

## **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. In May 2014, the Health Assembly adopted decision WHA67(14) on the framework of engagement with non-State actors. In the decision, among other things, the Director-General was requested:
  - (a) to prepare a comprehensive report of the comments made by Member States during the Sixty-seventh World Health Assembly and the follow-up comments and questions raised, including clarification and response thereon from the Secretariat, by the end of July 2014; and
  - (b) to submit a paper to the Executive Board at its 136th session in January 2015, ensuring that Member States receive it by mid-December 2014, in order to allow them sufficient time to study the content and to be better prepared for discussion and deliberation.
3. In response to decision WHA67(14), the Secretariat prepared the comprehensive report, which was then submitted to the six regional committees for their consideration. The reports of the regional committees' discussions on the matter are submitted to the Executive Board in a separate document.<sup>1</sup>
4. The present report, which responds to the second request made above, sets out (i) the main issues raised by Member States<sup>2</sup> and (ii) the Secretariat's proposals for addressing these issues. A revised version of the draft framework of engagement with non-State actors based on the comments made is proposed in the Annex.

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<sup>1</sup> Document EB136/INF./2. Further information requested by Member States is provided on the WHO reform webpage, which is available at [http://www.who.int/about/who\\_reform/non-state-actors/en/](http://www.who.int/about/who_reform/non-state-actors/en/) (accessed 20 November 2014).

<sup>2</sup> Provided as follows: during the Health Assembly; in written comments submitted by 17 June 2014; and at the regional committees (including in preparatory meetings).

## **MAIN ISSUES RAISED BY MEMBER STATES**

### **Conflicts of interest**

5. Conflict of interest and its management were identified by all regions as the most critical aspects of the framework of engagement. There were several calls for a stronger approach or policy on conflict of interest as integral part of the framework of engagement.

### **Due diligence: process and criteria**

6. Further 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.

### **Receipt by WHO of financial resources from private sector entities**

7. Member States stressed that WHO should accept financial resources from private sector entities only if potential conflicts of interest are ruled out and if this engagement does not compromise WHO's integrity and reputation.

### **Secondments**

8. 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 actors. 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**

9. 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 subcategory of "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. 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. There was uncertainty over which organizations should be eligible for admission into official relations, with particular regard to international business associations. Some Member States proposed that national and regional affiliates of non-State actors that are themselves in official relations, should not be considered "by definition" to be in official relations.

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

11. Although there is agreement that WHO should not engage with the tobacco and arms industries, this restriction, in the view of a number of Member States, should be extended to others, including notably the alcohol, food and beverage industries.

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

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

**Partnerships**

13. It was pointed out that it is not clear whether the framework applies also to partnerships that WHO is hosting or involved with or 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 the Organization.

14. 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**

15. It was suggested that WHO should introduce the concept of "competitive neutrality" (also known as "level playing field," or "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 that are subject to market forces do not confer undue competitive advantages upon the entities concerned or place them at a competitive disadvantage.

**Medicine donations**

16. 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 disguised dumping of medicines in the form of 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**

17. It was asked whether WHO is using the appropriate mechanism and measures to ensure the protection of its name and emblem against misuse for promotional purposes, in particular by private sector entities.

### **Evaluation of the framework**

18. 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.

### **Role of academic institutions**

19. One WHO region proposed that the revised framework should better reflect the role and function of academic institutions, in particular regarding the ways in which such institutions can complement WHO's work.

### **Readability of the document**

20. Some Member States have suggested that the readability of the framework of engagement should be further improved in order to allow an easier understanding.

## **PROPOSALS BY THE SECRETARIAT FOR ADDRESSING ISSUES RAISED BY MEMBER STATES**

21. This section provides a broad overview of how the Secretariat proposes to deal with issues raised by Member States. It also provides some clarifications, particularly for those issues that do not appear to require the text of the framework to be changed.

### **Conflicts of interest**

22. The framework has been strengthened through the addition of a section on the management of institutional<sup>1</sup> conflict of interest and other risks of engagement.<sup>2</sup> Although a lack of engagement with non-State actors would create a risk to WHO's relevance and to the Organization's role as the directing and coordinating authority of international health work, any uncontrolled engagement could place WHO's integrity, impartiality and reputation at risk.

23. The new section defines conflict of interest, both in general and in the institutional context. For WHO, the most important institutional conflicts of interest arise in situations where the economic interests of private sector entities are in conflict with the Organization's interests, its independence and impartiality in setting norms and standards. This new section also includes provisions on how conflict of interest will be managed through due diligence, risk assessment, risk management and strengthened oversight by Member States.

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<sup>1</sup> The management of individual conflict of interest is not within the scope of the framework of engagement with non-State actors. The separate reform efforts in this area will, however, be closely coordinated with the implementation of the framework.

<sup>2</sup> See paragraphs 22–43 of the overarching framework.

**Due diligence: process and criteria**

24. The process and criteria of due diligence have been further specified and integrated as a part of the above-mentioned section on management of institutional conflict of interest and other risks of engagement.

**Receipt by WHO of financial resources from private sector entities**

25. In order to preserve WHO's integrity when accepting financial contributions from the private sector, the relevant rules of the policy on engagement with private sector entities are both more detailed and more restrictive than the rules for other non-State actors. In the context of the risk-management approach to due diligence and risk assessment, such engagements have to undergo the most detailed analysis and monitoring. Furthermore the Director-General can set up pooling mechanisms to protect WHO further from any undue influence of private sector entities.

