After several years of intense discussions and negotiations, the World Health Assembly (WHA) adopted the World Health Organization’s Framework of Engagement with non-State Actors (FENSA) on 28 May 2016. The establishment of the framework was a response to the growing concerns of many governments and civil society organizations about the corporate influence on the World Health Organization’s (WHO) normative and operational activities. The objective of the new framework was therefore to provide guidelines for clear and informed decision making on WHO’s engagement with non-State actors, and to improve transparency and accountability.

FENSA constitutes a precedent. It is the first comprehensive regulatory framework within the United Nations system that covers all types of interaction with non-State actors, including nongovernmental organizations, private sector entities, philanthropic foundations, and academic institutions. Some observers regard FENSA as a major step forward and an adequate safeguard against undue private influence. Others criticize its principle of “inclusiveness” and the equal treatment of public interest and for-profit interest groups. It remains controversial if FENSA can serve as a blueprint for future regulatory frameworks of other UN agencies and programs in their engagement with non-State actors.

This briefing paper provides an overview on the recently adopted framework. It outlines the process leading up to this document, presents the agreed provisions, describes lobbying attempts by the private sector, and discusses the final outcome.

Background

In recent years, the global health architecture has become complex and fragmented. More and more private actors have been entering the scene and have expanded their relations with the World Health Organization (WHO).

In light of the growing role of corporate philanthropy and private companies in the WHO decision-making process, many governments and civil society organizations (CSOs) have called for a comprehensive and effective revision of the principles and guidelines that govern WHO’s engagement with non-State actors, particularly the “guidelines on working with the private sector to achieve health outcomes” of 2000. They were seen as insufficient by many member states and civil society organizations. WHO Director-General Margaret Chan reaffirmed the importance of public interest safeguards in a speech at the 8th Global Conference on Health Promotion in June 2013:

“In the view of WHO, the formulation of health policies must be protected from distortion by commercial or vested interests.”

What made such safeguards a matter of urgency is the fact that WHO’s financial situation is highly precarious and that the organization is increasingly dependent on contributions from the private sector. By 2014, assessed contributions by WHO member states represented just 23 per cent of its total budget. Most of WHO’s budget comprises voluntary contributions, including those from private entities. Recent WHO figures suggest contributions from philanthropic foundations make up 13 per cent and from private companies around 2 per cent of total voluntary contributions for the biennium 2014–2015. As these contributions are mostly earmarked, WHO’s agenda has increasingly become shaped by the priorities of donors, public and private.

But the private actors’ influence on WHO goes beyond mere funding. Philanthropic foundations such as the Bill & Melinda Gates Foundation and the United Nations Foundation have seconded their staffers to top management positions at the World Health Organization. Between 2012 and 2015, WHO had 37 secondments from non-State actors. Three current top-level secondments have Gates Foundation connections.

Funding selected research initiatives is another way of influencing policies at UN level and shaping the discourse. Head of WHO Margaret Chan describes further dangers with regard to the corporate influence on health promotion:

“In my view, this is one of the biggest challenges facing health promotion. [...] it is not just Big Tobacco anymore. Public health must also contend with Big Food, Big Soda, and Big Alcohol. All of these industries fear regulation, and protect themselves by using the same tactics.”

“Research has documented these tactics well. They include front groups, lobbies, promises of self-regulation, lawsuits, and industry-funded research that confuses the evidence and keeps the public in doubt.

“Tactics also include gifts, grants, and contributions to worthy causes that cast these industries as respectable corporate citizens in the eyes of politicians and the public. They include arguments that place the responsibility for harm to health on individuals, and portray government actions as interference in personal liberties and free choice.”

There also has been a marked change in the way in which private actors have engaged with the UN in general over the last two decades. In recent years, numerous global health partnerships and vertical funds have been established, such as Every Woman every Child, Scaling up Nutrition, the vaccine and immunization alliance GAVI, the Global Fund, the Partnership for Maternal, Newborn and Child Health, the Medicines for Malaria Venture, the Roll Back Malaria Partnership, the TB Alliance, the Stop TB Partnership, and many more. These global partnerships allow the corporate sector and their interest groups growing influence over agenda setting and political decision-making by governments and have contributed to the institutional weakening of the WHO and the entire UN system.

