

Framework of engagement with non-State actors

Report by the Secretariat

1. The Open-ended Intergovernmental Meeting on the draft framework of engagement with non-State actors met from 8 to 10 July at WHO headquarters in Geneva. As it did not conclude its work as requested by the Health Assembly in resolution WHA68.9 (2015) it suspended its work and mandated the Chair to conduct informal consultations with Member States with a view to holding a resumed session of the Intergovernmental Meeting from 7 to 9 December.
2. The Chair of the Intergovernmental Meeting conducted four, one-day issue-specific consultations on 1, 9, 18 and 22 September 2015, respectively. This was followed by a full week of informal consultations held from 19 to 23 October 2015, during which the entire text of the draft framework was examined.
3. The outcome of these informal consultations is reflected in the Annex of this document and its Appendix. For reference purposes the text as it stood at the suspension of the Intergovernmental Meeting as of 10 July is also made available to Member States as an informal background document.¹
4. The annexed text for the consideration of the resumed session of the Intergovernmental Meeting uses the following colour code.
 - (a) Text highlighted in **GREEN** was agreed ad referendum during the negotiations at one of three meetings, namely: the Sixty-eighth World Health Assembly, the Intergovernmental Meeting in July 2015 or the informal consultations in October 2015.
 - (b) Text highlighted in **BLUE** was proposed at the informal consultations in September as text to be agreed: (i) ~~Strikethrough AND blue~~ refers to text deleted by consensus during the informal consultations in September 2015; (ii) **Blue** indicates text on which there was consensus during the informal consultations in September 2015; (iii) Underlined AND blue refers to text added by consensus during the informal consultations in September.
 - (c) Text highlighted in **YELLOW** was considered but no consensus was reached.

¹ This document, together with the other, required background documents, is available under <http://www.who.int/about/collaborations/non-state-actors/en/> and in the meeting room.

(d) Text highlighted in GREY in the Chair's proposal suggested earlier in the process for a compromise concerning the preceding yellow highlighted paragraph.

(e) Text highlighted in BROWN is the Chair's proposal for compromise text submitted to the October consultations.

(f) Text highlighted in ROSE is a proposal based on the consistency check mandated by the October informal consultations.

(g) Text not highlighted has not been considered yet.

5. Proposed changes arising from the informal consultation and changes proposed by the Chair are presented following the original text as at the suspension of the Intergovernmental Meeting on 10 July in two alternative boxes as follows:

VERSION AS OF 10 JULY
VERSION AS PROPOSED BY INFORMAL CONSULTATIONS or AS PROPOSED BY THE CHAIR ON 9 OCTOBER or AS PROPOSED BY THE OCTOBER 2015 INFORMAL CONSULTATIONS

6. Furthermore the October informal consultations have mandated the Chair to further consult with the Secretariat and with Member States in order to provide to the Intergovernmental Meeting with the Chair's proposals for the remaining outstanding issues. These proposals will be submitted by the Chair in a separate informal document.

ANNEX

Framework of engagement with non-State actors

Draft resolution

[The Sixty-ninth World Health Assembly,

PP1 Having considered the report on the framework of engagement with non-State actors and the revised draft framework of engagement with non-State actors;

PP2 Recalling resolution WHA64.2 and decision WHA65(9) on WHO reform, and decisions WHA67(14) and EB136(3) on a framework of engagement with non-State actors;

PP3 Acknowledging the importance to WHO of engagement with non-State actors that benefits from a robust management of the risks of such engagement for all three levels of the Organization,

(OP1) 1. APPROVES the Framework of Engagement with non-State actors, as set out in the Annex to this resolution;¹

(OP2) 2. DECIDES that the Framework of Engagement with non-State actors shall replace the Principles governing relations between the World Health Organization and nongovernmental organizations² and Guidelines on interaction with commercial enterprises to achieve health outcomes;³

(OP3) 3. REQUESTS the Director General:

(1) to implement the Framework of Engagement with non-State actors;

(2) to establish the register of non-State actors in time for the Sixty-ninth World Health Assembly;

(3) to report on the implementation of the Framework of Engagement with non-State actors to the Executive Board at each of its January sessions under a standing agenda item, through the Programme Budget and Administration Committee;

(4) to conduct in 2018 an evaluation of the implementation of the Framework of Engagement with non-State actors and its impact on the work of WHO with a view to submitting the results, together with any proposals for revisions of the Framework, to the Executive Board in January 2019, through the Programme Budget and Administration Committee.]

¹ Consisting of an overarching framework and four specific policies on engagement with nongovernmental organizations, private sector entities, philanthropic foundations and academic institutions.

² Adopted in resolution WHA40.25. See Basic documents, 48th ed. Geneva: World Health Organization; 2014.

³ Document EB107/20, Annex.

REMINDER – THIS WAS TAKEN FROM P66 AND WAS PARKED HERE:

(i bis alternative) [The Independent Expert Oversight Advisory Committee includes, as part of its annual report, an examination of financial contributions from non-State actors according to the Financial Rules and Regulations.] [and on cases handled by the Engagement Coordination Group] **(DEL) (CHAIR TO PROPOSE TEXT)**

THIS IS TAKEN FROM PARA 72 alt (DELETED)

(ii bis) to roll out the categorization of non-State actors as set out in the framework immediately.

(ii ter) to complete within three years the submission of all non-State actors in official relations for review by the Executive Board

Appendix

[DRAFT] FRAMEWORK OF ENGAGEMENT WITH NON-STATE ACTORS**DRAFT OVERARCHING FRAMEWORK OF ENGAGEMENT
WITH NON-STATE ACTORS****INTRODUCTION**

1. The overarching framework of engagement with non-State actors and the WHO policy and operational procedures on management of engagement with non-State actors apply to all engagements with non-State actors at all levels of the Organization,¹ whereas the four specific policies and operational procedures on engagement are limited in application to, respectively, nongovernmental organizations, private sector entities, philanthropic foundations and academic institutions.

ENGAGEMENT: RATIONALE, PRINCIPLES, BENEFITS AND RISKS**Rationale**

2. WHO is the directing and coordinating authority in global health in line with its constitutional mandate. The global health landscape has become more complex in many respects; among other things, there has been an increase in the number of players including non-State actors. WHO engages with non-State actors in view of their significant role in global health for the advancement and promotion of public health and to encourage non-State actors to use their own activities to protect and promote public health.

3. The functions of WHO, as set out in Article 2 of its Constitution, include: to act as the directing and coordinating authority on international health work; to establish and maintain effective collaboration with diverse organizations; and to promote cooperation among scientific and professional groups which contribute to the advancement of health. The Constitution further mandates the Health Assembly or the Executive Board, and the Director-General, to enter into specific engagements with other organizations.² WHO shall, in relation to non-State actors, act in conformity with its Constitution and resolutions and decisions of the Health Assembly, and bearing in mind those of the United Nations General Assembly or the Economic and Social Council of the United Nations, if applicable.