**Secondments**

26. It is proposed as a new rule that WHO does not accept secondments from non-State actors.<sup>1</sup>

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

27. The provisions distinguishing private sector entities from other groupings of non-State actors can now be found in the section defining non-State actors and the section on due diligence.<sup>2</sup> Any non-State actor clearly influenced by private sector entities will be considered as a private sector entity. Thus, engagement with such entities will be circumscribed by the policy on engagement with private sector entities with its more stringent rules. If a non-State actor is clearly independent from private sector entities, but still receives funding from such entities, the individual engagement will be examined to determine if the provisions of the private sector policy should be applied. Funding from such a non-State actor would for instant not be acceptable for normative work linked to the interest of those private sector entities that provide funding to them. Evidence provided by such non-State actors would be considered as potentially influenced, while funding for, or other collaborations on, an implementation project in the area of expertise of this non-State actor could be acceptable.

**Official relations**

28. Official relations has been used as the main channel for interaction with nongovernmental organizations since the creation of WHO in 1948. In practice, however, over time WHO has had interactions with many more nongovernmental organizations than those in official relations, with the main significance of official relations for the nongovernmental organizations concerned being the privilege of attending the meetings of the Organization's governing bodies. During the informal consultations and the governing body debates on this matter, Member States have indicated their preference for keeping the system of official relations and not replacing it by another accreditation system.

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<sup>1</sup> See paragraph 46 of the overarching framework.

<sup>2</sup> See paragraphs 14 and 31 of the overarching framework.

29. In the past, the Executive Board has consistently given a broad interpretation to the term “nongovernmental organizations” and has also admitted business associations and philanthropic foundations into official relations. The draft framework for engagement proposes to increase transparency by narrowing the definition of nongovernmental organizations compared with past practice, while still allowing international business associations and philanthropic foundations to be accepted as non-State actors in official relations.

30. In the framework, most of the text regulating official relations is fundamentally similar to the Principles governing relations between the World Health Organization and nongovernmental organizations (adopted by the Health Assembly in 1987 in resolution WHA40.25). However, the implementation of the framework will involve the following changes.

- Until now official relations were the central part of the policies governing interaction, whereas in the framework they will be only one aspect. The status of non-State actors in official relations does not mean that any engagement with such entities would be accepted. Engagements other than attending governing body meetings will be subject to due diligence and management of risks similar to any other engagement with non-State actors.
- The framework applies to engagement with all non-State actors, not only the engagements with non-State actors in official relations.
- All non-State actors will have to provide information on their organization that will be published in the register of non-State actors. For non-State actors in official relations, this published information will include the joint work plan, a report on its implementation and a summary of individual engagements with this non-State actor.
- The Executive Board and its subcommittee will have more information to decide on admissions and confirmations of non-State actors in official relations. This information is newly in the public domain.
- International business associations are only admissible for official relations if they represent a business sector. Entities considered by WHO as private sector entities and which do not represent a business sector in the sense of international business associations will not qualify for admission into official relations.

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

31. Most of the provisions of the former paragraph on boundaries have been moved to the paragraph on principles.<sup>1</sup> The provisions concerning non-engagement with the tobacco and arms industries have been moved into a new paragraph on engagement with particular industries in the section on specific provisions.<sup>2</sup> For other industries affecting health or being affected by WHO’s norms and standards, no simple total exclusion from any engagement is proposed, but WHO should apply particular caution when engaging with them.

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<sup>1</sup> See paragraph 6 of the overarching framework.

<sup>2</sup> See paragraph 44 of the overarching framework.

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

32. The oversight function of Member States in respect of engagement with non-State actors will be significantly strengthened. The version of the framework considered by the Sixty-seventh World Health Assembly<sup>1</sup> set out the functions for a Committee on Non-State Actors of the Executive Board. It is now proposed that these should be performed by the Board's Programme, Budget and Administration Committee. The annual report on engagement of the Director-General to the Executive Board through the Programme, Budget and Administration Committee will allow the governing bodies to provide guidance on the interpretation and implementation of the framework of engagement. The register of non-State actors will give transparency on all the non-State actors with which WHO engages, and on the individual engagements, and will also allow the governing bodies to request clarification if there are inconsistencies in the implementation of the framework.

## **Partnerships**

33. The framework will apply throughout the Organization, for headquarters, regional offices, country offices, hosted partnerships and entities set up under WHO (e.g. IARC). On the other hand, when WHO engages in a partnership that it does not host, this engagement will follow the policy on WHO's engagement with global health partnerships and hosting arrangements and be managed in accordance with the framework of engagement, meaning that WHO's engagement is subject to an explicit management decision based on due diligence and risk assessment. In support of increased transparency, all partnerships and other collaborative arrangements in which WHO is currently involved will soon be listed on the WHO website.

## **Competitive neutrality**

34. Even if there are no conflicts of interest or other risks in engagement, WHO should not provide a competitive advantage to one private sector entity over another. To make this explicit a clause on competitive neutrality has been added.<sup>2</sup>

## **Medicine donations**

35. The paragraph on donations of medicines and other health technologies has been amended to clarify flexibilities necessary in emergencies and assure that producers cannot discharge products at the end of their shelf life through donations.<sup>3</sup>

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

36. WHO has always been very cautious in allowing the use of its name and emblem. The framework does not change the policy on the protection of WHO's name and emblem; however, application of the framework should enable the policy to be implemented more consistently throughout the Organization.

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<sup>1</sup> Document A67/6.