The process towards the adoption of FENSA

In 2011, the WHO started a reform process to enable the organization to better fulfill its historic mandate and to re-establish its role as leading actor in global health. The process has three aims:

“programmatic reform to improve people’s health; governance reform to increase coherence in global health and managerial reform in pursuit of organizational excellence.”

As part of the WHO reform process, governments have requested the Director-General to develop a Framework of Engagement with non-State Actors (FENSA), and separate policies on engagement with different groups of non-State actors.
The WHO Secretariat has worked on a draft framework since 2012 and presented reports in May and December 2014. In response to the first draft, several WHO member states raised serious concerns for consideration in the final framework, while others, among them European Union Member States, wanted to see the WHA adopt the draft framework in its presented form. As no consensus could be found, Open-ended Intergovernmental Meetings (OEIGM) were requested by the member states, and the discussions were reopened.

The final version of the framework was expected to be adopted during the sixty-eighth session of the WHA 2015. However, the intense negotiations did not lead to a consensus among governments on crucial issues, such as conflict of interest policies, definitions of resources, secondments, the relation of WHO with industries other than the tobacco and arms industry, transparency requirements, oversight mechanism of engagements with non-State actors, and ceilings on financial resources. Therefore, the WHA requested the Director-General to submit the final draft to the WHA for adoption in 2016. In addition, it asked the WHO secretariat to set up a register of non-State actors to manage WHO’s interaction with them transparently.

In October 2015, the WHO secretariat circulated a non-paper on the implications of the implementation of FENSA, listing supposed risks and warning of “detrimental consequences on the work of WHO.” According to the secretariat, the workload would increase significantly as there are thousands of non-State actors the WHO engages with and tens of thousands of engagements per year. Additional human and financial resources would be needed. The direct costs of implementing FENSA would include:

- “a. Building up and maintaining system for the Register of non-State actors: Global engagement management (in 2015): 734’000 USD start-up costs; thereafter 76’000 USD/year.
- “b. Training costs for launching the Register of non-State actors and FENSA: Estimate 100’000 USD (for 2016)
- “c. Communication of change internally and externally: Estimate 50’000 USD (for 2016)
- “d. Possibly an extra day of PBAC [Programme, Budget and Administration Committee of the WHO Executive Board]: 30’000 USD/year (As of 2017)
- “e. Publication requirements for inputs received from non-State actors in consultations have resource implications.”

It could lead to, inter alia, a “systematic overload of the clearance system” if all engagements would have to go through the full system. Furthermore “Transparency beyond a certain level could lead to unwillingness of some key actors to engage with WHO (…)” and “expose some non-State actors to major risks such as during conflict and civil war situations.” It also added that “WHO could not perform its work on preparing norm and standards if no experts connected to a non-State actors (sic) could be involved (…)”.

In a joint statement of January 2016, the EU and its member states took up these concerns with regard to the practical and financial implications of the framework, for example the supposed shrinking flexibility of the WHO to respond in emergency situations.

“The EU and its MS [member states] are concerned that if FENSA, as it stands, is fully implemented, it may place limitations on WHO’s flexibility to react effectively to an emergency with health consequences. This would potentially undermine WHO’s leadership role in global health and its standing with other UN agencies and humanitarian organizations.”

While in January 2015, the EU had supported the adoption of the framework at the WHA 2015, it now asked to continue the discussions and requested the WHO secretariat to prepare an objective and balanced report on the implications for WHO of the implementation of the framework ahead of the negotiations in April 2016. Some states, for instance Gambia, Namibia, Zambia and India, did not support this request as they were concerned that it could lead to the reopening of discussion.
The German delegation mentioned five concerns with regard to the draft framework:

“Firstly, it must be implementable;

“secondly, it must not be so rigid and complex as to deter country offices and prevent WHO from engaging with non-State actors;

“thirdly, it must not affect WHO’s day-to-day work, especially its work on substandard/spurious/false-labelled/ falsified/counterfeit medical products (SSFFC), pandemic influenza preparedness (PIP) and the Standard Material Transfer Agreements;

“fourthly, it must not impede WHO’s work in emergencies in anyway; and

“lastly, it must be implemented coherently in all regions, without double standards.” 23

The delegation of Switzerland said:

“It was important that the framework did not, through over-regulation, create a barrier to engagement (...). The framework should not absorb disproportionate resources (...); and it should be applied identically across all regions.” 24