4. **(DELETED)**

5. WHO's engagement with non-State actors supports implementation of the Organization's policies and recommendations as decided by the governing bodies, as well as the application of

¹ Headquarters, regional offices and country offices, entities established under WHO, as well as hosted partnerships. For hosted partnerships the framework of engagement with non-State actors will apply, subject to the policy on WHO's engagement with global health partnerships and hosting arrangements (resolution WHA63.10). Hosted, as well as external partnerships are explained in paragraph 48.

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

WHO's technical norms and standards. Such an effective engagement with non-State actors at global, regional and country levels, also calls for due diligence and transparency measures applicable to non-State actors under this framework. In order to be able to strengthen its engagement with non-State actors for the benefit and interest of global public health, WHO needs simultaneously to strengthen its management of the associated potential risks. This requires a robust framework that enables engagement and serves also as an instrument to identify the risks, balancing them against the expected benefits, while protecting and preserving WHO's integrity, reputation and public health mandate.

Principles

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

Any engagement must:

- (a) demonstrate a clear benefit to public health;
- (a bis) conform with WHO's Constitution, mandate and general programme of work
- (b) respect the intergovernmental nature of WHO and the decision-making authority of Member States as set out in the WHO's Constitution;
- (c) support and enhance, without compromising, the scientific and evidence-based approach that underpins WHO's work;
- (d) Protect WHO from any undue influence, in particular on the processes in setting and applying policies, norms and standards;¹
- (e) not compromise WHO's integrity, independence, credibility and reputation;
- (f) be effectively managed, including by, where possible avoiding conflict of interest² and other forms of risks to WHO;
- (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 in fulfilment of its constitutional principles and objectives, including its directing and coordinating role in global health. Engagements range from major, longer-term collaborations to smaller, briefer interactions. Benefits arising from such engagement can also include:

- a) (DELETED)
- b) the contribution of non-State actors to the work of WHO
- c) the influence that WHO can have on non-State actors to enhance their impact on global public

¹ Policies, norms and standard setting includes information gathering, preparation for, elaboration of and the decision on the normative text.

² As set out in paragraphs 23 to 26)

- health or to influence the social, economic and environmental determinants of health
- d) the influence that WHO can have on non-State actors' compliance with WHO's policies, norms and standards
- e) the additional resources non-State actors can contribute to WHO's work
- f) the wider dissemination of and adherence by non-State actors to WHO's policies, norms and standards

Risks of engagement

8 WHO's engagement with non-State actors can involve risks which need to be effectively managed and, where appropriate, avoided. Risks relate inter alia to the occurrence in particular of the following:

- (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, policies, norms and standard setting;¹
- (c) a negative impact on WHO's integrity, independence, ~~reputation and credibility and reputation~~; and public health mandate;
- (d) the engagement being primarily used to serve the interests of the non-State actor concerned with limited or no benefits for WHO and public health;
- (e) the engagement conferring an endorsement of the non-State actor's name, brand, product, views or activity;²
- (f) the whitewashing of a non-State actor's image through an engagement with WHO;
- (g) a competitive advantage for a non-State actor.

NON-STATE ACTORS

9. For the purpose of this framework, non-State actors are 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 are free from concerns which are primarily of a private, commercial or profit-making nature. They could include, for example, grassroots community organizations, civil society groups and networks, faith-based organizations, professional groups, disease-specific groups, and patient groups.

¹ Policies, norms and standard setting includes information gathering, preparation for, elaboration of and the decision on the normative text.

² Endorsement does not include established processes such as prequalifications or the WHO Pesticide Evaluation Scheme (WHOPES).

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 arm’s length”¹ from their commercial sponsors, and partially or fully State-owned commercial enterprises acting like private sector entities.

International business associations are private sector entities that do not intend to make a profit for themselves but represent the interests of their members, which are commercial enterprises and/or national or other business associations. For the purposes of this framework, they shall have the authority to speak for their members through their authorized representatives. Their members shall exercise voting rights in relation to the policies of the international business association.

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.

13. **Academic institutions** are entities engaged in the pursuit and dissemination of knowledge through research, education and training.²

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 to the extent that the non-State actor has to be considered itself a private sector entity. Such influence can be exerted through financing, participation in decision making or otherwise. Provided that the decision-making processes and bodies of a non-State actor remain independent of undue influence from the private sector, WHO can decide to consider the entity as a nongovernmental organization, a philanthropic foundation or an academic institution, but may apply relevant provisions of the WHO’s policy and operational procedures on engagement with private sector entities, such as not accepting financial and in-kind contributions for use in the normative work.

TYPES OF INTERACTION

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.

¹ An entity is “at arm’s length” from another entity if it is independent from the other entity, does not take instructions and is clearly not influenced or clearly not reasonably perceived to be influenced in its decisions and work by the other entity.

² This can include think tanks which are policy-oriented institutions, as long as they primarily perform research; while international associations of academic institutions are considered as non-governmental organizations, subject to paragraph 14.

VERSIONS AS PROPOSED BY THE OCTOBER 2015 CONSULTATION

[15bis The Director General shall have flexibility in the application of the procedures of this framework when responding to acute public health events described in the International Health Regulations (2005) or other emergencies with health consequences, consistent with the functions of WHO as set out in the Constitution including article 2d thereof and without prejudice to the principles identified in paragraph 6 of this framework. [The Director General will include information on and provide justification of use of such flexibilities in the annual report on engagement with non-State actors.]

OR[The Director General will inform Member States that flexibility has been required if and when he or she deems necessary, and will include summary information with justification on the use of such flexibility in the annual report on engagement with non-State actors.]

OR[The Director General will notify in advance all Member States about the decision/action he or she deems necessary. In this regard, DG will provide summary information as well as justification on the decisions/actions in the annual report on engagement with non-State actors.]]

(PLACEMENT OF THIS PARAGRAPH TO BE DECIDED)

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. The format, modalities, and the participation of non-State actors in consultations, hearings, and other meetings is decided on a case-by-case basis by the WHO governing bodies or by the Secretariat.

(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. Inputs received from non-State actors shall be made publicly available, wherever possible.

(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 and shall be made publicly available, wherever possible.

(d) **Other meetings.** These are meetings that are not part of the process of setting policies, or norms or standards; examples include information meetings, briefings, scientific conferences, and platforms for coordination of actors.

17. WHO's involvement in meetings organized wholly or partly by a non-State actor can – subject to the provisions of this framework, its four specific policies and operational procedures, and other applicable WHO 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 meeting¹ 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

VERSION AS PROPOSED BY THE OCTOBER 2015 CONSULTATION

18. Resources are ~~funds~~ financial or in-kind contributions. In-kind contributions include donations of medicines and other goods and free provision of services on a contractual basis.

(THE SECRETARIAT WILL PROVIDE A NONPAPER TO DECEMBER MEETING.)

NEW PROPOSAL RECEIVED FROM A MEMBER STATE ON 26 OCTOBER 2015

[18 FOOTNOTE: Contract for services, provided to WHO by non-State actor free of charge must be signed by non-State actor as organization, free (/1 dollar) individual contract with the persons for these free services cannot replace the contract with non-State actor.]

Evidence

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

Advocacy

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.