<sup>2</sup> See paragraph 3 of the private sector policy.

<sup>3</sup> See paragraph 20 of the private sector policy.

## Evaluation of the framework

37. A clause requiring regular monitoring of the implementation of the framework has been added. Furthermore the implementation of the framework should be periodically evaluated. In addition it is proposed that the resolution adopting the framework should ask for the first evaluation to be initiated after two years in order to allow a revision of the framework to be proposed to the Seventieth World Health Assembly in 2018 through the Executive Board.

## Role of academic institutions

38. The policy on engagement with academic institutions provides a framework for collaboration with such institutions, insuring that the same due diligence and transparency as for other non-State actors are applied. The policy will be applied in conjunction with the Regulations for Study and Scientific Groups, Collaborating Institutions and Other Mechanisms of Collaboration,<sup>1</sup> which provides to WHO additional possibilities for enhanced collaboration with academic institutions, such as the designation of WHO collaborating centres.

## Readability of the document

39. In order to improve the readability of the document, the structure of the overarching framework has been slightly adjusted to provide the following main sections:

- **Introduction**, describing the relation of the overarching framework and the four separate policies
- **Rationale, principles, benefits and risks of engagement**
- **Non-state actors**, defining nongovernmental organizations, private sector entities, philanthropic foundations and academic institutions, as well as the limit between private sector entities and other non-State actors
- **Types of interaction**, describing the five types of interaction: participation, resources, evidence, advocacy and technical cooperation
- **Management of conflict of interest and other risks of engagement**, defining conflict of interest and describing the transparent process of management of engagement involving due diligence, risk assessment and risk management
- **Specific provisions** on engagement with particular industries, association with WHO's name and emblem and secondments
- **Relation of the framework to WHO's other policies**
- **Official relations**
- **Oversight of engagement**

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<sup>1</sup> Basic documents, 47th ed. Geneva: World Health Organization; 2009.

- **Non-compliance with the framework**
- **Monitoring and evaluation of the framework**

Each of the four specific policies on WHO engagement – namely, those on engagement with nongovernmental organizations, private sector entities, philanthropic foundations and academic institutions – contains an introduction followed by provisions on participation, resources, evidence, advocacy and technical collaboration.

#### **ACTION BY THE EXECUTIVE BOARD**

40. The Executive Board is invited to note this report and to provide guidance on the attached draft framework of engagement with non-State actors to be submitted to the Health Assembly.

## ANNEX

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

#### **INTRODUCTION**

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

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

##### **Rationale**

2. The health landscape has become more complex in many respects; among other things, there has been an increase in the number of players in global health governance. Non-State actors play a major role in all aspects of global health and WHO can only fulfil its leadership role in global health and its mandate if the Organization proactively engages with Member States, other international organizations and non-State actors. In support of this aim, WHO engages with non-State actors in the advancement and protection of public health in order to foster the use of non-State actors' resources (including knowledge, expertise, commodities, personnel and finances) in favour of public health and to encourage non-State actors to improve their own activities to protect and promote public health.

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

4. The objectives of WHO's engagement with non-State actors are to promote global health as articulated in WHO's General Programme of Work and to support implementation of the Organization's policies and recommendations as decided by the governing bodies, as well as the application of WHO's technical norms and standards.

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

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<sup>1</sup> Headquarters, regional offices and country offices, as well as hosted partnerships.

<sup>2</sup> WHO Constitution, Articles 18, 33, 41 and 71.

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

## **Principles**

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

- (a) demonstrate a clear benefit to public health;
- (b) respect the intergovernmental nature of WHO, where the decision-making by WHO's governing bodies is the exclusive prerogative of Member States;
- (c) support and enhance the scientific and evidence-based approach that underpins WHO's work;
- (d) protect WHO's processes in setting norms and standards from any undue influence;
- (e) avoid compromising WHO's integrity, independence, credibility and reputation;
- (f) be actively managed so as to mitigate any form of risk to WHO (including conflicts of interest);
- (g) be conducted on the basis of transparency, openness, inclusiveness, accountability, integrity and mutual respect.

## **Benefits of engagement**

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

## **Risks of engagement**

8. WHO's engagement with non-State actors can involve risks which need to be avoided or mitigated in accordance with WHO's risk management framework. Major risks relate to the occurrence of the following:

- (a) conflicts of interest;

- (b) undue or improper influence exercised by a non-State actor on WHO's work, especially in, but not limited to, normative and standard-setting activities;
- (c) a negative impact on WHO's reputation and credibility;
- (d) the collaboration being primarily used to serve the interests of the non-State actor concerned with limited benefits for WHO and public health;
- (e) the collaboration conferring an endorsement of the non-State actor's name, brand, product or activity;
- (f) the whitewashing of a non-State actor's image through an association with WHO;
- (g) a competitive advantage for a non-State actor.

## NON-STATE ACTORS

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

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

11. **Private sector entities** are commercial enterprises, that is to say businesses that are intended to make a profit for their owners. The term also refers to entities that represent, or are governed or controlled by, private sector entities. This group includes (but is not limited to) business associations representing commercial enterprises, entities not "at arms' length"<sup>1</sup> from their commercial sponsors, and partially or fully State-owned commercial enterprises acting like private sector entities.

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

12. **Philanthropic foundations** are non-profit entities whose assets are provided by donors and whose income is spent on socially useful purposes. They shall be clearly independent from any private sector entity in their governance and decision-making.

