

## 53rd DIRECTING COUNCIL

### 66th SESSION OF THE REGIONAL COMMITTEE OF WHO FOR THE AMERICAS

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#### WHO's ENGAGEMENT WITH NON-STATE ACTORS (REGIONAL CONSULTATION)

##### Background

1. As part of the World Health Organization (WHO) governance reform process initiated several years ago, the WHO Executive Board mandated the WHO Secretariat to develop a framework of engagement with non-State actors.
  2. In March 2013, the WHO Secretariat conducted a public web-based consultation on draft principles and policies of engagement with non-State actors. Inputs received from this consultation informed the further development of principles, policies, and procedures related to WHO's engagement with non-State actors, including nongovernmental organizations and private sector entities. The WHO Executive Board, at its 133rd session in May 2013, requested the Secretariat (Decision EB133(2)) to advance the work proposed towards the development of a more detailed framework of engagement with non-State actors for consideration at the 134th Session of the Executive Board in January 2014.
  3. Consultations were held with Member States and non-State actors in October 2013 to further develop the framework. A revised draft was presented to the Executive Board in January 2014. Under agenda item 5 regarding WHO Reform (EB134/8), the Executive Board requested the WHO Secretariat to organize another round of consultations with Member States, which were held on 27-28 March 2014.
  4. Based on the inputs received during WHO Governing Body debates, as well as consultations held with Member States and non-State actors, the WHO Secretariat updated the draft Framework of Engagement with non-State Actors (the Framework), which contains: *a*) an overarching framework for engagement; and *b*) four separate WHO policies and operational procedures on engagement with nongovernmental organizations, private sector entities, philanthropic foundations, and academic institutions. The draft
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Framework was presented to the Sixty-seventh World Health Assembly (WHA) in May 2014 in document A67/6 (attached as Annex A).

5. After discussions and debate at the WHA, Member States, through Decision WHA67(14), requested the WHO Secretariat to prepare a comprehensive report reflecting WHA discussions, including any comment or question received from Member States by the WHO Secretariat up to 17 June 2014. The WHA also decided that regional committees should discuss this matter, with reference to both the draft Framework (document A67/6) and the report prepared by the WHO Secretariat to the regional committees (attached as Annex B).

6. Accordingly, the 154th Session of the Executive Committee of the Pan American Health Organization (PAHO) in June 2014 requested the Pan American Sanitary Bureau (the Bureau) to facilitate this consultation in the Region of the Americas. As a result, a virtual collaborative site was established for PAHO Member States to review and comment on the draft WHO Framework and the report prepared by the WHO Secretariat. PAHO Member States were requested to submit comments or questions to the Bureau through the virtual collaborative site by 1 September 2014. The comments and questions received have been compiled and summarized by the Bureau (attached as Annex C). The Bureau will provide the verbatim comments submitted by Member States upon request.

7. Additionally, in order to support the consultation process, the Bureau has invited WHO staff to attend the 53rd Directing Council of PAHO to answer questions and to comment on the documents and processes, as necessary.

#### **Action by the Directing Council**

8. Member States are requested to take note of this document and its attachments. A report on the deliberations will be submitted by the Bureau to the WHA, through the Executive Board.

Annexes

## **Framework of engagement with non-State actors**

### **Report by the Secretariat**

1. As part of WHO reform, the governing bodies have requested the Director-General to develop a framework of engagement with non-State actors and separate policies on the engagement with different groups of non-State actors.
2. Based on the inputs received in governing body debates and consultations, the Secretariat submits as annexed to this report a draft framework for engagement with non-State actors, which contains:
  - (a) an overarching framework for engagement with non-State actors, and
  - (b) four separate WHO policies and operational procedures on engagement with nongovernmental organizations, private sector entities, philanthropic foundations and academic institutions.
3. The draft overarching framework applies to all WHO's engagement with non-State actors and provides the rationale, principles and boundaries of such engagement. As a whole, the draft framework defines the different non-State actors, five categories of interactions (participation, resources, evidence, advocacy and technical collaboration), and the benefits and risks of such engagement. It further outlines both the policies and the operational procedures for WHO's transparent management of engagement with non-State actors including due diligence, risk assessment and risk management. For the oversight of engagement it is proposed to replace the current Standing Committee on Nongovernmental Organizations by a committee of the Executive Board on non-State actors, for which terms of reference are also proposed. Finally, the draft framework regulates the admission and review of entities in official relations with WHO.
4. The four separate WHO policies and operational procedures on engagement specify for each group of non-State actors the possibilities and limits of engagement for the five categories of interactions defined in the draft overarching framework. Some of these provisions are identical for all four groups of non-State actors, but others are specific to one or two groups or differ between different groups.

### **ACTION BY THE HEALTH ASSEMBLY**

5. The Health Assembly is invited to note this report and to provide guidance on the annexed draft framework of engagement.

## **DRAFT OVERARCHING FRAMEWORK FOR ENGAGEMENT WITH NON-STATE ACTORS**

### **RATIONALE**

1. Today's health landscape has become more complex in many respects, including the increase in the number of players in global health governance. Non-State actors play a major role in all aspects of global health. WHO can only fulfil its leadership role in global health and its mandate if the Organization proactively engages with Member States, other international organizations and non-State actors. Therefore WHO engages with non-State actors in the creation and protection of global public goods in order to foster the use of non-State actors' resources (including knowledge, expertise, commodities, personnel and finances) in favour of public health and to encourage non-State actors to improve their own activities to protect and promote health.

2. The functions of the World Health Organization, 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.<sup>1</sup> WHO shall, in relation to non-State actors, act in conformity with its Constitution and any relevant resolutions of the World Health Assembly as well as those of the United Nations General Assembly or the Economic and Social Council of the United Nations, if applicable.

3. The objectives of WHO's engagement with non-State actors are to promote global health as articulated in WHO's General Programme of Work and to implement the Organization's policies and recommendations that have been decided by the governing bodies as well as its technical norms and standards.

4. Such a pro-active and constructive engagement with non-State actors at global, regional and country levels, in mutual respect and trust, also calls for a number of measures of caution. In order to be able to strengthen its engagement with non-State actors for the benefit of global health and in the interest of all actors, WHO needs simultaneously to strengthen its management of the associated potential risks. This requires a robust framework for engagement that encourages and increases involvement but serves also as an instrument to identify the risks, balancing them against the expected benefits, while protecting and preserving WHO's integrity and reputation. In this way WHO will manage its engagements with non-State actors actively and transparently.

### **PRINCIPLES**

5. WHO's engagement with non-State actors is guided by five overarching principles. Any engagement should:

- (a) demonstrate a clear benefit to public health;

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<sup>1</sup> WHO Constitution, Articles 18, 33, 41 and 71.

- (b) respect the intergovernmental nature of WHO;
- (c) support and enhance the scientific and evidence-based approach that underpins WHO's work;
- (d) be actively managed so as to reduce and mitigate any form of risk to WHO (including conflicts of interest);
- (e) be conducted on the basis of transparency, openness, inclusiveness, accountability, integrity and mutual respect.

## **BOUNDARIES**

6. WHO's engagement with non-State actors is limited by four clear boundaries:
- (a) decision-making by the governing bodies is the exclusive prerogative of Member States;
  - (b) WHO's processes in setting norms and standards must be protected from any undue influence;
  - (c) WHO does not engage with industries making products that directly harm human health, including specifically the tobacco or arms industries;
  - (d) engagement with non-State actors must not compromise WHO's integrity, independence, credibility and reputation.

## **ACTORS**

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

8. **Nongovernmental organizations** are non-profit entities that operate independently of governments. They are usually membership-based, with non-profit entities or individuals as members exercising voting rights in relation to the policies of the nongovernmental organization, or are otherwise constituted with non-profit, public-interest goals. They shall be free from concerns which are primarily of a private, commercial or profit-making nature. They shall have the authority to speak for their members through their authorized representatives. They include grassroots community organizations, civil society groups and networks, faith-based organizations, professional groups, disease-specific groups, and patient groups.

