

Framework of engagement with non-State actors

Textual proposals submitted by Member States on the draft overarching framework of engagement with non-State actors and the four specific policies contained in the Annex of document EB136/5

Report by the Director-General

1. The Executive Board at its 136th session considered a report by the Secretariat on the draft framework of engagement with non-State actors.¹ The Board adopted decision EB136(3), in which it invited Member States to submit to the Director-General, by 16 February 2015, specific proposals for amendments, inclusions or deletion of text from the draft overarching framework of engagement with non-State actors and the four specific policies contained in the Annex of document EB136/5. The Board also requested the Director-General (i) to compile these proposals and to make them available to Member States by 9 March 2015; (ii) to convene an open-ended intergovernmental meeting from 30 March to 1 April 2015 with a view to discussing the textual proposals submitted by Member States; and (iii) to submit, based on the outcome of the above intergovernmental meeting, a revised version of the Framework of Engagement with non-State actors to the Sixty-eighth World Health Assembly through the Programme, Budget and Administration Committee.
2. The textual proposals, as submitted by Member States, are set out in the Annex.

¹ Document EB136/5.

ANNEX

**TEXTUAL PROPOSALS SUBMITTED BY MEMBER STATES ON THE DRAFT
OVERARCHING FRAMEWORK OF ENGAGEMENT WITH NON-STATE ACTORS
AND THE FOUR SPECIFIC POLICIES CONTAINED IN THE ANNEX OF
DOCUMENT EB136/5**

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

INTRODUCTION

Paragraph 1

The overarching framework for engagement with non-State actors and the WHO policy and operational procedures on management of engagement with non-State actors apply to all engagements with non-State actors at all levels of the Organization,¹ whereas the four specific policies and operational procedures on engagement are limited in application to, respectively, nongovernmental organizations, private sector entities, philanthropic foundations and academic institutions. **This overarching framework and four specific policies shall govern WHO's all types of engagement with non-State actors including alliance or collaboration or partnership irrespective of any existing policies. (amendments proposed by India)**

In line with the remarks in § 33 of the Report by the Secretariat (Document EB 136/5), it would be useful to expand the list of « levels of the Organization » (see also the amendment to § 22) to which the framework would apply: Headquarters, regional offices and country offices, as well as hosted partnerships and *entities set up under WHO*. These entities (for example the International Agency for Research on Cancer, etc.) could usefully be listed in parentheses for greater clarity and precision. (footnote 1, comments presented by France)

ENGAGEMENT: RATIONALE, PRINCIPLES, BENEFITS AND RISKS

Paragraph 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 many~~-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 to fulfill its constitutional mandate to act as the directing and coordinating authority for 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.~~ **(amendments proposed by India)**

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

“...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.” For the United Kingdom of Great Britain and Northern Ireland (UK) this rationale is key to understanding the need for this to be an enabling document. We therefore support this being set out here (comments presented by UK)

Paragraph 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. 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 applicable¹. (footnote proposed by China)

“... to establish and maintain effective collaboration with diverse organizations;...” This is a critical point for the UK. This provides the constitutional basis for WHO’s proactive engagement with non-State actors. (comments presented by UK)

Paragraph 4

The objectives of WHO’s engagement with non-State actors are to promote ~~global~~ **public** health as articulated in WHO’s **Constitution** and General Programme of Work and to support implementation of the Organization’s policies and recommendations **as well as technical norms and standards including guidelines** as decided by the governing bodies; ~~or, as well as the application of WHO’s technical norms and standards.~~ (amendments proposed by India)

Paragraph 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 strengthen its engagement with non-State actors, **where appropriate**, for the benefit of global public health ~~and in the interest of all actors~~, WHO needs simultaneously to strengthen its **framework for engagement to avoid, or where unavoidable appropriately managed** ~~management~~ of the associated potential risks. This requires a robust framework for engagement that **governs, encourages and increases** ~~the~~ involvement but serves also as an instrument to identify the risks, balancing them against the expected benefits, in order to ~~while protecting and preserving~~ WHO’s integrity and reputation. In this way WHO will manage its engagements with non-State actors ~~actively—effectively—and~~ transparently. (amendments proposed by India)

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 **due diligence and transparency**

¹ In particular, ECOSOC Resolution 1996/31 (amendment proposed by China)

measures ~~of caution~~ **applicable to all non-State actors**. In order to be able to strengthen its engagement with non-State actors for the benefit of global health and in the interest of all actors, WHO needs simultaneously to strengthen its **identification and** 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. **(amendments proposed by the United States of America (USA))**

Paragraph 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~~ **should not compromise** the scientific and evidence-based approach that underpins WHO's work;
- (d) protect WHO's **from any undue influence in particular the process of evidence and information gathering, in elaborating regulatory frameworks and treaties**, setting norms and standards, **as well as policy implementation** ~~from any undue influence~~;
- (e) avoid compromising WHO's integrity, independence, credibility and reputation;
- (f) ~~be actively avoid, or where unavoidable, appropriately manage both actual and perceived conflict of interest as well as to managed so as to~~ mitigate any other form of risk to WHO ~~(including conflicts of interest)~~;
- (g) be conducted on the basis of transparency, openness, ~~inclusiveness~~, accountability, integrity ~~and mutual respect~~.

(amendments proposed by India)

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.

(amendments proposed by Brazil)

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);~~ **be effectively 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.

(amendments proposed by UK)

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) conform with WHO's mandate and work program;**
- ~~(b)~~ (c) respect the intergovernmental nature of WHO, where the decision-making by WHO's governing bodies is the exclusive prerogative of Member States;
- ~~(c)~~ (d) support and enhance the scientific and evidence-based approach that underpins WHO's work;
- ~~(d)~~ (e) protect WHO's processes in setting norms and standards from any undue influence;
- ~~(e)~~ (f) avoid compromising WHO's integrity, independence, credibility and reputation;

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

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

(amendment proposed by USA)

Sub-Section title: Benefits and risks of engagement (amendment proposed by USA)

Paragraph 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.” The UK support this section setting out the benefits of engagement, which underline the importance of this framework as one that will enable positive interaction. (comments presented by UK)

Sub-Section title: Risks Management of engagement (amendments proposed by USA)

Paragraph 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, **evidence and information gathering**, normative and standard-setting activities **as well as its implementation** ;
- (c) a negative impact on WHO’s **integrity, independence,** 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

(amendments proposed by India)

WHO’s engagement with non-State actors ~~can~~ **should** involve **the management of 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 **or disadvantage** for a non-State actor

(amendments proposed by USA)

General comments presented by Member States on the Section "ENGAGEMENT: RATIONALE, PRINCIPLES, BENEFITS AND RISKS"

Norway supports the objectives laid out in relevant paragraphs (including 2 and 7) with regards empowering WHO to fulfil its leadership role in global health and to proactively engage with non-state actors. It is important to preserve the needed balance in the document between the safeguards to protect WHO against undue influence on the one hand, and the need for WHO to fulfil its leadership role and to foster the use of non-state actors' resources on the other. This is however not first and foremost a question of the paragraphs mentioned, but to preserve such a balance in the entire document. (comments presented by Norway)

NON-STATE ACTORS

Paragraph 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. **The membership, governing or advisory bodies of the NGO shall not include private sector entities, individuals working for the private sector entities, philanthropic foundations or academic institutions which are not at arms length from the private sector entities including individuals working for such academic institutions or philanthropic foundations.** They shall be free from concerns, which are primarily of a private, commercial or profit-making nature. **Private commercial or profitmaking nature is assessed not only on the basis of the document of incorporation but also from its activities, governance structure, source of finance etc. NGOs shall not receive more than 30% of their financial resources from the private sector entities, philanthropic foundations or academic institutions which are not at arms length from the private sector entities.** 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. (amendments proposed by India)

Paragraph 11

Private sector entities are commercial enterprises, that is to say businesses that are intended to make a profit for their owners. The term also refers to entities that represent, or are governed or controlled by, private sector entities. This group includes (but is not limited to) business associations representing commercial enterprises, entities not “at arms’ length”¹ from their commercial sponsors, and partially or fully State-owned commercial enterprises acting like private sector entities. **(amendments to the footnote proposed by India)**

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” from their commercial sponsors, and partially or fully State-owned commercial enterprises acting like private sector entities. **In case such commercial enterprises are fully state-owned their inclusion as private sector entities will be decided on a case-by-case evaluation. (amendment proposed by Italy)**

Private sector entities are commercial enterprises, that is to say businesses that are **usually** 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”² from their commercial sponsors,~~ and partially or fully State-owned commercial enterprises acting like private sector entities. **(amendments proposed by USA, including deletion of the footnote)**

The current French translation of “ *business associations*” by “ *associations professionnelles*” creates a difficulty, because the text is talking about organizations that, in actual fact, protect industrial, commercial or financial interests as embodied by enterprises, whereas the French term refers to a different concept (for example, a grouping of midwives, dentists or students). We therefore suggest the formulation “ *associations d’entreprises*”, in keeping with the spirit of the text. (comments presented by France)

Paragraph 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, **objectives, programs and activities. Their programs and activities shall not further the commercial interest of the donor/donors. (amendments proposed by India)**

Paragraph 13

Academic institutions are entities engaged in the pursuit and dissemination of knowledge through research, education and training **as part of an university or public funded institutions. Academic**

¹ An entity is “at arm’s length” from another entity if it does not take instructions and is ~~not~~ clearly **not** influenced in its decisions, **objectives and activities** by the other entity. **(amendments proposed by India)**

² 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. **(amendments proposed by USA, including deletion of the footnote)**

institutions established by the private sector or the presence of private sector in the administration including governing and academic bodies would be treated as private sector entities. Further if an academic institution receives more than 30 % of their total revenue from private sector entities or any funding from private sector in the area where it seeks engagement with WHO would be considered as private sector. (amendments proposed by India)

Paragraph 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. **However to ensure consistency and certainty, if in its due diligence, the non-State actor fulfills one or more of the following criteria, such an entity shall be categorized as 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~~

- **Private sector entities including international business associations; philanthropic foundations and academic institutions not at arm's length from the private sector entities, are present in the membership or governing bodies or advisory bodies of the non-State actor.**
- **More than 30% of the non-State actor's revenue or funding is from private sector entities including international business associations; philanthropic foundations and academic institutions not at arm's length with the private sector entities.**
- **The activities and publications of the non-State actor to find out whether it promotes the interest of private sector entities against public health goals.**
- **The key office bearers of the non-State actor have significant past and present connections with private sector entities.**

(amendments proposed by India)

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.~~ **The Secretariat will submit to the Executive Board a document concerning criteria applied in such evaluation.** (amendment proposed by Italy)

~~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.~~

For all non-State actors, the overarching framework and the respective specific policy on engagement apply. WHO will determine through its due diligence if a non-State actor does not meet the criteria above and take appropriate action, with opportunity for the non-State actor in question to have opportunity to both provide further information and to seek information on the WHO assessment. (amendments proposed by USA)

Finland agrees with the importance of clear criteria when the private sector policy is applied to an entity. (comments presented by Finland)

New paragraph 14 bis (proposed by USA)

Public-private partnerships between non-governmental organizations, academia, philanthropic foundations, and private sector entities can be important business models resulting in affordable and accessible innovations with significant positive impact on global public health, particularly for developing countries. WHO's engagement with public-private partnerships should not be prohibited or restricted solely on the basis of a business model which includes multiple types of non-State actors.

TYPES OF INTERACTION

Paragraph 15

The following are categories of interaction in which WHO engages with non-State actors. **Further, this Framework would also apply to WHO's any existing or future collaborations, partnership both hosted and external.** 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.

The following are categories of ~~interaction~~ **participation** in which WHO engages with non-State actors. Each type of interaction can take different forms, be subject to different levels of **benefits and** risk and can involve different levels and types of engagement by the Organization. **(amendments proposed by USA)**

Paragraph 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 or **accredited NGOs**.
- (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.~~ **Participation of non-State actors in Consultations are subject to the corresponding mandate from the Governing**

Bodies and in absence of such mandate the consultation shall be carried out on web based platform and inputs received from NSAs shall be made publicly available.