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

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

14. For each of the four groups of entities above, the overarching framework and the respective specific policy on engagement apply. WHO will determine through its due diligence if a non-State actor is subject to the influence of private sector entities such that the non-State actor has to be considered itself a private sector entity. If the decision-making processes of a non-State actor remain independent of the private sector influence, WHO can decide to consider the entity as a nongovernmental organization, a philanthropic foundation or an academic institution, but may apply relevant provisions of the private sector policy, such as not accepting funding for normative work.

## TYPES OF INTERACTION

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

### Participation

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

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

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

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

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

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

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

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

### **Resources**

18. Resources can be funds, personnel or in-kind contributions. In-kind contributions include donations of medicines and other goods and free provision of services.

### **Evidence**

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

### **Advocacy**

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

### **Technical collaboration**

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

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

## **MANAGEMENT OF CONFLICT OF INTEREST AND OTHER RISKS OF ENGAGEMENT**

22. Managing conflict of interest and other risks of engagement requires a series of steps, as set out below.<sup>1</sup>

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<sup>1</sup> The framework is designed to regulate institutional engagements; its implementation is closely coordinated with the implementation of other organizational policies regulating conflict of interest in respect of individuals (see paragraph 48).

- WHO needs to know the non-State actors that it engages with. Therefore each non-State actor is required to provide information about itself and its activities, following which WHO conducts the necessary due diligence.
- WHO conducts a risk assessment in order to identify the specific risks of engagement associated with each engagement with a non-State actor.
- Risks of engagement need to be managed and communicated coherently throughout the Organization. To that end, WHO manages engagement through a single, Organization-wide electronic tool.<sup>1</sup>
- Member States need to exercise oversight over WHO's engagement with non-State actors. With this in mind, the Director-General reports on engagement involving non-State actors to the Executive Board through the Programme, Budget and Administration Committee and makes all engagements publicly known through the register of non-State actors.

### Conflict of interest

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

24. All institutions have multiple interests, which means that in engaging with non-State actors WHO is often faced with a combination of converging and conflicting interests. An **institutional conflict of interest** is a situation where WHO's primary interest may be influenced by the conflicting interest of a non-State actor in a way that affects, or may reasonably be perceived to affect, the independence and objectivity of WHO's work.

25. In actively managing institutional conflict of interest and the other risks of engagement mentioned in paragraph 8 above, WHO aims to avoid allowing the conflicting interests of a non-State actor to exert undue influence over the Organization's decision-making process or to prevail over its interests.

26. For WHO the **most important institutional conflicts of interest** arise in situations where the economic interests of private sector entities are in conflict with WHO's interests, especially the Organization's independence and impartiality in setting norms and standards.

### Due diligence and risk assessment

27. When the possibility of entering into an engagement is being considered, the relevant technical unit in the Secretariat conducts an initial examination in order to establish whether such an engagement would be in the interest of the Organization and in line with the priorities defined in the

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<sup>1</sup> WHO uses an electronic tool for managing engagement. The publicly visible part of the tool is the register of non-State actors; the tool also provides an electronic workflow for the internal management of engagement. A similar electronic tool is used for the management of individual conflicts of interest in order to harmonize the implementation of the framework with the implementation of the policy on management of individual conflicts of interest for experts.

General Programme of Work and Programme budget. If this seems to be the case, the technical unit asks the non-State actor to provide its basic information. Using the Organization-wide electronic tool, the unit then complements this information with a description of the proposed engagement and its own assessment of the benefits and risks involved. This information is then transmitted to a specialized central unit which is responsible for analysing the information provided.

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

29. **Due diligence** combines a review of the information provided by the non-State actor, a search for information about the entity concerned from other sources, and an analysis of all the information obtained. This includes a screening of different public and commercial sources of information, including: media; companies' analyst reports, directories and profiles; and public and governmental sources (governmental registers, charity commissions, registers of trade and industry).

30. The principal functions of due diligence are to:

- clarify the interest of the entity in engaging with WHO and what they expect in return;
- determine the entity's status, area of activities, governance, sources of funding, constitution, statutes, and by-laws and affiliation;
- define the main elements of the history and activities of the entity in terms of the following: human and labour issues; environmental, ethical and business issues; reputation and image; and financial stability;
- identify "red lines" such as: activities that are incompatible with WHO's work and mandate (e.g. links to the tobacco and arms industries) or that require the Organization to exercise particular caution when engaging with the entity (e.g. links to other industries affecting human health or affected by WHO's norms and standards).<sup>1</sup>

31. Due diligence also allows the Secretariat for the purpose of its engagement to categorize each non-State actor in relation to one of the four groups of non-State actors on the basis of its nature, objectives, governance, funding, independence and membership. This categorization is indicated in the register of non-State actors.

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

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<sup>1</sup> As described in paragraph 44.

## Risk management

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

34. The unit responsible for performing due diligence and risk assessment formulates recommendations on the engagement-related options listed in paragraph 33 above. If the proposing unit agrees with the recommendations it implements them. If there are disagreements they can be referred to the engagement coordination group.

35. The **engagement coordination group** is a Secretariat group appointed by the Director-General that includes representation from regional offices. When a significant risk is identified, the engagement coordination group reviews referred proposals of engagement and recommends engagement, risk mitigation measures, disengagement, non-engagement and termination of engagement. In cases where the unit responsible for the engagement disagrees with this recommendation the final decision rests with the Director-General.

36. In line with WHO's risk management framework, WHO takes a risk-management approach to engagement, only entering into an engagement with a non-State actor when the benefits in terms of direct or indirect contributions to the fulfilment of the Organization's mandate and the public health gains involved clearly justify any residual risk of engagement as well as the time and expense involved in establishing and maintaining the engagement.