9. **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 includes (but is not limited to) business associations representing commercial enterprises, entities not at "arms' length" of their commercial sponsors, and partially or fully State-owned commercial enterprises acting like private sector entities.

10. **International business associations** are entities that do not intend to make a profit for themselves but represent the interests of their members, which are private enterprises and/or national or other business associations. 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. International business associations are considered as private sector entities.

11. **Philanthropic foundations** are non-profit entities whose assets are provided by donors and whose income is spent on socially useful purposes. They shall be clearly independent from any private sector entity in their governance and decision-making. If a philanthropic foundation is clearly influenced by a private sector entity, it is considered as a private sector entity.

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

## TYPES OF INTERACTION

13. The following are categories of interaction in which WHO engages with non-State actors. Each type of interaction can take different forms, be subject to different levels of risk and can involve different levels and types of engagement by the Organization.

### Participation

14. Participation can take the form of attendance by non-State actors at meetings of WHO's governing bodies, or participation of non-State actors in other meetings organized by WHO, and involvement of WHO in meetings organized by a non-State actor. Attendance at WHO's **governing body** meetings refers to the sessions of the World Health Assembly, the Executive Board and the six regional committees, and would be in accordance with the governing bodies' respective rules of procedure, policies and practices as well as the section of this framework on official relations.

15. Participation of non-State actors in meetings organized by WHO other than those of the governing bodies can take the following forms:

(a) **Consultations** are any physical or virtual meeting other than governing body sessions for the purpose of exchanging information and views.

(b) **Hearings** 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.

(c) **Other meetings**, not part of the process of setting policies or norm, such as information meetings, briefings, scientific conferences, and platforms for coordination of actors.

16. Participation of WHO in meetings organized by a non-State actor can be either an institutional engagement of WHO as co-organizer or cosponsor of the entire meeting or a session thereof or the attendance of WHO staff members as speakers, moderators or panellists.

### Resources

17. Resources are funds, personnel or in-kind contributions. In-kind contributions include donations of medicines and other goods, free provision of services, and pro-bono work.

## Evidence

18. Evidence includes gathering and generation of information and management of knowledge and research.

## Advocacy

19. Advocacy is action to increase awareness of health issues, including issues that receive insufficient attention; to change behaviours in the interest of public health; and to foster collaboration and greater coherence between non-State actors where joint action is required.

## Technical collaboration

20. For the purpose of this framework, technical collaboration refers to other collaboration with non-State actors, as appropriate, in activities that fall within the General Programme of Work, including:

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

## BENEFITS AND RISKS OF ENGAGEMENT

21. WHO's engagement with non-State actors can bring important benefits to global public health and to WHO itself. Therefore WHO engages extensively with non-State actors in the types of engagement described in the four policies on engagement with nongovernmental organizations, with private sector entities, with philanthropic foundations and with academic institutions. Engagements range from major, longer-term collaborations to smaller, briefer interactions.

22. There can be risks in engagement with non-State actors. WHO takes a risk-management approach to engagement, entering only when the benefits of the engagement in terms of direct or indirect contributions to the fulfilment of the Organization's mandate and the public health gains clearly outweigh the risk of engagement as well as the time and expense involved in establishing and maintaining the engagement.

23. The **main risks** WHO considers when deciding on an engagement with a non-State actors are:

- WHO's engagement with a non-State actor could lead to undue or improper influence (real or perceived) being exercised by this actor on WHO's work, especially but not limited to norms and standard setting.
- WHO's engagement with a non-State actor could have a negative impact on WHO's reputation and credibility, including diminishing the value and integrity of WHO's name, emblem and work, which would in turn undermine the value of WHO's work.

- Collaboration with WHO could be misused by a non-State actor for its own benefits. The risk includes influence of WHO by a non-State actor to obtain a competitive advantage or undue endorsement; where the interaction is aiming at achieving the partner's objectives with limited benefit and/or excessive burden to the Organization; or the whitewashing of a non-State actor's image through its association with WHO.

24. **Conflict of interest** is an important area for consideration of related risk. A conflict of interest is a set of circumstances in which professional judgment or actions regarding a primary interest (WHO's work) may be unduly influenced by a secondary interest (a vested interest in the outcome of WHO's work in a given area). This secondary interest may affect or may reasonably be seen to affect the independence and objectivity of WHO's work. A conflict of interest can be individual or institutional and can be based on a commercial or financial or any other interest.

## **DUE DILIGENCE, RISK ASSESSMENT AND RISK MANAGEMENT**

25. Before engaging with any non-State actor, and in order to preserve its integrity, WHO conducts **due diligence**. This refers to the reasonable steps taken by WHO to find and verify information on a non-State actor and to reach a basic understanding of its profile.<sup>1</sup>

26. A due diligence review implies at least the following:

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

27. **Risk assessment** refers to the identification and assessment of the likely impact and the likelihood of occurrence of a risk due to a proposed engagement. Due diligence focuses on the actor; risk assessment focuses on the interaction. Due diligence and risk assessment are interlinked.

28. **Risk management** is the Secretariat's process leading to a decision on engagement, engagement with measures to mitigate risks, non-engagement or disengagement from an ongoing or planned engagement.

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<sup>1</sup> WHO's due diligences are internally conducted in order to exclude any external undue influence and are drawn from readily available information as much as possible. The unit in charge of conducting due diligence proceeds by screening different public and commercial sources of information, including: press and media (newspapers, newsletters, aggregate sources, magazine and journals); companies' analyst reports, directories and profiles; and public and governmental sources (governmental registers, charity commissions, registers of trade and industry). Except for the mention of an engagement in the WHO register of non-State actors, WHO's assessments are not communicated publicly.



## TRANSPARENCY

29. WHO's interaction with non-State actors shall be managed **transparently**. Non-State actors engaging with WHO are required to provide basic information on their organization.<sup>1</sup> WHO provides to the governing bodies annual reports on its engagement with non-State actors and makes basic information on individual engagements publicly available.

30. The WHO register of non-State actors is an internet-based, publicly available electronic tool used by the Secretariat to document engagement with non-State actors. It contains standard information provided by non-State actors and descriptions of the engagement that WHO has with these actors.<sup>2</sup>

## POLICY, NORMS AND STANDARD SETTING

31. WHO distinguishes three phases of dealing with policies approved by the governing bodies and scientific and technical norms and standards:

Phase 1: Information gathering

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

Phase 3: Implementation.

Reference to specific protection of the norms and standard setting process refers to the second phase.

## ASSOCIATION WITH WHO'S NAME AND EMBLEM

32. WHO's **name and emblem** are recognized symbols of integrity and quality assurance to the public. WHO's name, acronym and emblem shall not be used for, or in conjunction with, commercial and/or promotional purposes. This includes, but is not limited to, use for the promotion, advertisement or marketing of products or services. Any use of the name or emblem needs an explicit written authorization by the Director-General of WHO.<sup>3</sup>

## RELATION OF THE FRAMEWORK AND THE FOUR SPECIFIC POLICIES ON ENGAGEMENT

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

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<sup>1</sup> This basic information includes: name, legal status, objective, governance structure, composition of main decision-making bodies, assets, annual income and funding sources, main relevant affiliations (especially but not limited to other entities on the register), webpage and one or more focal points for WHO contacts.

<sup>2</sup> Information on financial contributions received from non-State actors are documented in this register and in the Programme budget web portal.

<sup>3</sup> See <http://www.who.int/about/licensing/emblem/en/>.

34. When other non-State actors, such as nongovernmental organizations, philanthropic foundations and academic institutions, receive funding from private sector entities, they will not automatically be considered as being themselves private sector entities, unless the level and modalities of funding are such that the non-State actor can no longer be considered as independent of the funding private sector entities. The attribution of the non-State actor to one of the four categories does not change, but relevant provisions of the private sector policy may apply, subject to an assessment of the relevant circumstances, such as the level of funding provided by the private sector entity and the nature and purpose of the engagement.