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

(xx) Meetings of Bodies for setting Norms, Standards and Policies (frameworks, strategies, plan of action, guidelines etc.): Private sector entities as well as non-State actors with links to private sector entities shall not be allowed to attend or participate in any WHO meetings including expert committee meetings or intergovernmental negotiations, involved in the formulation or setting of policies, norms, standards or guidelines.

(d) Other meetings. These are meetings that are not part of the process of setting policies or norms, **standards (frameworks, strategies, plan of action, guidelines etc.)**; examples include information meetings, briefings, scientific conferences, and platforms for coordination of actors. **Participation of non-State actors will be subject to the corresponding mandate from the governing bodies requiring such meetings, and in absence of such a mandate, applicable rules, policies and procedures of the organization.** ~~There are no limits imposed on non-State actors' participation at such meetings.~~

(amendments proposed by India)

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.~~

(amendments proposed by China)

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.~~ **The format of such consultations and the participation of non-state actors is decided on a case-by-case basis either by the governing body at the session at which it is mandated or in other cases by the Secretariat.**

(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.~~ **The format of such other meetings and the participation of non-state actors is decided on a case-by-case basis either by the governing body at the session at which it is mandated or in other cases by the Secretariat.**

(amendments proposed by Brazil)

Canada is satisfied with the Framework's current policies regarding non-State actors participation in WHO meetings. The Framework establishes fair and inclusive procedures to allow a range of non-State actors to participate in consultations, hearings, and other meetings, while reserving the right to participate in governing body meetings to non-State actors in official relations. We believe it is important that the WHO remain open to the views of all interested parties during hearings and consultations. (comments presented by Canada)

Subparagraph "(b) Consultations": some editing required.

- If the idea of consultations includes *consultations in electronic or written form*, this should be stated *explicitly* and, in fact, there is no limit to the systematic participation of non-State actors in consultations of this type.
- If it means *physical presence at meetings*, it cannot be categorically stated that: "*There are no limits imposed on non-State actors' participation at such meetings*" because there are cases, for example, in which Member States decide to meet alone, among themselves, for intermediate consultations outside meetings of the governing bodies covered by subparagraph (a). This scenario appears to be envisaged later on, and quite rightly, in the section entitled «Participation» for each of the specific policies (cf "*The format of such consultations is decided on a case-by-case basis ...*") and contradicts the general principle stated in 16 b ("*There are no limits ...*").

(comments presented by France)

Paragraph 17

Should there be an additional provision for Member State sponsored events which are co-sponsored by a non-State actor? (comments presented by UK)

Paragraph 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. **(amendments proposed by Zimbabwe, on behalf of the African group)**

Resources can be funds, ~~personnel~~ or in-kind contributions. In-kind contributions include donations of medicines and other goods and free provision of services. **(amendments proposed by India)**

We would like to receive more information what is meant by “personnel” in relation to sections on “resources”. The same caveat as for secondments should apply here: it should be limited to activities relating to implementation of policies, only. (comments presented by Finland)

The definition of resources contained in the framework (paragraph 18) states that these may be funds, personnel and in-kind contributions. In the draft WHO policy and operational procedures on engagement with the private sector, the Secretariat should exclude personnel in order to avoid any conflicts of interest. (comments presented by Mexico)

Paragraph 19

Evidence includes the gathering, analysis and generation of information, and the management of knowledge and research. **However, utmost care should be taken to ensure that gathering, analyses and generation of information and the management of knowledge and research is free from the conflict of interest. The Secretariat should always make available the evidence gathered with the cooperation of non-state actors for independent verification. (amendments proposed by India)**

Paragraph 20

We repeat that the paragraph on donations of medicines should clarify the criteria used in the selection of recipient countries, communities or patients. (comments presented by Mexico)

Paragraph 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.

(amendments proposed by India)

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

(amendments proposed by Zimbabwe, on behalf of the African group)

MANAGEMENT OF CONFLICT OF INTEREST, AND OTHER RISKS OF ENGAGEMENT

~~MANAGEMENT OF CONFLICT OF INTEREST, AND OTHER RISKS OF ENGAGEMENT~~ **(amendment proposed by India)**

Paragraph 22

Managing conflict of interest, and other risks of engagement requires a series of steps, as set out below.

- 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, **which will be audited by a group of twelve representatives of Member States (hereinafter, the Group). The Group will be composed of two representatives from each Regional Office. Each Regional Office will establish the mechanism for the selection of the representatives.**
- WHO conducts a risk assessment in order to identify the specific risks of engagement associated with each engagement with a non-State actor, **which will be audited by the Group.**
- 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.
- 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.

(option A, amendments proposed by Argentina)

Managing conflict of interest, and other risks of engagement requires a series of steps, as set out below.

- 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 and Member States, through the open-ended group**, conducts the necessary due diligence.
- **WHO and the Member States, through the open-ended group**, 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.
- 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.

(option B, amendments proposed by Argentina)

Managing conflict of interest, and other risks of engagement requires a series of steps, as set out below.

- 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~~ **Risks of engagement need to be managed and communicated coherently in each of the three levels of the Organization and throughout the Organization.** To that end, WHO manages engagement through a single, Organization-wide electronic tool.
- 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.

(amendments proposed by France)

Avoiding or if unavoidable appropriately Managing conflict of interest, and other risks of engagement requires a series of steps, as set out below.

- 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.
- 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.

(amendments proposed by India)

Managing conflict of interest, and other risks of engagement requires a series of steps, as set out below.

- 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.
- Member States need to exercise oversight over WHO's engagement with non-State actors. With this in mind, the Director-General reports on engagement involving non-State actors to the Executive Board through the Programme, Budget and Administration Committee and makes all engagements publicly known through the register of non-State actors.
- **Member State may have access upon request to the full documentation related to each engagement with non-State actors and may ask WHO for clarification on the assessment.**

(amendment proposed by Italy)

Managing conflict of interest, and other risks of engagement requires a series of steps, as set out below.

- 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 **benefit**/risk assessment in order to identify the specific risks **and benefits** 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.
- 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.

(amendment proposed by USA)

Footnote 1 *“The framework is designed to regulate institutional engagements; its implementation is closely coordinated with the implementation of other organizational policies regulating conflict of interest in respect of individuals (see paragraph 48)”* Conflicts of interest at the institutional level are usually defined as conflicts of financial interests. Thus, the draft framework overlooks the possibility of non-State actors' bias due to their nonfinancial interests – like strongly held personal or professional beliefs, declared policy positions, personal relationships (even adversarial), or the desire for individual or organizational recognition or advancement. (See, Viswanathan, Meera, et al., “Identifying and managing nonfinancial conflicts of interest for systematic reviews” (2013), at <http://www.ncbi.nlm.nih.gov/books/NBK148586/>) (comments presented by Zambia)

Footnote 2 *“WHO uses an electronic tool for managing engagement. The publicly visible part of the tool is the register of non-State actors; the tool also provides an electronic workflow for the internal management of engagement. A similar electronic tool is used for the management of individual conflicts of interest in order to harmonize the implementation of the framework with the implementation of the policy on management of individual conflicts of interest for experts.”* The Secretariat should provide an explanation regarding this footnote. What “part” is the publicly visible part of the tool? What functions does the internal management of engagement involve? (option A, comments presented by Argentina)

Paragraph 23

A conflict of interest arises in circumstances where a secondary interest (a vested interest in the outcome of WHO's ~~work~~ **constitutional mandate** 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 **constitutional mandate** ~~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 **and therefore to be avoided, or if unavoidable appropriately managed. There are three types of conflict of interest: individual conflict of interest, institutional conflict of interest and conflicting interest.** (amendments proposed by India)

The addition of the word “may” would correct an apparent drafting error, as evidenced in the last sentence of this paragraph. Undue or improper influence exercised on the WHO’s work is identified in paragraph 8(b) of the framework as one of the major risks of engagement (page 12). Conflict of interest represents a potential for, and not the occurrence of, undue influence. (comments presented by Zambia)

New paragraph 23 bis (proposed by India)

An individual conflict of interest occurs when an individual who is a consultant or expert engaged or commissioned by WHO, influences the decisions of WHO at the cost of its integrity, independence and objectivity of WHO. An individual conflict of interest also can occur in the following situations:

- (a) Where the financial interest or other interest of a consultant or expert engaged by WHO could affect the conduct of the consultant or expert’s duties and responsibilities with respect to WHO or result in a reasonable perception that such a conflict exists. The financial and other interest also includes the financial or other interest of the spouse or children or siblings of the said consultant or expert or the institutions or firms or company whom the consultant or expert associated with.**
- (b) Where the action or actions of a consultant or experts engaged by WHO compromise or undermine the trust that the public places in the WHO; and**
- (c) Where the actions of the consultant or expert create the perception that the staff is using his or her position at WHO for personal benefit or for the direct financial benefit of an Institution for whom he or she, or their spouse, children or siblings are working or worked.**

Following are a non-exhaustive list of examples

- (a) A consultant or expert or his or her spouse, children or siblings received financial resources from a vaccine company for research or for any other consultancy service and then advises WHO for the procurement of a vaccine from that company.**
- (b) A consultant or expert associated with private sector or business associations sitting in WHO expert committees or working groups or similar bodies and participating in activities like evidence gathering, developments of norms, standards, guidelines, or strategies or action plans**
- (c) A consultant or expert or his or her spouse, children or siblings having stocks or any financial interest in a private sector firm participating in WHO expert committees or working groups or similar bodies participating in activities like evidence gathering, developments of norms, standards, guidelines, or strategies or action plans.**

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) **may** 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. (amendments proposed by UK)

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) ~~may unduly influence, or may reasonably be perceived to unduly influence,~~ the independence and objectivity of professional judgment or actions regarding a primary interest (WHO's work). **Conflicts of interest are not always financial.** 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. **(amendments proposed by USA)**

No reservations on the substance but some editing is required.

- **3rd bullet point:** for greater clarity, we propose the following wording: « *Risks of engagement need to be managed and communicated coherently in each of the three levels of the Organization and throughout the Organization* » in order to bring out the *vertical* and the *horizontal* aspects of collaboration between WHO and non-State actors.
- **4th bullet point:** we wish to retain the wording *in its present version*, to make clear that the issue is one of *oversight*, i.e. overall *ex post facto* oversight, vesting in the WHO governing bodies and relying on transparency, rather than co-management and micromanagement of decisions on a case-by-case basis.

