World Health Organization

SIXTY-EIGHTH WORLD HEALTH ASSEMBLY DRAFT **A68/5**
Provisional agenda item 11.2 **1 May 2015**

Framework of engagement with non-State actors

Report by the Director-General

1. The Open-ended Intergovernmental Meeting on the draft framework of engagement with non-State actors, convened as decided by the Executive Board,[1] met in Geneva from 30 March to 1 April 2015 under the chairpersonship of Dra Andrea Carbone (Argentina).

2. The Open-ended Intergovernmental Meeting reviewed the draft framework of engagement with non-State actors taking into account the proposals submitted by Member States[2] for amendments of, additions to or deletions from the text of the draft framework of engagement with non-State actors and the four specific policies as contained in the annex to document EB136/5.[3]

3. The outcome of the Open-ended Intergovernmental Meeting was a revised version of the draft framework of engagement with non-State actors, which reflects the discussions at the meeting.

4. The Director-General herewith submits the revised version of the draft framework of engagement with non-State actors. Text highlighted in green has been agreed by the Open-ended Intergovernmental Meeting. Text highlighted in yellow was considered during the meeting but no consensus was reached. Text highlighted in grey is the Chairperson's proposal for a compromise concerning the preceeding yellow highlighted paragraph. Text not highlighted could not be considered by the Open-ended Intergovernmental Meeting owing to time constraints.

5. The Open-ended Intergovernmental Meeting has encouraged Member States to consult informally with each other through their permanent missions in Geneva between the closure of the meeting and the opening of the Sixty-eighth World Health Assembly, in order to identify possible common ground and thereby facilitate the work of the Health Assembly.

ACTION BY THE HEALTH ASSEMBLY

6. The Health Assembly is invited to note this report and to provide guidance on the annexed revised draft framework of engagement with non-State actors and the four specific policies.

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[1] Decision EB136(3).

[2] And, where applicable, regional economic integration organizations, as provided for by decision EB136(3), paragraph 2, footnote 4.

[3] The compilation of textual proposals submitted by Member States by 16 February 2015 is contained in document EB/FENSA/OEIGM/4. This document, as well as a background document including corrections to these textual proposals received from Member States after its publication, are available at http://www.who.int/about/who_reform/non-state-actors/en/ (accessed 16 April 2015).

ANNEX

DRAFT OVERARCHING FRAMEWORK OF ENGAGEMENT WITH NON-STATE ACTORS

INTRODUCTION

1. The overarching framework for 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. The health landscape has become more complex in many respects; among other things, there has been an increase in the number of players in global health governance. Non-State actors play a major role in all aspects of global health and WHO can only fulfil its leadership role in global health and its mandate if the Organization proactively engages with Member States, other international organizations and non-State actors. In support of this aim, 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.

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 any relevant resolutions of the Health Assembly as well as those of the United Nations General Assembly or the Economic and Social Council of the United Nations, if applicable.

4. The objectives of WHO's engagement with non-State actors are to promote global health as articulated in WHO's General Programme of Work and to support 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.

5. Such a proactive and constructive engagement with non-State actors at global, regional and country levels, in mutual respect and trust, also calls for a number of measures of caution. In order to

[1] Headquarters, regional offices and country offices, as well as hosted partnerships.

[2] WHO Constitution, Articles 18, 33, 41 and 71.

be able to strengthen its engagement with non-State actors for the benefit of global health and in the interest of all actors, WHO needs simultaneously to strengthen its management of the associated potential risks. This requires a robust framework for engagement that encourages and increases involvement but serves also as an instrument to identify the risks, balancing them against the expected benefits, while protecting and preserving WHO's integrity and reputation. In this way WHO will manage its engagements with non-State actors actively and transparently.

Principles

6. WHO's engagement with non-State actors is guided by the following overarching principles. Any engagement should:

(a) demonstrate a clear benefit to public health;

(b) respect the intergovernmental nature of WHO, where the decision-making by WHO's governing bodies is the exclusive prerogative of Member States;

(c) support and enhance the scientific and evidence-based approach that underpins WHO's work;

(d) protect WHO's processes in setting norms and standards from any undue influence;

(e) avoid compromising WHO's integrity, independence, credibility and reputation;

(f) be actively managed so as to mitigate any form of risk to WHO (including conflicts of interest);

(g) be conducted on the basis of transparency, openness, inclusiveness, accountability, integrity and mutual respect.

