WHO's governance and how the Framework can potentially create significant obstacles for small NSAs getting into official relations:

> The barriers to entry are high enough that it precludes anything other than international NGOs from entering into official relations. For instance, you have to have an assigned focal point inside WHO, to have a three-year work plan, to show proof of existing and prior collaboration with WHO, et cetera. Those barriers to entry are sufficiently high that it already restricts and will continue to restrict the inclusion of civil society that are nationally based or from lower-middle-income countries or regions where those barriers to entry are sometimes just too high. And so then you get an inadvertent favouring of big international NGOs.

Regarding the controversy surrounding secondments, the interviewee confirmed that the UN Foundation had seconded personnel at the WHO. Although understanding the fear of many NGOs, 'the barriers to entry are so high and the kind of legal instruments and arrangements and agreements between the seconding organisation and the host organisation or the WHO are quite rigorous (…) [that we are] inability to influence or prejudice or even directly manage any employee of ours that is seconded to WHO'. For the UN Foundation interviewee, therefore, secondments should have not loudened so many tenseness.

It can be noted that non-State actors have an overall more critical perspective regarding FENSA. According to the interviewees, ‘FENSA is not a panacea. FENSA should be helpful in structuring the way that WHO engages with the external world. But I think the challenges are much bigger than that’ (Private Sector 2); ‘it really comes down to how the organisation will implement and how they will interpret FENSA, will they be encouraged and empowered to use FENSA in an enabling way and not use it as a fence?’ (Private Sector 1), ‘I do not think it is sufficient, it is a technical document to deal with a deep multilateral political issue’ (NGO 1). Considering both interviews with NSAs and with MS alongside the statements, NGOs and the private sector are revealed to be more interested in the FENSA negotiation. At the same time, for academic institutions, FENSA did not seem to be a priority, and philanthropic foundations appeared to have conducted dubious behaviour. The next and last chapter will consider all the data gathered to discuss and analyse the results with reference to the hypothesis and the theoretical approach, and conclude with some final remarks.

CHAPTER SEVEN: ANALYSIS OF RESULTS

The Framework of Engagement with non-State Actors was born as part of the Reform of the World Health Organisation, launched in 2011. The report entitled 'WHO reforms for a healthy future', presented in a Special Session of the Executive Board, stated that 'WHO has been at the forefront of improving health around the world since its founding in 1948. But the challenges confronting public health have changed in profound ways and with exceptional speed. While WHO continues to play a leading role in global health, it needs to evolve to keep pace with these changes. This is the overall purpose of reform' (EB, 2011, p.1).

While it is typically the Member States that push for reforms in international organisations, the reform that started inside the WHO was led by Margaret Chan, the Director-General at that time. The preliminary focus was on financing:

> The reform agenda began with a focus on financing and the need for better alignment between objectives and resources. A Member State-led process has since evolved to address more fundamental questions about WHO's priorities, its changing role in global health governance, and internal governance and managerial reforms needed for the Organization to be more effective and accountable. The continuing financial crisis means that the need for predictable and sustainable financing remains a central concern (EB, 2011, p.1).

However, it was proven impossible to ignore the functioning of the Organisation due to a background of leadership and legitimacy crisis, as analysed in Chapter 2. The reform, therefore, was divided into three dimensions: priorities, governance and management.

FENSA was not initially considered to be a comprehensive global policy, but as a way to regulate the relationship of the WHO with non-governmental organisations and the private sector. Historically, as explained in Chapter 3, the engagement with the private sector was only noted, and not approved, by the Executive Board. Its implementation, therefore, was beholden to the Secretariat, who did not entirely follow through. Additionally, one of the main critiques of the 1987 Principles was the lack of distinction between the different types of NGOs which, consequently, led to a lack of transparency concerning the interest groups behind them.

The private sector, therefore, has always been seen as the main contentious topic within the Organisation that needed to be controlled. According to interviewees 19 and 21, current and former high-level staff at the WHO, some Member States blocked many attempts to improve regulation of the WHO's relationship with non-State actors, explicitly non-

governmental organisations and the private sector. The problem with NGOs, according to the interviewees, was that some Member States perceive them as sometimes excessively political and active, especially on the domestic side. As explained in Chapter 2, a strict State-centrism of some Member States had historically blocked debates to advance in the reform of the relationship between the WHO and NGOs in the years before FENSA.

The initial idea for the new rules was to develop two different documents, one to 'people-oriented NGOs' and another to 'business-oriented'. As explained, the leading critique of the official relations' policy (part of the 'Principles governing relations between the World Health Organisation and nongovernmental organisations' (1987)) was that under the rubric of NGOs, organisations representing private sector entities were also considered. In this regard, according to interviewee 19, a former advisor to the Director-General, the Secretariat changed its position and decided upon a single document that would include both NGOs and the private sector. Therefore, in March 2013, the Executive Board decided that a document should be prepared, outlining overarching principles and operational procedures for non-governmental organisations and private commercial entities. Interviewee 19 believes that this was due to pressure exerted by Member States. Moreover, it was stated that 'evidently, the Member States that have pressed the most in this direction were the countries that historically have more conservative positions: the United States, the United Kingdom, some countries - not all - of the European Union'. It can, therefore, be observed that the FENSA negotiation process was polarised from the beginning.

According to the documents, the Secretariat proposed the inclusion of not-for-profit philanthropic foundations, however, interviewee 20, a former high-level staff member at the WHO, affirmed that this was at the request of the Member States, without mentioning specifically which. The consensual assertion of the three interviewees from WHO was that philanthropies were included because of the Bill and Melinda Gates Foundation, referred to by one of the interviewees as 'the proverbial elephant in the room'. The Gates Foundation was also a contentious point between the Member States because, while it was orienting a good part of WHO's policies and priorities (the already explained donor-driven agenda problem) without accountability, and, at a certain point, kidnapping the multilateralism and collective governance of the Member States, no one was able to afford the amount given by the Gates Foundation to the WHO. Interviewee 20, then, affirmed: 'it is very easy to let the

Gates Foundation give us $650, $700 million every two years, so they [the Member States] didn't have to put up that money, but inevitably that brought philanthropic foundations into FENSA'. It was impossible, therefore, to elaborate a framework to control the interaction with non-State actors and leave the Gates Foundation unregulated, as its role, particularly the financial role, was immense, and continues to be. Hence, 'obviously this is not the Gates Foundation policy, it is a philanthropic foundation policy, but everybody had in mind Gates'.

When analysing the available documents since 2012 and comparing them with the 21 conducted interviews, it became clear which topics were blocking the negotiations: 1) conflict of interest; 2) FENSA being applied in all regional offices, including PAHO; 3) distinction of the different types of non-State actors; 4) secondments; 5) how to apply FENSA during emergencies crisis; 6) engagement with other industries affecting human health (paragraph 44); 7) the engagement with the private sector. The disagreements during the negotiations went beyond the official discussions between the Member States at the WHO's Governing Bodies, non-State actors, particularly NGOs and the private sector, were also trying to indirectly enforce their perspectives and interests.

7.1 Conflict of Interest

Conflict of interest occurs at all levels of governance, from local to global, both in the public and private spheres. It can influence, and distort, decision-making processes and lead to inappropriate outcomes. As outlined in Chapter 3, insufficient safeguards against conflicts of interest was one of the weaknesses of the 1987 Principles. Establishing proper safeguarding mechanisms against conflicts of interest requires a comprehensive and robust definition. The Member States had long-lasting debates on the definitions and conceptualisation of conflicts of interest, one of the issues that blocked the negotiations.

The initially proposed definition was 'a conflict of interest can be defined as a set of circumstances that creates a risk that judgment or actions regarding a primary interest will be unduly influenced by a secondary interest' (WHO, 2013, p.7). The final and approved version of FENSA establishes that:

> a conflict of interest arises in circumstances where there is potential for a secondary interest (a vested interest in the outcome of WHO's work in a given area) to unduly influence, or where it may be reasonably perceived to unduly influence, either the independence or objectivity of professional judgement or actions regarding a primary interest (WHO's work). The existence of conflict of interest in all its forms does not as such mean that improper action has occurred, but rather the risk of such improper action occurring. Conflicts of interest are not only financial but can take other forms

as well. (WHA69.10, 2016, p.10)

Entities representing the private sector such as IFBA and IFPMA, as well as all developed countries interviewed, along with Zambia, advocated that FENSA should not imply or assume that conflict of interest concerns apply only to the private sector and, therefore, be used to exclude any stakeholder 'who can positively contribute to improving health'. In the same direction, the United States, a clear supporter of the private sector, took the position that conflict of interest should be uniform across the four specific policies.

On the other hand, the so-called publicly interested NGOs heavily criticised what they called a poor conceptualisation of conflict of interest, precisely what a perceived or real conflict of interest would be. The alignment between these NGOs and India, Bolivia Brazil and Egypt, as perceived through the document analysis, is clear. They were all interested in the distinction between real and perceived conflicts of interest as well as that between individual and institutional conflicts of interest. Moreover, for them, conflict of interest was a concerning topic when considering the private sector, or non-State actors with links to the private sector.

One should note that, considering the Member States' positions as analysed through documents and interviews, the position taken by Zambia contrasts with those taken by the developing countries group as a whole. Zambia warned that FENSA should not imply that the financial conflict of interest of the private sector would be somehow more important than of other non-State actors, as this would create 'a clear bias against the private sector'. The Zambian position was stressed by Interviewee 15, from IFPMA, who affirmed that the country 'was very vocal but in a positive way for us'. In this regard, it is interesting to point out that Interviewee 5, from Brazil, put forward that the power imbalances that permeate global governance processes represent a way to understand Zambia's position.

It is worth noting that scholars of International Relations, particularly from the realist school, have an impoverished conception of power, which focuses almost exclusively on material capabilities and coercion. In this regard, Barnett and Duvall (2005) present four categories of power, providing an important challenge and a vital contribution to IR studies. Although the first category still relies on the 'direct control over another', the authors describe power overall as 'the production, in and by way of social relations, of effects that shape the capacities of actors to determine their circumstances and fate'. The conception of institutional power is particularly important for this thesis and is defined by Barnett and

Duvall (2005) as ‘actors’ control over socially distant others’ focusing ‘on the formal and informal institutions that mediate between A and B, as A, working through the rules and procedures that define those institutions, guides, steers, and constrains the actions (or non-actions) and conditions of existence of others’. The focus, therefore, lies on the social relations between nation States. Although including the social structures that open the door to persuasion and to collective decision-making, Barnett and Duvall excluded persuasion and collective decision-making processes per se.

In health-related negotiations, imbalances can emerge between negotiators that have access to public health experts; the Brazilian Interviewee 5 explained the alignment between diplomats from developing countries and non-governmental organisations from the global North. This can be seen as an example of structural power. Moreover, imbalances in the negotiating power and capacity between developed and developing countries is not the only variable; one must also consider the inequalities in health, which make low and middle countries even less powerful, as their health systems rely on donors’ money.

Sweden, for instance, is the leading donor to Zambia’s health sector. The country also receives large funds from The Global Fund and the Bill and Melinda Gates Foundation. Therefore, the literature review of the first chapter cited the article ‘Challenges for nationwide vaccine delivery in African countries’ written by Mario Songane (2018), which investigates the role of GAVI in the development, purchase, and delivery of vaccines and the Bill and Melinda Gates Foundation acting as a sponsor. Zambia is one example of how many governments need support from Gavi, currently the largest external funding source for vaccine purchases in Africa. One should consider that The Gates Foundation pledged $750 million to establish Gavi in 1999. The Foundation is a crucial partner of GAVI in vaccine market shaping.

There is another variable that similarly cannot be overlooked and was argued by Interviewee 12 from Zambia; NGOs, which usually work in low and middle-income countries, are seen as ‘just as problematic as the private sector’. The Zambian perspective was that not only are NGOs driven by money, but they usually push an agenda that it is of their own interests.

In light of how the FENSA approached the topic of conflict of interest, it is possible to see that the two groups of countries’ (e.g. developing and developed) positions were not

consensual. While the United Kingdom suggested a clearer understanding of institutional conflict of interest, the United States was advocating for the withdrawal of its definition. Initially, institutional conflict of interest was directly linked to 'the economic interests of private sector entities', however, this raised discussions among Member States, supported by NSAs, mainly the private sector aiming to homogenise the rules for all non-State actors, and NGOs seeking to curb the WHO's engagement with for-profit institutions.

The final document establishes both individual and institutional conflict of interest. India, therefore, was partly pleased as already analysed in Chapter 4; the topic was a primary concern of the country, which suggested three types of conflict of interest: individual, institutional, and conflicting interest. It's important to note, however, that a direct mention of private sector entities was withdrawn, indicating that the developed countries' perspective, mainly that of the United States, was also taken into account.

7.2 Distinction Between the Different Types of Non-State Actors

Another major topic was the clear distinction between entities with and without commercial interests; this has been a central issue at the WHO for a very long time. In this sense, interviewee 20 admitted that most of the sensitive discussions were related to the private sector. This can be verified by examining the first consultation that involved the Member States and non-State actors, as some NGOs suggested that more strict transparency and accountability actions should be taken concerning entities with commercial interests. In this regard, some Member States, especially the developed and Global North countries, were advocating for standard rules for all non-State actors, arguing that 'it is not because someone is coming from the private sector that it is a bad person' – as stated by interviewee 10 from the European Union. On the other hand, some Member States like Brazil and India, strongly backed by the so-called public-interest NGOs, were seeking stricter rules for private sector entities and were extremely critical of the unification of all actors under the term 'non-State actors'.

The main argument of those backing a generic treatment of non-State actors was that differentiation was unnecessary as long as FENSA could provide full and public disclosure of information and robust mechanisms for risk assessment. On the other hand, developing countries on the whole kept arguing that a relationship with a profitable entity has the potential to risk the WHO's integrity, even with adequate safeguards to prevent conflicts of

interest.

The distinction of the different types of non-States actors was a much-pursued agenda by public-interest NGOs. Civil society groups argued that treating the four categories in the same way, under the label of NSA, would 'once and for all, legitimise lobbying by business associations and philanthropic foundations at WHO governing bodies'. The NGO International Baby Food Action Network (IBFAN), for instance, was vigorously active in demanding a clear distinction between 'public-interest actors and those whose primary interest is market-led'. As already mentioned, some interviewees, namely 7, 9, 20 and 21, even accused NGOs of having written the statements for the most vocal developing countries.

By and large, when analysing documents and the interviews, developing countries were pushing for 'clearer' distinctions, as they were worried about the implications of an excessive engagement, especially with private sector entities and with NGOs, philanthropic foundations and academic institutions controlled by the private sector. On the other hand, the United Kingdom, the United States, Norway, Germany, among others, argued that the WHO's work would be negatively impacted if the FENSA decided to limit work with institutions that are privately funded. For developed countries, the FENSA should allow for greater engagement between the WHO and all NSAs and focus on providing the necessary safeguards against conflicts of interest.