## **RELATION TO OTHER WHO POLICIES**

35. This framework replaces the Principles governing relations between the World Health Organization and nongovernmental organizations (adopted in resolution WHA40.25 in 1987) and the Guidelines on working with the private sector to achieve health outcomes (noted by the Executive Board<sup>1</sup>).

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

(a) WHO's involvement in external partnerships is regulated by the policy on WHO's engagement with global health partnerships and hosting arrangements.<sup>2</sup> For the management of risks of WHO's engagement in these partnerships the framework for engagement with non-State actors applies.

(b) The management of WHO's relations with individual experts is regulated by the Regulations for Expert Advisory Panels and Committees and the Guidelines for Declaration of Interests (WHO Experts).<sup>3</sup>

(c) Scientific collaborations are regulated by the Regulations for Study and Scientific Groups, Collaborating Institutions and other Mechanisms of Collaboration.<sup>4</sup>

(d) The procurement of goods and services is not covered by the framework for engagement with non-State actors, although pro-bono contributions from non-State actors are covered.

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

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<sup>1</sup> See document EB107/2001/REC/2 and the summary records of the Executive Board at its 107th session (document EB107/2001/REC/2).

<sup>2</sup> Endorsed by the World Health Assembly in resolution WHA63.10.

<sup>3</sup> See Basic Documents, <http://apps.who.int/gb/bd/PDF/bd47/EN/regu-for-expert-en.pdf>.

<sup>4</sup> Last amended by the Executive Board in resolution EB105R.7.

## **PROCESS OF MANAGEMENT OF ENGAGEMENT**

37. The Secretariat<sup>1</sup> distinguishes non-State actors on the basis of their nature, objectives, governance, independence and membership and not necessarily on the basis of their legal status or funding. The attribution of a non-State actor to one of the four categories can change over time. The Secretariat decides on engagement, continuation of engagement and termination of engagements with non-State actors on the basis of an explicit management decision.

38. When the Secretariat decides on an engagement with a non-State actor, the information submitted by that non-State actor in the WHO register of non-State actors is made publicly available. The content of this information is the responsibility of the non-State actor and does not constitute any form of endorsement by WHO.<sup>2</sup> Non-State actors described in the register must update their information annually or on the request of WHO.

### **Specific operational procedures for the initiation, continuation and discontinuation of engagement**

39. When a significant risk is identified, the Senior Management Committee on Engagement discusses referred proposals of engagement. It can decide on engagement, risk mitigation or non-engagement, or refer the case to the Director-General for decision.

40. Decisions on engagement, risk management or non-engagement and the documentation of engagements are facilitated through an electronic workflow system,<sup>3</sup> whereby the information provided by the non-State actor on its nature and the description of the proposed engagement is subject to due diligence and risk assessment. If the risk assessment shows there to be a clearly greater benefit than risk in the engagement, then the responsible manager can decide on the engagement. Any proposal with potentially significant risks shall be referred to the Senior Management Committee on Engagement.

41. 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”.

42. WHO maintains a handbook guiding non-State actors in their interaction with WHO and a guide for staff on the implementation of the framework for engagement with non-State actors.

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<sup>1</sup> All three levels of the Organization: global, regional and country levels, including hosted partnerships and joint programmes.

<sup>2</sup> This responsibility is clarified in a disclaimer in the WHO register of non-State actors protecting WHO from being responsible for wrong information provided by a non-State actor.

<sup>3</sup> The electronic workflow system is closely coordinated with the management of individual conflicts of interest in order to coordinate the implementation of the framework with the implementation of the policy on management of individual conflicts of interest for experts.

## **TERMS OF REFERENCE OF THE COMMITTEE ON NON-STATE ACTORS OF THE EXECUTIVE BOARD**

43. The Committee on Non-State Actors shall be composed of six members, one from each WHO region, selected from among Executive Board members during the May session of the Executive Board.

44. The Committee shall conduct its work in accordance with the applicable rules of the Rules of Procedure of the Executive Board.

45. The Committee shall review, provide guidance and, as appropriate, make recommendations to the Executive Board on:

- (a) oversight of WHO's implementation of the framework for engagement with non-State actors including:
  - (i) consideration of the annual report on engagement with non-State actors submitted by the Director-General
  - (ii) any other matter on engagement referred to the Committee by the Board
- (b) non-State actors in official relations with WHO
  - (i) proposals for admitting non-State actors into official relations
  - (ii) review of renewals of non-State actors in official relations
- (c) any proposal, when needed, for revision of the framework of engagement with non-State actors.

46. The Committee shall meet annually during the January session of the Executive Board. The Board may, however, decide to convene extraordinary meetings of the Committee in order to deal with urgent matters that fall within the terms of reference of the Committee and that need to be considered between regular meetings of the Committee.

47. Committee members shall serve for a two-year period. The selection of the Committee members shall be staggered in such way that each year three new members will be elected for two years. There shall be two office-bearers: a Chairman and a Vice-Chairman. They shall be appointed from among Committee members, each for a one-year term.

## **OFFICIAL RELATIONS**

48. **“Official relations”** is a privilege that the Executive Board may grant to nongovernmental organizations, international business associations and philanthropic foundations that have a sustained and systematic engagement<sup>1</sup> 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

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<sup>1</sup> 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.

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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.

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

50. A plan for collaboration based on mutually agreed objectives and outlining activities for the coming three-year period structured in accordance with the General Programme of Work and Programme budget shall form the basis of official relations between WHO and organizations in official relations. This plan shall also be published in the WHO register of non-State actors. These organizations shall provide annually a short report on the progress made in implementing the plan of collaboration and other related activities which will also be published in the WHO register.

51. The Executive Board shall be responsible for deciding on the admission of organizations into official relations with WHO and shall review these privileges 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.

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

- (a) the right to appoint a representative to participate, without right of vote, in meetings of WHO's governing bodies or in meetings of the committees and conferences convened under its authority;
- (b) the right to make a statement at the invitation of the Chairman of the meeting or the Chairman acceding to a request from an organization during a session of the World Health Assembly, the Executive Board or regional committee, when it discusses an item in which the related entity is particularly interested;
- (c) the right to submit the statement referred to in subparagraph (b) above in advance of the debate for the Secretariat to post on a dedicated website.

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

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

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

## **Procedure for admitting and reviewing organizations in official relations**

55. The application shall be based on the up-to-date entries in the WHO register of non-State actors, providing all the necessary information as requested on the non-State actor's nature and activities. The application shall include a summary of past collaboration as documented in the register of non-State actors and a three-year plan for collaboration with WHO that has been developed and agreed on jointly by the non-State actor and WHO.

56. A signed letter certifying the accuracy of the application submitted online shall reach WHO headquarters no later than the end of the month of July for the submission to the Executive Board 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 for admission.

57. The non-State actors and the Secretariat are expected to name focal points for the 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.

58. During the Board's January session, the Committee on Non-State Actors shall consider applications submitted and shall make recommendations to the Board. The Committee can invite the organization to speak before it in connection with its application. Should the applicant organization be considered not to meet the established criteria, and bearing in mind the desirability of ensuring a valuable continuing partnership based on defined objectives and evidenced by a record of successful past collaboration and a framework for future collaborative activities, the Committee may recommend postponement of consideration or rejection of an application.

59. The Board, after considering the recommendations of the Committee, shall decide whether an organization is to be admitted into official relations with WHO. A re-application from a non-State actor shall not normally be considered until two years have elapsed since the Board's decision on the previous application.

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

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

62. The Director-General can propose earlier reviews of official relations of a non-State actor in case of difficulties, such as non-fulfilment of its part in the plan of collaboration, lack of contact, the non-State actor failing to fulfil its reporting requirements or changes in the nature or activities of the organization, the non-State actor no longer fulfilling the criteria, or any potential new risks for the collaboration.