Benefits of engagement

7. 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.

Risks of engagement

8. 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.

NON-STATE ACTORS

9. For the purpose of this framework, a non-State actor is an entity that is not part of any State or public institution. Non-State actors include nongovernmental organizations, private sector entities, philanthropic foundations and academic institutions.

10. **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 shall be free from concerns which are primarily of a private, commercial or profit-making nature. They shall have the authority to speak for their members through their authorized representatives. They include grassroots community organizations, civil society groups and networks, faith-based organizations, professional groups, disease-specific groups, and patient groups.

11. **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 arms' 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.

12. **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.

[1] An entity is "at arm's length" from another entity if it does not take instructions and is not clearly influenced in its decisions by the other entity.

13. **Academic institutions** are entities engaged in the pursuit and dissemination of knowledge through research, education and training.

14. 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 such that the non-State actor has to be considered itself a private sector entity. 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 organization, 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.

TYPES OF INTERACTION

15. 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.

Participation

16. Non-State actors may attend various types of meetings organized by WHO. The nature of their participation depends on the type of meeting concerned.

(a) **Meetings of the governing bodies.** This type involves sessions of the World Health Assembly, the Executive Board and the six regional committees. Non-State actors' participation is determined by the governing bodies' respective rules of procedure, policies and practices as well as the section of this framework that deals with official relations.

(b) **Consultations.** This type includes any physical or virtual meeting, other than governing body sessions, organized for the purpose of exchanging information and views. There are no limits imposed on non-State actors' participation at such meetings.

(c) **Hearings.** These are meetings in which the participants can present their evidence, views and positions and be questioned about them but do not enter into a debate. Hearings can be electronic or in person. All interested entities should be invited on the same basis. The participants and positions presented during hearings shall be documented.

(d) **Other meetings.** These are meetings that are not part of the process of setting policies or norms; examples include information meetings, briefings, scientific conferences, and platforms for coordination of actors. There are no limits imposed on non-State actors' participation at such meetings.

17. WHO's involvement in meetings organized by a non-State actor can – subject to the provisions of this framework and the Organization's applicable rules, policies and procedures – consist of any one of the following possibilities:

- WHO jointly organizes the meeting with the non-State actor
- WHO cosponsors a meeting organized by the non-State actor

- WHO staff make a presentation or act as panellists at a meeting organized by the non-State actor
- WHO staff attend a meeting organized by a non-State actor.

Resources

18. Resources [can be]/[include] funds, [personnel] OR [personnel for technical work or implementation of WHO's programmes and policies and emergency response,] or in-kind contributions. In-kind contributions include donations of medicines and other goods and free provision of services.

OR

New text to be proposed

AND/OR

18bis [SPECIFY TYPE OF PERSONNEL]

AND/OR

[ADD FOOTNOTE SPECIFYING PERSONNEL]

Evidence

19. Evidence includes the gathering, analysis and generation of information, and the management of knowledge and research.

Advocacy

20. 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

21. 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
- support to policy-making at the national level
- operational collaboration in emergencies
- contributing to the implementation of WHO's policies.

MANAGEMENT OF CONFLICT OF INTEREST AND OTHER RISKS OF ENGAGEMENT

22. 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 (ADD FOOTNOTE TO PARAGRAPH 38) information about itself and its activities, following which WHO conductsthe 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.

- 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.[2] (ADD REFERENCE TO PARAGRAPH 38 IN FOOTNOTE).

- Member States need to exercise oversight over WHO's engagement with non-State actors. With this in mind, the Director-General reports on engagement involving non-State actors to the Executive Board through the Programme, Budget and Administration Committee and makes all engagements publicly known through the register of non-State actors.

- Member States may have access [when possible], upon request to the full documentation related to each engagement with non-State actors and may ask WHO for clarification on the assessment;

  OR

  (MOVE TO PARAGRAPH 38ter FOR FURTHER DISCUSSION)

[There will be a 12 member group within the PBAC with a specific role …] which will be [audited]/[supported and supervised] by a group of twelve representatives of Member States (hereinafter, the Group). The Group will be composed of two representatives from each Region. Each Regional Office will establish the mechanism for the selection of the representatives]

OR

[PBAC will have a specific role to review the recommendations of the Engagement Coordination Group]

OR

[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 48).

[2] WHO uses an electronic tool for managing engagement. 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.