(comments presented by France)

Paragraph 24

~~All institutions have multiple interests, which means that in engaging with non-State actors WHO is often faced with a combination of converging and conflicting interests. An institutional conflict of interest is a situation where WHO's primary interest as articulated in its Constitution may be influenced or compromised by an individual or individuals acting on behalf of WHO the conflicting interest of a non-State actor in a way that affects, or may reasonably be perceived to affect, the independence, integrity and objectivity of WHO's constitutional functions and work mentioned in the General Programme of Work. The institutional conflict of interest may occur in the following situations.~~

- (a) **Where WHO staff's financial interests or other interest, could affect the conduct of his or her duties and responsibilities with respect to the WHO or result in a reasonable perception that such a conflict exists. The financial interest or other interest includes the financial interest or other interest of the Staff's spouse, children or siblings or the financial or other interest of the institution or institutions to which WHO staff has/had association with.**
- (b) **Where WHO staff's actions compromise or undermine the trust that the public places in the WHO; and**

(amendments proposed by India)

~~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.~~ **(amendments proposed by USA)**

“An institutional conflict of interest...”. We need to understand more clearly what is meant by “institutional conflict of interest”. What elements would be covered by non-institutional conflict of interest and how can these be best captured in the Framework? (comments presented by UK)

Paragraph 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. (amendment proposed by India)~~

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. (amendment proposed by USA)

Paragraph 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.~~

In addition to individual and institutional conflict of interests, of important concern are situations of conflicting interests where the commercial interests of private sector entities including international business associations or other non-State actors not at arm’s length from the private sector entities are in conflict with WHO’s constitutional mandate and affect the Organization’s independence and impartiality in evidence and information gathering, setting norms and standards and policy implementation. A conflicting interest can occur *inter alia* in the following circumstances:

- (a) Private sector entities influences or is perceived to influence WHO, in pursuance of direct or indirect commercial interest, and thereby compromising the objectivity, independence and integrity of WHO.**
- (b) The likelihood of private sector entities using its engagement with WHO to further its commercial interests.**
- (c) Potential or real conflict or divergence of objectives, interest or activities of private sector entities and the public health goals or mandate of WHO as per its Constitution, decisions or resolutions of the governing Bodies.**

Following are a non-exhaustive list of examples

- (a) Engaging in a public private partnership with food and beverages companies or their associations to set norms, standards, guidelines or strategies to address the public health concerns of NCDs.**
- (b) Participation of WHO in a public private partnership to set norms and standards for the quality, safety and efficacy of medical products.**

- (c) **Collaboration of WHO with private sector or an international business association which would further the commercial interests of the private sector entities or the members of the international business associations.**
- (d) **Accepting resources from private sector entities which are advocating policies which are detrimental to WHO's constitution, resolutions, norms and standards, guidelines, strategies or action plans.**
- (e) **An International Business Associations with a mandate to further the interest of the industry would come in conflict with the public health objectives mandated under WHO's Constitution or decisions or resolutions of Governing Bodies.**

(amendments proposed by India)

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 **promotion of public health** and the Organization's independence and impartiality in setting norms and standards.

(amendments proposed by Brazil)

~~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.~~ **(amendment proposed by USA)**

~~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.~~ **(amendment proposed by Zambia)**

Is there a strong rationale for why the private sector have been singled out here? How does it compare with the economic and other vested interests of other non-State actors, for example? **(comments presented by UK)**

This paragraph inappropriately implies that the financial conflict of interest of the private sector are somehow more important than the financial conflict of interest of other non-State actors. This, combined with the draft's narrow focus on institutional-level (ie financial) COI, creates a clear bias against the private sector -- as if only private sector conflict of interest should be carefully considered. Instead, what is needed is a clear and comprehensive definition to be consistently applied across all types of non-State actors. **(comments presented by Zambia)**

Sub-Section title: Due diligence and benefit/risk assessments (amendments proposed by USA)

Paragraph 27

When the possibility of entering into an engagement is being considered, the relevant technical ~~unit~~ **units** 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 General Programme of Work and Programme budget. If this seems to the case, ~~the technical unit~~ **the Secretariat** asks the non-State actor to provide its basic information. Using the Organization-wide electronic tool, the technical ~~unit~~ **units** then complements this information with a description of the proposed engagement and ~~its own~~ **the** 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. (option A, amendments proposed by Argentina)~~

When the possibility of entering into an engagement is being considered, ~~the relevant technical unit in the Secretariat~~ **the open-ended group of Member States, with the advice of the relevant technical units 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 General Programme of Work and Programme budget, **the overarching principles of engagement listed in paragraph 6 and the specific provision contained in paragraph 44**. If this seems to be the case, the ~~technical unit Secretariat~~ asks the non-State actor to provide its basic information. Using the Organization-wide electronic tool, the ~~unit~~ **open-ended group of Member States, with the advice of the technical units**, 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. (option B, amendments proposed by Argentina)~~

When the possibility of entering into an engagement is being considered, the relevant technical unit in the Secretariat conducts an initial examination in order to establish whether such an engagement would be in the interest of the Organization and in line with **the principles of WHO's engagement with non-State actors in paragraph 6** and priorities defined in the General Programme of Work and Programme budget. If this seems to be the case, the technical unit asks the non-State actor to provide its basic information. Using the Organization-wide electronic tool, the unit then complements this information with a description of the proposed engagement and its own assessment of the benefits and risks involved. This information is then transmitted to a specialized central unit which is responsible for analysing the information provided. **(amendment proposed by USA)**

Canada is satisfied with the measures outlined in the Framework to conduct due diligence and mitigate risks associated with conflicts of interest. However, these practices could be further refined to incorporate existing WHO structures, such as the Office of Compliance, Risk Management, and Ethics, and should be amended to protect against individual conflicts of interest. For example, paragraph 27 states that the relevant technical unit is to perform an initial assessment for engaging a non-State actor which is subsequently transmitted to a specialised central unit responsible for analysing the information provided. This responsibility could be assumed by the WHO's Office of Compliance, Risk Management, and Ethics. (comments presented by Canada)

Paragraph 28

Before engaging with any non-State actor, ~~WHO, in order to preserve its integrity, conducts~~ **technical units conduct** 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. **(option A, amendments proposed by Argentina)**

Before engaging with any non-State actor, ~~WHO, in order to preserve its integrity,~~ **the open-ended group of Member States, with the advice of the technical units**, 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. **(option B, amendments proposed by Argentina)**

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. **A benefit/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.** While due diligence refers to the nature of the non-State actor concerned, **benefit/risk** assessment refers to the assessment of a specific proposed engagement with that non-State actor. **(amendment proposed by USA)**

Paragraph 29

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

Canada believes no non-State actor should be able to directly fund the salaries of WHO staff. However, non-State actors could contribute funds to a pooled human resources fund, or contribute to a programme, then have their contributions spent as the programme area deemed appropriate. It is imperative that all funds are accepted in compliance with the Framework, and that proper policies are implemented to ensure that WHO staff are free from any obligations to donors and are able to remain unbiased in completing their work. (comments presented by Canada)

The final framework must retain the possibility for non-State actors to earmark financial contributions as appropriate, and for WHO to spend part of such contributions on staff salaries as appropriate, provided that the contributions fall within the priorities and activities reflected in any adopted programme budget and when all relevant safeguards in the framework has been applied. (comments presented by Norway)

***"... a search for information about the entity concerned from other sources, and an analysis of all the information obtained"*. For the purposes of transparency, shouldn't there be a provision here for a non-State actor to comment on the information once it has been collected? (comments presented by UK)**

Paragraph 30

The principal functions of due diligence are to:

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

- 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 **of the entity** that are incompatible with WHO’s work and mandate (e.g. links to the tobacco and arms industries) that require the Organization to exercise particular caution when engaging with the entity (e.g. links to other industries affecting human health or affected by WHO’s norms and standards).¹
- **examine whether the entity complies with the norms, standards, guideline, strategies or action plans established by WHO or whether its activities undermine any of WHO’s norms, standards, guideline, strategies or action plans established by WHO.**

(amendments proposed by India)

The ~~principal~~ **core** 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. ~~i.e.~~ 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);~~
- **identify activities of the entity that may require the Organization to consider setting more narrow parameters for the engagement, or that are affected by WHO’s norms and standards.**

(amendments proposed by USA)

On boundaries, we agree that WHO should not engage in any form with the tobacco or arms industries. We believe that there are some industries that have clear interests in health policies (such as those linked with control of NCDs) with whom WHO should use high level of restriction but where there may still be the need to engage in e.g. information sharing or advocacy. (comments presented by Finland)

“... 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)”. The use of the phrase “links to” is unhelpful in that it potentially captures a very broad spectrum of entities, some of whom may have a positive role to play in global health. We support the principle here but the language needs to be tightened. (comments presented by UK)

“.....

- *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). ”*

These could also usefully include their ultimate objectives. (comments presented by UK)

The newly-introduced functions described in the 4th bullet point are inconsistent with the specific provisions described in paragraph 44 of the framework (page 18). The term “links to” is used twice, but it is undefined and has potentially unlimited application, and draws unintended consequences that appear not to have been fully considered. Barring WHO engagement with any entity having links to the tobacco industry would, for example, bar the WHO from engaging with anyone connected to the current effort to produce Ebola and other vaccines more quickly by growing them in tobacco leaves. “Particular caution” is not defined, and would be interpreted and applied differently across the levels and departments of the WHO – eliminating the inclusiveness and predictability the framework was meant to establish. “Industries affecting human health or affected by WHO’s norms and standards” is already broad (would it include agriculture? automotive?). Applying particular caution to any entity with links to such industries means that it could be arbitrarily applied to exclude just about anyone. (Asset managers? Travel agencies?) These provisions are inconsistent with the overall framework, and would needlessly deny WHO access to appropriate input from qualified non-State actors. They must be deleted. (comments presented by Zambia, see also paragraph 44)

Paragraph 31

Due diligence also allows ~~the Secretariat for the purpose of its engagement~~ **technical units** 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. **(option A, amendments proposed by Argentina)**

Due diligence also allows ~~the Secretariat for the purpose of its engagement~~ **the open-ended group of Member States, with the advice of the technical units,** 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. **(option B, amendments proposed by Argentina)**

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. **The due diligence reports including the risk assessment report shall be made available in public domain for independent verification and scrutiny. (amendments proposed by India)**

Due diligence also allows the Secretariat for the purpose of its register ~~engagement~~ to categorize each non-State actor in relation to ~~one of the four~~ **the defined** 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. **(amendments proposed by USA)**

No reservations on the substance but some editing is required. It would be preferable to define more precisely the notion of the “status” of entities (in the glossary, if necessary), in order to guard against the subsequent interpretation, throughout paragraph 31, that solely the entity’s status sometimes suffices to categorize each non-State actor in relation to one of the four groups (paragraph 31). (comments presented by France)

Paragraph 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.~~ **(option A and option B, amendments proposed by Argentina)**

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~~ **after the** 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. **(amendments proposed by India)**

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~~ **following the** 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. **(amendments proposed by Italy)**

~~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.~~ **(amendment proposed by USA)**

Paragraph 32 should add procedures of risks assessment. (comment presented by China)

Paragraph 33

Risk management concerns the process leading to a management decision on the part of the Secretariat ~~–The Secretariat decides~~, **deciding** 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.~~

Risk management will be audited by the Group. (option A, amendments proposed by Argentina)

Risk management concerns the process leading to a management decision on the part of ~~the Secretariat. The Secretariat decides~~ **the open-ended group, with the advice the technical units, deciding** 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.~~

(option B, amendments proposed by Argentina)

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 **based on the recommendation of the specialized central unit. (amendments proposed by India)**

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~~ **Subject to paragraphs 34 and 35, the** decision is usually taken by the management of the unit engaging with a non-State actor. **(amendments proposed by France)**

Add a footnote in paragraph 33, to clarify, since decision makers for the general “engagement” and “establish official relations” are not the same. (comments presented by China)

Paragraph 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.~~ **(option A and option B, amendments proposed by Argentina)**

The **specialized central** unit responsible for performing due diligence and risk assessment formulates recommendations on the engagement-related options listed in paragraph 33 above **along with reasons for such recommendations**. If the proposing unit agrees with the recommendations it implements them. If there are disagreements they can be referred to the engagement coordination group. **The recommendations of the specialized unit regarding risk management along with the reasons shall be made public. (amendments proposed by India)**

Since the Secretariat will collect additional information on non-State actors from sources which are not necessarily reliable or neutral, non-State actors must be given an opportunity to review and respond to the information on which risk assessments, recommendations and risk management decisions are based. Transparency, consistency, and the WHO’s credibility demand it. (comments presented by Zambia)

Paragraph 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. (option A and option B, amendments proposed by Argentina)~~

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. **The decision of the engagement coordination groups as well as the Director General related to the risk management shall be made publicly available.** (amendments proposed by India)

The Secretariat should provide further information about the engagement coordination group (paragraph 35 of the draft framework), especially its terms of reference and functions, and also the mechanism for regional representation. Does the coordination group have an obligation to submit reports to States through any of its governing bodies? (comments presented by Mexico)

“The engagement coordination group ...”. The UK supports the establishment of an engagement coordination group as drafted. (comments presented by UK)

Paragraph 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. (option A and option B, amendments proposed by Argentina)~~

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 fulfillment of the Organization’s mandate under the **Constitution and decisions and resolutions of the Governing Bodies** and the public health gains **significantly outweighs the risks mentioned in Para 8.** involved clearly justify any residual risk of engagement as well as the time and expense involved in establishing and maintaining the engagement.