63. The Board may discontinue official relations if it considers that such relations are no longer appropriate or necessary in the light of changing programmes or other circumstances. Similarly, the

Board may suspend or discontinue official relations if an organization no longer meets the criteria that applied at the time of the establishment of such relations, fails to update its information and report on the collaboration in the WHO register on non-State actors or fails to fulfil its part in the agreed programme of collaboration.

## **OVERSIGHT OF ENGAGEMENT**

64. The Executive Board, through its Committee on Non-State Actors,<sup>1</sup> oversees the implementation of WHO's policy on engagement with non-State actors, proposes revisions to the framework and can grant the privileges of official relations to international nongovernmental organizations, philanthropic foundations and international business associations.

65. The **Committee on Non-State Actors** is a subcommittee of the Executive Board in accordance with Rules 16 and 16bis of the Rules of Procedure of the Executive Board. The Committee reviews the proposals for admitting or confirming the privileges of official relations of non-State actors and reviews the annual report of the Director-General on WHO's engagement with non-State actors and proposals for revisions of this framework. The Committee makes recommendations for decisions by the Executive Board.

66. The **Senior Management Committee on Engagement** is a Secretariat committee appointed by the Director-General and including representation from regional offices. This Committee decides on engagement, risk mitigation measures, non-engagement and termination of engagement in cases where significant risks could be associated with an engagement.

## **NON-COMPLIANCE WITH THIS FRAMEWORK**

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

68. Non-compliance by a non-State actor with the provisions of this framework can have consequences after a 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 privileges of official relations by the Executive Board can be expected 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 concerned non-State actor 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 for engagement with non-State actors shall be returned to the contributor.

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<sup>1</sup> See the terms of reference of the Committee on Non-State Actors of the Executive Board in paragraphs 43-47 above.

## **DRAFT WHO POLICY AND OPERATIONAL PROCEDURES ON ENGAGEMENT WITH NONGOVERNMENTAL ORGANIZATIONS**

1. Nongovernmental organizations make important contributions to global health because they often have deep roots in local communities, have special flexibilities to respond to health needs, represent affected populations and other key groups, and promote innovative solutions. Therefore WHO engages with this group of key actors in global health in order to leverage their support in the fulfilment of WHO's mandate.
2. This policy regulates specifically WHO's engagement with nongovernmental organizations by type of interaction. The generic provisions of the framework also apply to all engagements with nongovernmental organizations.

### **PARTICIPATION**

#### **Participation by nongovernmental organizations in WHO meetings<sup>1</sup>**

3. WHO can hold consultations with nongovernmental organizations in the preparation of policies. Consultations can be electronic or in person, including in the form of hearings at which nongovernmental organizations can present their views. The format of such consultations is decided on a case-by-case basis either by the governing body at the session at which a hearing or consultation is mandated or in other cases by the Secretariat.
4. WHO can invite nongovernmental organizations to participate in other WHO meetings. Such participation would be 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 outcome of the meeting. Such participation would also be for the exchange of information and views, but never for the formulation of any advice.

#### **Involvement of the Secretariat in meetings organized by nongovernmental organizations**

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

#### *Operational procedures*

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

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<sup>1</sup> Other than sessions of the governing bodies, which are regulated by the policy on management of engagement.



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## RESOURCES

7. WHO can accept funds, personnel and in-kind contributions from nongovernmental organizations as long as such contributions fall within WHO's General Programme of Work, do not create conflicts of interest, are managed in accordance with the framework, and comply with other relevant regulations, rules and policies of WHO.

8. WHO can provide resources to a nongovernmental organization for implementation of particular work in accordance with the Programme budget, the Financial Regulations and Financial Rules and other applicable rules and policies.

### *Specific policies and operational procedures*

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

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

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

12. Contributions received from nongovernmental organizations are listed in the financial report and audited financial statements of WHO as well as the Programme budget web portal and the WHO register of non-State actors.

13. Nongovernmental organizations may not use the fact that they have made a contribution in their promotional materials. 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.

### *Seconded personnel*

14. Secondments from nongovernmental organizations to WHO are acceptable, provided that:

(a) there is no conflict of interest between the person's proposed activities for WHO and his or her activities for the employer nongovernmental organization;

(b) the seconded person should be clearly informed of his or her obligations of confidentiality (both during and after the secondment); the said person should not seek or accept any instructions from, nor report to, any authority or entity external to WHO during the secondment including, specifically, the employer entity;

(c) the seconded person must follow the same rules of conduct as other staff members of WHO and will report only to WHO;

(d) failure of the seconded person to abide by WHO's standards of conduct may result in disciplinary measures and ultimately in termination of the secondment.

## **EVIDENCE**

15. Nongovernmental organizations can provide up-to-date information and knowledge on technical issues, and share their experience and engage with WHO in the generation of evidence, in knowledge management, in scientific reviews, in information gathering and in research.

## **ADVOCACY**

16. WHO collaborates on advocacy for health and increasing awareness of health issues; for changing behaviours in the interest of public health; and for fostering collaboration and greater coherence between non-State actors where joint action is required.

17. WHO favours independent monitoring functions and therefore engages with nongovernmental organizations working in this field. Nongovernmental organizations are encouraged to disseminate WHO's policies, guidelines, norms and standards and other tools through their networks so as to extend WHO's own reach.

## **TECHNICAL COLLABORATION**

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

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

1. Private sector entities are key players in global health as providers of goods and services, both within and beyond the health sector, that can have important effects on health. Therefore WHO engages with this group of key actors in global health both to improve their positive contribution and to limit their negative effects on health and also to leverage their support in the fulfilment of WHO's mandate.
2. This policy regulates specifically WHO's engagement with private sector entities by type of interaction. The generic provisions of the framework also apply to all engagements with private sector entities.

### **PARTICIPATION**

#### **Participation by private sector entities in WHO meetings<sup>1</sup>**

3. WHO can hold consultations with private sector entities in the preparation of policies. Consultations can be electronic or in person, including in the form of hearings at which private sector entities can present their views. The format of such consultations is decided on a case-by-case basis either by the governing body at the session at which a hearing or consultation is mandated or in other cases by the Secretariat.
4. WHO can invite private sector entities to participate in other WHO meetings. Such participation would be 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 outcome of the meeting. Such participation would also be for the exchange of information and views, but never for the formulation of any advice.

#### **Involvement of the Secretariat in meetings organized by private sector entities**

5. WHO staff members may participate in meetings organized by a private sector entity as long as the integrity, independence and reputation of the Organization are preserved and as long as this participation furthers WHO's objectives as expressed in the General Programme of Work. The private sector entity shall not misrepresent WHO's participation as official WHO support for, or endorsement of, the meeting, and shall agree not to use WHO's participation for commercial and/or promotional purposes.

#### *Specific policies and operational procedures*

6. The participation of WHO staff members in meetings of private sector entities as panellists, speakers or in other capacity shall be managed according to the provisions of the framework for engagement with non-State actors.
7. WHO does not cosponsor meetings organized by specific private sector entities. It may, however, cosponsor a meeting for which the scientific initiators have hired a commercial conference

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<sup>1</sup> Other than sessions of the governing bodies, which are regulated by the policy on management of engagement.

organizer to deal with the logistical aspects, provided that the commercial organizer makes no contribution to the scientific content of the meeting.

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

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

10. 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**

11. 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 the resources are used for and the modalities of the contributions.

(a) Funds may be accepted from private sector entities whose business is unrelated to that of WHO, provided they are not engaged in any activity that is incompatible with WHO's work.

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

(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.

12. Financial and in-kind contributions from private sector entities to WHO 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, 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 award the contributor with 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.

13. The Director-General can set up mechanisms for pooling contributions from multiple sources, if the mechanisms are designed in such a manner as to avoid any perceived influence from the contributors on WHO's work; if the mechanism is open to all interested contributors; and if the mechanism is subject to the conditions in paragraph 12 above and transparency is achieved through the WHO register of non-State actors and the Programme budget web portal.