## Transparency

37. WHO's interaction with non-State actors is managed **transparently**. WHO provides the governing bodies with annual reports on its engagement with non-State actors and makes publicly available basic information on the non-State actors it engages with and the individual engagements concerned.

38. The **WHO register of non-State actors** is an Internet-based, publicly available electronic tool used by the Secretariat<sup>1</sup> to document and coordinate engagement with non-State actors. It contains the main standard information provided by non-State actors and high-level descriptions of the engagement that WHO has with these actors.<sup>2</sup> Non-State actors engaging with WHO are required to provide information on their organization. This information includes: name, legal status, objective, governance structure, composition of main decision-making bodies, assets, annual income and funding sources, main relevant affiliations, webpage and one or more focal points for WHO contacts.

39. When the Secretariat decides on an engagement with a non-State actor, a summary of the information submitted by that entity and held in the WHO register of non-State actors is made public.

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<sup>1</sup> The register covers all three levels of the Organization – global, regional and country – and includes hosted partnerships and joint programmes.

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

The accuracy of the information provided by the non-State actor and published in the register is the responsibility of the non-State actor concerned and does not constitute any form of endorsement by WHO.

40. Non-State actors described in the register must update the information provided on themselves annually or upon the request of WHO. Information in the WHO register of non-State actors will be dated. Information on entities that are no longer engaged with WHO or that have not updated their information will be marked as “archived”. Archived information from the WHO register of non-State actors can be considered in relation to future applications for engagement, where relevant.

41. WHO maintains a handbook to guide non-State actors in their interaction with WHO. A guide for staff is also maintained on the implementation of the framework for engagement with non-State actors; this shall be applied in conjunction with the framework.

### **Policy, norms and standard setting**

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

Type 1: Information gathering

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

Type 3: Implementation.

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

## **SPECIFIC PROVISIONS**

### **Engagement with particular industries**

44. WHO does not engage with the tobacco or arms industries. In addition, WHO will exercise particular caution when engaging with other industries affecting human health or affected by WHO’s norms and standards.

### **Association with WHO’s name and emblem**

45. WHO’s **name and emblem** are recognized by the public as symbols of integrity and quality assurance. WHO’s name, acronym and emblem shall not, therefore, be used for, or in conjunction with, commercial, promotional marketing and advertisement purposes. Any use of the name or emblem needs an explicit written authorization by the Director-General of WHO.<sup>1</sup>

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

## Secondments

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

## RELATION OF THE FRAMEWORK TO WHO'S OTHER POLICIES

47. This framework replaces the Principles Governing Relations between the World Health Organization and Nongovernmental Organizations<sup>1</sup> and the Guidelines on interaction with commercial enterprises to achieve health outcomes (noted by the Executive Board)<sup>2</sup>.

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

(a) WHO's involvement in external partnerships is regulated by the policy on WHO's engagement with global health partnerships and hosting arrangements.<sup>3</sup> For the management of risks of WHO's engagement in these partnerships the present framework for engagement with non-State actors applies.

(b) The management of WHO's relations with individual experts is regulated by the Regulations for Expert Advisory Panels and Committees<sup>4</sup> and the Guidelines for Declaration of Interests (WHO Experts).

(c) The Organization's Staff Regulations and Staff Rules and in particular the provisions of declaration of interest therein: according to Article 1.1 of the Staff Regulations of the World Health Organization, all staff members "pledge themselves to discharge their functions and to regulate their conduct with the interests of the World Health Organization only in view."

(d) Scientific collaborations are regulated by the Regulations for Study and Scientific Groups, Collaborating Institutions and other Mechanisms of Collaboration.<sup>5</sup>

(e) The procurement of goods and services is regulated by the Financial Rules and Financial Regulations;<sup>6</sup> it not covered by the framework for engagement with non-State actors, although pro-bono contributions from non-State actors are covered.

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

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<sup>1</sup> Basic documents, 47th ed. Geneva: World Health Organization; 2009: 81–86.

<sup>2</sup> See document EB107/2001/REC/2, summary record of the twelfth meeting.

<sup>3</sup> Endorsed by the Health Assembly in resolution WHA63.10 on partnerships.

<sup>4</sup> See Basic documents, 47th ed. Geneva: World Health Organization; 2009, pp 104–112 (<http://apps.who.int/gb/bd/PDF/bd47/EN/basic-documents-47-en.pdf>, accessed 1 December 2014).

<sup>5</sup> Basic documents, 47th ed. Geneva: World Health Organization; 2009, pp.113–120.

<sup>6</sup> Basic documents, 47th ed. Geneva: World Health Organization; 2009, pp.87–97.

## OFFICIAL RELATIONS

49. “**Official relations**” is a privilege that the Executive Board may grant to nongovernmental organizations, international business associations and philanthropic foundations that have had and continue to have a sustained and systematic engagement<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 relations can attend governing body meetings of WHO but are otherwise subject to the same rules as other non-State actors when engaging with WHO.

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

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

52. The Executive Board shall be responsible for deciding on the admission of organizations into official relations with WHO and shall review this status every three years. The Director-General may propose international nongovernmental organizations, philanthropic foundations and international business associations for admission. The Director-General can also propose an earlier review based on the experience in the collaboration with the organization concerned.