The report on implications was finally presented to member states at the end of March 2016. However, to the EU’s discontent, the financial implications of FENSA were not indicated. Although the report revealed that the draft FENSA showed a “lack of clarity of (or inconsistency between) many of the terms and provisions,” 25 it recommended its adoption.26

The US delegation urged to highlight the need for multi-stakeholder partnerships and collaboration with NSAs in the nutrition sector and proposed to include two paragraphs on Goal 17 of the Sustainable Development Goals and the Rome Declaration on Nutrition and the Framework for Action on Nutrition, which call for collaboration and partnerships with NSAs, including the private sector. 27

They further asked to exclude the Codex Alimentarius Commission and its intergovernmental committees and task forces from being subject to FENSA. 28

After almost two years of negotiation, the final version of FENSA was adopted on 28 May 2016 by the World Health Assembly. 29 FENSA now replaces the “Principles governing relations between the World Health Organization and nongovernmental organizations” 30 and the “Guidelines on interaction with commercial enterprises to achieve health outcomes.” 31

**General content of FENSA**

The first part of FENSA formulates the rationale behind the establishment of such a framework, the possible benefits and risks of WHO’s engagement with non-State actors, as well as several overarching principles. It identifies the following different types of non-State actors:

» Nongovernmental organizations (NGOs)

» Private sector including international business associations

» Philanthropic foundations

» Academic institutions.

Furthermore, it lists different types of interaction, which can be the participation in WHO meetings (e.g. meetings of the governing bodies, consultations and hearings), contributions of resources (financial or in-kind contributions), the gathering, analysis and generation of information, advocacy and awareness-raising of health issues, and technical collaboration (product development, capacity-building, operational collaboration in emergencies, contributing to the implementation of WHO’s policies).

The framework further sets out several general steps to manage conflict of interest and other potential risks of engagement. These steps include due diligence and a risk assessments, a publicly available

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23 Ibid., p. 12.
24 Ibid., p. 13.
26 Ibid., para. 86.
28 Cf. Ibid., Footnote to para. 48 a ii. The Codex Alimentarius Commission is the principal organ of the joint FAO/WHO food standards program for which the administration is not solely provided by WHO. Its meetings are regulated by the Rules of Procedure and other decisions adopted by the Codex Alimentarius Commission.
29 Cf. WHO Doc. Resolution WHA69.10.
register of non-State actors, and an electronic tool for the management of individual conflicts of interest.

In the section “Specific Provisions”, the framework states that WHO does not engage with the tobacco industry and the arms industry. Member states could not agree to add other industries to the list, such as fast food or alcohol. They only added a paragraph on “engagement where particular caution should be exercised” which says:

“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.”

In this section, the framework also states that WHO does not accept secondments of staff from private sector entities.

FENSA also describes the relation of the new framework to other WHO policies. Furthermore, it applies, for instance, to WHO’s engagement with global health partnerships.

The framework clarifies that “official relations” status can be granted to NGOs, international business associations and philanthropic foundations. NSAs with this privilege are allowed, inter alia, to attend governing body meetings of the WHO.

Finally, provisions for the implementation, the monitoring and evaluation of the framework are set out.

In the second part of FENSA, specific policies and operational procedures are defined for WHO’s engagement with each of the four different types of non-State actors.

Lobbying by the private sector

The business lobby has not remained passive in the process. On the contrary, the food and beverage industry as well as representatives of the pharmaceutical industry have been trying to actively influence the negotiations. In particular, the US business lobby was very involved in the process, seeking to shape the position of the US government in Geneva. The United States Council for International Business (USCIB), for instance, even claimed as a direct result of its lobby activities in 2015 that “WHO member states opted to continue discussions on FENSA for another year, averting a damaging outcome.”

The daily newspaper Times of India reported of a leaked mail which revealed how the International Food and Beverage Association (IFBA) was engaged in direct lobbying of member states (several countries of Western Europe, Australia, Canada, Israel, New Zealand, and the US) to ensure that their industries were not excluded from FENSA. According to the leaked mail, there was “full alignment among these countries on a position that is essentially equivalent to ours [IFBA’s].” It further states that this group of countries “(...) will not accept any document that excludes the food and beverage industry from the framework.” Members of IFBA are companies like Coca-Cola, Pepsico, Nestlé, McDonald’s, and Unilever.