The hypothesis that a North/South division was not very strict is proven to be correct, as Zambia was against a different treatment of NSAs. The FENSA ended up producing similar policies for the four categories. For instance, the four policies on Participation in WHO meetings are precisely the same, but, regarding involvement in meetings organised by NSAs, the participation of WHO staff members in meetings of private sector entities is much more restricted.

7.3 Pan American Health Organisation (PAHO)

Although not initially expected, it was perceived, during interviews, that the Pan American Health Organisation (PAHO) was a concern for many Member States and became 'a very big issue, especially towards the end of the negotiation', according to interviewee 20. Developed countries, mainly from Europe, claimed that the full appliance of FENSA, in all three levels of the Organisation, was as a precondition for the adoption of the Framework.

As already explained in Chapter 5, the FENSA would not be automatically applied to the PAHO after its adoption by the World Health Assembly as it would also have to be approved by PAHO Member States through its own governing bodies. In this regard, interviewee 19, a former staff member at the WHO, who also worked in the PAHO, affirmed that the PAHO needs to be more articulated with the Headquarters in Geneva, as the Regional Office 'claims independence' whenever it is convenient - this happened during FENSA negotiations. Many countries, however, perceived a risk of double standards within the WHO system, regarding FENSA.

Brazil argued that the European Union countries wanted to control PAHO through WHO Headquarters in Geneva. In fact, the European countries consolidated a strong position and were supported by some developing countries, like Zambia. At the final session of the Intergovernmental Working Group, in April 2016, Norway led the Europeans on the PAHO issue and declared that 'FENSA needs to be implemented across all WHO levels, with one single registry and the DG as final decision-maker'.

The Pan American Health Organisation, therefore, certainly represents a topic in which the logic of North versus South division cannot be applied, as countries from the Americas were seeking a common position which was counterbalanced by other countries under European leadership.

7.4 Secondments

Secondments, particularly from the private sector, evidently polarised the Member States into a North/South cleavage, despite notable exceptions. For interviewee 20, this was a discussion more focused on the theoretical principle than addressing a real problem, as the former WHO staff member assured that the Organisation had almost no seconded personnel from the private sector in recent years The United Kingdom appeared to be one of the most vocal countries against the prohibition of secondments from commercial entities, and was supported mainly by France, Germany and the United States. In contrast, Brazil was against the WHO accepting secondments from any non-State actors, but in the interview stressed that while the number of seconded personnel from industries could be unimportant, their influence was not. Egypt was, until the last moment, seeking to ensure that the ban on private sector secondments would be kept. On the other hand, according to a Summary made by the

United States Council on International Business,[97] at the 138th session of the Executive Board (January 2016), the World Heart Federation and the NCD Alliance were trying to preserve secondments from NGOs and academic institutions.

The topic, therefore, divided the Member States into three main groups, one recommending that the WHO should not allow secondments from any non-State actors, others pursuing to exclude only secondments from the private sector and others, mostly the developed countries, in favour of secondments from all NSAs. A clear and direct convergence of positions between the Member States and non-State actors can only be observed in view of the position taken by developed countries and the private sector entities, who were not happy to be the only NSAs excluded. Although mentioning the private sector, public-interest NGOs were more worried about secondments from philanthropic foundations, specifically the Bill & Melinda Gates Foundation and the United Nations Foundation, a concern that cannot be observed among the Member States.

In May 2016, the FENSA was approved and paragraph 47 of the final version establishes that the WHO does not accept secondments from private sector entities. Moreover, the General–Director was requested 'to develop, in consultation with Member States, a set of criteria and principles for secondments from nongovernmental organizations, philanthropic foundations and academic institutions', taking into account, 'specific technical expertise needed and excluding managerial and/or sensitive positions; the promotion of equitable geographical distribution; transparency and clarity regarding positions sought, including public announcements; secondments are temporary in nature not exceeding two years'.

Finally, as only secondments from the private sector were, eventually, prohibited, it can be argued that this topic signified a defeat for the Global North.

7.5 Emergencies

The engagement with non-State actors in the context of emergencies was another controversial point and divided the Member States into two main groups. It is worth reiterating that the Ebola outbreak happened during FENSA negotiations, which, for many countries, influenced the debate. Developed countries, namely Germany, Norway, the United

[97] Brief Summary of the WHO Executive Board Discussion on FENSA. Available at: http://globalhealth.org/wp-content/uploads/Brief-Summary-of-the-WHO-Executive-Board-Discussion-on-FENSA-Feb-2016.pdf

States, Switzerland and the United Kingdom, sought to suspend the application of FENSA while responding to emergencies. The issue made Norway 'seriously consider' blocking the Framework, as interviewee 6 declared. Both interviewee 9, from the United States, and interviewee 20, from the WHO, affirmed that Iran was the main opponent of flexibilities during emergencies crisis with 'a very few countries supporting it'. However, interviewee 5, from Brazil, and 12, from Zambia, declared themselves to also be against using emergency contexts to flexibility FENSA.

The suspension of the FENSA while dealing with an emergency was one of the topics that made the European countries, headed by Norway, threat to block the adoption of the Framework at the end of the negotiations. In the Executive Board of January 2016, Malta, speaking for the European Union affirmed that the EU Member States were worried that a limitation on the flexibility of the WHO to act in emergencies could undermine the Organisation's leadership and effectiveness. Sweden, Denmark, Estonia, Latvia, Lithuania, Finland, Iceland, Switzerland and Germany also expressed their concern on the issue, seeing it as the most important unresolved subject. During the EB, Egypt, speaking on behalf of the EMRO (Regional Office for the Eastern Mediterranean) was the only country outside the European Region to request clarification on NSAs' engagement rules in emergencies.

When it comes to the non-State actors, the IFPMA explicitly manifested in favour of flexibilities and exceptions in an emergency context. The watchdog NGO Third World Network, when reporting Norway's proposal on emergency exception, claimed that it would weaken FENSA rules and neutralise safeguards. At the 139th of the Executive Board, January 2016, Medicus Mundi International declared that the emergency response clause should not be used as an excuse to prevent the adoption of a strong framework (EB, 2012, p.50).

The final version of FENSA, however, has the text proposed by Norway with few language amendments. Paragraph 73 of the Implementation Section establishes, therefore, that the Director-General when responding to 'acute public health events described in the International Health Regulations (2005) or other emergencies with health consequences (…) may exercise flexibility as might be needed in the application of the procedures of this framework in those responses'. This point was certainly a victory for developed countries, particularly the Europeans.

7.6 Engagement With Other Industries Affecting Human Health

Paragraph 44 was notably polemical. Although there was an overall division between South and North countries, the United States and India were the protagonists on the topic. There was a consensus since the beginning that the WHO does not engage with the tobacco and arms industry. However, some developing countries, principally India, were pushing to add 'food, beverage, alcohol and infant formula' industries to the no-go engagement list. The influence of the NGO International Baby Food Action Network (IBFAN), which mainly focuses on breast milk substitutes manufactures such as Nestlé, can be easily noted in its criticisms about the engagement of the WHO with the private sector. On the other hand, the United States, supported by developed countries such as Norway, Germany, Canada and France, were against explicitly mentioning other industries. They advocated for a wide-ranging clause of extra caution when engaging with the private sector, without mentioning any particular industry.

The original proposal of the Secretariat was only one paragraph stating: 'WHO does not engage with the tobacco or arms industries. In addition, WHO will exercise particular caution when engaging with other industries affecting human health or affected by WHO's norms and standards'. In the final version of the FENSA, paragraph 44 establishes that 'WHO does not engage with the tobacco industry or non-State actors that work to further the interests of the tobacco industry. WHO also does not engage with the arms industry'. Paragraph 45 was added in the end, asserting that the Organisation 'will exercise particular caution, especially while conducting due diligence, risk assessment and risk management, when engaging with private sector entities and other non-State actors whose policies or activities are negatively affecting human health and are not in line with WHO's policies, norms and standards, in particular those related to noncommunicable diseases and their determinants'.

Interviewee 9, from the United States, stressed several times that paragraph 44 was a key topic for the country, and this was confirmed by data gathered from documents, media reports and interviews. For instance, interviewee 20, a former high-level staff member at the WHO, affirmed that 'the US was very active [on paragraph 44], such as big food and beverage industries that they felt on the spot clearly'. The debate on paragraph 44, however, did not divide the countries into North and South coalitions, as India, Denmark, Finland,

Greece and Zimbabwe were recommending a more cautious approach to the alcohol, food and beverage industries. Interviewee 20, hence, declared that adding paragraph 45 was adding a 'code-language' for the food and beverage industry. The topic, therefore, ended up with a compromised solution.

7.7 Engagement With the Private Sector

After considering all the data collected, it can be concluded that the private sector was the key topic of the FENSA negotiations. Not only regarding the specific policy and operational procedures, but because all topics that were discussed, apart from those merely related to language adjustments, had some level of disagreement amongst the Member States concerning the private sector. A clear example was the discussion about secondments, labelled as 'surreal' by the interviewed WHO staff, because even though the Organisation had not accepted seconded personnel from the industry for decades, it was the only non-State actor from which secondments were forbidden.

The concern towards the private sector was evident since the beginning; interviewee 19, who delineated the first proposal for a framework to regulate the relation of WHO with non-State actors, recommended two different documents, one for NGOs and another for the private sector. In this regard, the FENSA negotiation process clearly called attention to the divergent positions of Member States. While there was no opposition to the WHO's engagement with the four NSAs, developing countries mostly took a more restrictive approach and pushed for robust firewalls and safeguards, particularly concerning the private sector. On the other hand, many developed countries pressed for greater engagement with all NSAs and more trust in the Secretariat.

It is worth noting, however, that all Member States interviewed recognised the importance of a more careful attitude towards the private sector, even though some of them were advocating for the same treatment of all NSAs during the negotiation process. FENSA is not an anti-industry document; nonetheless, an ambivalence towards the private sector can be perceived. Almost all Member States affirmed that the FENSA approved text constituted a balanced outcome.

7.8 General Considerations

Although the private sector was the main focus during the FENSA negotiations, the concern of many Member States regarding NGOs cannot be ignored. Interviewee 19 revealed

that, initially, the idea was to foster a better dialogue with civil society while maintaining the intergovernmental nature of the WHO but seeking more plural governance. Historically, many countries, with China being the most prominent example, have a very negative attitude towards the participation of civil society due to a perspective of central State control. Giving NGOs some 'excessive' space, therefore, would undermine the power of State.

Considering that the Latin American countries were amongst the most outspoken, despite some progressive governments, the countries were generally not in favour of expanding the space for civil society in decision-making. While they sought more democracy, it was very much focused on governments, despite an increasing awareness that civil society is an important element of democratic processes. Within all of the United Nations organisations, civil societal actors are not allowed to have any kind of formal influence or voice over agenda-setting, policy design or implementation processes. However, their 'indirect' influence is very clear, due to their ability to shape the prioritisation of global health policies.

Interventions and positions taken by WHO Member States, therefore, are not linear nor easy to understand. While countries such as Brazil, on the one hand, were concerned and cautious about the potential undue influence from the private sector in the WHO decision-making process, on the other hand, they did not pursue more inclusive participation for civil society in policy-making processes. When it comes to African countries, where non-governmental organisations are generally much more active, NGOs were seen to be as problematic as the private sector, sometimes even more. From the African perspective, NGOs are not only driven by money but also push an agenda that takes other interests into account more than local needs. Consequently, African countries had a largely State-centric perspective. The interviewee from Zambia made it clear several times during the interview that no non-State actor was allowed at 'the negotiation table'.

Curiously, philanthropic foundations did not receive considerable attention, especially when thinking about the Bill and Melinda Gates Foundation which, according to interviewee 20, was treated like a Member State, as 'Gates comes to Geneva once or twice a year, if not him, the team, the Director of the health program. And they literally sit with the Secretariat, like would sit the United States or Japan or Germany'. Although some countries, like Brazil, had some reservations about the Gates Foundation, due to its enormous financial role at

WHO, no one could afford to pay what Gates donates. When asked why the BMGF was so quiet during the negotiations, interviewee 19 answered: 'There's no FENSA that can stop Gates. When you give 600 million, $700 million within a budget of four and a half billion, you call the shots. (…) Gates has too much influence'.

Academic institutions were, undoubtedly, the less controversial category of non-State actor during FENSA negotiations, although there were some issues and concerns relating to them. They were included because, since the Secretariat was proposing a comprehensive framework, it would not make sense to omit an essential sector with which the WHO has plentiful engagement. It is important to note, however, that the most common issue concerning academic institutions is conflict of interest, given that many universities have private funds. Whilst interviewees from the WHO affirmed that academic institutions were very much noticed during FENSA negotiations, no Member State or non-State actor interviewed mentioned them. In contrast with other categories of NSAs, academic institutions can apply for official relations under FENSA rules or be a collaborating centre. Moreover, the regulations for collaboration with academic institutions was the only document the FENSA did not replace which directly guided a relation with an NSA. While the collaborating centres typically perform services for the WHO, the FENSA allows academic institutions to participate in meetings, therefore including them in the governance of the WHO. Academic institutions are, on the whole, different from NGOs or the private sector, which generally have more political and economic interests than bringing expertise to the Organisation. Interviewee 20, hence, affirmed that academic institutions could take a more relaxed position than NGOs and industry, 'as FENSA could not really damage them'.

One should note, however, Shiffman's (2014) argument that the Lancet has emerged as 'one of the most powerful actors in global health' since the late 1990s. Besides the more visible issue of being backed by donors, the author also argued that commissions promoted by the medical journal have influenced policy in low- and middle-income countries, a clear exertion of normative power that can indeed impact which issues are more likely to be taken into account, as well as whose voices should be privileged.

With respect to the participation of the non-State actors during the negotiation process and whether they were able to influence the Member States' positions, as argued by Lowery (2013), there is a paradox when analysing influence in politics; we look for it without being

able to find evidence of it. NSAs can lobby in the international setting, but they mainly pressure governments at the national level. The interviews confirmed this argument. Both Member States and NSAs assumed that, during FENSA negotiations, governments and non-State actors had meetings in the Capitals, far from the WHO headquarters.

It was clear that NGOs and the private sector were the most active non-State actors during FENSA negotiations, insofar as several interviewees affirmed that the discussions sometimes turned into 'who is the good guy and who is the bad guy?', a Manichaeism approach that does not represent the approved Framework. One justification was that academic institutions and philanthropic foundations had less access to the negotiations, as many NGOs and private sector, under the umbrella of non-governmental organisations, were in official relations and could be 'physically present' in many debates that happened during the Health Assembly and the Executive Board.