Specific example of which a recommendation for non-engagement or disengagement shall be made includes:

Engagement of WHO with private sector entities including international business associations, philanthropic foundations or academic institutions not at arm’s length with private sector either in the form of a public private partnership or as an observer status for WHO in a public private partnership or a forum or any collaboration for the purposes

of setting norms and standard, development of guidelines, strategies and action plans including issues addressing quality, safety and efficacy of medical products.

(amendments proposed by India)

In line with WHO's risk management framework, WHO takes a **benefit/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. **(amendment proposed by USA)**

No reservations on the substance but some editing is required. A precise definition of the "risk management framework" referred to here would be very helpful: is it the framework of engagement as a whole? Or some other framework? Depending on the response, the § might need to be redrafted. (comments presented by France)

Paragraph 38

The WHO register of non-State actors is an Internet-based, publicly available electronic tool used by the Secretariat **and the Member States** 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. 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. **(option B, amendments proposed by Argentina)**

The WHO register of non-State actors is an Internet-based, publicly available electronic tool used by the Secretariat 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. 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, **contributions made or proposed to be made to WHO**, main relevant affiliations, webpage and one or more focal points for WHO contacts. **(amendments proposed by India)**

The WHO register of non-State actors is an Internet-based, publicly available electronic tool used by the Secretariat to document and coordinate engagement with non-State actors. It contains the main standard information ~~provided on~~ non-State actors and high-level descriptions of the engagement that WHO has with these actors. 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.~~ **(amendments proposed by France)**

Finland highly appreciates the development of the web based registry on non-State actors. (comments presented by Finland)

The WHO register of non-State actors The UK supports the establishment of a non-State actor register, as drafted. (comments presented by UK)

New paragraph 38 bis (proposed by France)

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.

Paragraph 39

~~When the Secretariat~~ **the open-ended group, with the advice of the technical units**, decides on an engagement with a non-State actor, a summary of the information submitted by that entity and held in the WHO register of non-State actors is made public. The accuracy of the information provided by the non-State actor and published in the register is the responsibility of the non-State actor concerned and does not constitute any form of endorsement by WHO. **(option B, amendments proposed by Argentina)**

No reservations on the substance but some editing is required. Paragraphs 38 and 39: these two paragraphs should be aligned more closely, because:

- **paragraph 39 clearly states that only “a summary is made public”.**
- **paragraph 38 could be interpreted more broadly (potentially all the data).**

(comments presented by France)

Paragraph 40

Non-State actors described in the register must update the information provided on themselves **at least** 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. **(amendment proposed by USA)**

Paragraph 43

~~References elsewhere in this framework to the norms and standard-setting process and normative work concern the second type of activity.~~ **(amendment proposed by Brazil)**

General comments presented by Member States on the Section “MANAGEMENT OF CONFLICT OF INTEREST, AND OTHER RISKS OF ENGAGEMENT”

Canada agrees that the WHO needs to equip itself with the right tools to transparently manage its engagement with non-State actors. In our view, the proposed registry and disclosure policies as demonstrated at PBAC will assure transparency of the Organisation’s engagements.
(comments presented by Canada)

The concept of “WHO’s interests” is not very precisely defined; moreover, the concept seems to vary slightly depending on the paragraph of the text, and paragraph 36 which refers to the Organization’s “mandate”. It would therefore be preferable to provide a *clear definition* in the

future *glossary* and then to ensure concordance with paragraph 23 which identifies the “primary interests” (of WHO) exclusively with WHO’s *work*. (comments presented by France)

Once the drafting error (addition of the word “may”) discussed in *previous* comment is corrected, the definitions in paragraphs 23 and 24 are essentially the same. The quality, independence and objectivity of the WHO’s work are all primary interests of the WHO, which should not be unduly influenced by the competing interests of any NSA. Thus, the draft does not clearly distinguish institutional conflict of interest from conflict of interest generally. Nor should it. Institutional conflict of interest are equated with financial conflict of interest – an improperly narrow scope for this framework. The framework must instead address financial and nonfinancial conflict of interest, at institutional and individual levels. (comments presented by Zambia)

We are concerned regarding the influence of non-State actors on WHO’s normative and standard setting work. More clarity is required on this matter on how the description provided in paragraphs 42 and 43 (page 18) is linked or delinked with paragraph 31 (page 32) and paragraph 17 (page 36). (comments presented by Zimbabwe, on behalf of the African group)

Conflict of interest policy to be included in the framework. The current information provided in paragraphs 23, 24, 25 and 26 is not clearly reflecting a definitive policy on conflict of interest. (comments presented by Zimbabwe, on behalf of the African group)

SPECIFIC PROVISIONS

Paragraph 44

WHO does not engage with the tobacco or arms industries. In addition, WHO will exercise particular caution ~~when engaging~~ **during the process of due diligence, risk assessment and management of risks** with other industries affecting human health or affected by WHO’s norms and standards. (option A and option B, amendments proposed by Argentina)

WHO does not engage with the tobacco or arms industries, **or with organizations having any direct or indirect affiliation with these industries. WHO will set up a mechanism of screening and identification of such organizations.** In addition, ~~WHO will exercise particular caution when engaging~~ with other industries affecting human health or affected by WHO’s norms and standards such as food and beverages, alcohol, **infant formula, WHO will exercise particular caution and WHO’s engagement will be strictly limited to assisting such industries to comply with WHO’s norms and standards or guideline or policy.** (amendments proposed by India)

WHO does not engage with the tobacco or arms industries. In addition, WHO will exercise particular caution, **especially while conducting due diligence and risk assessment analyses,** when engaging with other industries affecting human health or affected by WHO’s norms and standards. (amendments proposed by Brazil)

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.~~ (amendment proposed by USA)

Canada appreciates that the approach developed in the Framework strives for balance in engaging with all NSAs and abides by the principles of openness, fairness, and inclusivity. To be

an effective leader to address health issues and improve health outcomes globally, the WHO is required to engage with a wide range of actors from several sectors. We recognise the importance of excluding engagement with the tobacco and arms industries, but would not like to see any further limitations formalized. Canada trusts the WHO to use sound judgement to engage appropriately with actors from different sectors while respecting the provisions of the Framework; we also understand that these provisions should be closely monitored and modified as necessary to ensure the organization's protection from undue influence. (comments presented by Canada)

Denmark does not support the request of some Member States to include new specific industries in addition to the tobacco and arms industries. (comments presented by Denmark)

On boundaries, we agree that WHO should not engage in any form with the tobacco or arms industries. We believe that there are some industries that have clear interests in health policies (such as those linked with control of NCDs) with whom WHO should use high level of restriction but where there may still be the need to engage in e.g. information sharing or advocacy. (comments presented by Finland)

We wish to retain the wording *in its present version*; the important thing is to have a *clear and fixed* definition of the excluded sectors, leaving no room for multiple interpretations that would have to be decided upon on a case-by-case basis. (comments presented by France)

WHO should not engage with the tobacco, arms, alcohol, food and beverage industries. Moreover, strict rules should govern its engagement with the pharmaceutical industries. (Comments presented by Greece)

Norway fully supports WHO not engaging with the tobacco or arms industries. The present wording also encourages particular caution when WHO engages with other industries. We believe this provides sufficient safeguards concerning potential engagement with other industries and would not want to see any additional industries or sectors specified, keeping in mind that the purpose of the framework should be for the WHO to manage risk rather than attempting to eliminate it. (comments presented by Norway)

“*Particular caution*” is neither defined nor limited, and would be interpreted and applied differently at different levels of the WHO – eliminating the inclusiveness and predictability intended by the framework, and needlessly denying WHO access to appropriate input from qualified non-State actors. Any risks of engagement would best be managed by the consistent, diligent and transparent application of the terms of this framework. (comments presented by Zambia)

We support that there should be boundaries on engagement with the tobacco and arms industry. However, the framework should explicitly list the types of industries that WHO will deal cautiously with and the reasons for the cautious engagement. Industries such as the alcohol, food and beverage industries should be engaged with caution. (comments presented by Zimbabwe, on behalf of the African group)

The newly-introduced functions described in the 4th bullet point are inconsistent with the specific provisions described in paragraph 44 of the framework (page 18). The term “links to” is used twice, but it is undefined and has potentially unlimited application, and draws unintended consequences that appear not to have been fully considered. Barring WHO engagement with any

entity having links to the tobacco industry would, for example, bar the WHO from engaging with anyone connected to the current effort to produce Ebola and other vaccines more quickly by growing them in tobacco leaves. “*Particular caution*” is not defined, and would be interpreted and applied differently across the levels and departments of the WHO – eliminating the inclusiveness and predictability the framework was meant to establish. “*Industries affecting human health or affected by WHO’s norms and standards*” is already broad (would it include agriculture? automotive?). Applying particular caution to any entity with links to such industries means that it could be arbitrarily applied to exclude just about anyone. (Asset managers? Travel agencies?) These provisions are inconsistent with the overall framework, and would needlessly deny WHO access to appropriate input from qualified non-State actors. They must be deleted. (comments presented by Zambia, see also paragraph 30)

Paragraph 46

~~WHO does~~ **shall** not accept secondments from non-State actors. (amendments proposed by India)

~~WHO does not accept secondments from non-State actors.~~ (amendment proposed by UK)

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

WHO can accept secondments from Non State Actors provided that criteria of due diligence, risk assessment and risk management as contained in the overarching framework are rigorously applied. (amendments proposed by Italy)

~~WHO does not accept secondments from non-State actors.~~ (amendment proposed by Japan)

WHO does not accept secondments from ~~non-State actors~~ private sector entities. Secondements from other types of non-State actors shall be accepted, in accordance with document A67/7. (amendment proposed by Thailand)

We support the proposal that WHO should not accept secondments from non-State actors as presented in paragraph 46 page 19. (comments presented by Zimbabwe, on behalf of the African group)

Australia holds reservations in relation to the non-acceptance of secondments from non-State actors. Australia considers that this exclusion may restrict WHO’s platform of engagement and potentially limit the expertise available to WHO. We are particularly concerned that prohibiting secondments from non-State actors may impede WHO mobilizing the world’s best technical experts, whether they come from non-government organizations, academia or elsewhere, when the need arises.

Australia considers that the Framework’s proposed conflict of interest and due diligence processes will sufficiently increase transparency and reduce actual or perceived conflicts of interest, making the prohibition of secondments from non-States actors unnecessary.

Australia proposes that paragraph 46 be removed from the Framework and replaced with a paragraph which specifies that secondments will be managed in accordance with the policy and operational procedures for each non-State actor group.

- As a safeguard, clear criteria, as was included in previous iterations of the policy documents for non-government organizations and academic institutions, (which describe the circumstances under which WHO can accept secondments), should be included in each of the relevant policy and operational procedures documents.
- Australia also supports secondments from philanthropic organizations and is open to considering secondments from the private sector, on the condition that robust arrangements for managing conflicts of interest are in place.