[Empower]/[Request] the Independent Expert Oversight Advisory Committee [is required] to report annually on WHO's engagement with non-State actors, focusing particularly on cases handled by the Engagement Coordination Group, and to provide Member States with the opportunity to discuss the report with the Independent Expert Oversight Advisory Committee prior to its adoption by the Programme, Budget and Administration Committee.]

OR

[Request the Independent Expert Oversight Advisory Committee to report annually on WHO's engagement with non-State actors, focusing particularly on cases handled by the Engagement Coordination Group, and to provide Member States with the opportunity to discuss the report with the Chairperson of the Independent Expert Oversight Advisory Committee prior to its adoption by the Programme, Budget and Administration Committee]

[Conflict of interest] (NOTE: ENTIRE SECTION IN BRACKETS)

23. 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.[1] (REPLACE FOOTNOTE WITH: 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)

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 8 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 **most important institutional conflicts of interest** arise in situations where the [economic] [and financial] interests of [non-State actors] [addressed under this framework]/[in particular private sector entities] are in conflict with WHO's [public health [and constitutional] mandate and] interests, especially the Organization's independence and impartiality [in evidence and information gathering] in setting norms and standards [and implementation]. /(DELETE PARAGRAPH). [ADD FOOTNOTE] (FOOTNOTE REFERENCE TO PARAGRAPH 9)

[1] [Individual conflicts of interest within WHO are those involving experts, regardless of their label, and staff members. In the case of experts, conflicts of interest are regulated by the guidelines for declaration of interest. As regards staff members, provisions on conflict of interest are established in the Staff Rules and Regulations.]

OR

[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.]
[ADD REFERENCE TO the norms and standards and evidence gathering] [and implementation]
[ADD 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)]

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 6 and the priorities defined in the General Programme of Work and Programme budget. If this seems to be the case, the technical unit asks the non-State actor to provide its basic information. 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. This information is then transmitted to a specialized central unit which is responsible for analysing the information provided. (TO REVIEW WITH PARAGRAPH 6)

28. 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 [all relevant]/(DELETE) 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.]
[While due diligence refers to the nature of the non-State actor concerned, risk assessment refers to the assessment of [possible outcome of] a specific proposed engagement with that non-State actor [and its [potential] impact on WHO's work].] (DELETE)

OR

28bis. Before engaging with any non-State actor, WHO, in order to preserve its integrity, conducts due diligence [and risk assessment]. [This]/[Due diligence] refers to the steps taken by WHO to find and verify [all relevant] information on a non-State actor and to reach a [basic]/[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. [and its impact on WHO's work]

OR

[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.]

29. **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.

30. The [principal]/[core] functions of due diligence are to:

- [clarify the nature and objectives of the entity proposed to engage with WHO;]
- clarify the interest of the entity in engaging with WHO and what they expect in return;
- determine the entity's status, area of activities, [membership,] governance, sources of funding, constitution, statutes, and by-laws and affiliation;

  ADD [location] AND [branches of the entity]
- 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 ["red lines" such as:] (DELETE) activities that are incompatible with WHO's work and mandate ([e.g.]/[i.e.] [links to] (DELETE) the tobacco and arms industries)

  AND ADD NEW BULLET
  [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).[1]] (DELETE)

  OR

  [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] [RETAIN ORIGINAL TEXT OF BULLET]
- [Examine whether the entity [complies]/[is in line]/[is compatible with] with the norms, standards, guidelines, 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] (DELETE)

OR REPLACE ENTIRE PARAGAPH WITH:

[The core functions of due diligence are to:

- clarify the nature and objectives of the entity proposed to engage with WHO;
- clarify the interest of the entity in engaging with WHO and what it expects in return;
- determine the entity's status, area of activities, membership, governance, sources of funding, constitution, statutes, and by-laws and affiliation;

[1] As described in paragraph 44.

- 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 the nature or activities of a non-State actor are incompatible with WHO's work and mandate (e.g. links to the 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).[1]]

31. 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.