*Specific policies and operational procedures*

14. 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.
15. For reasons of transparency, contributions from private sector entities must be publicly acknowledged by WHO in accordance with its policies and practices.
16. 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]".
17. 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.
18. Private sector entities may not use the results of WHO's work for commercial purposes and may not use the fact that they have made a contribution in their promotional materials. However, they may make reference to their contribution in their corporate annual reports or similar documents. In addition they may mention the contribution in transparency listing on their websites, in special non-promotional or product-related corporate responsibility pages of their website and similar publications provided that the content and context have been agreed with WHO.
19. WHO does not accept in principle secondments from private sector entities.

*Donations of medicines and other health technologies<sup>1</sup>*

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 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.
- (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 by creating a demand for the products that is not sustainable once the donation has ended.
- (f) A phase-out plan for the donation has been agreed upon with recipient countries.
- (g) A system for monitoring adverse reactions to the product has been set up with the participation of the donating company.

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

*Financial contributions for clinical trials*

22. Except as provided in paragraph 38 below on product development, financial contributions from a commercial enterprise for a clinical trial arranged by WHO on that company's proprietary product are considered on a case-by-case basis and always decided by the Senior Management Committee on Engagement. 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

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<sup>1</sup> 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.

(c) if WHO is not involved in the research, it would either not be undertaken or not be undertaken in conformity with internationally accepted technical and ethical standards and guidelines.

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

*Contributions for WHO meetings*

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

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

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

*Contributions for WHO staff participating in external meetings*

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

(a) meetings held by the private sector entity paying for travel: financing for travel may be accepted in accordance with WHO's rules if the private sector entity or trade association is also supporting the travel and ancillary expenses of other participants in the meeting, and the risk of a conflict of interest has been assessed;

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

*Contributions for publications*

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

*Contributions for financing staff salaries*

29. Funds designated to support the salary of specific staff members or posts (including short-term consultants) may not be accepted from private sector entities if they could give rise to a real or perceived conflict of interest in relation to WHO's work.

*Cost recovery*

30. In cases where a WHO evaluation scheme is in place (i.e. to evaluate certain products, processes or services against official WHO guidelines), the Organization may charge private sector entities for such services on the basis of cost recovery. The purpose of WHO's evaluation schemes is always to provide advice to governments and/or international organizations for procurement. Evaluation does not constitute endorsement by WHO of the product(s), process or service in question.

**EVIDENCE**

31. WHO can only collaborate with private sector entities in the generation of evidence, in knowledge management, in information gathering and in research when potential conflicts of interest are managed in accordance with this framework and the collaboration is transparent.

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

**ADVOCACY**

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

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

35. International business associations are encouraged to work with their members in order to improve their public health impact and the implementation of WHO policies, norms and standards.

**TECHNICAL COLLABORATION**

36. Technical collaboration with the private sector is welcomed if potential risks of engagement are managed or mitigated, provided that the normative work of WHO is protected from any undue influence and there is no interference with WHO's advisory function to Member States.

*Specific policies and operational procedures*

37. If WHO has drawn up official specifications for a product, it may provide technical advice to manufacturers for development of their product in accordance with these specifications, provided that all private sector entities known to have an interest in such a product are given the opportunity to collaborate with WHO in the same way.

*Product development*

38. WHO collaborates with private sector entities in the development of health-related technology, either by conducting research and development on their products, 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 Legal Counsel, which ensures that the final product will ultimately be made widely available and accessible, including to the public sector of low- and middle-income countries at a preferential price. If such an agreement is concluded, financing may be accepted from the private sector entity for a clinical trial arranged by WHO on the product in question, as contractual commitments obtained from the entity in the public interest outweigh any potential conflict of interest in accepting the financial contribution. These contributions should be distinguished from the acceptance of contributions for a clinical trial arranged by WHO on a proprietary product as described in paragraph 23.

## **DRAFT WHO POLICY AND OPERATIONAL PROCEDURES ON ENGAGEMENT WITH PHILANTHROPIC FOUNDATIONS**

1. Philanthropic foundations are making significant contributions to global health in general and to WHO's work in particular in many areas ranging from innovation to capacity-building to service delivery. Therefore WHO engages with this group of key actors in global health to leverage their support in the fulfilment of WHO's mandate.
2. This policy regulates specifically WHO's engagement with philanthropic foundations by type of interaction. The generic provisions of the framework also apply to all engagements with philanthropic foundations.

### **PARTICIPATION**

#### **Participation by philanthropic foundations in WHO meetings<sup>1</sup>**

3. WHO can hold consultations with philanthropic foundations in the preparation of policies. Consultations can be electronic or in person, including in the form of hearings at which philanthropic foundations can present their views. The format of such consultations is decided on a case-by-case basis either by the governing body at the session at which a hearing or consultation is mandated or in other cases by the Secretariat.
4. WHO can invite philanthropic foundations to participate in other WHO meetings. Such participation would be 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 outcome of the meeting. Such participation would also be for the exchange of information and views, but never for the formulation of any advice.

#### **Involvement of the Secretariat in meetings organized by philanthropic foundations**

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

#### *Operational procedures*

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

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<sup>1</sup> Other than sessions of the governing bodies, which are regulated by the policy on management of engagement.

## RESOURCES

7. WHO can accept funds, personnel and in-kind contributions from philanthropic foundations as long as such contributions fall within WHO's General Programme of Work, do not create conflicts of interest, are managed in accordance with the framework, and comply with other relevant regulations, rules and policies of WHO.
8. As for all contributors, philanthropic foundations shall align their contributions to the priorities set by the World 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 transparency listing on their websites, in special non-promotional pages of their website and similar publications, provided that the content and context have been agreed with WHO.

## **EVIDENCE**

17. Philanthropic foundations can provide up-to-date information and knowledge on technical issues, and share their experience and engage with WHO in the generation of evidence, in knowledge management, in scientific reviews, in information gathering and in research.

## **ADVOCACY**

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

## **TECHNICAL COLLABORATION**

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

## **DRAFT WHO POLICY AND OPERATIONAL PROCEDURES ON ENGAGEMENT WITH ACADEMIC INSTITUTIONS**

1. Academic institutions contribute to global health through education, research, clinical care and the generation, synthesis and analysis of evidence. Therefore WHO engages with this group of key actors in global health to leverage their support in the fulfilment of WHO's mandate.
2. This policy regulates specifically WHO's engagement with academic institutions by type of interaction. The generic provisions of the framework also apply to all engagements with academic institutions.
3. The engagement with academic institutions at the institutional level has to be distinguished from the collaboration with individual experts working for academic institutions.

### **PARTICIPATION**

#### **Participation by academic institutions in WHO meetings**

4. WHO can hold consultations with academic institutions in the preparation of policies. Consultations can be electronic or in person, including in the form of hearings at which academic institutions can present their views. The format of such consultations is decided on a case-by-case basis either by the governing body at the session at which a hearing or consultation is mandated or for other cases by the Secretariat.
5. WHO can invite academic institutions to participate in other WHO meetings. Such participation would be 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 outcome of the meeting. Such participation would also be for the exchange of information and views, but never for the formulation of any advice.

#### **Involvement of the Secretariat in meetings organized by academic institutions**

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

#### *Operational procedures*

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

## RESOURCES

8. WHO can accept funds, personnel and in-kind contributions from academic institutions as long as such contributions fall within WHO's General Programme of Work, do not create conflicts of interest, are managed in accordance with the framework, and comply with other relevant regulations, rules and policies of WHO.

9. WHO can provide resources to an academic institution for implementation of particular work (such as research, a clinical trial, laboratory work and preparation of a document) This can be either for a project of the institution which WHO considers merits support and is consistent with WHO's programme of work, or for a project organized or coordinated by WHO. The former constitutes a grant, the latter a service. Grants are normally provided on the basis of review and recommendations by a group of external experts convened by WHO. If no such review mechanism is followed, WHO's Contract Review Committee should be consulted. The provision of financial resources for a project organized or coordinated by WHO is subject to WHO's procurement rules.