Even though no empirical investigation was carried out to assure how NSAs' inputs on FENSA were taken into account through the Member States, all interviewees assured that NSAs undeniably influenced the negotiation process. The Member States as well the WHO staff who were interviewed confirmed that non-State actors were closely following the FENSA process and lobbying the national delegations. Interviewee 20, a former high-level staff member who followed all the negotiations, affirmed that:

> FENSA is in high polarisation in the WHO, in particular concerning the private sector. And you could see that numbers of delegations were clearly lobbied by NGOs, sort of public interest NGOs suspicious of the motives of the industry. And when you listen to statements by the Member States sometimes after a number of years, you start reading between the lines, and you could clearly see that number of statements were drafted by NGOs themselves and given to delegation who just read them. So legitimately, I think everybody tried to lobby on behalf of its own interest. Developed countries, in particular those with big pharmaceutical industries, clearly had the interest of the industries in mind. So we have no doubts that there were consultations in Geneva, or in capitals with the industry. They [NSAs] certainly work behind the scenes.

Furthermore, it was clear that NGOs, specifically those referred to as public interest, were much more organised than the private sector - not only due to shared interests that made the coordination of positions more straightforward, but also because the most important private sector actor, the pharmaceutical industry, did not want to be aligned with the food, beverage and alcohol industries, the other very powerful actors in the negotiation process. The pharmaceutical industry, therefore, was more successful in lobbying governments instead of making coalitions, in a way that they could leave to the governments (mainly those

of developed countries) to try to represent the interests of the industry. This became particularly clear when analysing the positions taken by the United States, the United Kingdom and other industrialised countries. The private sector, therefore, did not have to be very aggressive.

Regarding the pharmaceutical industry, interviewee 5, supported by interviewees 18 and 20, brought attention to the TRIPs agreement. Bearing in mind that developing countries frequently seek to strengthen multilateral approaches to facilitate coordination and, therefore, use different forums to discuss specific policies, the dispute between developing countries and the private sector, particularly the pharmaceutical industry, was seen as a consequence of the TRIPs agreement, negotiated at the World Trade Organisation (WTO). Recognising that intellectual property protection was a clear victory of the United States and other countries that host big pharma, many developing countries, mainly Brazil and India, brought the debate to the WHO. By using 'soft power' instruments, developing countries tried to delegitimise TRIPs' hard perspective on pharmaceutical patents. This also explains the defensive behaviour taken by the pharmaceutical industry as the sector had to deal with an image problem – that of a business that just seeks profit without caring about human lives. Interviewee 20, however, affirmed that within the WHO, big pharma can lobby governments more successfully than any other non-State actor, through their immense financial power and influence, and can push their position on key issues.

Described by many as a 'Pandora's Box', it is undeniable that the FENSA will provide, for the first time, a comprehensive policy instrument to guide and regulate the engagement of the World Health Organisation with all kinds of NSAs. The way in which FENSA is being implemented is a crucial issue that was not assessed in this research. Although all the interviewees universally recognised the inevitability of the framework, their perspectives towards the document were quite diverse and almost no one, Member State or non-State actor, seems fully satisfied with the FENSA.

7.9 Verifying the Hypothesis

When formulating the hypothesis of this research, which was initially enlightened by Nitsan Chorev's book 'The World Health Organization between the North and the South', I designed the objectives to be pursued and the questions to be answered. After detailing the interviews and the negotiation-related documentation, I conducted the so-called

triangulation method through the cross-verification of the data gathered. The goal was to either reject or accept the three hypotheses that were previously presented.

We learn from Chigbu (2019) that framing and testing hypotheses in qualitative research (which does not strictly mean the same thing as in quantitative research) always comes with challenges, particularly the issue of bias. Qualitative hypothesis testing is the process of using qualitative research data to determine whether the reality of an event described in a specific hypothesis is true or false.

1st Hypothesis: the North/South division that characterises the WHO's history was reflected in FENSA negotiations with the formation of two groups of negotiators: developed and developing countries.

The analysis revealed a general split between two groups: one in favour of extensive and standardised engagement with all kinds of non-State actors, as an essential and inevitable way to support the WHO's work as the leader of global health; and another group whose primary focus was to protect the WHO from undue influence, particularly from the private sector, and therefore advocated a more restrictive approach. On the whole, developed countries often advocated for increasing engagement with non-State actors while developing countries were more worried about undue influence. Additionally, to some extent, this restrictive approach sought by some Member States to protect the WHO from undue influence, underlies the effort to diminish the influence of all NSAs, due to a State-centered perspective. However, a simple, clear and strict division did not occur. Although the North/ South division that characterises the WHO's history was indeed reflected in the negotiations, it did not create cohesive groups of negotiators. The research revealed that Member States changed the coalitions depending on the topics being discussed. In this sense, an ambivalent dynamic can be observed in the behaviour of most Member States during the FENSA negotiations, which inevitably points out how the domestic variable is essential for understanding the positions of States in the international negotiations.

2nd Hypothesis: the final text of the FENSA reflects the positions of North countries more than the position of the Global South.

Even though all countries had to make concessions to have the FENSA approved, from the nine Member States interviewed, two believed that the Framework reflects the positions of the Global South more, two that it echoes more the demands of the North, four that the

FENSA is a consensual document and two did not answer. Conversely, interviewees from the World Health Organisation that followed the entire negotiation process (interviewees 20 and 21) consensually declared that FENSA reflects the perspectives of developing countries more. Based on document analysis, it is clear that both groups had important victories, such as the prohibition of secondments of the private sector, essentially the Global South's request, and no explicit mention of Food and Beverage industries, a demand mainly pursued by developed countries.

3rd Hypothesis: the positions taken by the most active Member States in the negotiations embraced the interests of non-State actors, especially the philanthropic and private sectors.

Regarding the influence of non-State actors on the WHO policy process, it can be affirmed that the Member States undoubtedly supported specific interests of some non-State actors as it was confirmed by almost all interviewees; only Argentina and Norway did not endorse it. There is evidence that, behind the scenes, while the private sector acted through developed countries, the so-called public-interest NGOs performed through developing countries. Nevertheless, no evidence can support the assertion that philanthropic foundations tried to influence the FENSA negotiations through Member States. While four interviewees affirmed that the Gates Foundation was lobbying national delegations, it might have been done silently, as it was not a consensual assertion amongst the interviewees, nor it was clear when analysing the documents. Historically, non-State actors, mainly the private sector, had indeed influenced WHO policies indirectly through the Member States and this didn't differ during FENSA negotiations. While the available statements of NGOs in official relations during the informal consultations of 2013 do not seem to have influenced the FENSA drafts, the analysis points out that the NSAs, did, in fact, influence the negotiation process to some extent. The influence of NSAs became expressly apparent as several Member States started advocating the positions they were expressing outside the confines of the World Health Organisation's negotiation table.

This research indicates, therefore, that there is, in fact, an enduring, although not strict, division between the global North and South at the WHO. The blurring of North and South boundaries in some issues, however, might be a result of power imbalances in global health governance, and should be further investigated. Moreover, I conclude that the FENSA

negotiation process successfully achieved a balanced outcome, able to please, although not entirely, even the most unmanageable and opposing Member States' positions (specifically, the United States versus India) by improving and increasing transparency while expanding the range of non-State actors with whom the WHO collaborates, including actors widely recognised as being problematic and demanding more accountability. Finally, this research also looks further than the traditional and inadequate perspective of power and coercion, which would lead to powerful for-profit entities being the only actors able to indirect influence the negotiations; this was not the case, as the so-called public-interest non-governmental organisations played a central and determining role during the FENSA negotiations.

CONCLUSION AND FINAL REMARKS

The global health landscape has become more complex as it witnessed an unprecedented growth in the number of international actors. The four non-State actors embraced by this research constitute an essential portion of these 'new' players that can have powerful economic, political or social influence at the national and sometimes international level, without necessarily aligning themselves to a particular State. If, on one hand, this has opened up new spaces for civil society participation in global health governance through their role in agenda-setting, advocacy, trustee knowledge, galvanising resources, implementing and evaluating public policies and international projects, and bringing attention to marginalised communities; on the other hand this participation usually happens without formal oversight or the constraints of international law.

Following demands for more democratic participation in International Organisations, but particularly due to the growing dependency on external resources, the World Health Organisation has been trying to improve its relationship with civil society and non-governmental organisations since the beginning of the 2000s, however, it was precisely in the past decade that the WHO started to incisively seek a reform that would embrace a multistakeholder approach. The engagement with non-governmental organisations was already foreseen in the World Health Organisation constitution of 1948, and the Member States have historically been trying to regulate the relationship with NGOs and the private sector. However, gradually, the WHO, including the Secretariat but primarily the Member States, started to perceive the strong influence of the private philanthropic sector, most notably the Bill and Melinda Gates Foundation.

In this regard, aware of the inevitability of the engagement with different actors to promote public health guidelines and successfully exercise its role as the global health authority, but also of conflicts between commercial interests and public health goals, the WHO has been seeking to strengthen its engagement with NSAs while simultaneously strengthening its management of potential conflict of interests. In a broad context of a budget and legitimacy crisis as well as an internal atmosphere of mistrust by the Member States towards the Secretariat, Margaret Chan, the Director-General of WHO from 2007 to 2017, pushed for a reform with three dimensions: priorities, governance and management.

The governance reform included a better alignment of the three levels of the WHO headquarters, regions and countries, the working methods of the governing bodies, and the engagement with non-State actors. While at the beginning the idea was to include only NGOs and the private sector, philanthropic foundations and academic institutions were also added, all under the category of non-State actors. The Framework of Engagement with non-State Actors which became better known as FENSA was negotiated between 2012 and 2016 when it was approved at the 69th session of the World Health Assembly.

The Framework was designed to encourage more engagement while, at the same time, protecting the integrity of the WHO. It recognises five types of interaction: (1) participation of NSAs in consultations, hearings, and other meetings of the Organisation; (2) provision of financial or in-kind contributions; (3) provision of up-to-date information and knowledge on technical issues; (4) advocacy activities; and (5) technical collaboration, including through product development, capacity-building, operational collaboration in emergencies and contribution to the implementation of the WHO's policies. It also establishes mechanisms to manage conflicts of interest and other risks of engagement.

FENSA debates initially included some consultations with non-State actors in official relations, and it was led by the Secretariat, but then it turned into a Member States' negotiation that started to discuss the document 'line-by-line'. Formal and informal conversations, mainly behind closed doors, were conducted in order to settle differences among the Member States. The disagreements, however, went beyond the WHO headquarters in Geneva, as the non-State actors embraced by the framework also had different perspectives about it and tried to enforce their demands through the Member States. How much influence interest groups have on policy outcomes in the World Health Organisation while being highly relevant for the democratic legitimacy of the WHO, is this research main limitation, as it was impossible to measure precisely this amount of influence. However, the document analysis, combined with the interviews conducted leaves no room for doubt about the influence of NSAs on policy-making processes.

The aim of this research was to scrutinise the FENSA negotiation process through the positions taken by the Member States, and also by understanding the all-encompassing context inside and outside the World Health Organisation that led to the FENSA proposal and approval. The primary source was official documents from the WHO which I divided into

three categories: Governing Bodies' documents, basic documents and FENSA-related documents, and the interviews conducted with involved actors, which were also divided into three categories: Member States, non-State actors and WHO Staff. By comparing how the versions evolved from the first full version presented in May 2014 until the final and approved version in May 2016, I could map the most controversial topics and analyse which changes were made. Therefore, I compared the document analysis with the interviews made and reports from watchdog organisations that followed FENSA negotiations. Triangulating the three sources enable me to verify my initial hypothesis. Whilst a North/South division, although not strict, was observed during the negotiations and Member States were advocating positions which met some NSAs' demands, this research could not prove that the FENSA reflects the positions of North countries more than those of the Global South. It was also found that there is no homogeneity between non-State actors, even within the same category, particularly amongst the private sector, and each side has its own interests and different perspectives on the same story.

It is important to emphasise that although FENSA was accused of being used as a tool to address the underfunding of the World Health Organisation, as it would open the Organisation to the private sector and philanthropic foundations which, consequently, would bring in more funding, this accusation was proven untruthful in this research. Even though funding was at the centre of the FENSA's proposal, this investigation points in a different direction. Both private sector entities and philanthropic foundations seemed to be more satisfied with the status quo before FENSA, as the framework added many rules which were seen as an obstacle to further finance. The Member States were trying to regulate the relationship with non-State actors (mainly the private sector and some contentious NGOs) with a slight focus on funding, in particular, due to the Bill and Melinda Gates Foundation, as the Organisation experienced an increasingly donor-driven agenda that didn't always follow the priorities voted for by the Member States. Additionally, there was a lack of confidence in the Secretariat, who was seen as excessively close to the Gates Foundation, and to the industry. It was, hence, failing to prevent conflicts of interest. Interviews revealed that the FENSA was also developed to increase the accountability of the Secretariat's actions, which is controversial since the Framework leaves much discretion to the Secretariat's interpretation to make several decisions on a case-by-case basis, such as deciding which category the NSA

falls within. However, one should recognise it as an advancement, because one of the main critique of the 1987 Principles was that it failed to distinguish public interest and business-oriented NGOs. With the FENSA, even if a non-State actor does not categorise itself as a private sector entity, the Secretariat is able to determine otherwise if it finds private sector influence on the NSA's interests, objectives, governance, sources of funding and affiliations.

FENSA was a fairly polarised and contentious negotiation process, mainly related to engagement with the private sector. I initially considered both the private sector and philanthropic foundations as the most important and forceful NSAs, however, I concluded that , in fact, the private sector and NGOs were the key actors. Discussion about the private sector referred particularly to the pharmaceutical industry and Big Food, both with a background of scandals of undue influence at the WHO, as detailed in chapter three. Furthermore, several interviewees affirmed that Big Food individuals took part in national delegations to attend the WHO's governing bodies meetings. Paragraph 44 illustrates both the power of Big Food to influence policymaking, and of the United States at the WHO, even when it is almost alone supporting a position. FENSA requires the WHO to undertake 'particular caution' when 'engaging with private sector entities (…) whose policies (…) are negatively affecting human health (…) in particular those related to non-communicable diseases'. Despite the scientific consensus that sugar, salt and trans-fats increase the risk of NCDs, the United States managed to not directly mention Food and Beverage industries. The cause-consequence relationship becomes clear when looking at the domestic level, where although the prevalence of obesity in the country was 42.4% in 2017/2018 (CDC, 2020), the Food and Beverage industries have spent millions on federal political lobbying while financing advocacy groups and scientists to downplay harms from sugar, salt, and saturated fats in dietary advice.