AND

[The due diligence reports including the risk assessment [shall] be made available [to Member States] [, upon request]/[relevant information [shall] be included in the public domain]/MOVE YELLOW PART TO ANOTHER PARAGRAPH

32. [Risks are the expression of the likelihood and potential [adverse] 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]/[in parallel to]/[following the]/[subsequent to] due diligence. This] (DELETE) involves the assessment of risks [as described in paragraph 8] [associated with an engagement with a non-State actor, in particular [not limited to] the risks described in paragraph 8.] (DELETE)
[ADD TEXT ON PROCEDURES FOR RISK ASSESSMENT]

OR

DELETE PARAGRAPH 32

OR

[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.] – REFER TO PARAGRAPH 28

OR

MOVE RELEVANT PARTS FROM PARAGRAPH 28 to PARAGRAPH 32

OR

[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

[1] As described in paragraph 44.

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 8]
(ADD FOONOTE)
(ADD RISK ASSESSMENTS)

Risk management

33. **Risk management** concerns the process leading to a management decision whereby the Secretariat decides explicitly and justifiably on entry into engagement (ADD FOOTNOTE: While those in official relations are a non-State actor for the purposes of this framework, the process by which those non-State actors enter into official relations with WHO remains as set out in paragraphs 49 to 55), continuation of engagement, engagement with measures to mitigate risks, non-engagement or disengagement from an existing or planned engagement with non-State actors [is a management decision taken by the unit engaging with the non-State actor [that may require],/[according to] recommendation from Member States in the context of PBAC]/(DELETE). [The management decision is usually taken by the management of the unit engaging with a non-State actor] (DELETE)

OR

[**Risk management** concerns the process leading to a management decision whereby the Secretariat decides explicitly and justifiably on entry into engagement (ADD FOOTNOTE: Other than decisions related to official relations as set out in paragraphs 49 to 55), 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 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 38ter.]

34. The unit responsible for performing due diligence and risk assessment, as described in paragraph 27, formulates recommendations on the engagement-related options listed in paragraph 33 above [along with reasons for such recommendations]/(DELETE). If the proposing unit agrees with the recommendations it implements them. If there are disagreements they can be referred to the Engagement Coordination Group. [ADD FOOTNOTE to describe what the Engagement Coordination Group will be.]

OR

[The unit responsible for performing due diligence and risk assessment, as described in paragraph 27, formulates recommendations on the engagement-related options listed in paragraph 33 above, along with reasons for such recommendations. If the proposing unit agrees with the recommendations, it implements them. If there are disagreements, they can be referred to the Engagement Coordination Group. [ADD FOOTNOTE: The **Engagement Coordination Group** is a Secretariat group appointed by the Director-General that includes representation from regional offices.)]

35. The **Engagement Coordination Group** [will be]/[is] a Secretariat group [to be] appointed by the Director-General that includes representation from [each]/[concerned] regional offices. When a significant risk is identified, the Engagement Coordination Group reviews referred proposals of engagement and recommends [engagement] (DELETE), 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 unit responsible for the engagement disagrees

with this recommendation, the final decision rests with the Director-General. [The decision and the related information of the risk management will be made publicly available [through the oversight mechanism to Member States]/(DELETE: – DISCUSS IN TRANSPARENCY SECTION)

OR

[The Engagement Coordination Group reviews referred proposals of engagement 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 unit responsible for the engagement disagrees with this recommendation, the final decision rests with the Director-General.]

36. In line with WHO's risk management framework (ADD FOOTNOTE See EB133/10), 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 7 outweigh any residual risks of engagement as mentioned in paragraph 8, as well as the time and expense involved in establishing and maintaining the engagement. (REVIEW WITH PARAGRAPHS 7 AND 8)

Transparency

37. WHO's interaction with non-State actors [is]/[should be] managed transparently. WHO provides the governing bodies with annual reports on its engagement with non-State actors [, including the work of the Engagement Coordination Group] and makes publicly available basic information on the non-State actors it engages with and the individual engagements concerned.

OR

[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, including the work of the Engagement Coordination Group, and makes publicly available appropriate information on the non-State actors it engages with and the individual engagements concerned.]

38. The **WHO register of non-State actors** is an Internet-based, publicly available electronic tool used by the Secretariat[1] to document and coordinate engagement with non-State actors. It contains the main standard information provided by non-State actors and high-level descriptions of the engagement that WHO has with these actors.[2] [The register will be finished in March 2016 and can be consulted [and updated] in an ongoing fashion, including its preliminary versions]/[MOVE this text to the resolution] [Non-State actors engaging with WHO are required to provide information on their organization. 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.] (DELETE, put in paragraph 38bis) [ADD FOOTNOTE on the three levels of access]

[1] The register covers all three levels of the Organization – global, regional and country – and includes hosted partnerships and joint programmes.