¹ Cosponsorship of a meeting means: (1) another entity has the primary responsibility for organizing the meeting; and (2) WHO supports and contributes to the meeting and its proceedings; and (3) WHO reserves the right to clear the agenda of the meeting, the list of participants and the outcome documents of the meeting.

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
- 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 relevant² information about itself and its activities, following which WHO conducts the necessary due diligence.
- WHO conducts a risk assessment in order to identify the specific risks of engagement associated with each engagement with a non-State actor.
- 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.³
- Member States exercise oversight over WHO's engagement with non-State actors in accordance with the provisions in paragraphs 65 and 66

[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

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 As defined in paragraph 38bis.

³ WHO uses an electronic tool for managing engagement. As described in footnote 1 of paragraph 38, the publicly visible part of the tool is the register of non-State actors; the tool also provides an electronic workflow for the internal management of engagement. A similar electronic tool is used for the management of individual conflicts of interest, in order to harmonize the implementation of the framework with the implementation of the policy on management of individual conflicts of interest for experts.

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.

23bis. Individual conflicts of interests within WHO are those involving experts, regardless of their status, and staff members; these are addressed in accordance with the policies listed under paragraph 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 potential risk of institutional conflicts of interest could be the highest in situations where the interest of non-State actors, in particular economic, commercial or financial, are in conflict with WHO's public health policies, constitutional mandate and interests, in particular the Organization's independence and impartiality in setting policies, norms and standards.

Due diligence and risk assessment

27. When the possibility of entering into an engagement is being considered, the relevant technical unit in the Secretariat conducts an initial examination in order to establish whether such an engagement would be in the interest of the Organization and in line with the principles of WHO's engagement with non-State actors in paragraph 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.

28. 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 core functions of due diligence are to:

- clarify the nature and purpose of the entity proposed to engage with WHO;
- clarify the interest and objectives of the entity in engaging with WHO and what it expects in return;
- determine the entity's legal status, area of activities, membership, governance, sources of funding, constitution, statutes, and by-laws and affiliation;
- define the main elements of the history and activities of the entity in terms of the following: health, human and labour issues; environmental, ethical and business issues; reputation and image; and financial stability;
- identify if paragraph 44 or 44bis should be applied.

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.

32. Risks are the expression of the likelihood and potential impact of an event that would affect the Organization's ability to achieve its objectives. A **risk assessment** on a proposed engagement is conducted in addition to due diligence. This involves the assessment of risks associated with an engagement with a non-State actor, in particular the risks described in paragraph 8.

Risk management

33. **Risk management** concerns the process leading to a management decision whereby the Secretariat decides explicitly and justifiably on entry into engagement,¹ continuation of engagement, engagement with measures to mitigate risks, non-engagement or disengagement from an existing or planned engagement with non-State actors. It is a management decision usually taken by the unit engaging with the non-State actor.

34. The specialized 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 Group².

35. The Engagement Coordination Group reviews proposals of engagement referred to it by directors and recommends engagement, continuation of engagement, engagement with measures to mitigate risks, non-engagement or disengagement from an existing or planned engagement with non-State actors. In cases where the Regional Director or Assistant Director-General disagrees with this recommendation, the final decision rests with the Director-General.

¹ Other than decisions related to official relations as set out in paragraphs 49 to 55.

² The **Engagement Coordination Group** is a Secretariat group appointed by the Director-General that includes representation from regional offices.

36. In line with WHO's risk management framework,¹ 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.

Transparency

37. WHO's interaction with non-State actors is managed transparently. WHO provides an annual report to the governing bodies on its engagement with non-State actors, including summary information on due diligence, risk assessment and risk management undertaken by the Secretariat, including the Engagement Coordination Group. WHO also makes publicly available appropriate information on its engagement with non-State actors.

38. The **WHO register of non-State actors** is an Internet-based, publicly available electronic tool used by the Secretariat² to document and coordinate engagement with non-State actors. It contains the main standard information provided by non-State actors³ and high-level descriptions of the engagement that WHO has with these actors.⁴

VERSION AS OF 10 JULY

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.

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.]

VERSION AS PROPOSED BY SEPTEMBER INFORMAL CONSULTATIONS

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

¹ See document EB133/10.

² The register of non-State actors is the first level of a tool used by the Secretariat containing four levels of information: a publicly available level, a level made available to Member States, a working level for the Secretariat, and a level of confidential and sensitive information accessible to a limited number of individuals within the Secretariat.

³ Information on financial contributions received from non-State actors is documented in this register and in the Programme Budget web portal.

⁴ The register covers all three levels of the Organization – global, regional and country – and includes hosted partnerships and joint programmes.

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.]

38ter. OLD CHAIR's TEXT: [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.]

NEW CHAIR's TEXT: 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.] Furthermore Member States can search for such information concerning cases considered by the engagement coordination group.

AND

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

(CHAIR'S PROPOSAL TO KEEP THE CHAIRS TEXT FOR 38, 38BIS AND 38TER. A REFERENCE TO THE ROLLING OUT OF THE REGISTER HAS BEEN ADDED TO THE RESOLUTION)

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~~ of engagement with non-State actors.

42. (DELETED)

43. (DELETED)

SPECIFIC PROVISIONS

44. WHO does not engage with the tobacco industry or non-State actors that work to further the interests of the tobacco industry. WHO also does not engage with the arms industry.

Engagement where particular caution should be exercised

44bis WHO will exercise particular caution, especially while conducting due diligence, risk assessment and risk management, when engaging with private sector entities and other non-State actors whose policies or activities are negatively affecting human health and are not in line with WHO's policies, norms and standards, in particular those related to noncommunicable diseases and their determinants.

Association with WHO's name and emblem

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.] (DEL)

OR

[WHO does not accept secondments from private sector entities. Secondments from other types of non-State actors shall be accepted, in accordance with this framework]

OR

[WHO can accept secondments from non-State actors for technical work or implementation of WHO's programmes and policies and emergency response.]

CHAIRS PROPOSAL: 46. WHO does not accept secondments from non-State actors

RELATION OF THE FRAMEWORK TO WHO'S OTHER POLICIES

47. This framework replaces the Principles Governing Relations between the World Health Organization and Nongovernmental Organizations² and the Guidelines on interaction with commercial enterprises to achieve health outcomes (noted by the Executive Board).³

¹ See <http://www.who.int/about/licensing/emblem/en/>.

² Basic documents, 48th ed. Geneva: World Health Organization; 2014: pp.97–102.

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

48. The implementation of the policies listed below as they relate to WHO's engagement with non-State actors will be coordinated and aligned with the framework of engagement with non-State actors. In the event that a conflict is identified, it will be brought to the attention of the Executive Board through the PBAC.

(a) Policy on WHO's engagement with global health partnerships and hosting arrangements¹.

(i) Hosted partnerships derive their legal personality from WHO and are subject to the Organization's rules and regulations. Therefore the Framework of engagement with non-State actors applies to their engagement with non-State actors. They have a formal governance structure, separate from that of the WHO governing bodies, in which decisions are taken on direction, work plans and budgets; and their programmatic accountability frameworks are also independent from those of the Organization. In the same way the framework applies to other hosted entities which are subject to the Organizations Rules and Regulations.