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

- (a) the right to appoint a representative to participate, without right of vote, in meetings of WHO’s governing bodies or in meetings of the committees and conferences convened under its authority;
- (b) the right to make a statement if the Chairman of the meeting (i) invites them to do so or (ii) accedes to their request when an item in which the related entity is particularly interested is being discussed;
- (c) the right to submit the statement referred to in subparagraph (b) above in advance of the debate for the Secretariat to post on a dedicated website.

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

54. Non-State actors participating in WHO meetings shall designate a head of their delegation and declare the affiliations of their delegates. This declaration shall include the function of each delegate

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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.

within the non-State actor itself and, where appropriate, the function of that delegate within any affiliated organization.

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

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

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

57. A signed letter certifying the accuracy of the application submitted online shall reach WHO headquarters no later than the end of the month of July for submission to the Executive Board at its session the following January. Applications for official relations shall be reviewed to ensure that the established criteria and other requirements are fulfilled as set out in this framework. Applications should be transmitted to the Executive Board members by the Secretariat six weeks before the opening of the January session of the Executive Board at which they will be considered.

58. The non-State actors in official relations and the Secretariat are expected to name focal points for collaboration who are responsible for informing each other and their organizations of any developments in the implementation of the plan for collaboration and who are the first points of contact for any changes or problems.

59. During the Board's January session, the Programme, Budget and Administration Committee shall consider applications submitted and shall make recommendations to the Board. A representative of an applicant organization may be invited by the Committee to speak before it in connection with that organization's application. Should the applicant organization be considered not to meet the established criteria, and bearing in mind the desirability of ensuring a valuable continuing partnership based on defined objectives and evidenced by a record of successful past collaboration and a framework for future collaborative activities, the Committee may recommend postponement of consideration or rejection of an application.

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

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

62. The Board, through its Programme, Budget and Administration Committee, shall review collaboration with each non-State actor every three years and shall determine the desirability of maintaining official relations or defer the decision on the review to the following year. The Board's

review shall be spread over a three-year period, one third of the non-State actors in official relations being reviewed each year.

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

64. The Board may discontinue official relations if it considers that such relations are no longer appropriate or necessary in the light of changing programmes or other circumstances. Similarly, the Board may suspend or discontinue official relations if an organization no longer meets the criteria that applied at the time of the establishment of such relations, fails to update its information and report on the collaboration in the WHO register on non-State actors or fails to fulfil its part in the agreed programme of collaboration.

## **OVERSIGHT OF ENGAGEMENT**

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

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

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

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

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

68. Non-compliance by a non-State actor with the provisions of this framework can have consequences for the entity concerned after due process including a reminder, a warning, a cease-and-desist letter, a rejection of renewal of engagement and termination of engagement. The review of the status of official relations by the Executive Board can be anticipated and non-compliance can be the reason for non-renewal of official relations. Except in the case of important and intentional cases of non-compliance the non-State actor concerned should not be automatically excluded from other engagements with WHO.

69. Any financial contribution received by WHO that is subsequently discovered to be non-compliant with the terms of this framework shall be returned to the contributor.

### **MONITORING AND EVALUATION OF THE FRAMEWORK**

70. The implementation of the framework will be constantly monitored internally through the engagement coordination group and by the Executive Board through the Programme, Budget and Administration Committee in the annual report on engagement with non-State actors and the assessment of information available in the register of non-State actors.

71. Furthermore, the implementation of the framework should be periodically evaluated. The results of such evaluation, together with any proposals for revisions of the framework, shall also be submitted to the Executive Board through the Programme, Budget and Administration Committee.

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

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

### **PARTICIPATION**

#### **Participation by nongovernmental organizations in WHO meetings<sup>2</sup>**

3. WHO can hold consultations with nongovernmental organizations in the preparation of policies. Consultations can be electronic or in person, and may take the form of hearings at which nongovernmental organizations can present their views. The format of such consultations is decided on a case-by-case basis either by the governing body at the session at which a hearing or consultation is mandated or in other cases by the Secretariat.
4. WHO can invite nongovernmental organizations to participate in other WHO meetings. Such participation is on the basis of discussion of an item in which the nongovernmental organization has a particular interest and where its participation adds value to the deliberations of the meeting. Such participation is for the exchange of information and views, but never for the formulation of advice.

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

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

#### *Operational procedures*

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

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<sup>1</sup> See paragraphs 15–21 of the overarching framework for the five types of interaction.

<sup>2</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 nongovernmental organizations as long as such contributions fall within WHO's General Programme of Work, do not create conflicts of interest, are managed in accordance with the framework, and comply with other relevant regulations, rules and policies of WHO.

8. WHO can provide resources to a nongovernmental organization for implementation of particular work in accordance with the Programme budget, the Financial Regulations and Financial Rules and other applicable rules and policies. The resources concerned can be either for a project of the institution which WHO considers merits support and is consistent with WHO's programme of work, or for a project organized or coordinated by WHO. The former constitutes a grant, the latter a service.

### Specific policies and operational procedures

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

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

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

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

13. Nongovernmental organizations may not use the fact that they have made a contribution in their materials used for commercial, promotional, marketing and advertisement purposes. However, they may make reference to the contribution in their annual reports or similar documents. In addition, they may mention the contribution on their websites, and in special non-promotional publications, provided that the content and context have been agreed with WHO.