Similar to the negotiation process, the implementation of the FENSA was described as a 'heavy and lengthy process'. While the Member States seemed annoyed and the Secretariat was hard-pressed due to the high level of scrutiny, none of the NSAs seemed to be entirely satisfied. On one hand, NGOs kept criticising and denouncing conflicts of interest within the WHO and accusing FENSA of not being able to address corporate influence in the Organisation's norm-setting activities; on the other hand, private sector entities were more worried about the increasing bureaucratic burden of the Framework. Regarding philanthropic

foundations, it is important to note that the Bill and Melinda Gates Foundation entered into official relations with the WHO for the first time in January 2017, which was greatly criticised by some civil society groups, who argued that a great amount of the BMGF's incomes come not only from investments in the private sector but precisely from Food and Beverage entities such as Coca-Cola, Kraft and Big Pharma, like Pfizer; both sectors that are seen by civil society as 'villains' and very likely to have conflicts of interest. In an open letter to the Executive Board, over thirty civil society organisations expressed their concerns about conflict of interest and stated that 'these investments make the Gates Foundation a beneficiary of sales of several categories of products that are the subject of WHO standards and advice to governments related to nutrition and physical activity (…) It is, of course, deeply troubling from a governance standpoint that the Executive Board is being asked to approve applicants for Official Relations and verify compliance with conflicts of interest safeguards without being provided with any relevant evidence – verified or otherwise – on the public record'[98].

At the 145th Executive Board, January 2020, a report by the Director-General on the implementation of FENSA was presented. It was affirmed that the Secretariat had conducted numerous due diligence and risk assessments throughout the year 2019. The report pointed out that the Secretariat was restructuring the functions of the specialised unit responsible for performing due diligence and risk assessment, that training sessions for the staff have been developed and conducted, and that the WHO Register of non-State actors, one of the core parts of the FENSA, has been improved. However, to observe the implementation is of utmost importance as almost all interviewees affirmed that an accurate evaluation of FENSA will only be possible after its complete implementation.

Notwithstanding the enormous disagreements about the content and process of FENSA, this research concludes that FENSA has already led to an increase in the transparency of the WHO's engagement with NSAs due to the Register of non-State actors that provides: general information, governance structure, financial information, membership, activities and country presence (countries where the entity has activities, members and regional offices or representatives). The register, however, is not fully implemented yet. When checking on the Bill and Melinda Gates Foundation register, key information is

[98] WHO: Civil society calls for deferment of "official relations" status to Gates Foundation. Available at: https://www.twn.my/title2/health.info/2017/hi170104.htm

missing - income sources for example. Moreover, a handbook for non-State actors on engagement with the WHO and a guide for staff on engagement with non-State actors were developed, although the guide is fairly vague and does not robustly determine the criteria for identifying private sector influence or conflicts of interest nor for conducting risk assessment and due diligence.

After a profound analysis of the FENSA's negotiation process, there is no doubt that non-State actors have significant influence at the World Health Organisation. The donor-driven agenda is a consequence not only of the earmarked extrabudgetary funds but also of that fact that non-State actors can successfully lobby, especially together with donor countries, the WHO to not negatively impact them. As a result, the World Health Organisation has been experiencing significant distortion, given that there is a gap between what the Member States decide collectively and what they later do as donors. This is possibly the main weakness of FENSA, although the Framework establishes that financial contributions must 'fall within WHO's General Programme of Work' in a clear aim to reduce the donor-driven problem, some critics affirm that this made the WHO's budget be planned in accordance with expected sources. It is no coincidence that a substantial portion of the WHO budget goes to the development of vaccines for infectious diseases, which are aligned to private industry's primary focus. There is an increasing focus on expensive, sophisticated and technological-oriented programmes over inexpensive and long-term solutions, such as the overarching goal strategic priority 4: *More effective and efficient WHO providing better support to countries*, which includes 'advocate for health as a human right and advance the vital role of health in human development at the highest political level'. This understanding of the right to health is based on an expanded concept of health that lies upon the social determination of health and to establish policies that positively influence social and economic conditions can consequently improve health for large numbers of people in ways that can be sustained over time.

Moreover, it is important to highlight that voluntary contributions from Member States are not regulated, allowing NSAs to outmanoeuvre the requirement and lobby governments to direct funding to specific causes. While the FENSA only addresses the relationship between the WHO and NSAs, the influence has proven to rely more on the relation between NSAs and Member States.

At the end of this doctoral thesis, a new epidemic has assaulted the world, endorsing what Albert Camus wrote in his novel The Plague (1947, p.30): ‘there have been as many plagues in the world as there have been wars, yet plagues and wars always find people equally unprepared’. First reported in Wuhan, China, the coronavirus disease (COVID-19) was declared a Public Health Emergency of International Concern (PHEIC) on January 30th, 2020. The World Health Organisation, therefore, is more than ever, at the centre of all debates, in a positive and negative sense. Positive, because a once lesser-known organisation, now, governments, domestic and transnational institutions not necessarily related to public health are realising and recognising the urgent need for public investment in health and the importance of an international organisation to lead efforts to tackle a pandemic. It’s important to highlight that the WHO is currently leading the strategy to assure fair and equitable access to a COVID-19 vaccine. The World Health Organisation is proving to be responsible for advocating health as a public common good that must be above profit. However, on the other hand, in times of ‘fake news’, unfounded accusations have increased due to a delegitimising campaign led by the United States’ president Donald Trump. In the context of a pandemic, this thesis is especially relevant as it elucidates the WHO’s roles, responsibilities and limits while highlighting the importance of an effective, empowered and independent organisation, which the FENSA, if carefully and robustly implemented can have a central role. Moreover, as the case of emergencies was a controversial topic during the negotiation process and, in the end, the Director-General was allowed to somehow relax the application of FENSA, it is essential to observe how FENSA will be applied. More than ever, the World Health Organisation faces new challenges and needs to reinvent itself.

Analysing the FENSA negotiation process was a challenging task. While the context and content of the Framework are now disclosed, it is essential to follow the implementation stage. Although the initial goal was to achieve full operationalisation within a two-year timeframe, according to the interviewees, this has not happened yet. While FENSA implementation is being discussed at the Governing Bodies, the Member States do not seem particularly involved in the topic anymore. Contrarily, in the midst of organised civil society, precisely in the health field, the negotiation and now implementation of FENSA is frequently discussed. For example, the Geneva Global Health Hub (G2H2) is a membership-based association that has been organising side events to the governing bodies meetings to enable

the civil society to share knowledge and create initiatives to advocate for more democratic global health governance. Within the academic world, however, researchers have not yet demonstrated interest. By looking ahead, some significant enquiries can be pursued. For instance, the role of individual negotiators in policy processes and the 'pre-decision' stage, mainly how non-State actors' influence at the domestic level is transferred to international negotiations.

Moreover, as the involvement of international organisation with non-State actors is increasing and FENSA is the first and only comprehensive and detailed framework to encourage engagement while mitigating the risks of such relations within the UN system, this research effectively contributes to understanding the successes and limitations of such an initiative that can be a model for other IOs. Besides being one of the first, globally, to approach this object in-depth, especially from an interdisciplinary approach between Global Health and International Relations, this research also contributes to the debate of the power and influence of non-State actors on the priorities of the global health agenda by acting through the WHO.

The inclusion of civil society and business in contemporary global health governance processes can give a false impression of legitimacy through more participation, however, without adequate safeguards, it can capture the decision-making processes. This research offers a robust analysis for revealing not only the WHO's challenges but also how the debate of global health governance must adopt a more critical perspective on this much encouraged and demanded participation, that can end up hijacking real public interest priorities in the global health agenda.

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ANEX 1: FRAMEWORK OF ENGAGEMENT WITH NON-STATE ACTORS (FENSA)

SIXTY-NINTH WORLD HEALTH ASSEMBLY **WHA69.10**

Agenda item 11.3 **28 May 2016**

Framework of engagement with non-State actors

The Sixty-ninth World Health Assembly,

Having considered the report on the framework of engagement with non-State actors and the revised draft framework of engagement with non-State actors;[1]

Having noted the report of the Programme, Budget and Administration Committee of the Executive Board to the Sixty-ninth World Health Assembly;[2]

Recalling resolution WHA64.2 (2011) and decision WHA65(9) (2012) on WHO reform, and decisions WHA67(14) (2014), EB136(3) (2015), EB138(3) (2016) and resolution WHA68.9 (2015) on a framework of engagement with non-State actors;

Recalling also United Nations General Assembly resolution 70/1 "Transforming our world: the 2030 Agenda for Sustainable Development", and the equally important Goals, targets and means of implementation contained therein, which calls, inter alia, for a revitalized global partnership for sustainable development, based on the spirit of strengthened global solidarity, focused in particular on the needs of the poorest and most vulnerable and with participation of all countries, all stakeholders and all people;

Recalling also United Nations General Assembly resolution 69/313 on the Addis Ababa Action agenda of the Third International Conference on Financing for Development (Addis Ababa, 13–16 July 2015), which is an integral part of the 2030 Agenda for Sustainable Development;

Recalling further the Rome Declaration on Nutrition and the Framework for Action on Nutrition adopted by the Second International Conference on Nutrition (Rome, 19–21 November 2014);

Underscoring the full political commitment of all Member States towards the consistent and coherent implementation of the framework of engagement with non-State actors across the three levels of the Organization,

1. ADOPTS the Framework of Engagement with Non-State Actors, as set out in the Annex to this resolution;[3]

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[1] Document A69/6.

[2] Document A69/60.

[3] Consisting of an overarching framework and four specific policies on engagement with nongovernmental organizations, private sector entities, philanthropic foundations and academic institutions.

1. DECIDES that the Framework of Engagement with Non-State Actors shall replace the Principles governing relations between the World Health Organization and nongovernmental organizations[1] and Guidelines on interaction with commercial enterprises to achieve health outcomes;[2]

2. REQUESTS the Director General:

(1) to immediately start implementation of the Framework of Engagement with Non-State Actors;

(2) to take all necessary measures, working with Regional Directors, to fully implement the Framework of Engagement with Non-State Actors in a coherent and consistent manner across all three levels of the Organization, with a view to achieving full operationalization within a two-year timeframe;

(3) to expedite the full establishment of the register of non-State actors in time for the Seventieth World Health Assembly;

(4) to report on the implementation of the Framework of Engagement with Non-State Actors to the Executive Board at each of its January sessions under a standing agenda item, through the Programme Budget and Administration Committee;

(5) to include in the report on the implementation of the Framework of Engagement with Non-State Actors, when deemed necessary, any matter or types of engagement with non-State actors that would benefit from further consideration by the Executive Board, through its Programme Budget and Administration Committee, due to their unique characteristics and relevance;

(6) to conduct an initial evaluation in 2019 of the implementation of the Framework of Engagement with Non-State Actors and its impact on the work of WHO with a view to submitting the results, together with any proposals for revisions of the Framework, to the Executive Board in January 2020, through its Programme Budget and Administration Committee;

(7) to include in the guide to staff, measures that pertain to application of the relevant provisions contained in the existing WHO policies on conflict of interest, with a view to facilitating the implementation of the Framework of Engagement with Non-State Actors;

(8) to develop, in consultation with Member States, a set of criteria and principles for secondments from nongovernmental organizations, philanthropic foundations and academic institutions and to submit the criteria and principles for the consideration of and establishment by, as appropriate, the Seventieth World Health Assembly, through the Executive Board, taking into account, amongst others, the following identified issues:

(a) specific technical expertise needed and excluding managerial and/or sensitive positions;

[1] Adopted in resolution WHA40.25. See Basic documents, 48th ed. Geneva: World Health Organization; 2014.

[2] Document EB107/20, Annex.

(a) the promotion of equitable geographical distribution;

(b) transparency and clarity regarding positions sought, including public announcements;

(c) secondments are temporary in nature not exceeding two years;

(2) to make reference to secondments from non-State actors in the annual report on engagement with non-State actors to be submitted, including justification behind secondments;

2. REQUESTS the Independent Expert Oversight Advisory Committee, in accordance with its current terms of reference, to include a section on the implementation of the Framework of Engagement with Non-State Actors in its report to the Programme, Budget and Administration Committee of the Executive Board at each January session;

3. REQUESTS the Seventieth World Health Assembly to review progress on the implementation at the three levels of the Organization, with a view to taking any decisions necessary to enable the full, coherent and consistent implementation of the Framework of Engagement with Non-State Actors.

ANNEX

FRAMEWORK OF ENGAGEMENT WITH NON-STATE ACTORS

(adopted in resolution WHA69.10)

OVERARCHING FRAMEWORK OF ENGAGEMENT WITH NON-STATE ACTORS

INTRODUCTION

1. The overarching framework of engagement with non-State actors and the WHO policy and operational procedures on management of engagement with non-State actors apply to all engagements with non-State actors at all levels of the Organization,[1] whereas the four specific policies and operational procedures on engagement are limited in application to, respectively, nongovernmental organizations, private sector entities, philanthropic foundations and academic institutions.

ENGAGEMENT: RATIONALE, PRINCIPLES, BENEFITS AND RISKS

Rationale

2. WHO is the directing and coordinating authority in global health in line with its constitutional mandate. The global health landscape has become more complex in many respects; among other things, there has been an increase in the number of players including non-State actors. WHO engages with non-State actors in view of their significant role in global health for the advancement and promotion of public health and to encourage non-State actors to use their own activities to protect and promote public health.

3. The functions of WHO, as set out in Article 2 of its Constitution, include: to act as the directing and coordinating authority on international health work; to establish and maintain effective collaboration with diverse organizations; and to promote cooperation among scientific and professional groups which contribute to the advancement of health. The Constitution further mandates the Health Assembly or the Executive Board, and the Director-General, to enter into specific engagements with other organizations.[2] WHO shall, in relation to non-State actors, act in conformity with its Constitution and resolutions and decisions of the Health Assembly, and bearing in mind those of the United Nations General Assembly or the Economic and Social Council of the United Nations, if applicable.

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[1] Headquarters, regional offices and country offices, entities established under WHO, as well as hosted partnerships. For hosted partnerships the framework of engagement with non-State actors will apply, subject to the policy on WHO's engagement with global health partnerships and hosting arrangements (resolution WHA63.10). Hosted, as well as external partnerships are explained in paragraph 48.

[2] WHO Constitution, Articles 18, 33, 41 and 71.

4. WHO's engagement with non-State actors supports implementation of the Organization's policies and recommendations as decided by the governing bodies, as well as the application of WHO's technical norms and standards. Such an effective engagement with non-State actors at global, regional and country levels, also calls for due diligence and transparency measures applicable to non-State actors under this framework. In order to be able to strengthen its engagement with non-State actors for the benefit and interest of global public health, WHO needs simultaneously to strengthen its management of the associated potential risks. This requires a robust framework that enables engagement and serves also as an instrument to identify the risks, balancing them against the expected benefits, while protecting and preserving WHO's integrity, reputation and public health mandate.

Principles

5. WHO's engagement with non-State actors is guided by the following overarching principles.

Any engagement must:

(a) demonstrate a clear benefit to public health;

(b) conform with WHO's Constitution, mandate and general programme of work

(c) respect the intergovernmental nature of WHO and the decision-making authority of Member States as set out in the WHO's Constitution;

(d) support and enhance, without compromising, the scientific and evidence-based approach that underpins WHO's work;

(e) protect WHO from any undue influence, in particular on the processes in setting and applying policies, norms and standards;[1]

(f) not compromise WHO's integrity, independence, credibility and reputation;

(g) be effectively managed, including by, where possible avoiding conflict of interest[2] and other forms of risks to WHO;

(h) be conducted on the basis of transparency, openness, inclusiveness, accountability, integrity and mutual respect.