(ii) WHO's involvement in external partnerships is regulated by the policy on WHO's engagement with global health partnerships and hosting arrangements. The framework of engagement with non-State actors also applies to WHO's engagement in these partnerships.

(b) Regulations for Expert Advisory Panels and Committees and the Guidelines for Declaration of Interests (WHO Experts). The management of WHO's relations with individual experts is regulated by the Regulations for Expert Advisory Panels and Committees² and the Guidelines for Declaration of Interests (WHO Experts).

(c) Staff Regulations and Staff Rules. All staff are subject to the Organization's Staff Regulations and Staff Rules, noting in particular the provisions of declaration of interest therein: 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) Regulations for Study and Scientific Groups, Collaborating Institutions and other Mechanisms of Collaboration. Scientific collaborations are regulated by the Regulations for Study and Scientific Groups, Collaborating Institutions and other Mechanisms of Collaboration.³

(e) Financial Rules and Financial Regulations.

(i) The procurement of goods and services is regulated by the Financial Rules and Financial Regulations;⁴ it is not covered by the framework of engagement with non-State actors, although pro-bono contributions from non-State actors are covered.

¹ Endorsed by the Health Assembly in resolution WHA63.10 on partnerships and its Annex 1.

² See Basic documents, 48th ed. Geneva: World Health Organization; 2014: pp.121–130.

³ Basic documents, 48th ed. Geneva: World Health Organization; 2014: pp.131–138

⁴ Basic documents, 47th ed. Geneva: World Health Organization; 2009, pp.87–97. 48th ed. Geneva: World Health Organization; 2014: pp.103–113

(ii) Like any other financing of WHO, financing from non-State actors is regulated by the Financial Rules and Financial Regulations and the decision on accepting such financial contributions is also regulated by this framework.

OFFICIAL RELATIONS

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 engagement¹ 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. Entities in official relations are international in membership and /or scope. All entities in official relations shall have a constitution or similar basic document, an established headquarters, a governing body, an administrative structure, and a regularly updated entry in the WHO register of non-State actors.

51. Official relations shall be based on a plan for collaboration between WHO and the entity with agreed objectives and outlining activities for the coming three-year period structured in accordance with the General Programme of Work and Programme budget and consistent with this framework. This plan shall also be published in the WHO register of non-State actors. These organizations shall provide annually a short report on the progress made in implementing the plan of collaboration and other related activities which will also be published in the WHO register. These plans shall be free from concerns which are primarily of a commercial or profit-making nature.

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 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. Entities in official relations are invited to participate in sessions of WHO’s governing bodies. This privilege shall include:

(a) the possibility to appoint a representative to participate, without right of vote, in meetings of WHO’s governing bodies or in meetings of the committees and conferences convened under its authority;

(b) the possibility to make a statement if the Chairman of the meeting (i) invites them to do so or (ii) accedes to their request when an item in which the related entity is particularly interested is being discussed;

¹ 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.

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

54. Non-State actors participating in WHO governing bodies' meetings shall designate a head of their delegation and declare the affiliations of their delegates. This declaration shall include the function of each delegate within the non-State actor itself and, where applicable, the function of that delegate within any affiliated organization.

55. Regional committees may also decide on a procedure granting accreditation to their meetings to other non-State actors not in official relations with WHO as long as the procedure is managed in accordance with this framework.

Procedure for admitting and reviewing organizations in official relations

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 engagement as documented in the register of non-State actors and a three-year plan for collaboration with WHO that has been developed and agreed on jointly by the non-State actor and WHO.

57. A signed letter certifying the accuracy of the application for official relations submitted online shall reach WHO headquarters no later than the end of the month of July for submission to the Executive Board at its session the following January. Applications for official relations shall be reviewed to ensure that the established criteria and other requirements are fulfilled as set out in this 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. (MOVED TO AFTER P61 AS 61BIS)

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 engagement 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 document decisions taken within the Secretariat and by the Executive Board on applications from non-State actors, reflect this status in the WHO register of non-State actors, and maintain a list of the organizations admitted into official relations.

61bis. The entities in official relations and the Secretariat should name focal points for collaboration who are responsible for informing each other and their organizations of any developments in the implementation of the plan for collaboration and who are the first points of contact for any changes or problems.

62. The Board, through its Programme, Budget and Administration Committee, shall review collaboration with each non-State actor in official relations every three years and shall decide on the desirability of maintaining official relations or defer the decision on the review to the following year. The Board's review shall be spread over a three-year period, one third of the entities in official relations being reviewed each year.

63. The Director-General can propose earlier reviews of a non-State actor's official relations with WHO by the Executive Board through its Programme, Budget and Administration Committee in case of issues such as non-fulfilment of the entity's part in the plan of collaboration, lack of contact, failure by the non-State actor to fulfil its reporting requirements or changes in the nature or activities of the organization concerned, the non-State actor ceasing to fulfil the criteria for admission, or any potential new risks for the collaboration.

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.

VERSION AS OF 10 JULY

[ACCREDITATION OF NGOS

[(MOVE TO POLICY AND O.P. ON ENGAGEMENT WITH NGOS)]

64 bis To be eligible for accreditation to the Health Assembly, Executive Board and committees and conferences convened under their authority, a nongovernmental organization shall:

- (a) have aims and purposes consistent with WHO's Constitution and in conformity with the policies of the Organization as well as resolutions and decisions adopted by the Executive Board and the World Health Assembly;
- (b) demonstrate competence in a field of activity related to the work of WHO;
- (c) have membership and/or activities that are international in scope;
- (d) be non-profit and public interest in nature, and in its activities and advocacy;
- (e) have an established structure, a constitutive act, and accountability mechanisms;
- (f) for a membership organization, have the authority to speak for its members and have a representative structure; The Membership should not contain private sector entities, individuals associated with private sector entities or philanthropic foundations and academic institutions not at arm's length with private sector;

(g) have existed formally for at least three years as of date of receipt of the application by WHO;

(h) disclose information on its objectives, structure, membership of executive body, field of activities and source of financing, and, where applicable, its status with other entities of the United Nations system;

(i) agree to provide WHO regularly with updated information as well as to inform WHO of any changes with respect to its status as « non-governmental organization » as soon such changes take place.

Completed applications should reach WHO headquarters by the beginning of June in order to be considered by the Executive Board in January of the following year. Applications should be transmitted to Member States by the Secretariat two months in advance of the session at which they will be considered. A re-application from a “nongovernmental organization” shall not be considered until two years have elapsed since the Board’s decision on the original application. Once a nongovernmental organization is accredited, information gathered on its objectives, structure, membership of executive body, field of activities and source of funding, including updated information, shall be made publicly available. A report on accredited nongovernmental organizations shall be submitted every two years to the Executive Board.]