## EVIDENCE

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

## ADVOCACY

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

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

#### **TECHNICAL COLLABORATION**

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

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

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

### **PARTICIPATION**

#### **Participation by private sector entities in WHO meetings<sup>2</sup>**

4. WHO can hold consultations with private sector entities in the preparation of policies. Consultations can be electronic or in person, and may take the form of hearings at which private sector entities can present their views. The format of such consultations is decided on a case-by-case basis either by the governing body at the session at which a hearing or consultation is mandated or in other cases by the Secretariat.
5. WHO can invite private sector entities to participate in other WHO meetings. Such participation is on the basis of discussion of an item in which the private sector entity has a particular interest and where its participation adds value to the deliberations of the meeting. Such participation is also for the exchange of information and views, but not for the formulation of advice.

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

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

#### *Specific policies and operational procedures*

7. The participation of WHO staff members in meetings of private sector entities as panellists, speakers or in any other capacity shall be managed according to the provisions of the framework for engagement with non-State actors.

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<sup>1</sup> See paragraphs 15–21 of the overarching framework for the five types of interaction.

<sup>2</sup> Other than sessions of the governing bodies, which are regulated by the policy on management of engagement.

8. WHO does not cosponsor meetings organized by specific private sector entities. It may, however, cosponsor a meeting for which the scientific initiators have hired a commercial conference organizer to deal with the logistical aspects, provided that the commercial organizer makes no contribution to the scientific content of the meeting.
9. WHO does not cosponsor meetings with one or more health-related private sector entities. Other instances of cosponsorship with private sector entities should be reviewed on a case-by-case basis and are subject to the provisions of the framework and this policy.
10. There shall be no commercial exhibitions on WHO premises and at WHO's meetings.
11. WHO does not cosponsor commercial exhibitions, whether as part of meetings organized by private sector entities or as part of meetings organized by other actors.

## RESOURCES

12. The level of risk associated with the acceptance of resources from private sector entities depends on the field of activity of the private sector entity, the WHO activity for which the resources are used and the modalities of the contributions.
  - (a) Funds may be accepted from private sector entities whose business is unrelated to that of WHO, provided they are not engaged in any activity that is incompatible with WHO's work.
  - (b) Funds may not be sought or accepted from private sector entities that have, themselves or through their affiliated companies, a direct commercial interest in the outcome of the project toward which they would be contributing, unless approved in conformity with the provisions for clinical trials or product development (see paragraph 38 below).
  - (c) Caution should be exercised in accepting financing from private sector entities that have even an indirect interest in the outcome of the project (i.e. the activity is related to the entities' field of interest, without there being a conflict as referred to above). In such an event, other commercial enterprises having a similar indirect interest should be invited to contribute, and the reason clearly described if this does not prove possible. The larger the proportion of the contribution from any one source, the greater the care that should be taken to avoid the possibility of a conflict of interest or appearance of an inappropriate association with one contributor.
13. Financial and in-kind contributions from private sector entities to WHO's programmes are only acceptable in the following conditions:
  - (a) the contribution is not used for normative work;
  - (b) if a contribution is used for activities other than normative work in which the private sector entity could have a commercial interest, the public health benefit of the engagement needs clearly to outweigh its potential risks;
  - (c) the proportion of funding of any activity coming from the private sector cannot be such that the programme's continuation would become dependent on this support;

- (d) the acceptance of the contribution does not constitute an endorsement by WHO of the private sector entity, or its activities, products or services;
- (e) the contributor may not use the results of WHO's work for commercial purposes or use the fact of its contribution in its promotional material;
- (f) the acceptance of the contribution does not afford the contributor any privilege or advantage;
- (g) the acceptance of the contribution does not offer the contributor any possibility for advising, influencing, participating in, or being in command of the management or implementation of operational activities;
- (h) WHO keeps its discretionary right to decline a contribution, without any further explanation.

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

*Specific policies and operational procedures*

15. Any acceptance of financial, personnel or in-kind contribution from private sector entities shall be managed in accordance with this framework and based on a signed agreement.
16. For reasons of transparency, contributions from private sector entities must be publicly acknowledged by WHO in accordance with its policies and practices.
17. Acknowledgements shall usually be worded along the following lines: "The World Health Organization gratefully acknowledges the financial contribution of [private sector entity] towards [description of the outcome or activity]".
18. Contributions received from private sector entities, are listed in the financial report and audited financial statements of WHO as well as the Programme budget web portal and the register of non-State actors.
19. Private sector entities may not use the results of WHO's work for commercial purposes and may not use the fact that they have made a contribution in their promotional materials. However, they may make reference to their contribution in their corporate annual reports or similar documents. In addition they may mention the contribution in a transparency listing on their websites, in special non-promotional or product-related corporate responsibility pages on their website and in similar publications provided that the content and context have been agreed with WHO.

*Donations of medicines and other health technologies<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 also preferably appear in the WHO Model List of Essential Medicines for that indication.
- (b) Objective and justifiable criteria for the selection of recipient countries, communities or patients have been determined. In emergency situations, flexibilities may be required.
- (c) A supply system is in place and consideration is given to means of preventing waste, theft and misuse (including leakage back into the market).
- (d) A training and supervision programme is in place for all personnel involved in the efficient administration of supply, storage and distribution at every point from the donor to the end-user.
- (e) A donation of medicines and other health-related products is not of a promotional nature, either with regard to the company itself or insofar as it creates a demand for the products that is not sustainable once the donation has ended.
- (f) WHO does not accept products at the end of their shelf.
- (g) A phase-out plan for the donation has been agreed upon with recipient countries.
- (h) A system for monitoring adverse reactions to the product has been set up with the participation of the donating company.

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

*Financial contributions for clinical trials*

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

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

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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.