Benefits of engagement

6. WHO's engagement with non-State actors can bring important benefits to global public health and to the Organization itself in fulfilment of its constitutional principles and objectives, including its directing and coordinating role in global health. Engagements range from major, longer-term collaborations to smaller, briefer interactions. Benefits arising from such engagement can also include:

(a) the contribution of non-State actors to the work of WHO

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[1] Policies, norms and standard setting includes information gathering, preparation for, elaboration of and the decision on the normative text.

[2] As set out in paragraphs 22 to 26.

(b) the influence that WHO can have on non-State actors to enhance their impact on global public health or to influence the social, economic and environmental determinants of health

(c) the influence that WHO can have on non-State actors' compliance with WHO's policies, norms and standards

(d) the additional resources non-State actors can contribute to WHO's work

(e) the wider dissemination of and adherence by non-State actors to WHO's policies, norms and standards

Risks of engagement

7. WHO's engagement with non-State actors can involve risks which need to be effectively managed and, where appropriate, avoided. Risks relate inter alia to the occurrence in particular of the following:

(b) conflicts of interest;

(c) undue or improper influence exercised by a non-State actor on WHO's work, especially in, but not limited to, policies, norms and standard setting;[1]

(d) a negative impact on WHO's integrity, independence, credibility and reputation; and public health mandate;

(e) the engagement being primarily used to serve the interests of the non-State actor concerned with limited or no benefits for WHO and public health;

(f) the engagement conferring an endorsement of the non-State actor's name, brand, product, views or activity;[2]

(g) the whitewashing of a non-State actor's image through an engagement with WHO;

(h) a competitive advantage for a non-State actor.

NON-STATE ACTORS

8. For the purpose of this framework, non-State actors are nongovernmental organizations, private sector entities, philanthropic foundations and academic institutions.

9. **Nongovernmental organizations** are non-profit entities that operate independently of governments. They are usually membership-based, with non-profit entities or individuals as members exercising voting rights in relation to the policies of the nongovernmental organization, or are otherwise constituted with non-profit, public-interest goals. They are free from concerns which are

[1] Policies, norms and standard setting includes information gathering, preparation for, elaboration of and the decision on the normative text.

[2] Endorsement does not include established processes such as prequalifications or the WHO Pesticide Evaluation Scheme (WHOPES).

primarily of a private, commercial or profit-making nature. They could include, for example, grassroots community organizations, civil society groups and networks, faith-based organizations, professional groups, disease-specific groups, and patient groups.

10. **Private sector** entities are commercial enterprises, that is to say businesses that are intended to make a profit for their owners. The term also refers to entities that represent, or are governed or controlled by, private sector entities. This group includes (but is not limited to) business associations representing commercial enterprises, entities not "at arm's length"[1] from their commercial sponsors, and partially or fully State-owned commercial enterprises acting like private sector entities.

International business associations are private sector entities that do not intend to make a profit for themselves but represent the interests of their members, which are commercial enterprises and/or national or other business associations. For the purposes of this framework, they shall have the authority to speak for their members through their authorized representatives. Their members shall exercise voting rights in relation to the policies of the international business association.

11. **Philanthropic foundations** are non-profit entities whose assets are provided by donors and whose income is spent on socially useful purposes. They shall be clearly independent from any private sector entity in their governance and decision-making.

12. **Academic institutions** are entities engaged in the pursuit and dissemination of knowledge through research, education and training.[2]

13. For each of the four groups of entities above, the overarching framework and the respective specific policy on engagement apply. WHO will determine through its due diligence if a non-State actor is subject to the influence of private sector entities to the extent that the non-State actor has to be considered itself a private sector entity. Such influence can be exerted through financing, participation in decision making or otherwise. Provided that the decision-making processes and bodies of a non-State actor remain independent of undue influence from the private sector, WHO can decide to consider the entity as a nongovernmental organization, a philanthropic foundation or an academic institution, but may apply relevant provisions of the WHO's policy and operational procedures on engagement with private sector entities, such as not accepting financial and in-kind contributions for use in the normative work.

TYPES OF INTERACTION

14. The following are categories of interaction in which WHO engages with non-State actors. Each type of interaction can take different forms, be subject to different levels of risk and can involve different levels and types of engagement by the Organization.

[1] An entity is "at arm's length" from another entity if it is independent from the other entity, does not take instructions and is clearly not influenced or clearly not reasonably perceived to be influenced in its decisions and work by the other entity.

[2] This can include think tanks which are policy-oriented institutions, as long as they primarily perform research; while international associations of academic institutions are considered as nongovernmental organizations, subject to paragraph 13.

Evidence

18. For the purposes of this framework, evidence refers to inputs based on up-to-date information, knowledge on technical issues, and consideration of scientific facts, independently analysed by WHO. Evidence generation by WHO includes information gathering, analysis, generation of information and the management of knowledge and research. Non-State actors may provide their up-to-date information and knowledge on technical issues, and share their experience with WHO, as appropriate, subject to the provisions of this framework, its four specific policies and operational procedures, and other applicable WHO rules, policies and procedures. Such contribution should be made publicly available, as appropriate, wherever possible. Scientific evidence generated should be made publicly available.

Advocacy

19. Advocacy is action to increase awareness of health issues, including issues that receive insufficient attention; to change behaviours in the interest of public health; and to foster collaboration and greater coherence between non-State actors where joint action is required.

Technical collaboration

20. For the purpose of this framework, technical collaboration refers to other collaboration with non-State actors, as appropriate, in activities that fall within the General Programme of Work, including:

- product development
- capacity-building
- operational collaboration in emergencies
- contributing to the implementation of WHO's policies.

MANAGEMENT OF CONFLICT OF INTEREST AND OTHER RISKS OF ENGAGEMENT

21. Managing, including by, where appropriate, avoiding, conflict of interest and other risks of engagement requires a series of steps, as set out below:[1]

- WHO needs to know the non-State actors that it engages with. Therefore each non-State actor is required to provide all relevant[2] information about itself and its activities, following which WHO conducts the necessary due diligence.
- WHO conducts a risk assessment in order to identify the specific risks of engagement associated with each engagement with a non-State actor.

[1] The framework is designed to regulate institutional engagements; its implementation is closely coordinated with the implementation of other organizational policies regulating conflict of interest in respect of individuals (see paragraph 49).

[2] As defined in paragraph 39.

- Risks of engagement need to be managed and communicated coherently in each of the three levels of the Organization and throughout the Organization. To that end, WHO manages engagement through a single, Organization-wide electronic tool.[1]

- Member States exercise oversight over WHO's engagement with non-State actors in accordance with the provisions in paragraphs 67 and 68.

Conflict of interest

22. A conflict of interest arises in circumstances where there is potential for a secondary interest (a vested interest in the outcome of WHO's work in a given area) to unduly influence, or where it may be reasonably perceived to unduly influence, either the independence or objectivity of professional judgement or actions regarding a primary interest (WHO's work) The existence of conflict of interest in all its forms does not as such mean that improper action has occurred, but rather the risk of such improper action occurring. Conflicts of interest are not only financial, but can take other forms as well.

23 Individual conflicts of interests within WHO are those involving experts, regardless of their status, and staff members; these are addressed in accordance with the policies listed under paragraph 49 of the present framework.

24. All institutions have multiple interests, which means that in engaging with non-State actors WHO is often faced with a combination of converging and conflicting interests. An **institutional conflict of interest** is a situation where WHO's primary interest as reflected in its Constitution may be unduly influenced by the conflicting interest of a non-State actor in a way that affects, or may reasonably be perceived to affect, the independence and objectivity of WHO's work.

25. In actively managing institutional conflict of interest and the other risks of engagement mentioned in paragraph 7 above, WHO aims to avoid allowing the conflicting interests of a non-State actor to exert, or be reasonably perceived to exert, undue influence over the Organization's decision-making process or to prevail over its interests.

26. For WHO, the potential risk of institutional conflicts of interest could be the highest in situations where the interest of non-State actors, in particular economic, commercial or financial, are in conflict with WHO's public health policies, constitutional mandate and interests, in particular the Organization's independence and impartiality in setting policies, norms and standards.

Due diligence and risk assessment

27. When the possibility of entering into an engagement is being considered, the relevant technical unit in the Secretariat conducts an initial examination in order to establish whether such an engagement would be in the interest of the Organization and in line with the principles of WHO's engagement with non-State actors in paragraph 5 and the priorities defined in the General Programme of Work and Programme budget. If this seems to be the case, the technical unit consults the WHO Register on non-State actors and as needed asks the non-State actor to provide its basic information.

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[1] WHO uses an electronic tool for managing engagement. As described in footnote 1 of paragraph 38, the publicly visible part of the tool is the register of non-State actors; the tool also provides an electronic workflow for the internal management of engagement. A similar electronic tool is used for the management of individual conflicts of interest, in order to harmonize the implementation of the framework with the implementation of the policy on management of individual conflicts of interest for experts.

Using the Organization-wide electronic tool, the unit then complements this information with a description of the proposed engagement and its own assessment of the benefits and risks involved, as needed.

28 The technical unit makes an initial assessment. If the engagement is of low risk, for example because of its repetitive nature[1] or because it does not involve policies, norms and standard setting, a simplified due diligence and risk assessment modulating the procedures in paragraphs 29 to 36 as well as 39 can be performed by the technical unit and the risk management decision taken, taking such steps as are necessary to ensure full compliance with paragraphs 5 to 7.[2] For all other engagements full procedures apply.

29. Before engaging with any non-State actor, WHO, in order to preserve its integrity, conducts due diligence and risk assessment. **Due diligence** refers to the steps taken by WHO to find and verify relevant information on a non-State actor and to reach a clear understanding of its profile. While due diligence refers to the nature of the non-State actor concerned, **risk assessment** refers to the assessment of a specific proposed engagement with that non-State actor.

30. **Due diligence** combines a review of the information provided by the non-State actor, a search for information about the entity concerned from other sources, and an analysis of all the information obtained. This includes a screening of different public, legal and commercial sources of information, including: media; the entity's website companies' analyst reports, directories and profiles; and public, legal and governmental sources.

31. The core functions of due diligence are to:

- clarify the nature and purpose of the entity proposed to engage with WHO;
- clarify the interest and objectives of the entity in engaging with WHO and what it expects in return;
- determine the entity's legal status, area of activities, membership, governance, sources of funding, constitution, statutes, and by-laws and affiliation;
- define the main elements of the history and activities of the entity in terms of the following: health, human and labour issues; environmental, ethical and business issues; reputation and image; and financial stability;
- identify if paragraph 44 or 45 should be applied.

32. Due diligence also allows the Secretariat for the purpose of its engagement to categorize each non-State actor in relation to one of the four groups of non-State actors on the basis of its nature, objectives, governance, funding, independence and membership. This categorization is indicated in the register of non-State actors.

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[1] Provided that due diligence and risk assessment have already been carried out and the nature of engagement has remained unchanged.

[2] The simplified due diligence and risk assessment, and information to be provided by non-State actors as well as the criteria of low risk engagements are described in the guide for staff.

33. Risks are the expression of the likelihood and potential impact of an event that would affect the Organization's ability to achieve its objectives. A **risk assessment** on a proposed engagement is conducted in addition to due diligence. This involves the assessment of risks associated with an engagement with a non-State actor, in particular the risks described in paragraph 7 and is to be conducted without prejudice to the type of non-State actor.

Risk management

34. **Risk management** concerns the process leading to a management decision whereby the Secretariat decides explicitly and justifiably on entry into engagement,[1] continuation of engagement, engagement with measures to mitigate risks, non-engagement or disengagement from an existing or planned engagement with non-State actors. It is a management decision usually taken by the unit engaging with the non-State actor based on a recommendation of the specialized unit responsible for performing due diligence and risk assessment.

35. A dedicated secretariat mechanism reviews proposals of engagement referred to it and recommends engagement, continuation of engagement, engagement with measures to mitigate risks, non engagement or disengagement from an existing or planned engagement with non-State actors. The Director-General, working with the Regional Directors, ensures coherence and consistency in implementation and interpretation of this Framework across all levels of the Organization.

36. WHO takes a risk-management approach to engagement, only entering into an engagement with a non-State actor when the benefits in terms of direct or indirect contributions to public health and the fulfilment of the Organization's mandate as mentioned in paragraph 6 outweigh any residual risks of engagement as mentioned in paragraph 7, as well as the time and expense involved in establishing and maintaining the engagement.

Transparency

37. WHO's interaction with non-State actors is managed transparently. WHO provides an annual report to the governing bodies on its engagement with non-State actors, including summary information on due diligence, risk assessment and risk management undertaken by the Secretariat. WHO also makes publicly available appropriate information on its engagement with non-State actors.

38. The **WHO register of non-State actors** is an Internet-based, publicly available electronic tool used by the Secretariat[2] to document and coordinate engagement with non-State actors. It contains the main standard information provided by non-State actors[3] and high-level descriptions of the engagement that WHO has with these actors.[4]

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[1] Other than decisions related to official relations as set out in paragraphs 50 to 57.

[2] The register of non-State actors is the first level of a tool used by the Secretariat containing four levels of information: a publicly available level, a level made available to Member States, a working level for the Secretariat, and a level of confidential and sensitive information accessible to a limited number of individuals within the Secretariat.

[3] Information on financial contributions received from non-State actors is documented in this register and in the Programme Budget web portal.

[4] The register covers all three levels of the Organization – global, regional and country – and includes hosted partnerships and joint programmes.

39 Non-State actors engaging with WHO are required to provide information on their organization. This information includes: name, membership, legal status, objective, governance structure, composition of main decision-making bodies, assets, annual income and funding sources, main relevant affiliations, webpage and one or more focal points for WHO contacts.

40. When the Secretariat decides on an engagement with a non-State actor, a summary of the information submitted by that entity and held in the WHO register of non-State actors is made public. The accuracy of the information provided by the non-State actor and published in the register is the responsibility of the non-State actor concerned and does not constitute any form of endorsement by WHO.

41. Non-State actors described in the register must update the information provided on themselves annually or upon the request of WHO. Information in the WHO register of non-State actors will be dated. Information on entities that are no longer engaged with WHO or that have not updated their information will be marked as "archived". Archived information from the WHO register of non-State actors can be considered in relation to future applications for engagement, where relevant.

42. In addition to the publicly available information, Member States have electronic access to a summary report on due diligence of each non-State actor and their respective risk assessment and risk management on engagement. Member States also have access, on demand, to the associated full report through a remote secure access platform.

43. WHO maintains a handbook to guide non-State actors in their interaction with WHO in line with this framework. A guide for staff is also maintained on the implementation of the framework of engagement with non-State actors.