### *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 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.

### *Seconded personnel*

15. Secondments from academic institutions to WHO are acceptable, provided that:

(a) there is no conflict of interest between the person's proposed activities for WHO and his or her activities for the employer academic institution;

(b) the seconded person should be clearly informed of his or her obligations of confidentiality (both during and after the secondment). The said person should not seek or accept any instructions from, nor report to, any authority or entity external to WHO during the secondment including, specifically, the employer entity;

(c) the seconded person must follow the same rules of conduct as other staff members of WHO and will report only to WHO;

(d) failure of the seconded person to abide by WHO's standards of conduct may result in disciplinary measures and ultimately in termination of the secondment.

## **EVIDENCE**

16. Academic institutions can provide up-to-date information and knowledge on technical issues, and share their experience and engage with WHO in the generation of evidence, in knowledge management, in scientific reviews, in information gathering and in research.

17. 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**

18. WHO collaborates 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**

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

20. Scientific collaborations are regulated by the Regulations for Study and Scientific Groups, Collaborating Institutions and other Mechanisms of Collaboration.<sup>1</sup>

21. Academic institutions or parts thereof can be designated as WHO collaborating centres in accordance with these regulations. In this context, before granting the status of WHO collaborating centre a due diligence and risk assessment in accordance with this framework is conducted. The collaboration with these collaborating centres is regulated by the aforementioned regulations and reflected in the register of non-State actors.

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<sup>1</sup> Last amended by the Executive Board in resolution EB105.R7 in January 2000.

## Framework of engagement with non-State actors

### Report by the Secretariat to the regional committees

1. This report is submitted to the regional committees in response to decision WHA67(14).<sup>1</sup> It summarizes the issues raised by Member States during and after the Sixty-seventh World Health Assembly, together with requests made to the Secretariat for action or for the provision of clarifications.<sup>2</sup>

#### ISSUES RAISED BY MEMBER STATES

2. Overall, comments showed that there is convergence on the importance of engagement with non-State actors. Furthermore, some Member States have suggested that WHO's role in engaging with non-State actors should be strengthened and seen as coordination rather than engagement so as to reflect the position of the Organization as the directing and coordinating authority for health. At the same time, there is general agreement that in order for WHO to fulfil its constitutional mandate and core function, the integrity and independence of the Organization must be protected and safeguarded, and public confidence maintained.

3. The draft framework of engagement is considered to be a good basis for establishing and, where appropriate, strengthening relations with non-State actors, as long as risks and conflicts of interest are accurately described and transparently managed, and if the benefits of engagement are weighed carefully against the risks involved.

#### Conflicts of interest

4. There were several calls for a stronger approach and more information on conflict of interest. A strengthened approach will have to ensure that WHO actively manages conflicts of interest so as to avoid compromising the integrity of the Organization; and that the Organization's system for managing risks, particularly conflicts of interest, and conducting due diligence is sufficiently flexible. The framework of engagement should also clarify: (i) the distinctions between real and perceived conflicts of interest, and between individual and institutional conflicts of interest; (ii) how WHO should deal with actors not sharing the interest of the Organization or where secondary interests undermine public health; and (iii) how the Organization should distinguish between direct and indirect interests.

#### Due diligence: process and criteria

5. The importance was stressed of conducting transparent due diligence and risk assessments before entering into engagement in order to protect and preserve WHO's integrity and reputation. More clarity was requested on the process and modalities of conducting due diligence, the criteria applied, and the link between due diligence and conflict of interest.

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<sup>1</sup> See document A67/DIV./3 (available at [http://apps.who.int/gb/e\\_e\\_wha67.html#Diverse\\_documents](http://apps.who.int/gb/e_e_wha67.html#Diverse_documents)), accessed 11 July 2014).

<sup>2</sup> See the summary records of the Sixty-seventh World Health Assembly, Committee A, second meeting, section 2 and twelfth meeting, section 4 for comments made by Member States during the Health Assembly. Subsequent comments and questions from Member States are posted on the WHO reform website (available at [http://www.who.int/about/who\\_reform/non-state-actors/](http://www.who.int/about/who_reform/non-state-actors/)).



## **Financial resources from private sector entities to WHO**

6. The potential influence of funding from private sector entities on WHO's programmes and priorities was frequently stressed. At the same time, the positive experience recorded with the Pandemic Influenza Preparedness (PIP) Framework was cited and it was proposed that such pooling of funds should be used as the preferred mechanism for receiving funds from private sector entities. Specific concerns were raised concerning: earmarking of funds; the use of funds from the private sector for information gathering, meeting participation and publications; private sector entities using their engagement with WHO for promotional purposes; the channelling of private sector funds through other non-State actors to WHO; and the importance of making sure that programmes are not too dependent upon individual funders.

## **Secondments**

7. Member States questioned the seconding of non-State actors' representatives to WHO. The key concern in this regard is to protect the independence and the integrity of WHO, particularly with respect to its normative and standard-setting functions. Member States pointed out that although the draft framework states explicitly that WHO does not accept secondments from private sector entities, it proposes accepting secondments from other types of non-State actor. Some Member States proposed that WHO should not allow secondments from any non-State actors, while others only sought to exclude secondments from private sector entities, allowing secondments from other types of non-State actors as long as there are clear criteria regarding the circumstances under which WHO could accept them.

## **Applicability of provisions of private sector policy to non-private sector entities**

8. Some Member States were worried that some non-private sector entities may be influenced by private sector entities. It was suggested that nongovernmental organizations, philanthropic foundations and academic institutions not "at arm's length" from private sector entities should be also considered as private sector entities. In this regard, it has been suggested that WHO may consider adding the definition of "international business associations" as a sub-category to the "private sector entities" since WHO has stated that these associations are considered private sector entities and that the Organization has not developed a separate policy for international business associations.

9. The importance of an explicit process and criteria to determine when the provisions of private sector policy should be applied to non-private sector entities was highlighted.

## **Official relations**

10. Some Member States referred to the continuation of the official relations' policy. Relevant submissions covered, for example, the question of which organizations should be eligible for admission into official relations, with particular regard to international business associations.

11. Some Member States proposed that national and regional affiliates of non-State actors who are themselves in official relations, should not "by definition" be considered to be in official relations.

12. Some Member States questioned the following: whether academic institutions can also be admitted; and what triggers the two-year period of collaboration prior to admission that was proposed in line with the principles governing relations between WHO and nongovernmental organizations.<sup>1</sup>

## **Boundaries: entities with which WHO will not engage**

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<sup>1</sup> The text of the current principles was adopted in 1987 by the Fortieth World Health Assembly in resolution WHA40.25.

13. Although there is an agreement on excluding engagement with the tobacco and arms industries, other Member States proposed that engagement should also be excluded with, for example, the alcohol and food and beverages industries, and those involved in labour law violations and environmental damage.

### **Involvement of Member States in oversight and management of engagement**

14. It was suggested that the respective roles of the governing bodies and of the Secretariat should be clarified, that private sector involvement should be open to Member States' scrutiny and that Member States should be involved in due diligence. It was further proposed to increase to more than six the number of members of the Committee on non-State actors of the Executive Board, to allow Member States not members of the Executive Board to be part of the Committee, and to require the Committee to report also to the Health Assembly.

15. Some Member States proposed that Member States should be able to participate in the Senior Management Committee on Engagement.

### **Partnerships**

16. It was pointed out that it is not clear whether the framework applies also to partnerships that WHO is hosting or involved with and how conflicts of interest are managed in such partnerships. It was further suggested that WHO should learn from successful multistakeholder initiatives and public-private partnerships outside WHO.

17. Some Member States suggested that the concept of "non-State actor" could be further refined to include entities falling outside the definition, such as public-private partnerships and multistakeholder initiatives.

### **Competitive neutrality**

18. It was suggested that WHO introduces the concept of "competitive neutrality" (also known as "level playing field," "competition on equal terms") with regard to WHO's engagement with the private sector. The suggestion was designed to ensure that the Organization's interactions with entities operating in an economic market do not result in undue competitive advantages or disadvantages for the entities concerned.