(CHAIRS PROPOSAL: DELETE) (NOTE THAT ISSUES ARE COVERED IN P16 AND P55 AND NGO POLICY P3, 4 AND 4bis) (PARK)

VERSION AS PROPOSED BY SEPTEMBER INFORMAL CONSULTATIONS, NO AGREEMENT REACHED IN OCTOBER

**~~[ACCREDITATION OF NGOS
(MOVE TO POLICY AND O.P. ON ENGAGEMENT WITH NGOS)]~~**

~~64 bis To be eligible for accreditation to the Health Assembly, Executive Board and committees and conferences convened under their authority, a nongovernmental organization shall:~~

~~(a) have aims and purposes consistent with WHO’s Constitution and in conformity with the policies of the Organization as well as resolutions and decisions adopted by the Executive Board and the World Health Assembly;~~

~~(b) demonstrate competence in a field of activity related to the work of WHO;~~

~~(c) have membership and/or activities that are international in scope;~~

~~(d) be non-profit and public interest in nature, and in its activities and advocacy;~~

~~(e) have an established structure, a constitutive act, and accountability mechanisms;~~

~~(f) for a membership organization, have the authority to speak for its members and have a representative structure; The Membership should not contain private sector entities, individuals associated with private sector entities or philanthropic foundations and academic institutions not at arm’s length with private sector;~~

(g) have existed formally for at least three years as of date of receipt of the application by WHO;

(h) disclose information on its objectives, structure, membership of executive body, field of activities and source of financing, and, where applicable, its status with other entities of the United Nations system;

(i) agree to provide WHO regularly with updated information as well as to inform WHO of any changes with respect to its status as « non governmental organization » as soon such changes take place.

Completed applications should reach WHO headquarters by the beginning of June in order to be considered by the Executive Board in January of the following year. Applications should be transmitted to Member States by the Secretariat two months in advance of the session at which they will be considered. A re application from a “nongovernmental organization” shall not be considered until two years have elapsed since the Board’s decision on the original application. Once a nongovernmental organization is accredited, information gathered on its objectives, structure, membership of executive body, field of activities and source of funding, including updated information, shall be made publicly available. A report on accredited nongovernmental organizations shall be submitted every two years to the Executive Board.]

~~(CHAIRS PROPOSAL: DELETE) (NOTE THAT ISSUES ARE COVERED IN P16 AND P55 AND NGO POLICY P3, 4 AND 4bis) (PARK)~~

OVERSIGHT OF ENGAGEMENT

65. The Executive Board, through its Programme, Budget and Administration Committee, oversees the implementation of WHO’s framework of engagement with non-State actors, proposes revisions to the framework and can grant the privileges of official relations to international nongovernmental organizations, philanthropic foundations and international business associations.

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 of engagement with non-State actors including:

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

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

(b) entities in official relations with WHO, including:

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

(ii) review of renewals of entities in official relations

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

NON-COMPLIANCE WITH THIS FRAMEWORK

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

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 its Programme, Budget and Administration Committee in the annual report on engagement with non-State actors and the assessment of information available in the register of non-State actors.

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 its Programme, Budget and Administration Committee.

72alt. DELETED

DRAFT WHO POLICY AND OPERATIONAL PROCEDURES ON ENGAGEMENT WITH NONGOVERNMENTAL ORGANIZATIONS

1. DELETED

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

PARTICIPATION

Participation by nongovernmental organizations in WHO meetings²

3. WHO can invite nongovernmental organizations to participate in consultations, hearings or other meetings in accordance with paragraph 16 of the overarching framework. Consultations and hearings can be electronic or in person.

4. Participation in other meetings is on the basis of discussion of an item in which the 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.

4bis. The nature of participation of nongovernmental organizations depends on the type of meeting concerned. The format, modalities, and the participation of nongovernmental organizations in consultations, hearings, and other meetings is decided on a case-by-case basis by the WHO governing bodies or by the Secretariat. Participation and inputs received from nongovernmental organizations shall be made publicly available, wherever possible. Nongovernmental organizations do not take part in any decision making process of the Organization.

Involvement of the Secretariat in meetings organized by nongovernmental organizations

5. WHO can organize joint meetings, or cosponsor meetings organized by nongovernmental organizations, as long as the integrity, independence and reputation of the Organization are preserved, and as long as this participation furthers WHO's objectives as expressed in the General Programme of Work. WHO staff members may participate in meetings organized by nongovernmental organizations in accordance with the internal rules of the Organization. The nongovernmental organization shall not misrepresent WHO's participation as official WHO support for, or endorsement of, the meeting, and shall agree not to use WHO's participation for promotional purposes.

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.

Specific policies and operational procedures

6. The participation of WHO in meetings organized by nongovernmental organizations as co-organizers, cosponsors, panellists or speakers shall be managed according to the provisions of this Framework.

RESOURCES**VERSION AS OF 10 JULY**

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.

KEEP TEXT; ADD FOOTNOTE TO PERSONNEL: Contribution of personnel are only acceptable for short term assignments that do not involve normative work and if potential risks are managed in accordance with this framework.

VERSION AS PROPOSED BY THE CHAIR ON 9 OCTOBER 2015

7. WHO can accept ~~funds~~ financial ~~,—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.

[7bis The acceptance of contributions (whether in cash or in kind) should be made subject to the following conditions:

- (a) the acceptance of a contribution does not constitute an endorsement by WHO of the nongovernmental organization;
- (b) the acceptance of a contribution does not confer on the contributor any privilege or advantage;
- (c) the acceptance of a contribution as such does not offer the contributor any possibility for advising, influencing, participating in, or being in command of the management or implementation of operational activities;
- (d) WHO keeps its discretionary right to decline a contribution, without any further explanation.]

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

ADVOCACY

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. Nongovernmental organizations are encouraged to disseminate WHO's policies, guidelines, norms and standards and other tools through their networks

VERSION AS OF 10 JULY

(16bis) [WHO favours [independent monitoring functions] and therefore engages with nongovernmental organizations working in this field.]

OR

[WHO encourages critical engagement and therefore engages in this constructive spirit with non-State actors.]

OR

[WHO recognises the usefulness of an independent monitoring function provided by some NGOs in the field]

OR

[WHO engages with NGOs which provide an independent monitoring function.]

OR

~~(DELETE 16bis)~~

(16ter) [Nongovernmental organizations 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 [and in a manner consistent with the principles and objectives underlying those norms and standards]. No partial or selective implementation is acceptable]. (SUBJECT TO AGREEMENT WITH SPECIFIC PARAGRAPHS IN THE FOUR SPECIFIC POLICIES)

16quart [WHO encourages NGOs to implement and advocate for the implementation of WHO's norms and standards. WHO engages in dialogue with NGOs in order to promote the implementation of WHO's policies, norms and standards.]