In September 2014, IFBA wrote a letter to WHO Director-General Margaret Chan, describing its member companies’ common “commitments on health and wellness” and highlighting the importance of multi-stakeholder collaborations: “We believe – and experience has shown – that multi-stakeholder collaborations represent one of the most cost-effective ways to address public health challenges.”

One year before, Chan had warned especially against the influence of the food and beverage industry on health policies. Chan finishes her term as WHO Director-General on June 30, 2017. Whether her successor is going to continue this critical stance on private sector influence on WHO is not yet clear.
The fight of the business lobby against “discriminatory treatment”

The element in the draft FENSA that met with the most opposition not only from IFBA but also from other business lobby groups was the proposed differentiated treatment of NGOs with “public” versus non-State actors with “for-profit” interests. IFBA argued that “(a) attempts 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 a letter to US Senator Orrin Hatch, chairman of the Senate Finance Committee, of 18 February 2016, a coalition of US business, including Biotechnology Innovation Organization, National Association of Manufacturers, National Foreign Trade Council, Pharmaceutical Research and Manufacturers of America, US Chamber of Commerce (USCC), and USCIB, expressed similar concerns:

“Inter-governmental organizations that are discriminatory towards business, or that focus on a limited range of factors potentially inhibiting innovation development, undermine evidence-based policy-making and hobble the delivery of solutions to healthcare and other sustainability challenges.”

So did the International Organization of Employers (IOE) in April 2015, mentioning that business groups had raised concerns in the following areas:

“– prejudicial and discriminatory treatment of the private sector as a whole and the proposed explicit exclusion of sectors, restricting business input and partnership;
– restriction and reclassification of entities — such as research, academic or NGOs — that work or have relationships with the private sector, as ‘private sector’ groups.”

USCIB raised concerns that the framework in its draft form could even “create precedents for anti-business bias in other UN forums” and “set a damaging precedent that could discourage ongoing public-private partnerships and private sector involvement in other international fora.” Ahead of the World Health Assembly in May 2016, USCIB warned the US Department of Health and Human Services, with regard to the draft framework of May 2016:

“In our view, FENSA extends already discriminatory and restrictive practices on business, is cumbersome, lacks minimum transparency and accountability, and will set negative precedents in other [United Nations] forums (…).”

“IT is a step backward and in contradiction to what has been the prevailing international trend by governments and inter-governmental bodies toward innovative and enhanced engagement with private sector entities to advance sustainable development.”

Pressure came not only from US business. During the negotiations, German business associations, including ICC Germany and the Federation of German Industries (BDI), reminded the German government that collaboration with and participation by the private sector in the political dialogue of the WHO would be indispensable for addressing the global challenges the WHO was facing. Collaboration would particularly include multi-stakeholder initiatives and public-private partnerships.47

After the adoption of FENSA in the end of May 2016, the business lobby seemed to be satisfied with their lobby impacts. IFBA stated: “We welcome the adoption of FENSA and look forward to building on the work already underway and to additional opportunities for engagement.”48

USCIB linked FENSA to the 2030 Agenda of the UN and its Sustainable Development Goals (SDGs), and stated:

“USCIB has consistently emphasized the need for partnerships between business, governments and other stakeholders to fully implement the UN Sustainable Development Goals, including SDG3 on Health, and called on WHO to catalyze those partnerships wherever possible.

“It is now our hope that the WHO will implement FENSA inclusively so that member states and the secretariat may fully benefit from the private sector’s practical knowledge expertise, experience, resources and research.”49

Rather a door opener than a safeguard against undue influence?

Civil society networks, including People’s Health Movement, the Health Action Network, Medicus Mundi International, International Baby-Food Action Network, and Third World Network have been actively following the FENSA negotiations. They advocated for a robust framework and repeatedly pointed out important shortcomings in the draft documents.