(comments presented by Australia)

Finland can accept the total ban on secondments from the non-State actors. However, should the policy change so that some secondments are allowed, the following needs to be taken into account: policy making is the prerogative of Member States. Therefore we are of the opinion that any secondments funded by the non-State actors should be limited to activities relating to implementation of policies, only. (comments presented by Finland)

We expect WHO continues to offer authoritative advice, based on the most updated science. When we look at our Ebola experience, the outbreak urged us to be more proactive in relationship with many entities, especially academic institutions. From this perspective, relationship with academic institutions should NOT be excluded for the sake of WHO as a technical organization. Therefore Japan wishes the secondment from academia should be accepted as far as proper steps are taken. (comments presented by Japan)

Another significant point is the principle that WHO does not accept secondments from non-State actors, in order to guarantee the independence and integrity of the Organization. (comments presented by Mexico)

The WHO should accept secondments from non-State actors but based on the robust due diligence and risk management processes set out in this framework. (comments presented by UK)

RELATION OF THE FRAMEWORK TO WHO'S OTHER POLICIES

Paragraph 48

The implementation of the framework for engagement with non-state actors is coordinated with ~~the following related~~ policies listed below, which remain valid. **A review of the following policies will be carried out to remove any contradiction/s with this Framework. In the case of conflict this framework of engagement with non-State actors shall prevail over the policies listed below.**

- (a) WHO's involvement in external partnerships is regulated by the policy on WHO's engagement with global health partnerships and hosting arrangements.³ 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 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.
- (e) The procurement of goods and services is regulated by the Financial Rules and Financial Regulations; 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.

(amendments proposed by India)

"WHO's involvement in external partnerships is regulated by the policy on WHO's engagement with global health partnerships and hosting arrangements". For the management of risks of WHO's engagement in these partnerships the present framework for engagement with non-State actors applies. Thank you for seeking to clarify the application to partnerships, however, we remain concerned about the practical implications on hosted partnerships and special programme operations. For example members of these partnerships can be drawn from the four groups and different policies may therefore apply. (comments presented by UK)

OFFICIAL RELATIONS

Paragraph 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 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. **International business associations and philanthropic foundations may obtain the status of "observers".** (amendments proposed by Brazil)

"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 in the interest of **public health and** 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. (amendment proposed by UK)

“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 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. **(amendment proposed by Italy)**

Paragraph 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~~

Non-State actors in official relations¹ are international in membership and/or scope. 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. (amendments and footnote proposed by China)

Paragraph 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. (amendments proposed by India)~~

Paragraph 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; **When making the statement, international business associations and**

¹ Before working relations are established between WHO and a national NGO, and before a programme of collaboration with such an organization is agreed, appropriate measures will be taken to consult the Government concerned in accordance with Article 71 of the WHO Constitution.

philanthropic foundations should declare their interest particularly commercial interest in the item.

(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.

(amendments proposed by India)

Paragraph 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.~~ **(amendments proposed by China)**

Paragraph 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~~ **twelve** weeks before the opening of the January session of the Executive Board at which they will be considered. **(amendments proposed by Italy)**

Paragraph 63

Paragraph 63 of the draft framework suggests that when the Director-General proposes earlier reviews of a non-State actor's official relations, the Executive Board is informed (perhaps through PBAC) with a view to guiding its decision to continue or suspend relations. **(comments presented by Mexico)**

Paragraph 64

Accreditation of NGOs (new paragraph 64 bis proposed by India)

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

- (a) have aims and purposes consistent with WHO's Constitution and in conformity with the policies of the Organization as well as resolutions and decisions adopted by the Executive Board and the World Health Assembly;**
- (b) demonstrate competence in a field of activity related to the work of WHO;**
- (c) have membership and/or activities that are international in scope**

- (d) be non-profit and public interest in nature, and in its activities and advocacy;
- (e) have an established structure, a constitutive act, and accountability mechanisms;
- (f) for a membership organization, have the authority to speak for its members and have a representative structure; The Membership should not contain private sector entities, individuals associated with private sector entities or philanthropic foundations and academic institutions not at arm's length with private sector
- (g) have existed formally for at least three years as of date of receipt of the application by WHO;
- (h) disclose information on its objectives, structure, membership of executive body, field of activities and source of financing, and, where applicable, its status with other entities of the United Nations system;
- (i) agree to provide WHO regularly with updated information as well as to inform WHO of any changes with respect to its status as « non-governmental organization » as soon such changes take place.

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

General comments presented by Member States on the Section “OFFICIAL RELATIONS”

Canada is satisfied with the procedures outlined in the Framework regarding NSAs in official relations. While WHO consultations and hearing should be open to a wide range of actors, the WHO should remain vigilant and judicious in selecting the NSAs to which it confers the privileges of official relations. We appreciate that organizations in official relations will be reviewed every three years and that they are required to provide yearly reports on progress made in implementing the plan of collaboration that will be published in the register of NSAs. (comments presented by Canada)

Paragraphs 49, 52 and 55 / coordination between definitions:

- paragraph 49 refers exclusively to already existing organizations (cf : *“that have had and continue to have a sustained and systematic engagement in the interests of the Organization.”*)
- paragraph 52 envisages the possibility admitting new organizations (cf: *“The Executive Board shall be responsible for deciding on the admission of organizations into official relations with WHO”*), which, strictly interpreted, contradicts § 49. Moreover, § 52 does not clarify on what criteria this decision will be taken.

- 55 stipulates that: “*Non-State actors in official relations are international in membership and/or scope.*”, whereas paragraph 52 limits the list to “*international nongovernmental organizations, philanthropic foundations and international business associations*”: what is the link between these paragraphs ?
- If paragraph 53 lays down the *principle* that: “*Non-State actors in official relations with WHO are invited to participate in sessions of WHO’s governing bodies*”, (i.e. in all cases), what then is the specific scope of the general provisions contained in paragraph 16: “*Non-State actors’ participation is determined by the governing bodies’ respective rules of procedure, policies and practices*”?

(comments presented by France)

One point we think should be reconsidered is that concerning the procedure for the establishment of official relations and the examination of organizations with which WHO already has official relations (paragraph 59), because all organizations requesting official relations should meet the established criteria to ensure that engagement will be fruitful.
(comments presented by Mexico)

The U.S.A. believes the section “*Procedure for admitting and reviewing organizations in official relations*” lacks a mechanisms for discussion with a non-State actor in the case of disagreement on the determination of eligibility. Suggest inclusion of language to define this process.
(comments presented by USA)

OVERSIGHT OF ENGAGEMENT

Paragraph 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
 - (iii) a report from the Independent Oversight Committee Advisory Committee every two years on engagement with non-State actors**
- (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.

(amendments proposed by India)

The oversight function of Member States in respect of engagement with non-State actors should be strengthened, by establishing a mechanism to oversee implementation of the engagement policy and report back to the Executive Board and World Health Assembly, and allow the governing bodies to provide guidance on the interpretation and implementation of the framework of engagement and also allow the governing bodies to request clarification if so required to address any inconsistency in the implementation of the framework.

Executive Board and WHA should have a Standing agenda item, that the aforementioned mechanism regularly report to the governing bodies on the engagement of the Organization with non-state actors.

With the aim of enhancing transparency and providing tools for overall overseeing by member states the Break-down of the received funds and its allocation should be reported to the EB and WHA. (comments presented by the Islamic Republic of Iran)

NON-COMPLIANCE WITH THIS FRAMEWORK

Paragraph 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; **activities by the Non State Actors (NSA) that go against WHO's mandate as set out by its Constitution, decisions and resolutions of the Governing Bodies; actions or activities of NSA that negatively affect the independence, integrity, reputation or credibility of WHO; activities of the NSA after the establishment of engagement lead to actual and perceived conflict of interest.** (amendments proposed by India)

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, **engage in political activities.** (amendment proposed by China).

Paragraph 67, specify that "significant delays in the provision of information to the WHO register of non-State actors" should be included in the definition of non-compliance with the framework, so as to leave no room for interpretation. (comments presented by Mexico)

MONITORING AND EVALUATION OF THE FRAMEWORK

Paragraph 71

Furthermore, the implementation of the framework should be ~~periodically~~ **evaluated every 2 after its adoption and thereafter every 3 years.** 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. **(amendment proposed by India)**

Furthermore, the implementation of the framework should be periodically evaluated, **both with respect to results relating to protection of the organization from conflicts of interest, and the extent to which the policy has facilitated meaningful engagement with non-State actors toward shared global health goals.** 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. **(amendment proposed by USA)**

Paragraph 71, Mexico notes with satisfaction that periodic evaluation of the framework is envisaged, given the constantly changing international context and the shifting relationship between State and non-State actors; however, it might be added that this evaluation should take place every five years or at the request of the Executive Board, before the five-year deadline if it is deemed necessary to revise and/or update the framework. (comments presented by Mexico)

General comments presented by Member States on the Section “MONITORING AND EVALUATION OF THE FRAMEWORK”

The suitability of secondment provisions can then be reviewed as part of the Framework’s evaluation process. (comments presented by Australia)

A process for evaluation of the Framework, is missing from the draft policy while this policy would have far-reaching implications for the Organization, 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. (comments presented by the Islamic Republic of Iran)

IMPLEMENTATION OF THE FRAMEWORK (NEW SECTION PROPOSED BY INDIA)

New paragraph 72 (proposed by India)

The following steps shall be taken for the effective implementation of the framework:

- (a) Review existing list of non-State actors in official relation and to apply the categorization of non-State actors as set out in this Framework.**
- (b) Review of WHO’s existing external and hosted partnerships, collaborations in the light of this Framework and to take appropriate measures to avoid and manage risk. Towards this purpose the Secretariat should invite comments from the public.**
- (c) Review and amend all the policies listed in Paragraph 48 of EB 136/5 to fully align those policies with the existing framework. Towards this end, the Secretariat will hold web consultations open for Member States and public to pinpoint the areas of the existing policies which need to be reviewed and amended in the light of framework;**
- (d) The NSA registry shall be made operational within six months of the adoption of the Framework of Engagement with Non-State actors.**

DRAFT WHO POLICY AND OPERATIONAL PROCEDURES ON ENGAGEMENT WITH NONGOVERNMENTAL ORGANIZATIONS

Paragraph 1

Nongovernmental organizations make important contributions to global health **particularly when** ~~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. **(amendments proposed by USA)**

New paragraph 1bis (proposed by USA)

The engagement with nongovernmental organizations at the institutional level has to be distinguished from the collaboration with individual experts working for nongovernmental organizations.

New paragraph 1 ter (proposed by USA)

In engaging with nongovernmental organizations, WHO will aim to operate on a competitively neutral basis.

PARTICIPATION

Paragraph 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. **All inputs of NGOs provided during consultation or hearing shall be made public. (amendments proposed by India)**

Paragraph 5

“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.” Language needs to be consistent here across all non-State actors. So should insert language on nongovernmental organizations not misrepresenting WHO's participation. **(comments presented by UK)**

RESOURCES

Paragraph 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. **(amendments proposed by Zimbabwe, on behalf of the African group)**

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. **Any contribution above USD 50000 shall be treated as a core voluntary contribution. WHO shall not receive resources from NGOs for the salary of staffs or publications. Further, resources for clinical trials shall be accepted on condition making the clinical trial data public for independent verification. Financing from NGOs shall not be accepted for activities leading to production of WHO guidelines or recommendations.** (amendments proposed by India)

How does the provision of "*personnel*" square with the prohibition on secondments? This might require an explanatory footnote. (comments presented by UK)

We would like to receive more information what is meant by "*personnel*" in relation to sections on "*resources*". The same caveat as for secondments should apply here: it should be limited to activities relating to implementation of policies, only. (comments presented by Finland)

Regarding the section on resources (paragraph 8 of the draft policy and operational procedures), does WHO provide resources to nongovernmental organizations and academic institutions? Are these actors the only recipients of resources from WHO in the document under consideration, and if so, what is the transparency and accountability mechanism in all cases? (comments presented by Mexico)

New paragraph 8 bis (proposed by Brazil)

Nongovernmental organizations 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.