SPECIFIC PROVISIONS

44. WHO does not engage with the tobacco industry or non-State actors that work to further the interests of the tobacco industry. WHO also does not engage with the arms industry.

Engagement where particular caution should be exercised

45 WHO will exercise particular caution, especially while conducting due diligence, risk assessment and risk management, when engaging with private sector entities and other non-State actors whose policies or activities are negatively affecting human health and are not in line with WHO's policies, norms and standards, in particular those related to noncommunicable diseases and their determinants.

Association with WHO's name and emblem

46. WHO's **name and emblem** are recognized by the public as symbols of integrity and quality assurance. WHO's name, acronym and emblem shall not, therefore, be used for, or in conjunction with, commercial, promotional marketing and advertisement purposes. Any use of the name or emblem needs an explicit written authorization by the Director-General of WHO.[1]

[1] See http://www.who.int/about/licensing/emblem/en/.

Secondments

47. WHO does not accept secondments from private sector entities.

RELATION OF THE FRAMEWORK TO WHO'S OTHER POLICIES

48. This framework replaces the Principles Governing Relations between the World Health Organization and Nongovernmental Organizations[1] and the Guidelines on interaction with commercial enterprises to achieve health outcomes (noted by the Executive Board).[2]

49. The implementation of the policies listed below as they relate to WHO's engagement with non-State actors will be coordinated and aligned with the framework of engagement with non-State actors. In the event that a conflict is identified, it will be brought to the attention of the Executive Board through its Programme, Budget and Administration Committee.

(a) Policy on WHO's engagement with global health partnerships and hosting arrangements.[3]

(i) Hosted partnerships derive their legal personality from WHO and are subject to the Organization's rules and regulations. Therefore the Framework of engagement with non-State actors applies to their engagement with non-State actors. They have a formal governance structure, separate from that of the WHO governing bodies, in which decisions are taken on direction, workplans and budgets; and their programmatic accountability frameworks are also independent from those of the Organization. In the same way the framework applies to other hosted entities which are subject to the Organizations Rules and Regulations.

(ii) WHO's involvement in external partnerships is regulated by the policy on WHO's engagement with global health partnerships and hosting arrangements. The framework of engagement with non-State actors also applies to WHO's engagement in these partnerships.[4]

(b) Regulations for Expert Advisory Panels and Committees and the Guidelines for Declaration of Interests (WHO Experts). The management of WHO's relations with individual experts is regulated by the Regulations for Expert Advisory Panels and Committees[5] and the Guidelines for Declaration of Interests (WHO Experts).

(c) Staff Regulations and Staff Rules. All staff are subject to the Organization's Staff Regulations and Staff Rules, noting in particular the provisions of declaration of interest therein:

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[1] Basic documents, 48th ed. Geneva: World Health Organization; 2014: pp.97–102.

[2] See document EB107/2001/REC/2, summary record of the twelfth meeting.

[3] Endorsed by the Health Assembly in resolution WHA63.10 on partnerships and its Annex 1.

[4] The Codex Alimentarius Commission is an intergovernmental body which is the principal organ of the joint FAO/WHO food standards programme for which the administration is not solely provided by WHO. The Commission is supported by subsidiary bodies including Codex committees, regional coordinating committees and task forces. Meetings of the Commission, Committees, including independent expert committees, and Task Forces are regulated by the Rules of Procedure and other decisions adopted by the Codex Alimentarius Commission.

[5] See Basic documents, 48th ed. Geneva: World Health Organization; 2014: pp.121–130.

according to Article 1.1 of the Staff Regulations of the World Health Organization, all staff members "pledge themselves to discharge their functions and to regulate their conduct with the interests of the World Health Organization only in view."

(a) Regulations for Study and Scientific Groups, Collaborating Institutions and other Mechanisms of Collaboration. Scientific collaborations are regulated by the Regulations for Study and Scientific Groups, Collaborating Institutions and other Mechanisms of Collaboration.[1]

(b) Financial Rules and Financial Regulations.

(i) The procurement of goods and services is regulated by the Financial Rules and Financial Regulations;[2] it is not covered by the framework of engagement with non-State actors, although pro-bono contributions from non-State actors are covered.

(ii) Like any other financing of WHO, financing from non-State actors is regulated by the Financial Rules and Financial Regulations and the decision on accepting such financial contributions is also regulated by this framework.

OFFICIAL RELATIONS

50. **"Official relations"** is a privilege that the Executive Board may grant to nongovernmental organizations, international business associations and philanthropic foundations that have had and continue to have a sustained and systematic engagement[3] in the interest of the Organization. The aims and activities of all these entities shall be in conformity with the spirit, purposes and principles of WHO's Constitution, and they shall contribute significantly to the advancement of public health. Organizations in official relations can attend governing body meetings of WHO but are otherwise subject to the same rules as other non-State actors when engaging with WHO.

51. Entities in official relations are international in membership and /or scope. All entities in official relations shall have a constitution or similar basic document, an established headquarters, a governing body, an administrative structure, and a regularly updated entry in the WHO register of non-State actors.

52. Official relations shall be based on a plan for collaboration between WHO and the entity with agreed objectives and outlining activities for the coming three-year period structured in accordance with the General Programme of Work and Programme budget and consistent with this framework. This plan shall also be published in the WHO register of non-State actors. These organizations shall provide annually a short report on the progress made in implementing the plan of collaboration and other related activities which will also be published in the WHO register. These plans shall be free from concerns which are primarily of a commercial or profit-making nature.

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[1] Basic documents, 48th ed. Geneva: World Health Organization; 2014:pp.131–138.

[2] Basic documents, 48th ed. Geneva: World Health Organization; 2014:pp.103–113.

[3] At least two years of systematic engagement as documented in the WHO register of non-State actors, assessed by both parties to be mutually beneficial. Participation in each other's meetings alone is not considered to be a systematic engagement.

53. For nongovernmental organizations working on global health issues, sustained and systematic engagement could include research and active advocacy around WHO meetings and WHO's policies, norms and standards. Official relations may be considered for such nongovernmental organizations based on at least three years of their activities and future work plan on research and advocacy on global public health issues.

54. The Executive Board shall be responsible for deciding on the admission of organizations into official relations with WHO and shall review this status every three years. The Director-General may propose international nongovernmental organizations, philanthropic foundations and international business associations for admission. The Director-General can also propose an earlier review based on the experience in the collaboration with the organization concerned.

55. Entities in official relations are invited to participate in sessions of WHO's governing bodies. This privilege shall include:

(a) the possibility to appoint a representative to participate, without right of vote, in meetings of WHO's governing bodies or in meetings of the committees and conferences convened under its authority;

(b) the possibility to make a statement if the Chairman of the meeting (i) invites them to do so or (ii) accedes to their request when an item in which the related entity is particularly interested is being discussed;

(c) the possibility to submit the statement referred to in subparagraph (b) above in advance of the debate for the Secretariat to post on a dedicated website.

56. Non-State actors participating in WHO governing bodies' meetings shall designate a head of their delegation and declare the affiliations of their delegates. This declaration shall include the function of each delegate within the non-State actor itself and, where applicable, the function of that delegate within any affiliated organization.

57. Regional committees may also decide on a procedure granting accreditation to their meetings to other international, regional, and national[1] non-State actors not in official relations with WHO as long as the procedure is managed in accordance with this framework.

Procedure for admitting and reviewing organizations in official relations

58. The application for admission into official relations shall be based on the up-to-date entries in the WHO register of non-State actors, providing all the necessary information as requested on the non-State actor's nature and activities. The application shall include a summary of past engagement as documented in the register of non-State actors and a three-year plan for collaboration with WHO that has been developed and agreed on jointly by the non-State actor and WHO.

59. A signed letter certifying the accuracy of the application for official relations submitted online shall reach WHO headquarters no later than the end of the month of July for submission to the Executive Board at its session the following January. Applications for official relations shall be reviewed to ensure that the established criteria and other requirements are fulfilled as set out in this

[1] In accordance with WHO Constitution, Article 71.

framework. Applications should be transmitted to the Executive Board members by the Secretariat six weeks before the opening of the January session of the Executive Board at which they will be considered.

60. During the Board's January session, the Programme, Budget and Administration Committee of the Executive Board shall consider applications submitted and shall make recommendations to the Board. A representative of an applicant organization may be invited by the Committee to speak before it in connection with that organization's application. Should the applicant organization be considered not to meet the established criteria, and bearing in mind the desirability of ensuring a valuable continuing partnership based on defined objectives and evidenced by a record of successful past engagement and a framework for future collaborative activities, the Committee may recommend postponement of consideration or rejection of an application.

61. The Board, after considering the recommendations of the Committee, shall decide whether an organization is to be admitted into official relations with WHO. A reapplication from a non-State actor shall not normally be considered until two years have elapsed since the Board's decision on the previous application.

62. The Director-General shall inform each organization of the Board's decision on its application. The Director-General shall document decisions taken within the Secretariat and by the Executive Board on applications from non-State actors, reflect this status in the WHO register of non-State actors, and maintain a list of the organizations admitted into official relations.

63. The entities in official relations and the Secretariat should name focal points for collaboration who are responsible for informing each other and their organizations of any developments in the implementation of the plan for collaboration and who are the first points of contact for any changes or problems.

64. The Board, through its Programme, Budget and Administration Committee, shall review collaboration with each non-State actor in official relations every three years and shall decide on the desirability of maintaining official relations or defer the decision on the review to the following year. The Board's review shall be spread over a three-year period, one third of the entities in official relations being reviewed each year.

65. The Director-General can propose earlier reviews of a non-State actor's official relations with WHO by the Executive Board through its Programme, Budget and Administration Committee in case of issues such as non-fulfilment of the entity's part in the plan of collaboration, lack of contact, failure by the non-State actor to fulfil its reporting requirements or changes in the nature or activities of the organization concerned, the non-State actor ceasing to fulfil the criteria for admission, or any potential new risks for the collaboration.

66. The Board may discontinue official relations if it considers that such relations are no longer appropriate or necessary in the light of changing programmes or other circumstances. Similarly, the Board may suspend or discontinue official relations if an organization no longer meets the criteria that applied at the time of the establishment of such relations, fails to update its information and report on the collaboration in the WHO register on non-State actors or fails to fulfil its part in the agreed programme of collaboration.

OVERSIGHT OF ENGAGEMENT

67. The Executive Board, through its Programme, Budget and Administration Committee, oversees the implementation of WHO's framework of engagement with non-State actors, proposes revisions to the framework and can grant the privileges of official relations to international nongovernmental organizations, philanthropic foundations and international business associations.

68. The Programme Budget and Administration Committee of the Executive Board shall review, provide guidance and, as appropriate, make recommendations to the Executive Board on:

(a) oversight of WHO's implementation of the framework of engagement with non-State actors including:

(i) consideration of the annual report on engagement with non-State actors submitted by the Director-General

(ii) any other matter on engagement referred to the Committee by the Board

(b) entities in official relations with WHO, including:

(i) proposals for admitting non-State actors into official relations

(ii) review of renewals of entities in official relations

(c) any proposal, when needed, for revisions of the framework of engagement with non-State actors.

NON-COMPLIANCE WITH THIS FRAMEWORK

69. Non-compliance can include inter alia the following: significant delays in the provision of information to the WHO register of non-State actors; provision of wrong information; use of the engagement with WHO for purposes other than protecting and promoting public health, such as for commercial, promotional, marketing and advertisement purposes; misuse of WHO's name and emblem; attempt at undue influence; and abuse of the privileges conferred by official relations.

70. Non-compliance by a non-State actor with the provisions of this framework can have consequences for the entity concerned after due process including a reminder, a warning, a cease-and-desist letter, a rejection of renewal of engagement and termination of engagement. The review of the status of official relations by the Executive Board can be anticipated and non-compliance can be the reason for non-renewal of official relations. Except in the case of important and intentional cases of non-compliance the non-State actor concerned should not be automatically excluded from other engagements with WHO.

71. Any financial contribution received by WHO that is subsequently discovered to be non-compliant with the terms of this framework shall be returned to the contributor.

IMPLEMENTATION

72. Consistent with the principles identified in paragraph 5, this framework will be implemented in its entirety in a manner that manages and strengthens WHO's engagement with non-State actors towards the attainment of public health objectives, including through multistakeholder partnerships, whilst protecting and preserving WHO's integrity, independence, credibility and reputation;

73. The Director-General, in the application of this framework, when responding to acute public health events described in the International Health Regulations (2005) or other emergencies with health consequences, will act according to the WHO Constitution[1] and the principles identified in this framework. In doing so, the Director-General may exercise flexibility as might be needed in the application of the procedures of this framework in those responses, when he/she deems necessary, in accordance with WHO's responsibilities as health cluster lead, and the need to engage quickly and broadly with non-State actors for coordination, scale up and service delivery[2]. The Director-General will inform Member States through appropriate means,[3] including in particular written communication, without undue delay when such a response requires exercise of flexibility, and include summary information with justification on the use of such flexibility in the annual report on engagement with non-State actors.

MONITORING AND EVALUATION OF THE FRAMEWORK

74. The implementation of the framework will be constantly monitored internally and by the Executive Board through its Programme, Budget and Administration Committee in the annual report on engagement with non-State actors and the assessment of information available in the register of non-State actors.

75. Furthermore, the implementation of the framework should be periodically evaluated. The results of such evaluation, together with any proposals for revisions of the framework, shall also be submitted to the Executive Board through its Programme, Budget and Administration Committee.

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[1] Including Article 2(d) of the WHO Constitution.

[2] Taking into account resolution WHA65.20 (WHO's response, and role as the health cluster lead, in meeting the growing demands of health in humanitarian emergencies).

[3] Including as described in United Nations General Assembly resolution 46/182 (Strengthening of the coordination of humanitarian assistance of the United Nations), which establishes the Secretary-General's emergency relief coordinator, and the International Health Regulations (2005).

WHO POLICY AND OPERATIONAL PROCEDURES ON ENGAGEMENT WITH NONGOVERNMENTAL ORGANIZATIONS

1. This policy regulates specifically WHO's engagement with nongovernmental organizations by type of interaction.[1] The provisions of the overarching framework also apply to all engagements with nongovernmental organizations.

PARTICIPATION

Participation by nongovernmental organizations in WHO meetings[2]

2. WHO can invite nongovernmental organizations to participate in consultations, hearings or other meetings in accordance with paragraph 15 of the overarching framework. Consultations and hearings can be electronic or in person.

3. Participation in other meetings is on the basis of discussion of an item in which the nongovernmental organization has a particular interest and where its participation adds value to the deliberations of the meeting. Such participation is for the exchange of information and views, but never for the formulation of advice.

4. The nature of participation of nongovernmental organizations depends on the type of meeting concerned. The format, modalities, and the participation of nongovernmental organizations in consultations, hearings, and other meetings is decided on a case-by-case basis by the WHO governing bodies or by the Secretariat. Participation and inputs received from nongovernmental organizations shall be made publicly available, wherever possible. Nongovernmental organizations do not take part in any decision-making process of the Organization.