[2] Information on financial contributions received from non-State actors is documented in this register and in the Programme budget web portal.

38bis. Non-State actors engaging with WHO are required to provide information on their organization. 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.

38ter. [The due diligence reports, [including] (DELETE) the decisions related to risk assessment and risk management [, including decisions to refuse to engage]/(DELETE) will be made available to Member States] [and relevant information shall be made publicly available]/(DELETE) OR [The 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.]

OR REPLACE 38, 38bis and 38ter WITH:

38. The **WHO register of non-State actors** is an Internet-based, publicly available electronic tool used by the Secretariat (FOOTNOTE 1) to document and coordinate engagement with non-State actors. It contains the main standard information provided by non-State actors (FOOTNOTE 2) and high-level descriptions of the engagement that WHO has with these actors (FOOTNOTE 3);
(FOOTNOTE 1: 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).
(FOOTNOTE 2: Information on financial contributions received from non-State actors is documented in this register and in the Programme Budget web portal)
[FOOTNOTE 3: The register covers all three levels of the Organization – global, regional and country – and includes hosted partnerships and joint programmes]

AND

38bis. [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.]

AND

38ter. [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.]

AND

[Add to resolution text a timeline for establishing and rolling out the register.]

39. 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.

40. 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.

41. 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 for engagement with non-State actors.

NOTE: The following text from paragraph 41 has been "parked" to serve as input for discussions on paragraph 48
[this shall be applied in conjunction with the framework] (DELETE:)

OR

[All the relevant WHO guidelines will be [aligned]/[coordinated] with this framework (FOOTNOTE: LIST ALL RELEVANT DOCUMENTS)]

OR

MOVE (AS FOOTNOTE) TO PARAGRAPH 48

Policy, norms and standard setting

42. With regard to the development of WHO's policies, norms and standards, the Organization's work can be divided in three main types of activity, namely:

Type 1: Information gathering

Type 2: Preparation for, elaboration of and decision on the normative text

Type 3: Implementation.

43. References elsewhere in this framework to the norms and standard setting process and normative work concern the second type of activity.

SPECIFIC PROVISIONS

Engagement with particular industries

44. 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.

Association with WHO's name and emblem

45. 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]

Secondments

46. [WHO does not accept secondments from non-State actors.]/(DELETE:)

OR

[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.]

RELATION OF THE FRAMEWORK TO WHO'S OTHER POLICIES

47. This framework replaces the Principles Governing Relations between the World Health Organization and Nongovernmental Organizations[2] and the Guidelines on interaction with commercial enterprises to achieve health outcomes (noted by the Executive Board).[3]

48. The implementation of the framework for engagement with non-State actors is coordinated with the following related policies, which remain valid.

(a) WHO's involvement in external partnerships is regulated by the policy on WHO's engagement with global health partnerships and hosting arrangements.[4] For the management of risks of WHO's engagement in these partnerships the present framework for engagement with non-State actors applies.

(b) 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).

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[1] See http://www.who.int/about/licensing/emblem/en/.

[2] Basic documents, 47th ed. Geneva: World Health Organization; 2009: 81–86.

[3] See document EB107/2001/REC/2, summary record of the twelfth meeting.

[4] Endorsed by the Health Assembly in resolution WHA63.10 on partnerships.

[5] See Basic documents, 47th ed. Geneva: World Health Organization; 2009, pp 104–112 (http://apps.who.int/gb/bd/PDF/bd47/EN/basic-documents-47-en.pdf, accessed 1 December 2014).

(c) The Organization's Staff Regulations and Staff Rules and in particular the provisions of declaration of interest therein: 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."

(d) Scientific collaborations are regulated by the Regulations for Study and Scientific Groups, Collaborating Institutions and other Mechanisms of Collaboration.[1]

(e) The procurement of goods and services is regulated by the Financial Rules and Financial Regulations;[2] it not covered by the framework for engagement with non-State actors, although pro-bono contributions from non-State actors are covered.

(f) Like any other financing of WHO, financing from non-State actors should be considered as part of the financing dialogue and is regulated by the Financial Rules and Financial Regulations; the decision on accepting such a financial contribution is regulated by this framework.

OFFICIAL RELATIONS

49. **"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.

50. All entities in official relations shall have a constitution or similar basic document, an established headquarters, a directing or governing body, an administrative structure, and a regularly updated entry in the WHO register of non-State actors.