Paragraph 10

For reasons of transparency, contributions and donations from nongovernmental organizations must be publicly acknowledged by WHO in accordance with its policies and practices. **The contribution from NGO shall disclose the source of its contribution and the Secretariat shall make it available to public.** (amendments proposed by India)

Paragraph 13

Taking into account what provided for in paragraph 12, 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. (amendment proposed by Italy)

EVIDENCE

Paragraph 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.~~

WHO can only collaborate with non-governmental organizations 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. (amendments proposed by Brazil)

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. **However, utmost care should be taken to ensure that gathering, analyses and generation of information and the management of knowledge and research is free from the conflict of interest. (amendments proposed by India)**

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, **when potential conflicts of interest are managed in accordance with this framework and the collaboration is transparent. (amendment proposed by USA)**

Managing risks of engagement with consistent diligence and transparency requires that the provisions in this paragraph be identical across each type of non-State actors. (comments presented by Zambia)

Paragraph 16

“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”. **The language should be consistent with the other non-State actors policies. So an obligation to fully implement WHO’s norms and standards. (comments presented by UK)**

TECHNICAL COLLABORATION

Paragraph 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. **However the collaboration for product development shall be based on the delinking principle to ensure innovation and access to the developed product at affordable cost. (amendments proposed by India)**

~~The Secretariat is encouraged to undertake technical~~ **Technical** collaboration with nongovernmental organizations **is welcomed**, provided that it is in the interests of the Organization and managed in

accordance with the framework for engagement with non-State actors. (**amendments proposed by USA**)

Managing risks of engagement with consistent diligence and transparency requires that the provisions in this paragraph be identical across each type of non-State actors. (comments presented by Zambia)

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

Paragraph 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. **This policy is applicable to private sector firm, international business associations, academic institutions and philanthropic foundations not at arm's length with the private sector and other not for profit organizations, which are not qualified as NGOs under the Overarching Framework on the engagement of Non-State actors. (amendments proposed by India)**

Private sector entities are key players in global health **as employers and** as providers, both within and beyond the health sector, **of products**, of goods and services that can have important effects on health. Therefore WHO engages with this group of key actors in global health **to maximize** improve their positive contribution, **to advance efforts to reduce significant health risks** ~~limit their negative effects on health~~ and leverage their support in the fulfilment of WHO's mandate. (amendments proposed by USA)

New paragraph 2 bis (proposed by USA)

The engagement with private sector entities at the institutional level has to be distinguished from the collaboration with individual experts working for private sector entities.

PARTICIPATION

Paragraph 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. **The information with regard to participation of private sector in consultation or hearing or any other WHO meeting including inputs of the private sector in such meeting such as presentation or oral or written submission shall be made public. (amendments proposed by India)**

Paragraph 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”. Is there a strong rationale for why the language here is different to the equivalent paragraph in the nongovernmental organizations policy? (comments presented by UK)

Paragraph 7

The participation of WHO staff members in meetings of private sector entities as panelists, ~~speakers or in any other capacity~~ shall be managed according to the provisions of the framework for engagement with non-State actors. **Any decision with regard to the participation of WHO staff in the meeting can be taken only after proper risk assessment including the actual or perceived conflict of interest. This risk assessment report shall be made public.** (amendments proposed by India)

Paragraph 8

WHO ~~does~~ **shall** 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.~~ (amendments proposed by India)

WHO does not cosponsor meetings organized by specific private sector entities, **whose business affects human health.** 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. (amendments proposed by Thailand)

The United States believes this paragraph should not be restrictive in comparison to other policy frameworks such as CODEX where WHO cosponsors workshops parallel with CODEX meetings. (Comments presented by USA)

Paragraph 9

WHO ~~does~~ **shall** 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.~~ (amendments proposed by India)

The United States believes this paragraph should not be restrictive in comparison to other policy frameworks such as CODEX where WHO cosponsors workshops parallel with CODEX meetings. (Comments presented by USA)

RESOURCES

Paragraph 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. **For instance, WHO shall not accept funds from the food and beverages or alcohol or infant formula industry for its work in NCD or WHO shall not accept resources from pharmaceutical industry for implementation of quality and safety standards of medical**

products. Further the WHO shall not accept financial resources from private sector as specified voluntary contribution.

(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. No project except product development and clinical trials shall be implemented with more than 50% of the financial resources form the private sector. Financing form the private sector shall not be accepted for activities leading to production of WHO guidelines or recommendations.~~

(d) WHO shall not receive any financial resources from any private sector entity whose activities and advocacy are undermining the mandate of WHO as stated in its constitution or decisions and resolutions of governing bodies. For instance, WHO shall not accept any resources from private sector entities which are acting or advocating against the full or partial implementation of the International Code of Marketing Breast Milk Substitutes or Global Strategy and Plan of Action on Public Health.

(amendments proposed by India)

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~~ **effects on profits or competitive advantage** 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.

(amendments proposed by USA)

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~~ **are** 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.

(amendments proposed by Thailand)

“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”. See point above on personnel (How does the provision of personnel square with the prohibition on secondments? This might require an explanatory footnote). Is there a reason why there is no provision for personnel contributions in this policy? (comments presented by UK)

The United States applauds innovative solutions to global health challenges like the recent Pandemic Influenza Preparedness Framework, which includes provisions for industry to provide financial support to WHO for the functioning of the Global Influenza Surveillance and Response System. We wish to ensure that nothing in this framework would impede such collaboration now or in the future, so would like to see clarification on the language in 12(b). (comments presented by USA)

Paragraph 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~~ **does** 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.

(amendments proposed by Thailand)

“... (a) 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”; Again, the United States believes clarification is required on how this will be implemented in relation to not only Pandemic Influenza Preparedness, but also many NTD programs, which are highly reliant on industry contributions for their success. (comments presented by USA)

“... (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;” The United States understands the basis for this paragraph and protecting WHO's brand being used for commercial purposes. However, public profiling of partnerships are important, both for building momentum and additional contributions, and often for the engagement of the non-State actors in question to be able to justify the commitment to its leadership. Too restrictive interpretation of this language could lead to loss of effectiveness of WHO as a global convener on global health matters from NCDs to pandemic preparedness. (comments presented by USA)

“... (g) the acceptance of the contribution does not offer the contributor any possibility for advising, influencing, participating in being in command of the management or implementation of operational activities;” The United States agrees that private sector non-State actors should not be involved in advising, influencing or leading management of operational activities, but excluding participation as well can mean the loss of valuable additional resources and expertise in a given project or even emergency response situation. Suggest narrowing the scope slightly while retaining the main protections to make this bullet more pragmatic. (comments presented by USA)

Paragraph 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. (amendments proposed by India)~~

Paragraph 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. **(amendments proposed by Zimbabwe, on behalf of the African group)**

We would like to receive more information what is meant by “personnel” in relation to sections on “resources”. The same caveat as for secondments should apply here: it should be limited to activities relating to implementation of policies, only. (comments presented by Finland)

Paragraph 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.

Anonymous donations may not be accepted under any circumstances.

Any donation received by WHO which is subsequently discovered to be noncompliant with these guidelines shall be returned to the donor. (amendments proposed by India)

Private sector entities ~~may do~~ 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.

(amendments proposed by Thailand)

Paragraph 20

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

- (a) Sound evidence exists of the safety and efficacy of the product in the indication for which it is being donated. The product is approved or otherwise authorized by the recipient country for use in that indication; it should also preferably appear in the WHO Model List of Essential Medicines for that indication.
- (b) Objective and justifiable criteria for the selection of recipient countries, communities or patients have been determined. In emergency situations, flexibilities may be required.

- (c) A supply system is in place and consideration is given to means of preventing waste, theft and misuse (including leakage back into the market).
- (d) A training and supervision programme is in place for all personnel involved in the efficient administration of supply, storage and distribution at every point from the donor to the end-user.
- (e) A donation of medicines and other health-related products is not of a promotional nature, either with regard to the company itself or insofar as it creates a demand for the products that is not sustainable once the donation has ended.
- (f) WHO does not accept products at the end of their shelf **life**.
- (g) A phase-out plan for the donation has been agreed upon with recipient countries.
- (h) A system for monitoring adverse reactions to the product has been set up with the participation of the donating company.

(amendments proposed by Finland)

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~~ **point where the product will pose a safety concern**.
- (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.

(amendments proposed by USA)

On the question of donations of medicines and other health technologies, we are of the opinion that such donations should be more directly linked to the WHO model list of essential medicines, taking into account flexibilities needed for emergency situations (such as with Ebola medicines and vaccines). (comments presented by Finland)

***“In determining the acceptability of large-scale donations of medicines and other health-related products, the following criteria should be met.”* The United States requests clarification on this reference to health-related products and whether it refers to food products or food assistance donation. (comments presented by USA)**

Paragraph 22

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

- (a) the research or development activity is of public health importance;
- (b) the research is conducted at WHO’s request and potential conflicts of interest are managed;
- (c) **The clinical trial data shall be made available for public**
- (d) **The clinical trial follows the ethical standards laid down in the Helsinki Protocol**
- (e) **The final product shall be made accessible to the needy people**
- (f) 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.

(amendments proposed by India)

Paragraph 23

If the above-mentioned requirements are met, a financial contribution may be accepted from a company having a direct commercial interest in the trial in question, provided that appropriate mechanisms are put in place to ensure that WHO controls the **conduct and disseminating outcomes** ~~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. (amendments proposed by USA)

Paragraph 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. **WHO can accept such financial contributions, only if the meeting would not take place without WHO's involvement or if WHO's involvement is necessary in order to ensure that the work is undertaken in conformity with internationally accepted technical and ethical standards and guidelines.**

(amendments proposed by USA)

The United States believes that meetings channelled through WHO should not be more restrictive than current WHO policy and joint work at CODEX and FAO regarding support for participation of invitees for meetings. (comments presented by USA)

Paragraph 26

“WHO receptions and similar functions shall not be paid for by private sector entities”. We would favour a more flexible approach here. So that against an agreed and robust set of criteria, a private sector entity could host and/or part fund events/meetings. (comments presented by UK)

Paragraph 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~~ **is** not be accepted from a private sector entity.

(amendments proposed by Thailand)

The United States believes that meetings channeled through WHO should not be more restrictive than current WHO policy and joint work at CODEX and FAO regarding support for participation of invitees for meetings. (comments presented by USA)

New Sub-Section (proposed by India): Donations for preparation of guidelines or recommendations (as a sub-section)

Financing may not be accepted from commercial enterprises for activities leading to production of WHO guidelines or recommendations.