OR

16ter/quart - alt [WHO encourages NGOs to implement and advocate for the implementation of WHO's norms and standards. Nongovernmental organizations 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]

(SECRETARIAT TO DEVELOP A MATRIX TO COMPARE)

VERSION AS PROPOSED BY SEPTEMBER INFORMAL CONSULTATIONS

~~[(16bis) [WHO favours [independent monitoring functions] and therefore engages with nongovernmental organizations working in this field.]~~

OR

~~[WHO encourages critical engagement and therefore engages in this constructive spirit with non-State actors.]~~

OR

~~[WHO recognises the usefulness of an independent monitoring function provided by some NGOs in the field]~~

OR

~~[WHO engages with NGOs which provide an independent monitoring function.]~~

OR

~~(DELETE 16bis)~~

(CHAIR'S EXPLANATION: THE FOLLOWING ARE 5 ALTERNATIVES FOR A POSSIBLE THIRD PARAGRAPH ON ADVOCACY IN THE NGO POLICY)

(16ter) [Nongovernmental organizations can only collaborate with WHO in advocacy for the implementation of a WHO policy, norm or standard if they commit themselves to implement ~~these~~

norms and standards]/[this policy, norm or standard] in [their]/its entirety. No partial or selective implementation is acceptable]. (SUBJECT TO AGREEMENT WITH SPECIFIC PARAGRAPHS IN THE FOUR SPECIFIC POLICIES) (DELETE 16ter)

[16 ter alt [Taking into account relevant national laws or policies,] Nongovernmental organization can only collaborate with WHO in advocacy for implementation of a WHO policy, norm and standard if they commit themselves [to implement]/[to as full an implementation as possible]/[when implementing] and are not inconsistent with the [relevant WHO policy, norm and standard for that NGO]/[policy, norm and standard in question]]

OR [Taking into account relevant national laws or policies, NGOs can only collaborate with WHO in advocacy for implementation of a policy, norm and standard, to the extent the implementing NGO, commits itself to implement this policy, norm and standard in its entirety.]

16quart [WHO encourages NGOs to implement and advocate for the implementation of WHO's norms and standards. WHO engages in dialogue with NGOs in order to promote the implementation of WHO's policies, norms and standards.]

OR

16ter/quart - alt [WHO encourages NGOs to implement and advocate for the implementation of WHO's norms and standards. Nongovernmental organizations 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] (SECRETARIAT TO DEVELOP A MATRIX TO COMPARE)

TECHNICAL COLLABORATION

VERSION AS OF 10 JULY

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.

VERSION AS PROPOSED BY SEPTEMBER INFORMAL CONSULTATIONS

~~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.~~

17. Technical collaboration [ADD FOOTNOTE: as defined in overarching framework paragraph 21] with NGOs is encouraged. This collaboration must be in the interest of WHO, and managed in accordance with this framework to protect WHO, and in particular, its normative work, from any undue influence and to ensure there is no interference with WHO's advisory function to member states.

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

1. DELETED

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

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 meetings²

4. WHO can invite private sector entities to participate in consultations, hearings or other meetings in accordance with paragraph 16 of the overarching framework. Consultations and hearings can be electronic or in person.

5. Participation in other meetings is on the basis of discussion of an item in which the private sector entity has a particular interest and where its participation adds value to the deliberations of the meeting. Such participation is for the exchange of information and views, but never for the formulation of advice.

5bis The nature of participation of private sector entities depends on the type of meeting concerned. The format, modalities, and the participation of private sector entities in consultations, hearings, and other meetings is decided on a case-by-case basis by the WHO governing bodies or by the Secretariat. Participation and inputs received from private sector entities shall be made publicly available, wherever possible. Private sector entities do not take part in any decision making process of the Organization.

Involvement of the Secretariat in meetings organized by private sector entities

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.

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.

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 overarching framework and this specific policy.
8. WHO does not cosponsor meetings organized wholly or partly by private sector entities. It may, however, cosponsor a meeting for which the scientific initiators have hired a commercial conference organizer to deal with the logistical aspects, provided that the commercial organizer makes no contribution to the scientific content of the meeting.
9. WHO does not cosponsor meetings organized by other actors where one or more health-related private sector entities are also cosponsors. Other instances of cosponsorship of meetings organized by other actors where non health-related private sector entities are also cosponsors should be reviewed on a case-by-case basis and are subject to the provisions of this framework.
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**VERSION AS OF 10 JULY**

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 [or affiliated with any entity] that is incompatible with WHO's mandate and 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.
 - [(d) WHO shall not receive financial resources from private sector entities as well as non-state actors with links to private sector entities whose activities [or advocacy] are undermining the mandate of WHO as stated in its Constitution]/DISCUSS WITH PARA 44

~~[(e) The WHO should establish ceiling in the voluntary contribution from non-state actors. Any contribution beyond that amount should go to the core voluntary fund which gives enough freedom to the Secretariat to allocate resources to underfunded programmes. The Member States assessed contributions should be allocated to the programmes that are underfunded under voluntary contribution]/OR MOVE TO 18ter in the overarching framework/DELETE~~

CHAIRS PROPOSAL 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 or have close ties with any entity that is incompatible with WHO's mandate and work.

DELETE d) AND e)

VERSION AS PROPOSED BY THE CHAIR ON 9 OCTOBER 2015

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 financial contributions~~ may be accepted from private sector entities whose business is unrelated to that of WHO, provided they are not engaged in any activity or have close ties with any entity that is incompatible with WHO's mandate and work.

(b) ~~Funds Financial contributions~~ may not be sought or accepted from private sector entities that have, themselves or through their affiliated companies, a direct commercial interest in the outcome of the project toward which they would be contributing, unless approved in conformity with the provisions for clinical trials or product development (see paragraph 38 below).

(c) Caution should be exercised in accepting ~~financing financial contributions~~ from private sector entities that have even an indirect interest in the outcome of the project (i.e. the activity is related to the entities' field of interest, without there being a conflict as referred to above). In such an event, other commercial enterprises having a similar indirect interest should be invited to contribute, and the reason clearly described if this does not prove possible. The larger the proportion of the contribution from any one source, the greater the care that should be taken to avoid the possibility of a conflict of interest or appearance of an inappropriate association with one contributor.

~~[(d) WHO shall not receive financial resources from private sector entities as well as non-state actors with links to private sector entities whose activities [or advocacy] are undermining the mandate of WHO as stated in its Constitution]/DISCUSS WITH PARA 44~~

~~[(e) The WHO should establish ceiling in the voluntary contribution from non state actors. Any contribution beyond that amount should go to the core voluntary fund which gives enough freedom to the Secretariat to allocate resources to underfunded programmes. The Member States assessed contributions should be allocated to the programmes that are underfunded under voluntary contribution]/OR MOVE TO 18ter in the overarching framework/DELETE~~

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.

VERSION AS OF 10 JULY

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].

CHAIRS PROPOSAL KEEP TEXT

VERSION AS PROPOSED BY THE CHAIR ON 9 OCTOBER 2015

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.

VERSION AS OF 10 JULY*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.

KEEP TEXT; ADD FOOTNOTE TO PERSONNEL: Contribution of personnel are only acceptable for short term assignments that do not involve normative work and if potential risks are managed in accordance with this framework.

VERSION AS PROPOSED BY THE CHAIR ON 9 OCTOBER 2015*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.

VERSION AS OF 10 JULY

19. Private sector entities may not use [WHO’s logo] / [[such] / [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.

CHAIRS PROPOSAL Art. 19 alt: Private sector entities may not use the results of WHO’s work to which they have contributed 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.