51. A plan for collaboration based on mutually agreed objectives and outlining activities for the coming three-year period structured in accordance with the General Programme of Work and Programme budget shall form the basis of official relations between WHO and organizations in official relations. 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.

52. 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

[1] Basic documents, 47th ed. Geneva: World Health Organization; 2009, pp.113–120.

[2] Basic documents, 47th ed. Geneva: World Health Organization; 2009, pp.87–97.

[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.

business associations for admission. The Director-General can also propose an earlier review based on the experience in the collaboration with the organization concerned.

53. Non-State actors in official relations are invited to participate in sessions of WHO's governing bodies. Their privileges shall include:

(a) the right 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 right 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 right to submit the statement referred to in subparagraph (b) above in advance of the debate for the Secretariat to post on a dedicated website.

These privileges do however not imply any automatic right for other forms of collaboration.

54. Non-State actors participating in WHO 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 appropriate, the function of that delegate within any affiliated organization.

55. Non-State actors in official relations are international in membership and/or scope. The organization or its affiliates can also attend meetings of the regional committees. Regional committees may decide on a procedure granting accreditation to their meetings to other non-State actors not in official relations as long as the procedure is managed in accordance with this framework.

Procedure for admitting and reviewing organizations in official relations

56. 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 collaboration 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.

57. A signed letter certifying the accuracy of the application 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 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.

58. The non-State actors in official relations and the Secretariat are expected to 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.

59. During the Board's January session, the Programme, Budget and Administration Committee 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 collaboration and a framework for future collaborative activities, the Committee may recommend postponement of consideration or rejection of an application.

60. 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.

61. The Director-General shall inform each organization of the Board's decision on its application. The Director-General shall maintain a list of the organizations admitted into official relations, reflect these privileges in the WHO register of non-State actors, and document decisions taken within the Secretariat and by the Executive Board on applications from non-State actors.

62. The Board, through its Programme, Budget and Administration Committee, shall review collaboration with each non-State actor every three years and shall determine 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 non-State actors in official relations being reviewed each year.

63. The Director-General can propose earlier reviews of a non-State actor's official relations with WHO in case of difficulties, 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.

64. 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

65. 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 organizations, philanthropic foundations and international business associations.

66. The Programme Budget and Administration Committee shall review, provide guidance and, as appropriate, make recommendations to the Executive Board on:

(a) oversight of WHO's implementation of the framework for engagement with non-State actors including:

(i) consideration of the annual report on engagement with non-State actors submitted by the Director-General

AND

(i bis) [consideration of the annual report of the Independent Expert Oversight Advisory Committee on WHO's engagement with non-State actors]

(ii) any other matter on engagement referred to the Committee by the Board

(b) non-State actors in official relations with WHO, including:

(i) proposals for admitting non-State actors into official relations

(ii) review of renewals of non-State actors in official relations

(c) any proposal, when needed, for revision of the framework of engagement with non-State actors.

NON-COMPLIANCE WITH THIS FRAMEWORK

67. Non-compliance can include the following: significant delays in the provision of information to the WHO register of non-State actors; the provision of wrong information; the use of the engagement with WHO for commercial, promotional, marketing and advertisement purposes; misuse of WHO's name and emblem; and abuse of the privileges conferred by official relations.

68. 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.

69. 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.

MONITORING AND EVALUATION OF THE FRAMEWORK

70. The implementation of the framework will be constantly monitored internally through the engagement coordination group and by the Executive Board through the 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.

71. 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 the Programme, Budget and Administration Committee.

DRAFT WHO POLICY AND OPERATIONAL PROCEDURES ON ENGAGEMENT WITH NONGOVERNMENTAL ORGANIZATIONS

1. Nongovernmental organizations make important contributions to global health because they often have deep roots in local communities, have special flexibilities to respond to health needs, represent affected populations and other key groups, and promote innovative solutions. Therefore WHO engages with this group of key actors in global health in order to leverage their support in the fulfilment of WHO's mandate.

2. This policy regulates specifically WHO's engagement with nongovernmental organizations by type of interaction.[1] The generic provisions of the framework also apply to all engagements with nongovernmental organizations.

PARTICIPATION

Participation by nongovernmental organizations in WHO meetings[2]

3. WHO can hold consultations with nongovernmental organizations in the preparation of policies. Consultations can be electronic or in person, and may take the form of hearings at which nongovernmental organizations 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.