Involvement of the Secretariat in meetings organized by nongovernmental organizations

5. WHO can organize joint meetings, or cosponsor meetings organized by nongovernmental organizations, as long as the integrity, independence and reputation of the Organization are preserved, and as long as this participation furthers WHO's objectives as expressed in the General Programme of Work. WHO staff members may participate in meetings organized by nongovernmental organizations in accordance with the internal rules of the Organization. The nongovernmental organization shall not misrepresent WHO's participation as official WHO support for, or endorsement of, the meeting, and shall agree not to use WHO's participation for promotional purposes.

Specific policies and operational procedures

6. The participation of WHO in meetings organized by nongovernmental organizations as co-organizers, cosponsors, panellists or speakers shall be managed according to the provisions of this Framework.

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[1] See paragraphs 14–20 of the overarching framework for the five types of interaction.

[2] Other than sessions of the governing bodies, which are regulated by the policy on management of engagement.

RESOURCES

7. WHO can accept financial and in-kind contributions from nongovernmental organizations as long as such contributions fall within WHO's General Programme of Work, do not create conflicts of interest, are managed in accordance with the framework, and comply with other relevant regulations, rules and policies of WHO.

8. The acceptance of contributions (whether in cash or in kind) should be made subject to the following conditions:

(a) the acceptance of a contribution does not constitute an endorsement by WHO of the nongovernmental organization;

(b) the acceptance of a contribution does not confer on the contributor any privilege or advantage;

(c) the acceptance of a contribution as such does not offer the contributor any possibility for advising, influencing, participating in, or being in command of the management or implementation of operational activities;

(d) WHO keeps its discretionary right to decline a contribution, without any further explanation.

9. WHO can provide resources to a nongovernmental organization for implementation of particular work in accordance with the Programme Budget, the Financial Regulations and Financial Rules and other applicable rules and policies. The resources concerned can be either for a project of the institution which WHO considers merits support and is consistent with WHO's general programme of work, or for a project organized or coordinated by WHO. The former constitutes a grant, the latter a service.

Specific policies and operational procedures

10. Any acceptance of resources from a nongovernmental organization is handled in accordance with the provisions of this framework and relevant other WHO rules and guidelines such as the Staff Regulations and Staff Rules, the Financial Regulations and Financial Rules and policies governing procurement, as well as WHO's guidelines for medicine donations and WHO's guidelines for health care equipment donations;

11. For reasons of transparency, contributions from nongovernmental organizations must be publicly acknowledged by WHO in accordance with its policies and practices.

12. Acknowledgements shall usually be worded along the following lines: "The World Health Organization gratefully acknowledges the financial contribution of [Nongovernmental organization] towards [description of the outcome or activity]".

13. Contributions received from nongovernmental organizations are listed in the financial report and audited financial statements of WHO as well as the Programme budget web portal and the WHO register of non-State actors.

14. Nongovernmental organizations may not use the fact that they have made a contribution in their materials used for commercial, promotional, marketing and advertisement purposes.[1] However, they may make reference to the contribution in their annual reports or similar documents. In addition, they may mention the contribution on their websites, and in special non-promotional publications, provided that the content and context have been agreed with WHO.

EVIDENCE

15 Nongovernmental organizations may provide their up-to-date information and knowledge on technical issues, and share their experience with WHO, as appropriate, subject to the provisions of the overarching framework, and this specific policy and operational procedures, and other applicable WHO rules, policies and procedures. Such contribution should be made publicly available, as appropriate, wherever possible. Scientific evidence generated should be made publicly available.

ADVOCACY

16. WHO collaborates with nongovernmental organizations on advocacy for health and increasing awareness of health issues; for changing behaviours in the interest of public health; and for fostering collaboration and greater coherence between non-State actors where joint action is required.

17. Nongovernmental organizations are encouraged to disseminate WHO's policies, guidelines, norms and standards and other tools through their networks.

18. WHO encourages nongovernmental organizations to implement and advocate for the implementation of WHO's policies, norms and standards. WHO engages in dialogue with nongovernmental organizations in order to promote the implementation of WHO's policies, norms and standards.[2]

19. Nongovernmental organizations can only collaborate with WHO in advocacy for the implementation of WHO policies norms or standards if they commit themselves to implement these policies, norms or standards in their entirety. No partial or selective implementation is acceptable.

TECHNICAL COLLABORATION

20. WHO may engage with the nongovernmental organizations for technical collaboration as defined in the overarching framework paragraph 20. Technical collaboration with nongovernmental organizations is encouraged. This collaboration must be in the interest of WHO, and managed in accordance with the overarching framework and this policy to protect WHO, and in particular, its normative work, from any undue influence or conflict of interest and to ensure there is no interference with WHO's advisory function to Member States.

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[1] In accordance with paragraph 46 of the overarching framework.

[2] Nongovernmental organizations working with WHO will be expected to conform to WHO's public health policies in areas such as food safety, chemical safety, ethical promotion of medicinal drug products, tobacco control, noncommunicable diseases, as well as health and safety at work.

WHO POLICY AND OPERATIONAL PROCEDURES ON ENGAGEMENT WITH PRIVATE SECTOR ENTITIES

1. This policy regulates specifically WHO's engagement with private sector entities by type of interaction.[1] The provisions of the overarching framework also apply to all engagements with private sector entities.

2. When engaging with private sector entities, it should be borne in mind that WHO's activities affect the commercial sector in broader ways, through, among others, its public health guidance, its recommendations on normative standards, or other work that might indirectly or directly influence product costs, market demand, or profitability of specific goods and services.

3. In engaging with private sector entities, WHO will aim to operate on a competitively neutral basis.

PARTICIPATION

Participation by private sector entities in WHO meetings[2]

4. WHO can invite private sector entities to participate in consultations, hearings or other meetings in accordance with paragraph 15 of the overarching framework. Consultations and hearings can be electronic or in person.

5. Participation in other meetings is on the basis of discussion of an item in which the private sector entity has a particular interest and where its participation adds value to the deliberations of the meeting. Such participation is for the exchange of information and views, but never for the formulation of advice.

6. The nature of participation of private sector entities depends on the type of meeting concerned. The format, modalities, and the participation of private sector entities in consultations, hearings, and other meetings is decided on a case-by-case basis by the WHO governing bodies or by the Secretariat. Participation and inputs received from private sector entities shall be made publicly available, wherever possible. Private sector entities do not take part in any decision making process of the Organization.

Involvement of the Secretariat in meetings organized by private sector entities

7. WHO staff members may participate in meetings organized by a private sector entity as long as the integrity, independence and reputation of the Organization are preserved and as long as this participation furthers WHO's objectives as expressed in the General Programme of Work. The private sector entity shall not misrepresent WHO's participation as official WHO support for, or endorsement of, the meeting, and shall agree not to use WHO's participation for commercial and/or promotional purposes.

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[1] See paragraphs 14–20 of the overarching framework for the five types of interaction.

[2] Other than sessions of the governing bodies, which are regulated by the policy on management of engagement.

Specific policies and operational procedures

8. The participation of WHO staff members in meetings of private sector entities as panellists, speakers or in any other capacity shall be managed according to the provisions of the overarching framework and this specific policy.

9. WHO does not cosponsor meetings organized wholly or partly by private sector entities. It may, however, cosponsor a meeting for which the scientific initiators have hired a commercial conference organizer to deal with the logistical aspects, provided that the commercial organizer makes no contribution to the scientific content of the meeting.

10. WHO does not cosponsor meetings organized by other actors where one or more health-related private sector entities are also cosponsors. Other instances of cosponsorship of meetings organized by other actors where non health-related private sector entities are also cosponsors should be reviewed on a case-by-case basis and are subject to the provisions of this framework.

11. There shall be no commercial exhibitions on WHO premises and at WHO's meetings.

12. WHO does not cosponsor commercial exhibitions, whether as part of meetings organized by private sector entities or as part of meetings organized by other actors.

RESOURCES

13. The level of risk associated with the acceptance of resources from private sector entities depends on the field of activity of the private sector entity, the WHO activity for which the resources are used and the modalities of the contributions.

(a) Financial contributions may be accepted from private sector entities whose business is unrelated to that of WHO, provided they are not engaged in any activity or have close ties with any entity that is incompatible with WHO's mandate and work.

(b) Financial contributions may not be sought or accepted from private sector entities that have, themselves or through their affiliated companies, a direct commercial interest in the outcome of the project toward which they would be contributing, unless approved in conformity with the provisions for clinical trials or product development (see paragraph 36 below).

(c) The provisions set out in paragraph 13(b) shall be without prejudice to specific mechanisms, such as the Pandemic Influenza Preparedness Framework ("PIP Framework"), set up by the Health Assembly that involve the receipt and pooling of resources.[1]

(d) Caution should be exercised in accepting financial contributions from private sector entities that have even an indirect interest in the outcome of the project (i.e. the activity is related to the entities' field of interest, without there being a conflict as referred to above). In such an event, other commercial enterprises having a similar indirect interest should be invited to contribute, and the reason clearly described if this does not prove possible. The larger the proportion of the contribution from any one source, the greater the care that should be taken to

[1] In accordance with paragraph 17 of the overarching framework.

avoid the possibility of a conflict of interest or appearance of an inappropriate association with one contributor.

14. Financial and in-kind contributions from private sector entities to WHO's programmes are only acceptable in the following conditions:

(a) the contribution is not used for normative work;

(b) if a contribution is used for activities other than normative work in which the private sector entity could have a commercial interest, the public health benefit of the engagement needs clearly to outweigh its potential risks;

(c) the proportion of funding of any activity coming from the private sector cannot be such that the programme's continuation would become dependent on this support;

(d) the acceptance of the contribution does not constitute an endorsement by WHO of the private sector entity, or its activities, products or services;

(e) the contributor may not use the results of WHO's work for commercial purposes or use the fact of its contribution in its promotional material;

(f) the acceptance of the contribution does not afford the contributor any privilege or advantage;

(g) the acceptance of the contribution does not offer the contributor any possibility for advising, influencing, participating in, or being in command of the management or implementation of operational activities;

(h) WHO keeps its discretionary right to decline a contribution, without any further explanation.

15. Any acceptance of resources from private sector entities is handled in accordance with the provisions of this framework and relevant other WHO rules and guidelines such as the Staff Regulations and Staff Rules, the Financial Regulations and Financial Rules and policies governing procurement, as well as WHO's guidelines for medicine donations and WHO's guidelines for health care equipment donations;

16 For reasons of transparency, contributions from private sector entities must be publicly acknowledged by WHO in accordance with its policies and practices.

17. Acknowledgements shall usually be worded along the following lines: "The World Health Organization gratefully acknowledges the financial contribution of [Private sector entity] towards [description of the outcome or activity]".

18. Contributions received from private sector entities, are listed in the financial report and audited financial statements of WHO as well as the Programme budget web portal and the register of non-State actors.

19. Private sector entities may not use the fact that they have made a contribution in their materials used for commercial, promotional, marketing and advertisement purposes.[1] However, they may make reference to the contribution in their annual reports or similar documents. In addition, they may mention the contribution on their websites, and in special non-promotional publications, provided that the content and context have been agreed with WHO.

Donations of medicines and other health technologies[2]

20. In determining the acceptability of large-scale donations of medicines and other health-related products, the following criteria should be met.

(a) Sound evidence exists of the safety and efficacy of the product in the indication for which it is being donated. The product is approved or otherwise authorized by the recipient country for use in that indication; it should also preferably appear in the WHO Model List of Essential Medicines for that indication.

(b) Objective and justifiable criteria for the selection of recipient countries, communities or patients have been determined. In emergency situations, flexibilities may be required.

(c) A supply system is in place and consideration is given to means of preventing waste, theft and misuse (including leakage back into the market).

(d) A training and supervision programme is in place for all personnel involved in the efficient administration of supply, storage and distribution at every point from the donor to the end-user.

(e) A donation of medicines and other health-related products is not of a promotional nature, either with regard to the company itself or insofar as it creates a demand for the products that is not sustainable once the donation has ended.

(f) WHO does not accept products at the end of their shelf life.

(g) A phase-out plan for the donation has been agreed upon with recipient countries.

(h) A system for monitoring adverse reactions to the product has been set up with the participation of the donating company.

21. In consultation with the department responsible for financial matters in WHO, the value of donations of medicines and other health-related products is determined and is formally recorded in the audited statements and the WHO register of non-State actors.

[1] In accordance with paragraph 46 of the overarching framework.

[2] Such donations shall be in line with interagency guidelines: World Health Organization, Ecumenical Pharmaceutical Network, International Pharmaceutical Federation, International Federation of Red Cross and Red Crescent Societies, International Health Partners, The Partnership for Quality Medical Donations, et al. Guidelines for medicine donations – revised 2010. Geneva: World Health Organization; 2011.

Financial contributions for clinical trials

22. Except as provided in paragraph 36 below on product development, financial contributions from a private sector entity for a clinical trial arranged by WHO on that company's proprietary product are considered on a case-by-case basis. In this connection, it should be ensured that:

(a) the research or development activity is of public health importance;

(b) the research is conducted at WHO's request and potential conflicts of interest are managed;

(c) WHO only accepts such financial contributions, if the research would not take place without WHO's involvement or if WHO's involvement is necessary in order to ensure that the research is undertaken in conformity with internationally accepted technical and ethical standards and guidelines.

23 If the above-mentioned requirements are met, a financial contribution may be accepted from a company having a direct commercial interest in the trial in question, provided that appropriate mechanisms are put in place to ensure that WHO controls the conduct and the dissemination of the outcomes of the trials, including the content of any resulting publication, and that the trial results are free from any inappropriate influence or perceived influence from the company concerned.

Contributions for WHO meetings

24. For meetings convened by WHO, a contribution from a private sector entity may not be accepted if it is designated to support the participation of specific invitees (including such invitees' travel and accommodation), regardless of whether such contribution would be provided directly to the participants or channelled through WHO.

25. Contributions may be accepted to support the overall costs of a meeting.

26. WHO receptions and similar functions shall not be paid for by private sector entities.

Contributions for WHO staff participating in external meetings

27. An external meeting is one convened by a party other than WHO. Support from private sector entities for travel of WHO staff members to attend external meetings or conferences may fall into two categories:

(a) meetings held by the private sector entity paying for travel: financing for travel may be accepted in accordance with WHO's rules if the private sector entity is also supporting the travel and ancillary expenses of other participants in the meeting, and the risk of a conflict of interest has been assessed and managed;

(b) meetings held by a third party (i.e. a party other than the private sector entity proposing to pay for the travel): financing for travel may not be accepted from a private sector entity.