(COMMENT: USE OF NAME AND EMBLEM IS REGULATED BY REGULATED BY PARAGRAPH 45 OF THE OVERARCHING FRAMEWORK)

VERSION AS PROPOSED BY THE CHAIR ON 9 OCTOBER 2015

19. Private sector entities may not use the results of WHO's work to which they have contributed 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 technologies¹

20. In determining the acceptability of large-scale donations of medicines and other health-related products, the following criteria should be met.

(a) Sound evidence exists of the safety and efficacy of the product in the indication for which it is being donated. The product is approved or otherwise authorized by the recipient country for use in that indication; it should also preferably appear in the WHO Model List of Essential Medicines for that indication.

(b) Objective and justifiable criteria for the selection of recipient countries, communities or patients have been determined. In emergency situations, flexibilities may be required.

(c) A supply system is in place and consideration is given to means of preventing waste, theft and misuse (including leakage back into the market).

(d) A training and supervision programme is in place for all personnel involved in the efficient administration of supply, storage and distribution at every point from the donor to the end-user.

(e) A donation of medicines and other health-related products is not of a promotional nature, either with regard to the company itself or insofar as it creates a demand for the products that is not sustainable once the donation has ended.

(f) WHO does not accept products at the end of their shelf life.

(g) A phase-out plan for the donation has been agreed upon with recipient countries.

(h) A system for monitoring adverse reactions to the product has been set up with the participation of the donating company.

21. In consultation with the department responsible for financial matters in WHO, the value of donations of medicines and other health-related products is determined and is formally recorded in the audited statements and the WHO register of non-State actors.

¹ Such donations shall be in line with interagency guidelines: World Health Organization, Ecumenical Pharmaceutical Network, International Pharmaceutical Federation, International Federation of Red Cross and Red Crescent Societies, International Health Partners, The Partnership for Quality Medical Donations, et al. Guidelines for medicine donations – revised 2010. Geneva: World Health Organization; 2011.

Financial contributions for clinical trials

22. Except as provided in paragraph 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;
- (b) the research is conducted at WHO's request and potential conflicts of interest are managed;
- (c) WHO only accepts such financial contributions, if the research would not take place without WHO's involvement or if WHO's involvement is necessary in order to ensure that the research is undertaken in conformity with internationally accepted technical and ethical standards and guidelines.

23. If the above-mentioned requirements are met, a financial contribution may be accepted from a company having a direct commercial interest in the trial in question, provided that appropriate mechanisms are put in place to ensure that WHO controls the conduct and the dissemination of the outcomes of the trials, including the content of any resulting publication, and that the trial results are free from any inappropriate influence or perceived influence from the company concerned.

Contributions for WHO meetings

24. For meetings convened by WHO, a contribution from a private sector entity may not be accepted if it is designated to support the participation of specific invitees (including such invitees' travel and accommodation), regardless of whether such contribution would be provided directly to the participants or channelled through WHO.

25. Contributions may be accepted to support the overall costs of a meeting.

26. WHO receptions and similar functions shall not be paid for by private sector entities.

Contributions for WHO staff participating in external meetings

27. An external meeting is one convened by a party other than WHO. Support from private sector entities for travel of WHO staff members to attend external meetings or conferences may fall into two categories:

- (a) meetings held by the private sector entity paying for travel: financing for travel may be accepted in accordance with WHO's rules if the private sector entity is also supporting the travel and ancillary expenses of other participants in the meeting, and the risk of a conflict of interest has been assessed and managed;
- (b) meetings held by a third party (i.e. a party other than the private sector entity proposing to pay for the travel): financing for travel may not be accepted from a private sector entity.

VERSION AS OF 10 JULY*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.

VERSION AS PROPOSED BY THE CHAIR ON 9 OCTOBER 2015*Contributions for publications*

28. ~~Funds~~ **Financial contributions** may be accepted from private sector entities for meeting the printing costs of WHO publications, as long as no conflict of interest arises. In no event may commercial advertisements be placed in WHO publications.

29. **DELETED**

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

[32. Individuals working for [interested] private sector entities are excluded from participating in expert groups; however, expert groups need to be able, where appropriate, to conduct hearings with such individuals in order to access their knowledge.]/**(DEL)**

ADVOCACY**VERSION AS OF 10 JULY**

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. [SUBJECT TO AGREEMENT ON SPECIFIC PARAGRAPHS IN THE FOUR SPECIFIC POLICIES]

CHAIRS PROPOSAL KEEP TEXT IN THIS POLICY ONLY

VERSION AS PROPOSED BY THE OCTOBER 2015 CONSULTATION

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

34. Private sector entities can only collaborate with WHO in advocacy for the implementation of a WHO policy norm or standard if they commit themselves to implement ~~[these norms and standards]~~/[this policy, norm or standard] in their entirety. No partial or selective implementation is acceptable. [SUBJECT TO AGREEMENT ON SPECIFIC PARAGRAPHS IN THE FOUR SPECIFIC POLICIES]

CHAIRS PROPOSAL KEEP TEXT IN THIS POLICY ONLY

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

VERSION AS OF 10 JULY

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.

OR

[Technical collaboration with the private sector is welcomed provided that it is in the interests of the Organization and managed in accordance with the framework for engagement with non-State actors.] [and [in particular] provided that the normative work of WHO is protected from any undue influence and there is no interference with WHO's advisory function to Member States.]

CHAIR PROPOSAL 36 alt: Technical collaboration with the private sector is welcomed provided that it is in the interests of the Organization and managed in accordance with this framework and in particular provided that the normative work of WHO is protected from any undue influence and there is no interference with WHO's advisory function to Member States.]

VERSION AS PROPOSED BY SEPTEMBER INFORMAL CONSULTATIONS

~~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.~~

OR

[Technical collaboration with the private sector is welcomed provided that it is in the interests of the Organization and managed in accordance with the framework for engagement with non State actors.] [and [in particular] provided that the normative work of WHO is protected from any undue influence and there is no interference with WHO's advisory function to Member States.]

CHAIR PROPOSAL 36 alt: Technical collaboration with the private sector is welcomed provided that it is in the interests of the Organization and managed in accordance with this framework and in particular provided that the normative work of WHO is protected from any undue influence and there is no interference with WHO's advisory function to Member States.]

36. Technical collaboration [ADD FOOTNOTE: as defined in overarching framework paragraph 21] with private sector entities is encouraged. This collaboration must be in the interest of WHO, and managed in accordance with this framework [and consistent with the specific policies and operational procedures outlined below] to protect WHO, and in particular, its normative work, from any undue influence and to ensure there is no interference with WHO's advisory function to member states.

NEW PROPOSAL RECEIVED FROM A MEMBER STATE ON 26 OCTOBER 2015

[36bis. Technical collaboration with private sector entities is consistent with the specific policies and operational procedures outlined below.]

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.

VERSION AS OF 10 JULY

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, [and affordable,] (DELETE) including to [the public sector] (DELETE) of low- and middle-income countries [at a preferential price] (DELETE). 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.

OR

[ALTERNATIVE LANGUAGE AT HIGHER LEVEL]

OR**[CHAIR'S PROPOSAL]**

38alt. 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 based on an agreement cleared by the Office of the Legal Counsel. Such collaboration must contribute to increasing access to quality, safe, efficacious and affordable medical products. 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.