(b) the research is conducted at WHO's request and potential conflicts of interest are managed;

(c) WHO only accepts such financial contributions, if the research would not take place without WHO's involvement or if WHO's involvement is necessary in order to ensure that the research is undertaken in conformity with internationally accepted technical and ethical standards and guidelines.

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

#### *Contributions for WHO meetings*

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

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

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

#### *Contributions for WHO staff participating in external meetings*

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

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

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

#### *Contributions for publications*

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

### *Contributions for financing staff salaries*

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

### *Cost recovery*

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

## **EVIDENCE**

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

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

## **ADVOCACY**

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

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

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

## **TECHNICAL COLLABORATION**

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

### *Specific policies and operational procedures*

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

*Product development*

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

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

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

### **PARTICIPATION**

#### **Participation by philanthropic foundations in WHO meetings<sup>2</sup>**

3. WHO can hold consultations with philanthropic foundations in the preparation of policies. Consultations can be electronic or in person, and may take the form of hearings at which philanthropic foundations can present their views. The format of such consultations is decided on a case-by-case basis either by the governing body at the session at which a hearing or consultation is mandated or in other cases by the Secretariat.
4. WHO can invite philanthropic foundations to participate in other WHO meetings. Such participation is on the basis of discussion of an item in which the philanthropic foundation has a particular interest and where its participation adds value to the deliberations of the meeting. Such participation is also for the exchange of information and views, but not for the formulation of any advice.

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

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

#### *Operational procedures*

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

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<sup>1</sup> See paragraphs 15–21 of the overarching framework for the five types of interaction.

<sup>2</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 Health Assembly in the approved Programme budget.
9. Philanthropic foundations are invited to participate in the financing dialogue, which is designed to improve the alignment, predictability, flexibility and transparency of WHO's funding and to reduce budgetary vulnerability.
10. WHO's programmes and offices should strive to ensure that they do not depend on one single source of funding.
11. The acceptance of contributions (whether in cash or in kind) should be made subject to the following conditions:
  - (a) the acceptance of a contribution does not constitute an endorsement by WHO of the philanthropic foundation;
  - (b) the acceptance of a contribution does not confer on the contributor any privilege or advantage;
  - (c) the acceptance of a contribution as such does not offer the contributor any possibility for advising, influencing, participating in, or being in command of the management or implementation of operational activities;
  - (d) WHO keeps its discretionary right to decline a contribution, without any further explanation.

### *Specific policies and operational procedures*

12. Any acceptance of resources from a philanthropic foundation is handled in accordance with the provisions of this framework and relevant other rules such as the Staff Regulations and Staff Rules, the Financial Regulations and Financial Rules and WHO's policies governing procurement.
13. For reasons of transparency, contributions from philanthropic foundations must be publicly acknowledged by WHO in accordance with its policies and practices.
14. Acknowledgements shall usually be worded along the following lines: "The World Health Organization gratefully acknowledges the financial contribution of [philanthropic foundation] towards [description of the outcome or activity]".
15. Contributions received from philanthropic foundations are listed in the financial report and audited financial statements of WHO as well as the Programme budget web portal and the WHO register of non-State actors.

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

## **EVIDENCE**

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

## **ADVOCACY**

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

## **TECHNICAL COLLABORATION**

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

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

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

### **PARTICIPATION**

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

4. WHO can hold consultations with academic institutions in the preparation of policies. Consultations can be electronic or in person, and may take the form of hearings at which academic institutions can present their views. The format of such consultations is decided on a case-by-case basis either by the governing body at the session at which a hearing or consultation is mandated or for other cases by the Secretariat.
5. WHO can invite academic institutions to participate in other WHO meetings. Such participation is on the basis of discussion of an item in which the academic institution has a particular interest and where its participation adds value to the deliberations of the meeting. Such participation is also for the exchange of information and views, but not for the formulation of any advice.

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

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

#### *Operational procedures*

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

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<sup>1</sup> See paragraphs 15–21 of the overarching framework for the five types of interaction.

## RESOURCES

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

9. WHO can provide resources to an academic institution for implementation of particular work (such as research, a clinical trial, laboratory work and preparation of a document). This can be either for a project of the institution which WHO considers merits support and is consistent with WHO's programme of work, or for a project organized or coordinated by WHO. The former constitutes a grant, the latter a service.

### *Specific policies and operational procedures*

10. Any acceptance of resources from an academic institution is handled in accordance with this framework and relevant other rules such as the Staff Regulations and Staff Rules, the Financial Regulations and Financial Rules and WHO's policies governing procurement.

11. For reasons of transparency, contributions from academic institutions must be publicly acknowledged by WHO in accordance with its policies and practices.

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

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

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

## EVIDENCE

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

16. Intellectual property arising from collaborations with academic institutions is regulated by the agreement with the academic institution. This should be addressed in consultation with the Office of the Legal Counsel.

## ADVOCACY

17. WHO collaborates with academic institutions on advocacy for health and increasing awareness of health issues; for changing behaviours in the interest of public health; and for fostering collaboration and greater coherence between non-State actors where joint action is required. WHO favours independent monitoring functions and therefore engages with academic institutions working in this field. Academic institutions are encouraged to disseminate WHO's policies, guidelines, norms and standards and other tools through their networks so as to extend WHO's own reach.

## TECHNICAL COLLABORATION

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

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

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

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<sup>1</sup> Basic documents, 47th ed. Geneva: World Health Organization; 2009, pp 113–120.