(amendments proposed by India)

Paragraph 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. WHO shall not accept contribution from the private sector to support the salary of staff including short-term consultancy. (amendments proposed by India)~~

~~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. (amendment proposed by Brazil)~~

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. (amendment proposed by Italy)~~

Funds designated to support the salary of specific staff members or posts (including short-term consultants) ~~may~~ **are** 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. (amendment proposed by Thailand)~~

The draft policy states that financial contribution can be accepted to finance the salary of the specific staff or post if it could not give rise to a real or perceived conflict of interest to WHO's work. On the contrary, accepting private sector contribution to finance the salary of WHO staff in clear defiance of the provisions of draft policy would undermine the independence and integrity of WHO. (comments presented by the Islamic Republic of Iran)

We submit reservations on the earmarking of funds from non-State actors as well as the use of such funds to pay staff salaries. (comments presented by Zimbabwe, on behalf of the African group)

General comments presented by Member States on the Section "RESOURCES"

Canada is satisfied that the conditions established under the "RESOURCES" heading in the draft policy on engagement with private sector entities provides the WHO with the necessary safeguards to protect against undue influence. When these conditions are satisfied, respecting the principles of fairness and inclusivity, private sector actors should be able to contribute funds like other non-State actors, as long as there is a clear policy that ensures that WHO staff are void from any obligation to donors and that they remain neutral and unbiased. (comments presented by Canada)

Clear criteria should be set to regulate the financial contributions from non-State actors to avoid the risk of donor-driven agenda. The Framework puts a limited set of regulation on funding from the private sector but it is insufficient, for instance, paragraph 29 states that WHO can accept contributions from the private sector for financing staff salary. (comments presented by the Islamic Republic of Iran)

A ceiling on the voluntary contributions from non-State actors should be established, and any contribution beyond that amount should go to the core voluntary fund, which gives enough freedom for the Secretariat to allocate resources in under funded programmes. Member States

Assessed Contributions should be allocated to the programmes that are unfunded under Voluntary Contributions. (comments presented by the Islamic Republic of Iran)

The United States believes the section “*Donations of medicines and other health technologies*” should be replicated in the NGO section as well, given how often they are involved in these types of donations (including suspect ones). (comments presented by USA)

EVIDENCE

Paragraph 31

WHO shall not ~~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.~~ (amendments proposed by India)

~~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.~~

Private sector entities can provide up-to-date information and knowledge on technical issues, and share their experience and engage with WHO in the generation of evidence, knowledge management, scientific reviews, information gathering and research, when potential conflicts of interest are managed in accordance with this framework and the collaboration is transparent. (amendments proposed by USA)

Another serious lapse in the new draft Framework is the absence of appropriate safeguards on WHO’s engagements with non-State actors for evidence gathering and technical collaborations. There should be adequate safeguards to avoid conflict of interest and commercial interest-driven public health policy making and norms and standard setting. (comments presented by the Islamic Republic of Iran)

“*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*”. There is more scope here for the language to be more consistent with the other non-State actors policies. (comments presented by UK)

Managing risks of engagement with consistent diligence and transparency requires that the provisions in this paragraph be identical across each type of non-State actors. (comments presented by Zambia)

Private sector entities do not inherently present risks for the WHO by their participation in scientific reviews on any and every subject. Indeed, the private sector may well have the most authoritative expertise on some issues. There is no justification for this paragraph’s sweeping exclusion of private sector entities from any collaborating on any type of scientific review. (comments presented by Zambia)

Paragraph 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. (amendments proposed by Japan)~~

Advisory groups can benefit from the participation of appropriate private sector professionals in some technical topics. Therefore, we think that WHO should accept experts from private entities while ensuring transparency and appropriate management on conflicts of interest. (comments presented by Japan)

It is not clear why advocacy groups and expert groups should not benefit from the full participation of appropriate professionals. Any risk should be managed through the diligent, consistent and transparent application of the terms of this framework - and not through random exclusion of even highly qualified professionals. (comments presented by Zambia)

ADVOCACY

Paragraph 34

~~Private sector entities can only collaborate with WHO in advocacy for the implementation of a WHO norm or standard by the concerned private sector if they commit themselves to implement these norms and standards in their entirety. No partial or selective implementation is acceptable. (amendments proposed by India)~~

~~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.~~

WHO may collaborate with private sector entities to advocate for the implementation of a WHO norm or standard if the entity commits to implement the subject norms and standards in their entirety. (amendments proposed by USA)

~~Private sector entities can only collaborate with WHO in advocacy for the implementation of a WHO norm or standard by the concerned private sector if they commit themselves to implement these norms and standards in their entirety. No partial or selective implementation is acceptable. (amendments proposed by Zambia)~~

“..... 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”. This needs to be applicable to all non-State actors. (comments presented by UK)

No other non-State actor is subject to this conditionality. Few Member States would be able to meet these conditions, which set the bar for private sector engagement impassably high. In so doing, the provision creates an unfairly broad argument to exclude a private sector entity, contradicting the spirit that Member States seek to capture in this framework. (comments presented by Zambia)

Paragraph 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 **among its membership. (amendments proposed by India)**

TECHNICAL COLLABORATION

Paragraph 36

Technical collaboration with the private sector might occur ~~is welcomed~~ only when 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. **WHO shall not collaborate with the private sector for contributing to the implementation of WHO norms and capacity building except for providing technical assistance to private sector to implement WHO norms. (amendments proposed by India)**

Technical collaboration with the private sector is welcomed **provided that it is in the interests of the Organization and managed in accordance with the framework for engagement with non-State actors** ~~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. (amendments proposed by USA)~~

Managing risks of engagement with consistent diligence and transparency requires that the provisions in this paragraph be identical across each type of non-State actor. (comments presented by Zambia)

Paragraph 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, at affordable prices.** ~~, to the public sector of low- and middle-income countries to developing countries.~~ 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. **(amendments proposed by India)**

WHO collaborates with private sector entities in the development of health-related technology, either by conducting research and development on their products and supporting transfers and licensing of technology or by licensing its intellectual property to such enterprises. Collaborative research and development, technology transfer and licensing should, as a general rule, be undertaken **only if WHO and the entity concerned have concluded an agreement cleared by the Office of the Legal Counsel that ensures that the final product will ultimately be made widely available, and accessible and affordable** 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. **(amendments proposed by Brazil)**

DRAFT WHO POLICY AND OPERATIONAL PROCEDURES ON ENGAGEMENT WITH PHILANTHROPIC FOUNDATIONS

Paragraph 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 fulfillment of WHO's mandate. **This policy is applicable only to those philanthropic foundations which are at arm's length from the private sector. (amendments proposed by India)**

New paragraph 2 bis (proposed by USA)

The engagement with philanthropic foundations at the institutional level has to be distinguished from the collaboration with individual experts working for philanthropic foundations.

PARTICIPATION

Paragraph 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. **The information with regard to participation of philanthropic foundation in consultation or hearing or any other WHO meeting as well as the inputs provided by the philanthropic foundation in such meetings such as presentation or oral or written submission shall be made public. (amendments proposed by India)**

Paragraph 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. **Any decision with regard to the participation of WHO staff in the meeting can be taken only after proper risk assessment including the actual or perceived conflict of interest. This risk assessment report shall be made public. (amendments proposed by India)**

RESOURCES

Paragraph 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. **(amendments proposed by Zimbabwe, on behalf of the African group)**

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. **(amendments proposed by India)**

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. **(amendments proposed by Brazil)**

We would like to receive more information what is meant by "personnel" in relation to sections on "resources". The same caveat as for secondments should apply here: it should be limited to activities relating to implementation of policies, only. (comments presented by Finland)

Paragraph 13

For reasons of transparency, contributions from philanthropic foundations must be publicly acknowledged by WHO in accordance with its policies and practices. **The source of the contributed resources shall be disclosed by the philanthropic foundation. (amendments proposed by India)**

EVIDENCE

Paragraph 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.~~

WHO can only collaborate with Philanthropic foundations 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. (amendments proposed by Brazil)

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. **Any decision in this regard can be taken only after proper risk assessment including the actual or perceived conflict of interest. This risk assessment report shall be made public. (amendments proposed by India)**

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, **when potential conflicts of interest are managed in accordance with this framework and the collaboration is transparent. (amendments proposed by USA)**

Managing risks of engagement with consistent diligence and transparency requires that the provisions in this paragraph be identical across each type of non-State actor. (comments presented by Zambia)

TECHNICAL COLLABORATION

Paragraph 19

~~The Secretariat is encouraged to undertake~~ Technical collaboration with philanthropic foundations **is welcomed** provided that it is in the interests of the Organization and managed in accordance with the framework for engagement with non-State actors. **(amendments proposed by USA)**

Managing risks of engagement with consistent diligence and transparency requires that the provisions in this paragraph be identical across each type of non-State actor. (comments presented by Zambia)

It is redundant and unnecessarily confusing to state that collaboration must be in the interests of the WHO, in light of the objectives outlined in paragraph 4 of the framework (page 10), as well as the seven overarching principles outlined in paragraph 6 of the framework (page 11). Any collaboration managed in accordance with the framework will necessarily be in the interests of the Organization. (comments presented by Zambia)

DRAFT WHO POLICY AND OPERATIONAL PROCEDURES ON ENGAGEMENT WITH ACADEMIC INSTITUTIONS

Paragraph 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. **This policy is not applicable to academic institutions established by the private sector or with the presence of private sector in the administration including governing or where the academic institution receives more than 30% of their total revenue from the private sector or any private funding from private sector in the area in which it seeks engagement with WHO. (amendments proposed by India)**

PARTICIPATION

Paragraph 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. **The information with regard to participation of academic institution in consultation or hearing or any other WHO meeting as well as the inputs provided by the academic institution in such meetings such as presentation or oral or written submission shall be made public. (amendments proposed by India)**

RESOURCES

Paragraph 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. **(amendments proposed by Zimbabwe, on behalf of the African group)**

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. **(amendments proposed by India)**

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. **(amendments proposed by Brazil)**

We would like to receive more information what is meant by “*personnel*” in relation to sections on “*resources*”. The same caveat as for secondments should apply here: it should be limited to activities relating to implementation of policies, only. (comments presented by Finland)

Paragraph 9

Regarding the section on resources, does WHO provide resources to nongovernmental organizations and academic institutions? Are these actors the only recipients of resources from WHO in the document under consideration, and if so, what is the transparency and accountability mechanism in all cases? (comments presented by Mexico)

EVIDENCE

Paragraph 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. **Any decision in this regard can be taken only after proper risk assessment including the actual or perceived conflict of interest. This risk assessment report shall be made public.** (amendments proposed by India)

~~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.~~

WHO can only collaborate with Academic institutions 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. (amendments proposed by Brazil)

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, **when potential conflicts of interest are managed in accordance with this framework and the collaboration is transparent.** (amendment proposed by USA)

Managing risks of engagement with consistent diligence and transparency requires that the provisions in this paragraph be identical across each type of non-State actor. (comments presented by Zambia)

Paragraph 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.~~ **However, WHO may ensure that the intellectual property arising from collaboration with academic institutions are freely accessible for further research and development or studies as well as non-commercial use.** (amendments proposed by India)

TECHNICAL COLLABORATION

Paragraph 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. **Any decision in this regard can be taken only after proper risk assessment including the actual or perceived conflict of interest. This risk assessment report shall be made public. (amendments proposed by India)**

~~The Secretariat is encouraged to undertake~~ Technical collaboration with academic institutions is **welcomed**, provided that it is in the interests of the Organization and managed in accordance with the framework for engagement with non-State actors. **(amendments proposed by USA)**

Managing risks of engagement with consistent diligence and transparency requires that the provisions in this paragraph be identical across each type of non-State actor. (comments presented by Zambia)

It is redundant and unnecessarily confusing to state that collaboration must be in the interests of the WHO, in light of the objectives outlined in paragraph 4 of the framework (page 10), as well as the seven overarching principles outlined in paragraph 6 of the framework (page 11). Any collaboration managed in accordance with the framework will necessarily be in the interests of the Organization. (comments presented by Zambia)

Paragraph 19

Scientific collaborations are regulated by the Regulations for Study and Scientific Groups, Collaborating Institutions and other Mechanisms of Collaboration.¹ In case of collaboration for product development **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 accessible at affordable prices. (amendments proposed by India)**

GENERAL COMMENTS PRESENTED BY MEMBER STATES ON THE FRAMEWORK OF ENGAGEMENT WITH NON-STATE ACTORS

In the draft WHO policies and operational procedures on engagement with nongovernmental organizations, private sector entities, philanthropic foundations and academic institutions, all references to the possibility of WHO's accepting secondments from the aforementioned non-State actors should be deleted. All such references clearly contradict paragraph 46 of the draft overarching framework of engagement with non-State actors, which stipulates: "46. WHO does not accept secondments from non-State actors." (comments presented by Argentina)

Australia thanks the Secretariat for its continued work on developing the *Framework of Engagement with non-State Actors*. Australia appreciates that our previous comments regarding competitive neutrality and evaluation, have been positively addressed in the revised Framework and welcomes the opportunity to provide further comments.

Australia continues to support a framework of engagement with non-State actors which provides WHO with sufficient flexibility to work with all global health actors as appropriate, while protecting the Organization's integrity and its fundamental role in setting global norms and standards.

Australia welcomes the addition of an evaluation mechanism which will facilitate continuous improvement and refinement of the overarching framework and the supporting documents, if required. The evaluation process, combined with strengthened oversight through the Programme, Budget and Administration Committee and the inclusion of a mechanism to discontinue official relations with a non-State actor, should the need arise, provides assurance that the Framework should be implemented.