(COMMENT TO CHAIR'S PROPOSAL ON PARAGRAPH: THE TEXT "increasing access to quality, safe, efficacious and affordable medical products" COMES FROM THE AGREED LEADERSHIP PRIORITIES OF THE 12TH GENERAL PROGRAMME OF WORK)

VERSION AS PROPOSED BY SEPTEMBER INFORMAL CONSULTATIONS

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, [and affordable,] ~~(DELETE)/(KEEP)~~ including to [the public sector] (DELETE) ~~(KEEP)~~ of [low- and middle-income countries]/[developing countries][at a preferential price] (DELETE) ~~(KEEP)~~. 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.

OR**[ALTERNATIVE LANGUAGE AT HIGHER LEVEL]**OR**[CHAIR'S PROPOSAL]**

38alt. 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 based on an agreement cleared by the Office of the Legal Counsel. Such collaboration must contribute to

increasing access to quality, safe, efficacious and affordable medical products. 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.

(COMMENT TO CHAIR'S PROPOSAL ON PARAGRAPH: THE TEXT "increasing access to quality, safe, efficacious and affordable medical products" COMES FROM THE AGREED LEADERSHIP PRIORITIES OF THE 12TH GENERAL PROGRAMME OF WORK)

DRAFT WHO POLICY AND OPERATIONAL PROCEDURES ON ENGAGEMENT WITH PHILANTHROPIC FOUNDATIONS

1. DELETED

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

PARTICIPATION

Participation by philanthropic foundations in WHO meetings²

3. WHO can invite philanthropic foundations to participate in consultations, hearings or other meetings in accordance with paragraph 16 of the overarching framework. Consultations and hearings can be electronic or in person.

4. Participation in other meetings is on the basis of discussion of an item in which the philanthropic foundation has a particular interest and where its participation adds value to the deliberations of the meeting. Such participation is for the exchange of information and views, but never for the formulation of advice.

4bis. The nature of participation of philanthropic foundations depends on the type of meeting concerned. The format, modalities, and the participation of philanthropic foundations in consultations, hearings, and other meetings is decided on a case-by-case basis by the WHO governing bodies or by the Secretariat. Participation and inputs received from philanthropic foundations shall be made publicly available, wherever possible. Philanthropic foundations do not take part in any decision making process of the Organization.

Involvement of the Secretariat in meetings organized by philanthropic foundations

5. WHO can organize joint meetings, or cosponsor meetings organized by philanthropic foundations, as long as the integrity, independence and reputation of the Organization are preserved, and as long as this participation furthers WHO's objectives as expressed in the General Programme of Work. WHO staff members may participate in meetings organized by philanthropic foundations in accordance with the Organization's internal rules. The philanthropic foundations shall not misrepresent WHO's participation as official WHO support for, or endorsement of, the meeting, and shall agree not to use WHO's participation for promotional purposes.

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.

Specific policies and operational procedures

6. The participation of WHO in meetings organized by philanthropic foundations as co-organizers, cosponsors, panellists or speakers shall be managed according to the provisions of the framework for engagement with non-State actors.

RESOURCES**VERSION AS OF 10 JULY**

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.

KEEP TEXT; ADD FOOTNOTE TO PERSONNEL: Contribution of personnel are only acceptable for short term assignments that do not involve normative work and if potential risks are managed in accordance with this framework.

VERSION AS PROPOSED BY THE CHAIR ON 9 OCTOBER 2015

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

ADVOCACY

18. WHO collaborates with philanthropic foundations on advocacy for health and increasing awareness of health issues; for changing behaviours in the interest of public health; and for fostering collaboration and greater coherence between non-State actors where joint action is required. Philanthropic foundations are encouraged to disseminate WHO's policies, guidelines, norms and standards and other tools through their networks so as to extend WHO's own reach.

TECHNICAL COLLABORATION**VERSION AS OF 10 JULY**

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.

VERSION AS PROPOSED BY SEPTEMBER INFORMAL CONSULTATIONS

~~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.~~

19. Technical collaboration [ADD FOOTNOTE: as defined in overarching framework paragraph 21] with philanthropic foundations is encouraged. This collaboration must be in the interest of WHO, and managed in accordance with this framework to protect WHO, and in particular, its normative work, from any undue influence and to ensure there is no interference with WHO's advisory function to member states.

DRAFT WHO POLICY AND OPERATIONAL PROCEDURES ON ENGAGEMENT WITH ACADEMIC INSTITUTIONS

1. DELETED

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

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 invite academic institutions to participate in consultations, hearings or other meetings in accordance with paragraph 16 of the overarching framework. Consultations and hearings can be electronic or in person.

5. Participation in other meetings is on the basis of discussion of an item in which the academic institution has a particular interest and where its participation adds value to the deliberations of the meeting. Such participation is for the exchange of information and views, but never for the formulation of advice.

5bis. The nature of participation of academic institution depends on the type of meeting concerned. The format, modalities, and the participation of academic institution in consultations, hearings, and other meetings is decided on a case-by-case basis by the WHO governing bodies or by the Secretariat. Participation and inputs received from academic institutions shall be made publicly available, wherever possible. Academic institutions do not take part in any decision making process of the Organization.

Involvement of the Secretariat in meetings organized by academic institutions

6. WHO can organize joint meetings, or cosponsor meetings organized by academic institutions, as long as the integrity, independence and reputation of the Organization are preserved, and as long as this participation furthers WHO's objectives as expressed in the General Programme of Work. WHO staff members may participate in meetings organized by academic institutions in accordance with the Organization's internal rules. The academic institution shall not misrepresent WHO's participation as official WHO support for, or endorsement of, the meeting, and shall agree not to use WHO's participation for promotional purposes.

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

Specific policies and operational procedures

7. The participation of WHO in meetings organized by academic institutions as co-organizers, cosponsors, panellists or speakers shall be managed according to the provisions of ~~the~~ **this** framework ~~for engagement with non State actors.~~

RESOURCES**VERSION AS OF 10 JULY**

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.

KEEP TEXT; ADD FOOTNOTE TO PERSONNEL: Contribution of personnel are only acceptable for short term assignments that do not involve normative work and if potential risks are managed in accordance with this framework.

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.

VERSION AS PROPOSED BY THE CHAIR ON 9 OCTOBER 2015

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

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

VERSION AS OF 10 JULY

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.

VERSION AS PROPOSED BY SEPTEMBER INFORMAL CONSULTATIONS

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

VERSION AS OF 10 JULY

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.

VERSION AS PROPOSED BY SEPTEMBER 2015 CONSULTATION

~~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.~~

18. Technical collaboration [ADD FOOTNOTE: as defined in overarching framework paragraph 21] with academic institutions is encouraged. This collaboration must be in the interest of WHO, and managed in accordance with this framework to protect WHO, and in particular, its normative work, from any undue influence and to ensure there is no interference with WHO's advisory function to member states.

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.

Ninth plenary meeting, 26 May 2015
A68/VR/9

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¹ Basic documents, 48th ed. Geneva: World Health Organization; 2014: pp.131–138