### **Medicine donations**

19. It was proposed that provisions be added in order to clarify how the Organization should act in emergency situations and how it should avoid the dumping of medicines as donations. Some Member States suggested the need for objective and justifiable criteria for the selection of the countries, communities or patients to benefit from such donations.

### **Protection of WHO's name and emblem**

20. Questions were raised on the appropriate mechanism and measures that WHO is using in order to protect its name and emblem, so as to avoid any misuse for promotional purposes, in particular by private sector entities.

### **Evaluation of the framework**

21. Some Member States noted that a process for evaluation of the Framework, including with regard to due diligence and risk assessment, is missing from the draft policy. They suggested that the evaluation function should be embedded into the framework in order to allow for: regular review, by

the Health Assembly through the Executive Board, of the application of the framework; identification of problems, obstacles and other challenges; and the identification of lessons learnt with a view to informing future decisions on the revision of the Framework two, three or five years after its approval.

## **SPECIFIC REQUESTS FOR SECRETARIAT ACTION PRESENTED BY MEMBER STATES**

22. The Secretariat was requested to facilitate easier access to documentation related to the development of the framework of engagement. The Secretariat has therefore updated the WHO reform website so as to provide a specific webpage that gathers together details of policies that are currently in force, other policies relevant to the process and additional background information.<sup>1</sup>

23. The Secretariat was requested to provide a summary explaining how other United Nations agencies handle issues relating to conflict of interest in respect of engagement with the private sector. United Nations agencies including WHO are exchanging experiences on the management of conflicts of interest and the conduct of due diligence, risk assessment and risk management at meetings of United Nations private sector focal points. The Secretariat has initiated a study of practices in the United Nations system that will be published on the WHO reform website once completed.

24. Member States have also requested the Secretariat to:

- provide information on financing, in-kind contributions, secondments and type and level of engagement with non-State actors;
- provide a list of secondments from non-State actors to WHO, including the entity funding them;
- provide the summary of the consultations conducted by the Special Envoy;
- present a list of Public–Private Partnerships in which WHO is currently involved;
- clarify the terms of reference of the Senior Management Committee On Engagement;
- conduct a more thorough investigation and analysis of all the types of non-State actors that should be covered by the Framework of engagement.

Information on the Secretariat's response will be made available on WHO's website.

25. Member States also made specific suggestions for the Secretariat to make wording changes to the draft framework of engagement, for example, replacing the term “global public goods” by “global public health”. Some of these proposals imply substantive changes, the aims of which have been referred to above in relation to issues raised by Member States. Other proposals are of an editorial nature and will be captured in the paper to be presented to the Executive Board.

## **CLARIFICATIONS REQUESTED FROM THE SECRETARIAT**

26. Clarifications were requested on which parts of the proposed framework would constitute policy changes and which parts would confirm current policies and practices. The framework of engagement is based on existing policies and practices. The consolidation of policies and practices into one framework and four policies will strengthen its coherent application at all levels of WHO. The major proposed policy changes are set out below.

- Using four groups for classifying actors (nongovernmental organizations, private sector entities, philanthropic foundations and academic institutions) and applying a definition of

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<sup>1</sup> Available at [http://www.who.int/about/who\\_reform/non-state-actors/](http://www.who.int/about/who_reform/non-state-actors/), accessed 11 July 2014.

when a non-State actor influenced by the private sector should be considered as a private sector entity.

- Strengthening transparency by requiring non-State actors to provide information on their governance and funding. This information on the nature of actors, together with information on WHO's engagement with them, will be disclosed in the register of non-State actors.
- Strengthening oversight on engagement by Member States and by senior management (through, respectively, the Committee on Non-State Actors of the Executive Board, Senior Management Committee on Engagement).
- Strengthening the accountability of organizations in official relations, including by giving the Executive Board the possibility of discontinuing official relations prior to the review scheduled after three years.

27. Clarification was sought concerning the information that will be provided in the register of non-State actors. All non-State actors engaging with WHO will be required to provide information on: their name, legal status, objective and governance structure; the composition of their main decision-making bodies; their assets, annual income and funding sources, main relevant affiliations and webpage; and one or more focal points for WHO contacts. For each non-State actor, this information will be made publicly available in the register together with a description of all WHO's engagements with the non-State actors concerned, including information on resources received by office and programme area.

28. It was asked whether nongovernmental organizations can participate on an ad hoc basis in meetings of WHO's governing bodies and whether the procedure for admitting organizations into official relations could be complemented by an accreditation procedure. The possible use of accreditation has been considered in previous consultations without eliciting enough support from Member States.

29. An explanation was requested of the meaning of "important and intentional" in the draft framework (in the section on non-compliance). Implementation depends on the actions of the Secretariat and compliance by the non-State actors themselves. Therefore the Secretariat needs tools to take action as a consequence of non-compliance, as described in this section. As in any non-compliance mechanism, the consequences of non-compliance need to be commensurate with the degree of non-compliance in line with the principle of proportionality. For example a small delay in providing information will only require a reminder, while the refusal to provide essential information constitutes the violation of terms of a signed agreement can lead to disengagement.

30. Clarification was sought on what resources nongovernmental organizations can receive. WHO contracts with nongovernmental organizations as implementing partners in situations such as humanitarian crises in order to provide key services for the populations affected. A similar practice is followed in other situations, including the organization of conferences and workshops, and the development of training materials. These resources are provided on the basis of a contractual agreement for the performance of work or by means of stand-by agreements for emergencies

31. An explanation was requested of the meaning of the term "scientific initiator" in the draft policy and operational procedure on engagement with private sector entities. Nongovernmental organizations and in particular scientific societies often mandate private companies to organize their congresses. This practice does not exclude WHO from participation or even from co-sponsoring such congresses as long as the nongovernmental organization (the scientific initiator) has sole responsibility for the content, with the responsibility of the private sector entity limited to logistical organization.

32. Clarification was requested concerning financial contributions for participants. This provision intends to ensure that the participation at meetings for specific participants or WHO staff cannot be financed by private sector entities. The only exception is a meeting where the cost of travel and/or accommodation is paid for all speakers and other participants and where the risk assessment has concluded that there are no significant conflicts of interest for WHO in participating and accepting this support.

33. The Secretariat was asked to clarify whether the term “product development” referred to health products. Product development refers to any health-related product, such as pharmaceuticals, health technologies, but also, for example, pesticides used to impregnate bednets.

34. Clarifications were requested on what contract modalities are used for engagement and if such contracts are made public. In its engagement with non-State actors, the Secretariat uses several contractual agreements and instruments for different purposes. For some of these, the Secretariat has developed model texts which are adapted to the particular circumstances. A non-exhaustive list of examples includes the following: Agreements for the Performance of Work; Technical Services Agreement, typically concluded with academic institutions; product research and development agreements; agreements for the acceptance of donations of pharmaceuticals for the public sector in developing and emerging countries; agreements for the transfer of technology to manufacturers in developing and emerging countries; and donation agreements for the receipt of financial resources. Currently, such instruments are not made public.

#### **ACTION BY THE REGIONAL COMMITTEES**

35. The regional committees are invited to discuss this report and the draft framework contained in document A67/6 and to report on their deliberations to the Sixty-eighth World Health Assembly, through the Executive Board.

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## **Annex C**

### **FRAMEWORK OF ENGAGEMENT WITH NON-STATE ACTORS**

#### **Summary of comments submitted by PAHO Member States prepared by the Pan American Sanitary Bureau**

1. Member States expressed appreciation with the process of discussion and dialogue around the proposed Framework for WHO Engagement with non-State Actors (the Framework). Suggestion was made for additional dialogue with different stakeholders in global public health. Member States acknowledged the importance of engagement with non-State actors under clear rules, emphasizing that conflicts of interest should be minimized to safeguard WHO's integrity and independence.