Contributions for publications

28. Financial contributions may be accepted from private sector entities for meeting the printing costs of WHO publications, as long as no conflict of interest arises. In no event may commercial advertisements be placed in WHO publications;

Cost recovery

29. In cases where a WHO evaluation scheme is in place (i.e. to evaluate certain products, processes or services against official WHO guidelines), the Organization may charge private sector entities for such services on the basis of cost recovery. The purpose of WHO's evaluation schemes is always to provide advice to governments and/or international organizations for procurement. Evaluation does not constitute endorsement by WHO of the product(s), process or service in question.

EVIDENCE

30. Private sector entities may provide their up-to-date information and knowledge on technical issues, and share their experience with WHO, as appropriate, subject to the provisions of the overarching framework, and this specific policy and operational procedures, and other applicable WHO rules, policies and procedures. Such contribution should be made publicly available, as appropriate, wherever possible. Scientific evidence generated should be made publicly available.

ADVOCACY

31. WHO encourages private sector entities to implement and advocate for the implementation of WHO's policies, norms and standards. WHO engages in dialogue with private sector entities in order to promote the implementation of WHO's policies, norms and standards.[1]

32. Private sector entities can only collaborate with WHO in advocacy for the implementation of WHO policies norms or standards if they commit themselves to implement these policies, norms or standards in their entirety. No partial or selective implementation is acceptable.

33. International business associations are encouraged to work with their members in order to improve their public health impact and the implementation of WHO policies, norms and standards.

TECHNICAL COLLABORATION

34. WHO may engage with the private sector for technical collaboration as defined in the overarching framework paragraph 20. Technical collaboration with private sector entities is encouraged. This collaboration must be in the interest of WHO, and managed in accordance with the overarching framework and this policy to protect WHO, and in particular, its normative work, from any undue influence or conflict of interest and to ensure there is no interference with WHO's advisory function to Member States.

[1] Private sector entities working with WHO will be expected to conform to WHO's public health policies in areas such as food safety, chemical safety, ethical promotion of medicinal drug products, tobacco control, noncommunicable diseases, as well as health and safety at work.

Specific policies and operational procedures

35. If WHO has drawn up official specifications for a product, it may provide technical advice to manufacturers for development of their product in accordance with these specifications, provided that all private sector entities known to have an interest in such a product are given the opportunity to collaborate with WHO in the same way.

36. WHO may collaborate with private sector entities in the research and development of health related technologies that contribute to increasing access to quality, safe, efficacious and affordable medical products. Collaborative research and development should, as a general rule, be undertaken only if WHO and the private sector entity have concluded an agreement which ensures that the final product will ultimately be widely available, including to the public sector of developing countries at a preferential price. If such an agreement is concluded, financing may be accepted from the private sector entity for a trial arranged by WHO on the product in question, on the basis that contractual commitments obtained from the private sector entity outweigh any potential conflict of interest in accepting such financing.

WHO POLICY AND OPERATIONAL PROCEDURES ON ENGAGEMENT WITH PHILANTHROPIC FOUNDATIONS

1. This policy regulates specifically WHO's engagement with philanthropic foundations by type of interaction.[1] The provisions of the overarching framework also apply to all engagements with philanthropic foundations.

PARTICIPATION

Participation by philanthropic foundations in WHO meetings[2]

2. WHO can invite philanthropic foundations to participate in consultations, hearings or other meetings in accordance with paragraph 15 of the overarching framework. Consultations and hearings can be electronic or in person.

3. Participation in other meetings is on the basis of discussion of an item in which the philanthropic foundation has a particular interest and where its participation adds value to the deliberations of the meeting. Such participation is for the exchange of information and views, but never for the formulation of advice.

4. The nature of participation of philanthropic foundations depends on the type of meeting concerned. The format, modalities, and the participation of philanthropic foundations in consultations, hearings, and other meetings is decided on a case-by-case basis by the WHO governing bodies or by the Secretariat. Participation and inputs received from philanthropic foundations shall be made publicly available, wherever possible. Philanthropic foundations do not take part in any decision making process of the Organization.

Involvement of the Secretariat in meetings organized by philanthropic foundations

5. WHO can organize joint meetings, or cosponsor meetings organized by philanthropic foundations, as long as the integrity, independence and reputation of the Organization are preserved, and as long as this participation furthers WHO's objectives as expressed in the General Programme of Work. WHO staff members may participate in meetings organized by philanthropic foundations in accordance with the Organization's internal rules. The philanthropic foundations shall not misrepresent WHO's participation as official WHO support for, or endorsement of, the meeting, and shall agree not to use WHO's participation for promotional purposes.

Specific policies and operational procedures

6. The participation of WHO in meetings organized by philanthropic foundations as co-organizers, cosponsors, panellists or speakers shall be managed according to the provisions of the framework for engagement with non-State actors.

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[1] See paragraphs 14–20 of the overarching framework for the five types of interaction.

[2] Other than sessions of the governing bodies, which are regulated by the policy on management of engagement.

RESOURCES

7. WHO can accept financial and in-kind contributions from philanthropic foundations as long as such contributions fall within WHO's General Programme of Work, do not create conflicts of interest, are managed in accordance with the framework, and comply with other relevant regulations, rules and policies of WHO.

8. As for all contributors, philanthropic foundations shall align their contributions to the priorities set by the Health Assembly in the approved Programme budget.

9. Philanthropic foundations are invited to participate in the financing dialogue, which is designed to improve the alignment, predictability, flexibility and transparency of WHO's funding and to reduce budgetary vulnerability.

10. WHO's programmes and offices should strive to ensure that they do not depend on one single source of funding.

11. The acceptance of contributions (whether in cash or in kind) should be made subject to the following conditions:

(a) the acceptance of a contribution does not constitute an endorsement by WHO of the philanthropic foundation;

(b) the acceptance of a contribution does not confer on the contributor any privilege or advantage;

(c) the acceptance of a contribution as such does not offer the contributor any possibility for advising, influencing, participating in, or being in command of the management or implementation of operational activities;

(d) WHO keeps its discretionary right to decline a contribution, without any further explanation.

Specific policies and operational procedures

12. Any acceptance of resources from a philanthropic foundation is handled in accordance with the provisions of this framework and relevant other WHO rules and guidelines such as the Staff Regulations and Staff Rules, the Financial Regulations and Financial Rules and policies governing procurement, as well as WHO's guidelines for medicine donations and WHO's guidelines for health care equipment donations.

13. For reasons of transparency, contributions from philanthropic foundations must be publicly acknowledged by WHO in accordance with its policies and practices.

14. Acknowledgements shall usually be worded along the following lines: "The World Health Organization gratefully acknowledges the financial contribution of [Philanthropic foundation] towards [description of the outcome or activity]".

15. Contributions received from philanthropic foundations are listed in the financial report and audited financial statements of WHO as well as the Programme budget web portal and the WHO register of non-State actors.

16. Philanthropic foundations may not use the fact that they have made a contribution in their materials used for commercial, promotional, marketing and advertisement purposes.[1] However, they may make reference to the contribution in their annual reports or similar documents. In addition, they may mention the contribution on their websites, and in special non-promotional publications, provided that the content and context have been agreed with WHO.

EVIDENCE

17. Philanthropic foundations may provide their up-to-date information and knowledge on technical issues, and share their experience with WHO, as appropriate, subject to the provisions of the overarching framework, and this specific policy and operational procedures, and other applicable WHO rules, policies and procedures. Such contribution should be made publicly available, as appropriate, wherever possible. Scientific evidence generated should be made publicly available.

ADVOCACY

18. WHO collaborates with philanthropic foundations on advocacy for health and increasing awareness of health issues; for changing behaviours in the interest of public health; and for fostering collaboration and greater coherence between non-State actors where joint action is required. Philanthropic foundations are encouraged to disseminate WHO's policies, guidelines, norms and standards and other tools through their networks so as to extend WHO's own reach.

19. WHO encourages philanthropic foundations to implement and advocate for the implementation of WHO's policies, norms and standards. WHO engages in dialogue with Philanthropic foundations in order to promote the implementation of WHO's policies, norms and standards.[2]

20. Philanthropic foundations can only collaborate with WHO in advocacy for the implementation of WHO policies norms or standards if they commit themselves to implement these policies, norms or standards in their entirety. No partial or selective implementation is acceptable.

TECHNICAL COLLABORATION

21. WHO may engage with the philanthropic foundations for technical collaboration as defined in the overarching framework paragraph 20. Technical collaboration with philanthropic foundations is encouraged. This collaboration must be in the interest of WHO, and managed in accordance with the overarching framework and this policy to protect WHO, and in particular, its normative work, from any undue influence or conflict of interest and to ensure there is no interference with WHO's advisory function to Member States).

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[1] In accordance with paragraph 46 of the overarching framework.

[2] Philanthropic foundations working with WHO will be expected to conform to WHO's public health policies in areas such as food safety, chemical safety, ethical promotion of medicinal drug products, tobacco control, noncommunicable diseases, as well as health and safety at work.

WHO POLICY AND OPERATIONAL PROCEDURES ON ENGAGEMENT WITH ACADEMIC INSTITUTIONS

1. This policy regulates specifically WHO's engagement with academic institutions by type of interaction.[1] The provisions of the overarching framework also apply to all engagements with academic institutions.

2. The engagement with academic institutions at the institutional level has to be distinguished from the collaboration with individual experts working for academic institutions.

PARTICIPATION

Participation by academic institutions in WHO meetings

3. WHO can invite academic institutions to participate in consultations, hearings or other meetings in accordance with paragraph 15 of the overarching framework. Consultations and hearings can be electronic or in person.

4. Participation in other meetings is on the basis of discussion of an item in which the academic institution has a particular interest and where its participation adds value to the deliberations of the meeting. Such participation is for the exchange of information and views, but never for the formulation of advice.

5. The nature of participation of academic institution depends on the type of meeting concerned. The format, modalities, and the participation of academic institution in consultations, hearings, and other meetings is decided on a case-by-case basis by the WHO governing bodies or by the Secretariat. Participation and inputs received from academic institutions shall be made publicly available, wherever possible. Academic institutions do not take part in any decision-making process of the Organization.

Involvement of the Secretariat in meetings organized by academic institutions

6. WHO can organize joint meetings, or cosponsor meetings organized by academic institutions, as long as the integrity, independence and reputation of the Organization are preserved, and as long as this participation furthers WHO's objectives as expressed in the General Programme of Work. WHO staff members may participate in meetings organized by academic institutions in accordance with the Organization's internal rules. The academic institution shall not misrepresent WHO's participation as official WHO support for, or endorsement of, the meeting, and shall agree not to use WHO's participation for promotional purposes.

Specific policies and operational procedures

7. The participation of WHO in meetings organized by academic institutions as co-organizers, cosponsors, panellists or speakers shall be managed according to the provisions of this framework.

[1] See paragraphs 14–20 of the overarching framework for the five types of interaction.

RESOURCES

8. WHO can accept financial and in-kind contributions from academic institutions as long as such contributions fall within WHO's General Programme of Work, do not create conflicts of interest, are managed in accordance with the framework, and comply with other relevant regulations, rules and policies of WHO.

9. WHO can provide resources to an academic institution for implementation of particular work (such as research, a clinical trial, laboratory work and preparation of a document), in accordance with the Financial Regulations and Financial Rules and other applicable rules and policies. This can be either for a project of the institution which WHO considers merits support, based on a clear public health interest, and is consistent with WHO's General Programme of Work, or for a project organized or coordinated by WHO. The former constitutes a grant, the latter a service.

Specific policies and operational procedures

10. Any acceptance of resources from an academic institution is handled in accordance with the provisions of this framework and relevant other WHO rules and guidelines such as the Staff Regulations and Staff Rules, the Financial Regulations and Financial Rules and policies governing procurement, as well as WHO's guidelines for medicine donations and WHO's guidelines for health care equipment donations;

11. For reasons of transparency, contributions from academic institutions must be publicly acknowledged by WHO in accordance with its policies and practices.

12. Acknowledgements shall usually be worded along the following lines: "The World Health Organization gratefully acknowledges the financial contribution of [academic institution] towards [description of the outcome or activity]".

13. Contributions received from academic institutions are listed in the financial report and audited financial statements of WHO as well as the Programme budget web portal and the WHO register of non-State actors.

14. Academic institutions may not use the fact that they have made a contribution in their materials used for commercial, promotional, marketing and advertisement purposes.[1] However, they may make reference to the contribution in their annual reports or similar documents. In addition, they may mention the contribution on their websites, and in special non-promotional publications, provided that the content and context have been agreed with WHO.

EVIDENCE

15. Academic institutions may provide their up-to-date information and knowledge on technical issues, and share their experience with WHO, as appropriate, subject to the provisions of the overarching framework, and this specific policy and operational procedures, and other applicable WHO rules, policies and procedures. Such contribution should be made publicly available, as appropriate, wherever possible. Scientific evidence generated should be made publicly available.

[1] In accordance with paragraph 46 of the overarching framework.

16. Intellectual property arising from collaborations with academic institutions is regulated by the agreement with the academic institution. This should be addressed in consultation with the Office of the Legal Counsel.

ADVOCACY

17. WHO collaborates with academic institutions on advocacy for health and increasing awareness of health issues; for changing behaviours in the interest of public health; and for fostering collaboration and greater coherence between non-State actors where joint action is required. Academic institutions are encouraged to disseminate WHO's policies, guidelines, norms and standards and other tools through their networks so as to extend WHO's own reach.

18. WHO encourages academic institutions to implement and advocate for the implementation of WHO's policies, norms and standards. WHO engages in dialogue with academic institutions in order to promote the implementation of WHO's policies, norms and standards.[1]

19. Academic institutions can only collaborate with WHO in advocacy for the implementation of WHO policies norms or standards if they commit themselves to implement these policies, norms or standards in their entirety. No partial or selective implementation is acceptable.

TECHNICAL COLLABORATION

20. WHO may engage with academic institutions for technical collaboration as defined in the overarching framework paragraph 20. Technical collaboration with academic institutions is encouraged. This collaboration must be in the interest of WHO, and managed in accordance with the overarching framework and this policy to protect WHO, and in particular, its normative work, from any undue influence or conflict of interest and to ensure there is no interference with WHO's advisory function to Member States.

21. Scientific collaborations are regulated by the Regulations for Study and Scientific Groups, Collaborating Institutions and other Mechanisms of Collaboration.[2]

22. Academic institutions or parts thereof can be designated as WHO collaborating centres in accordance with the Regulations mentioned above. In this context, before granting the status of WHO collaborating centre a due diligence and risk assessment in accordance with this framework is conducted. The collaboration with these collaborating centres is regulated by the aforementioned regulations and reflected in the register of non-State actors.

Eighth plenary meeting, 28 May 2016

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[1] Academic institutions working with WHO will be expected to conform to WHO's public health policies in areas such as food safety, chemical safety, ethical promotion of medicinal drug products, tobacco control, noncommunicable diseases, as well as health and safety at work.

[2] Basic documents, 48th ed. Geneva: World Health Organization; 2014: pp.131–138.