4. WHO can invite nongovernmental organizations to participate in other WHO meetings. Such participation 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.

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 and independence 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. WHO's participation in meetings organized by nongovernmental organizations does not constitute official WHO support for, or endorsement of, that nongovernmental organization, and shall not be used for promotional purposes.

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 the framework for engagement with non-State actors.

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[1] See paragraphs 15–21 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 funds, personnel 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. 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 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

9. Any acceptance of resources from a nongovernmental organization is handled in accordance with the provisions of this framework and relevant other rules such as the Staff Regulations and Staff Rules, the Financial Regulations and Financial Rules and WHO's policies governing procurement.

10. For reasons of transparency, contributions and donations from nongovernmental organizations must be publicly acknowledged by WHO in accordance with its policies and practices.

11. Acknowledgements shall usually be worded along the following lines: "The World Health Organization gratefully acknowledges the financial contribution of [NGO] towards [description of the outcome or activity]".

12. 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.

13. Nongovernmental organizations may not use the fact that they have made a contribution in their materials used for commercial, promotional, marketing and advertisement purposes. 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

14. Nongovernmental organizations 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.

ADVOCACY

15. 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.

16. WHO favours independent monitoring functions and therefore engages with nongovernmental organizations working in this field. Nongovernmental organizations 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.

TECHNICAL COLLABORATION

17. The Secretariat is encouraged to undertake technical collaboration with nongovernmental organizations, provided that it is in the interests of the Organization and managed in accordance with the framework for engagement with non-State actors.

DRAFT WHO POLICY AND OPERATIONAL PROCEDURE ON ENGAGEMENT WITH PRIVATE SECTOR ENTITIES

1. Private sector entities are key players in global health as providers, both within and beyond the health sector, of goods and services that can have important effects on health. Therefore WHO engages with this group of key actors in global health to improve their positive contribution, limit their negative effects on health and leverage their support in the fulfilment of WHO's mandate.

2. This policy regulates specifically WHO's engagement with private sector entities by type of interaction.[1] The generic provisions of the framework also apply to all engagements with private sector entities.

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 hold consultations with private sector entities in the preparation of policies. Consultations can be electronic or in person, and may take the form of hearings at which private sector entities 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.

5. WHO can invite private sector entities to participate in other WHO meetings. Such participation 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 also for the exchange of information and views, but not for the formulation of advice.

Involvement of the Secretariat in meetings organized by private sector entities

6. 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.

Specific policies and operational procedures

7. 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 framework for engagement with non-State actors.

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[1] See paragraphs 15–21 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.

8. WHO does not cosponsor meetings organized by specific 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.

9. WHO does not cosponsor meetings with one or more health-related private sector entities. Other instances of cosponsorship with private sector entities should be reviewed on a case-by-case basis and are subject to the provisions of the framework and this policy.

10. There shall be no commercial exhibitions on WHO premises and at WHO's meetings.

11. 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

12. 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) 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.

(b) Funds 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 38 below).

(c) Caution should be exercised in accepting financing 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 avoid the possibility of a conflict of interest or appearance of an inappropriate association with one contributor.

13. 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.

14. 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.

Specific policies and operational procedures

15. 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.

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 results of WHO's work for commercial purposes and may not use the fact that they have made a contribution in their promotional materials. However, they may make reference to their contribution in their corporate annual reports or similar documents. In addition they may mention the contribution in a transparency listing on their websites, in special non-promotional or product-related corporate responsibility pages on their website and in similar publications provided that the content and context have been agreed with WHO.

Donations of medicines and other health technologies[1]

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.

(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.

Financial contributions for clinical trials

22. Except as provided in paragraph 38 below on product development, financial contributions from a commercial enterprise for a clinical trial arranged by WHO on that company's proprietary product are considered on a case-by-case basis and always decided by the Engagement coordination group. In this connection, it should be ensured that:

(a) the research or development activity is of public health importance;

[1] 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.

(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 outcome of the trial, 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 or trade association 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;

(b) meetings held by a third party (i.e. a party other than the private sector entity or trade association proposing to pay for the travel): financing for travel may not be accepted from a private sector entity.

Contributions for publications

28. Funds 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.

Contributions for financing staff salaries

29. 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.

Cost recovery

30. 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

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.

ADVOCACY

33. WHO encourages private sector entities to implement and advocate for the implementation of WHO's norms and standards. WHO engages in dialogue with private sector entities in order to promote the implementation of WHO's policies, norms and standards.