Australia also welcomes the strengthening of sections relating to managing conflict of interests and conducting due diligence, recognising the value of these in increasing transparency. (comments presented by Australia)

Australia has no further concerns with the remainder of the Framework or supporting policy or operational procedural documents. Noting the importance of this work, Australia supports the need to finalise the framework and associated documents as a matter of urgency.

Australia strongly supports the adoption of the draft overarching Framework of Engagement with non-State Actors at the 68th World Health Assembly. (comments presented by Australia)

As the WHO continues to act as a leader in global health and engage with various non-State actors in different international contexts, the Organization must take the appropriate measures to protect against undue influence and conflicts of interest. These measures should be applied fairly, consistently, and most importantly, should promote an inclusive environment where various actors are able to collaborate to improve global health outcomes. To achieve this goal, Canada believes that the Framework should not include policies and regulations that would limit the WHO's ability to engage necessary non-State actors to fully inform its work and to leverage resources. The Framework should be adopted on a trial basis to test which practices are most effective and improve policies throughout their implementation. (comments presented by Canada)

The Framework clearly indicates that the WHO will not accept secondments from non-State actors. However, it also states that the WHO can accept resources, including personnel, from all four categories of non-State actors. We recognise that both the WHO and Member States can benefit from the work of personnel from non-State actors. However, to mitigate risks associated with individual and organizational conflicts of interest, the Framework should clarify the instances in which the WHO may accept personnel from non-State actors. For example, WHO could accept personnel from non-State actors to assist in the implementation of specific programmes, but should not accept this personnel to assist in the drafting of policies, norms and standard setting. Furthermore, when the WHO does accept personnel from non-State actors, the individuals in question should be required to complete a declaration of interests with the Office of Risk Management, Compliance and Ethics (as is required for staff and external experts). (comments presented by Canada)

The Framework has clarified the definitions of different NSAs and has laid out a clear and explicit review process to protect against undue influence. It also states that if a non-State actor is considered to be under the influence of a private sector actor through the due diligence practices, the WHO may apply relevant provisions of the private sector policy. Canada believes these provisions allow the WHO to adequately classify and engage with different NSAs as required to fulfil its mandate and complete work on pressing global health topics.

The Framework acknowledges that the attribution of a non-State actor to any one of the four categories (nongovernmental organisation, private sector entities, philanthropic foundations, and academic institutions) may change overtime. Canada would like to request that the criteria to inform and the mechanism responsible for decisions regarding the categorisation of non-State actors be made explicit in the Framework. This addition should include instructions on the process for evaluating non-State actor classifications and should specify the frequency at which these evaluations should take place. (comments presented by Canada)

The draft policy for engagement with private sector entities establishes firm criteria that must be met for private sector actors to be able to collaborate with the WHO for the generation of evidence. This same criteria should be applied consistently to all non-State actors to effectively protect the WHO's reputation as a norm and standard setting organisation. It is possible that NGOs, philanthropic organisations and academic institutions have vested competing interests and these risks must be mitigated diligently and fairly. (comments presented by Canada)

Canada believes that the Framework should be applied consistently, to the extent possible, across all levels of the Organization and all regions to ensure the greatest protection possible against conflicts of interest and undue influence. (comments presented by Canada)

Canada firmly believes that the Framework should be as inclusive as possible while providing the WHO with the proper tools to safely engage with a wide range of non-State actors. The Framework should allow the WHO to expand its current engagement with non-State actors to enable the organization to assume a greater leadership role in global health. (comments presented by Canada)

Canada recognises that several Member states have expressed concerns regarding definitions of the terms "arm's length" and "resources" among others. Regarding the first of these terms, Canada believes it is more important to define the process by which the categorisation of a non-State actor can change over time than it is to further define what is meant by "at an arm's length". We believe there is merit in keeping this definition sufficiently vague to allow the WHO the discretion to act based on the results of the due diligence process to categorise non-State

actors appropriately. Regarding the definition of “resources”, we reiterate that the WHO should specify the conditions under which “personnel” can be accepted from non-State actors, given that the Framework explicitly states that the WHO would not accept secondments. (comments presented by Canada)

Finland finds it important for WHO to have a clear, comprehensive and transparent strategy of engagement with non-State Actors. Such a strategy should be based on three principles:

1. WHO should be able to have different forms of engagement with a variety of actors
2. Such an engagement should be based on a clear benefit to public health
3. The strategy should have built in safeguards for WHO’s good name and respect the intergovernmental nature of the organization.

We believe that it is important to keep the right balance between engagement and protection, as has been achieved in the current version of the framework.

It is important that the same practices are implemented throughout the organization, at all levels and in all regions.

It is equally important that the non-State Actors have a clear understanding of the rules and right expectations for their engagement. (comments presented by Finland)

We endorse the preparation by the Secretariat of a *glossary* or *terminological annex* containing a series of fixed definitions. These will facilitate interpretation of the document which, in its current version, contains occasionally contradictory or not entirely consistent definitions in its various paragraphs. (comments presented by France)

Receipt by WHO of financial resources from private sector entities: In order to maintain WHO’s integrity and reputation, this issue should be clearly linked to the issue of transparency. The source of the financial support as well as its type (ex. donation, annual fee etc.) should in any case be clear-cut. (comments presented by Greece)

In order for WHO to fulfil its constitutional mandate and core function, the integrity and independence of the Organization must be protected and safeguarded, and public confidence maintained.

The draft framework of engagement a good basis for establishing and, where appropriate, strengthening relations with non-State actors, as long as any possible risks and conflicts of interest are accurately described and transparently managed, and if the benefits of engagement are weighed carefully against the risks involved. Improvement of the framework, including its monitoring and evaluation components is very important.

The respective roles of the governing bodies and of the Secretariat should be clarified and private sector involvement should be open to Member States’ oversight. (comment presented by the Islamic Republic of Iran)

It is no doubt that international norms including international standards, codes and guidelines must be based on the latest scientific evidence. And it is also obvious that Non-state Actors

including academia and private industrial entities often have superior scientific know-how and technologies than that of state actors. Therefore Japan believes that WHO cannot accomplish its normative function without their proper involvement. Japan would like to emphasis on the fact that building appropriate, cooperative relations with Non-State Actors is essential for the organization. Japan request secretariat and all member states to recall this principle when we discuss this issues and implement new framework in the future. (comments presented by Japan)

Regarding Non-ear-marked financial contributions from Non-State Actors, such contributions would possibly cause less conflict of interest against WHO compared to ear-marked contribution. Therefore Japan believes that we should discuss if we should deal with non-ear-marked contributions in a different manner from ear-marked contributions. We expect secretariat to include this agenda in the next working group. (comments presented by Japan)

With reference to the importance of One WHO and coherence between all the 6 regions and the three levels of the organization respectively, the final framework must apply organization wide. (comments presented by Norway)

The United States looks to WHO to align and harmonize its institutional and individual policies in relation to conflict of interest. Earlier drafts considered both institutional and individual conflicts of interest. Conflict of interest at the institutional level are usually defined as conflicts of financial interests – missing nonfinancial conflict of interest. This new limitation, combined with the new and undue emphasis on financial interests of the private sector [para. 23, p.4; and para. 26, p. 15], implies that potential financial conflict of interest of private entities are somehow more important than any type of conflict of interest of any other type of NSA. Member States need full information and confidence in exactly what the “separate reform efforts” in this area will be and when in order to remove the management of individual conflict of interest from the scope of this framework policy. Otherwise, the U.S. believes it must remain within this Framework Policy. The relationship between the two must be clarified. We support a sentence in the Framework that makes clear the direct linkage between the two policies. Financial and nonfinancial conflict of interest should be managed consistently across all types of non-State actors. (comments presented by USA)

The framework needs clear operational definitions. (comments presented by Zimbabwe, on behalf of the African group)

Mexico welcomes the report by the Secretariat on the framework of engagement with non-State actors, which confirms that certain comments by Member States have been taken into account, as has the progress made in supplementing the framework, which has been amended with a view to strengthening its normative force, thereby translating into enhanced cooperation and legitimacy for global health action to protect and promote public health.

In general, the submitted document represents a significant advance on the consultations mandated by the Sixty-seventh World Health Assembly. It certainly acknowledges the concerns of Member States regarding the definition and establishment of relations with non-State actors, and we particularly note with satisfaction that the terminology has been changed to eliminate the possibility of divergent interpretations.

Mexico is of the view that this draft should be considered as part of a wider agenda on governance reform.

Mexico believes it is essential to continue to emphasize the principles that should govern such engagement, such as inclusiveness, transparency, accountability, integrity and mutual respect between non-State actors and the World Health Organization (WHO).

The transparency component is essential if the framework of engagement is to be robust and effective. We welcome the proposal to establish a comprehensive register of engagements with non-State actors. However, the register should contain historical as well as current information. The document should also specify the timeline of deliverables to Member States regarding progress on the establishment of the register.

Information about the activities and forms of engagement that WHO already has with non-State actors (irrespective of type) is still lacking. We reiterate that information about experiences to date is of key importance for such engagement. The Secretariat should share this information. (comments presented by Mexico)

The terms of reference of the Committee on non-State actors of the Executive Board should define how the Member State from the Region will be chosen, given that paragraph 43 establishes that the Committee will have six members (one from each Region), but does not specify the selection criteria for the chosen member. (comments presented by Mexico)

The profile of seconded personnel should be better defined through a clear and concise statement on the budget area and human resources. (comments presented by Mexico)

Although the types of non-State actors and types of interaction with WHO are defined, this information should be supplemented by a “formalized” description of the mechanism or process applicable to each category, on the assumption that different mechanisms will apply to the private sector and to academic institutions, for example. (comments presented by Mexico)

It should be specified that the acceptance of resources by WHO should be included in the General Programme of Work, and that this process should be managed in accordance with the rules and policies of the Organization.

In addition, it should be specified that:

- The acceptance of a contribution does not afford the contributor any privilege or advantage, nor does it imply that the Organization endorses the activities, products or services of the non-State actors.
- The contributor may not use the results of WHO’s work for commercial purposes.
- In the interests of transparency, all contributions received must be included in the financial report and financial statements.
- Funds designated to support the salary of specific staff members or posts may not be accepted if they could give rise to a real or perceived conflict of interest in relation to WHO’s work. Accordingly, the conditions that might give rise to a conflict of this nature should be defined.

(comments presented by Mexico)

We have some specific comments in the attached document, but would also like to underline some general principles.

Firstly, as we have said previously, we believe that it is impossible for WHO to fulfil its convening role, if it is unable to engage with all actors who are able to contribute to the global health agenda. Engagement with non-state actors is, therefore, a critical component of WHO's role in global health governance. This is why we welcome the specific aspects of the document that set out the rationale and benefits of engagement and WHO's recognition of the need for that engagement.

Secondly, we believe it is vital that the policy be a platform for a proactive engagement with all actors that have a legitimate and positive role to play in advancing public health for all. So it should enable more engagement, not less, but with a clearer and more robust framework around that engagement. We feel it is important that the document fully captures that enabling spirit.

Thirdly, while we agree that there is a need, in some instances, for non-State actors to be treated differently, we want to see a focus on commonalities within the Framework, with a clear rationale where difference is necessary. In the current draft there remain a number of areas where the rationale for such differences is unclear, this will need to be resolved before we can move forward with a clear and shared understanding.

Fourthly, and more specifically, but illustrative of the principles set out above, we cannot accept a prohibition on all secondments from non-State actors. We believe that this is disproportionate and not in the interests of the WHO or global health more generally. We would like to see provision made for beneficial secondments within the policy, accepting of course that there will need to be robust safeguards around that.

Finally, whilst we would like to thank the Secretariat for seeking to clarify the situation in respect of partnerships, we still have some concerns about how the relationship between the partnership policy and this framework and how they will work together in practice. We would therefore be grateful for further clarification on this aspect during forthcoming discussions. (comments presented by UK)

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