While most member states and corporate interest groups welcomed the final framework, CSOs expressed serious concerns. Although the final document includes a few measures to reduce the risk of engagement (e.g. no secondments from private sector entities), CSOs are concerned that FENSA opens the door of undue influence by corporations and philanthropic foundations. The International Baby Food Action Network (IBFAN) states that the FENSA draft and the resolution “do not strengthen voices of public interest actors. On the contrary, they open channels for undue influences by the corporate and venture philanthropic sector.”50

Health Action International (HAI) warns that the (potential) influence of philanthropic foundations is not sufficiently addressed by FENSA:

“The approach to Philanthropic foundations deserves more attention, because the WHO has become extraordinarily dependent upon and influenced by perhaps two very large Philanthropic Foundations. Both inside and outside the WHO, the largest global philanthropic donor is now perceived to wield extraordinary influence over the institution, with inadequate transparency and oversight of this relationship.”51

HAI referred to the particular role of the Bill & Melinda Gates Foundation, which is (as of December 2015) WHO’s largest individual donor for the biennium 2016-2017, even ahead of the USA (Gates Foundation: US$573.6 million; USA: US$463.5 million).52 The contributions of the Gates Foundation are six times as high as those of Germany (Germany: US$92.5 million).53

The business lobby was successful in preventing any hierarchical distinction between different types of non-State actors and promoting a global governance model of “multi-stakeholderism.” In the current system, international business associations can participate in WHO processes as “NGOs” on the ground that they are nonprofit, even though they represent the interests of their corporate members. Many CSOs criticized that the framework was giving international business associations the same “official relations” status as public interest NGOs, allowing them to attend governing body meetings.

51 Cf. https://apps.who.int/ngostatements/content/stichting-health-action-international-hai-11.
53 Germany’s contributions are composed of Projected Funding: US$180 million, Assessed Contributions: US$61 million and Specified Voluntary Contributions: US$19.8 million Cf. ibid.
Instead of acknowledging the different nature of clearly public interest NGOs and private sector interest groups which represent their corporate members and the role they should play in global health governance, a principle of “inclusiveness” was accepted for all non-State actors without distinction.\(^\text{54}\)

According to Third World Network (TWN), the framework lacks a comprehensive conflict of interest policy to manage both institutional and personal conflicts of interest in the WHO.\(^\text{55}\) Furthermore, FENSA leaves a lot of space to the Secretariat for interpretation and unclear decision-making on a “case-by-case” basis.

Currently, WHO does not collaborate with the tobacco and arms industries. However, the framework does not take up the concerns raised by several member states and CSOs over extending this restriction to the alcohol, food and beverage industries.\(^\text{56}\)

The fact that FENSA also takes WHO’s engagement in the numerous global health partnerships into account and covers them too is to be welcomed. But TWN warns:

“To sum up, the challenge for WHO to develop solid rules for interaction with corporate and other non-State actors that could also serve as a blueprint for future standards of other UN entities has not been properly met. The process toward the final framework took more time than expected, and the negotiations between member states were extremely difficult. They made clear that the issue of undue influence is highly contested and the interests by the member states are very diverse. Despite this experience, there is still an urgent need for other UN agencies to start similar processes to protect them against uncontrolled corporate influence.

However, considering FENSA as the sole solution for preventing undue influence of non-State actors would be misleading anyway. An independent and effective WHO can only be achieved if member states enhance their political and financial support of WHO and increase their assessed contributions substantially.

Next steps and follow-up

As the next step, the WHO secretariat will draft a guidance document to facilitate the implementation of FENSA within a two-year time frame. By the next WHA in May 2017, it will also create a register of non-State actors.

The WHO secretariat is furthermore requested to develop a set of criteria and principles for secondments from NGOs, philanthropic foundations and academic institutions, to be submitted to the next WHA.

The implementation of the framework and its impact on the work of WHO will be evaluated by 2019, and the results will be submitted together with any proposals for revision to the WHO Executive Board meeting in January 2020.

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Further Information

Article by K.M. Gopakumar (Third World Network) on the adoption of FENSA
www.twn.my/title2/health.info/2016/h1160509.htm

FENSA
http://apps.who.int/gb/ebwha/pdf_files/WHA69/A69_R10-en.pdf?ua=1

Prototype of WHO’s register on non-State actors
http://apps.who.int/register-nonstate-actors/home.aspx

Statement by sixty civil society organizations on the proposed FENSA

Statements by NGOs in official relations with WHO at the WHO governing body meetings
https://apps.who.int/ngostatements/

WHO’s Website about its engagement with non-State actors with documentation of the process towards FENSA
www.who.int/about/collaborations/non-state-actors/en/

Imprint

FENSA – a fence against undue corporate influence?
The new Framework of Engagement with non-State Actors at the World Health Organization

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Author: Karolin Seitz
Editor: Jens Martens
Design and printing: www.kalinski.media
Aachen/Berlin/Bonn, September 2016