34. Private sector entities can only collaborate with WHO in advocacy for the implementation of a WHO norm or standard if they commit themselves to implement these norms and standards in their entirety. No partial or selective implementation is acceptable.

35. 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

36. 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.

Specific policies and operational procedures

37. 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.

Product development

38. 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.

DRAFT WHO POLICY AND OPERATIONAL PROCEDURES ON ENGAGEMENT WITH PHILANTHROPIC FOUNDATIONS

1. Philanthropic foundations are making significant contributions to global health in general, and to WHO's work in particular, in many areas ranging from innovation to capacity-building and to service delivery. Therefore WHO engages with this group of key actors in global health to leverage their support in the fulfilment of WHO's mandate.

2. This policy regulates specifically WHO's engagement with philanthropic foundations by type of interaction.[1] The generic provisions of the framework also apply to all engagements with philanthropic foundations.

PARTICIPATION

Participation by philanthropic foundations in WHO meetings[2]

3. WHO can hold consultations with philanthropic foundations in the preparation of policies. Consultations can be electronic or in person, and may take the form of hearings at which philanthropic foundations 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.

4. WHO can invite philanthropic foundations to participate in other WHO meetings. Such participation 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 also for the exchange of information and views, but not for the formulation of any advice.

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. WHO's participation in meetings organized by philanthropic foundations does not constitute an official WHO support for, or endorsement of, that philanthropic foundation, and shall not be used for promotional purposes.

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 15–21 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 funds, personnel 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 rules such as the Staff Regulations and Staff Rules, the Financial Regulations and Financial Rules and WHO's policies governing procurement.

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 promotional materials. However, they may make reference to the contribution in their annual reports or similar documents. In addition, they may mention the contribution in a transparency listing on their websites, in special non-promotional pages of their website and similar publications, provided that the content and context have been agreed with WHO.

EVIDENCE

17. Philanthropic foundations 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.

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.

TECHNICAL COLLABORATION

19. The Secretariat is encouraged to undertake technical collaboration with philanthropic foundations provided that it is in the interests of the Organization and managed in accordance with the framework for engagement with non-State actors.

DRAFT WHO POLICY AND OPERATIONAL PROCEDURES ON ENGAGEMENT WITH ACADEMIC INSTITUTIONS

1. Academic institutions contribute to global health through education, research, clinical care and the generation, synthesis and analysis of evidence. Therefore, WHO engages with this group of key actors in global health to leverage their support in the fulfilment of WHO's mandate.

2. This policy regulates specifically WHO's engagement with academic institutions by type of interaction.[1] The generic provisions of the framework also apply to all engagements with academic institutions.

3. 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

4. WHO can hold consultations with academic institutions in the preparation of policies. Consultations can be electronic or in person, and may take the form of hearings at which academic institutions 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 for other cases by the Secretariat.

5. WHO can invite academic institutions to participate in other WHO meetings. Such participation 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 also for the exchange of information and views, but not for the formulation of any advice.

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. WHO's participation in meetings organized by academic institutions does not constitute an official WHO support for, or endorsement of, that academic institution, and shall not be used for promotional purposes.

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 the framework for engagement with non-State actors.

[1] See paragraphs 15–21 of the overarching framework for the five types of interaction.

RESOURCES

8. WHO can accept funds, personnel 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). This can be either for a project of the institution which WHO considers merits support and is consistent with WHO's 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 this framework and relevant other rules such as the Staff Regulations and Staff Rules, the Financial Regulations and Financial Rules and WHO's policies governing procurement.

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 results of WHO's work for commercial purposes and may not use the fact that they have made a contribution in their promotional materials. However, they may make reference to the contribution in their annual reports or similar documents. In addition they may mention the contribution in a transparency listing on their websites, in special non-promotional pages of their website and similar publications, provided that the content and context have been agreed with WHO.

EVIDENCE

15. Academic institutions 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.

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. WHO favours independent monitoring functions and therefore engages with academic institutions working in this field. 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.

TECHNICAL COLLABORATION

18. 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.

19. Scientific collaborations are regulated by the Regulations for Study and Scientific Groups, Collaborating Institutions and other Mechanisms of Collaboration.[1]

20. 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.

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[1] Basic documents, 47th ed. Geneva: World Health Organization; 2009, pp 113–120.