2. Some Member States suggested that WHO's role in engaging with non-State actors should be strengthened and seen as coordination rather than engagement so as to reflect the position of the Organization as the directing and coordinating authority for health. Member States also signaled the need to clearly define what is understood by "global public good," and to consider the possibility that this expression should be replaced by one that more appropriately reflects the objective of the Framework, such as "global public health." Others proposed using a term other than "non-State" so that public-private partnerships are included.

#### **Issues Raised by Member States**

##### ***Evaluations***

3. It was suggested that additional analysis be conducted to determine the need for engaging non-State actors before adopting the Framework. Member States also proposed carrying out a more exhaustive evaluation on the types of non-State actors that should be included in the Framework. Member States recommended periodic reviews of the Framework, once adopted.

##### ***Boundaries***

4. Member States agreed that WHO should not engage with the tobacco and arms industry, but there were differing views on excluding other types of non-State actors, such as alcohol, food, and beverage industries, those with labor law violations, or industries that cause environmental damage. Some stressed that WHO should not engage any of these industries; while others suggested that there are opportunities to work with them in line with other WHO strategies, such as those related to the reduction of harmful use of alcohol and the prevention and control of NCDs. It was also mentioned that prohibiting all interaction with the food industry would prevent engagement with producers of dietary supplements, raw materials, food wholesalers, and companies with

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corporate social responsibility policies. Some also indicated that there could be opportunities to engage on issues like healthier workplaces.

### ***Defining Non-State Actors and Engagement***

5. Member States made several comments regarding the need to better define the criteria for determining a non-State actor's category, such as: when is a business association or philanthropic organization considered private sector, and how to categorize State academic institutions or public-private partnerships. The criteria could include analysis of the source of funds, although Member States suggested that the source of funds was not determinative. Examples could also be provided to illustrate and clarify the differences between categories, as well as the kinds of interactions permitted.

### ***Participation in WHO Meetings***

6. Concerns were raised about private sector participation at WHO meetings. Some Member States noted that WHO meetings include regulatory decisions and other deliberations in which the private sector should not participate. It was suggested that non-State actors might be able to participate in some, but not all meetings, depending on the subject matter. Some stressed that it would be inappropriate to accredit non-State actors at WHO meetings.

### ***Due Diligence, Risk Assessment and Risk Management***

7. The importance of conducting due diligence and risk assessments prior to engaging non-State actors was underscored. Clarity was sought on the criteria and parameters that will be applied and for the definition of the specific linkages between the risks of engagement and the types or forms of participation by non-State actors. Some Member States indicated that the due diligence process should be both transparent and sufficiently flexible, and the process for conducting due diligence could be more aligned to the goal of transparency. A question was raised whether to make the evaluations public.

8. There was a proposal to establish a new formula for due diligence and risk assessment in order to prohibit any engagement that could threaten WHO's integrity, as such a risk could not be overcome by any corresponding benefit.

9. More specificity was requested about which entity will be in charge of validating the due diligence and risk assessment process, as well as the role of the Executive Board. Some Member States want to be a part of the process to determine and analyze risks.

### ***Association with WHO's Name and Emblem***

10. The need for WHO to be judicious on authorizing use of its logo was noted. Member States indicated that WHO should have a system for reviewing instances in

which its name or logo will be used by another entity and clarification was sought on the consequences of improper or unauthorized use.

### ***Transparency***

11. It was suggested that the Register include the type of resource accepted: financial, human, or in-kind, and that the Secretariat regularly update the Register to delete obsolete entries. Additional transparency measures could be added, such as the inclusion of a self-disclosed interest statement. Some Member States proposed including a breakdown of all WHO financing in the Register.

12. To add confidence, Member States proposed elaborating the transparency section of the Framework to include how and by whom conflicts of interest will be identified, disclosed, managed, and reported.

### ***Relation to Other WHO Policies***

13. Clarification was sought on how the proposed Framework is coherent with the current procedures for establishing official relations and engaging non-State actors, and what the differences are between this new draft Framework and other, existing WHO policies.

### ***Involvement of Member States***

14. It was suggested that the respective roles of the Governing Bodies and of the Secretariat should be clarified, that private sector involvement should be open to Member States review, and that Member States should be involved in due diligence and risk assessment processes. It was further proposed to increase to more than six the number of members of the Committee on non-State actors of the Executive Board, to allow Member States not members of the Executive Board to be part of the Committee, and to require the Committee to report also to the Health Assembly.

15. More information was sought on the Senior Management Committee on Engagement membership. It was also proposed that Member States participate on it.

### ***Official Relations***

16. Some Member States referred to the continuation of the official relations' policy. If a new framework for "official relations" is being prepared, it was suggested that the new Framework be managed by the Committee on non-State actors of the Executive Board. The need for a clearly defined mechanism was stressed for official relations with private sector entities.

17. Clarification was sought on the criteria for establishing the period of two years of relations in order to qualify for Official Relations.



### ***International Business Associations***

18. There were several comments and questions related to a proposal to include a subcategory of private entities known as “international business associations.” Several Member States supported the proposal, but sought criteria to determine how to classify such associations. Some suggested it could be decided on a minimum percentage of private sector funding to the association. Others were against basing the criteria on the proportion of money an entity receives from the private sector; rather, in line with an assessment of the relevant issues, the process should include assessment around the nature of the organization, its relationship with the private sector funder, other potential conflicts of interest, and the nature and purpose of the engagement.

19. Some Member States indicated that this subcategory was not necessary, as any nongovernmental organization, academic institution, or philanthropic foundation should be treated as private sector if it is influenced by the private sector. The risk related to engagement with any non-State actor financed by the private sector was stressed.

### ***Secondment***

20. Member States questioned the seconding of non-State actors’ representatives to WHO. Several Member States agreed that secondments from private sector entities should be excluded, although others suggested WHO would be limiting access to critical expertise by excluding secondments from the private sector and questioned whether WHO could foresee a need to second someone from the private sector in extraordinary circumstances. Some Member States suggested that secondments from other non-State actors would be permissible if clear criteria were established. Several Member States requested information on the current practice regarding secondments and a list of the secondees.

### ***Financial Resources***

21. The potential influence of funding from private sector entities on WHO was raised. It was proposed that pooling of funds should be used as the preferred mechanism for receiving funds from private sector entities.

### ***Competitive Neutrality***

22. Some Member States would support a clear reference to WHO engagement with the private sector being undertaken on a competitively neutral basis, while others questioned how WHO could implement this, as WHO’s decisions can have an economic impact, whether positive or negative.

### ***Donations of Medicines***

23. Member States indicated that the Framework should include criteria for donations of medicines, including how WHO will select receiving countries, communities, or

patients, as well as the process to avoid conflicts of interest. In addition, Member States suggested that drug donations should respond to needs of Member States to prevent unwanted medicines or dumping of medicines.

### **Questions and Specific Requests**

24. Member States asked several questions and made various requests, including:

#### ***Questions***

- a) Which of the activities and forms of engagement proposed in Framework and its four policies and operational procedures are already currently used by WHO, and what information is available on the activities and forms of engagement with non-State actors?
- b) If an existing engagement does not meet new criteria under the Framework, how will WHO handle the transition to the new policy?
- c) Does the Framework apply when WHO is providing resources, and what type of resources can WHO provide to a nongovernmental organizations for implementation of specific work?
- d) What new information is presented in this version of the draft Framework and its four policies and operational procedures?
- e) Can the Secretariat explain how Member State comments from the Report and Regional Consultations will be incorporated into the document, and report on specific amendments to document A67/6 that have been requested?
- f) If WHO returns a contribution to a non-State actor for violations of the Framework, will it reimburse the full amount agreed upon or only unused balance?
- g) How will the Framework apply to partnerships involving or hosted by WHO?
- h) Does the term “product development” refer to public health products?

#### ***Requests***

- a) Member States requested a list of current public-private partnerships in which WHO participates.
- b) In the context of managing the process, clarification was sought on what constitutes “significant risk.”
- c) Member States request a report on the discussions of the WHA drafting group.
- d) Member States request a summary or report on how other UN agencies address conflicts of interest in their interactions with the private sector.

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