

## Contributions of the Plurinational State of Bolivia

Notes:

In bold and underlined; new text proposed by Bolivia

Strikethrough: deletions suggested by Bolivia

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

#### **Rationale**

2. The health landscape has become more complex in many respects; among other things, there has been an increase in the number of players in global health governance. Non-State actors play a major role in ~~all~~ **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 where appropriate with non-State actors. In support of this aim, WHO~~ engages with non-State actors **as appropriate to fulfill its constitutional mandate for** ~~in~~ the advancement and protection of public health in order to foster the use of non-State actors' resources (including knowledge, expertise, commodities, personnel and finances) in favour of public health and to encourage non-State actors to improve their own activities to protect and promote public health.

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

5. Such a proactive and constructive engagement with non-State actors at global, regional and country levels, ~~in mutual respect and trust~~, also calls for a number of measures of caution. In order to be able to strengthen its engagement with non-State actors, **where appropriate**, for the benefit of **public** ~~global~~ health ~~and in the interest of all actors~~, WHO needs simultaneously to strengthen its management of the associated potential risks. This requires a robust framework for engagement that **govern** ~~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~~ **and public health mandate**. In this way WHO will manage its engagements with non-State actors actively and transparently.

#### **Principles**

Paragraph 6

- c) ~~support and enhance~~ **not compromise** the scientific and evidence-based approach that underpins WHO's work;
- d) protect WHO's **from any undue influence in particular** processes in setting norms and standards, **evidence and information gathering and implementation** ~~from any undue influence~~
- '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~~);  
(New paragraph.)
- g) Not divert from its public health mandate

## Risk of engagement

### Paragraph 8

- 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, **and public health mandate**

## NON STATE ACTORS

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**.

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

## Participation

### Paragraph 16

- (b) **Consultations**. This type includes any physical or virtual meeting, other than governing body sessions, organized for the purpose of exchanging information and views. **Participation of non-State actors in Consultations are subject to the corresponding Mandate and in absence of the latter, by the rules, standards and procedures** ~~There of the organization~~ ~~are no limits imposed in non-State actors' participation in such meetings.~~
- 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. **Participation of non-State Actors are subject to the corresponding Mandate for consultations and in absences of the latter by the rules, standards and procedures of the organization** ~~There are no limits imposed on non-State actors' participation at such meetings.~~

**New paragraph.-**

**Participation of NSA in WHO bodies dealing with formulation or setting of policies, norms or standards, frameworks, strategies, plan of action, guidelines, toolkits, strategies etc. such as expert committee meetings or intergovernmental negotiations, shall not be allowed unless Members States decide otherwise to include NSA participation**

## **Resources**

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

## **Evidence**

19. Evidence includes the gathering, analysis and generation of information, and the management of knowledge and research. **Evidence gathered with the cooperation of non-state actors shall be available for independent verification.**

Paragraph 21

- ~~support to policy making at the national level~~

## **Conflict of Interest**

**(In general terms Bolivia considers that a comprehensive CoI policy should be developed, but we don't have language at this stage)**

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 **public health mandate and** interests, especially the Organization's independence and impartiality **in evidence and information gathering, setting norms and standards and implementation.**

## **Due diligence and risk assessment**

30. The principal functions of due diligence are to:

- determine the entity's status, area of activities, **membership,** governance, sources of funding, constitution, statutes, and by-laws and affiliation;

31. Due diligence also allows the Secretariat for the purpose of its engagement to categorize each non-State actor in relation to one of the four groups of non-State actors on the basis of its nature, objectives, governance, funding, independence and membership. This categorization is indicated in the register of non-State actors. **The due diligence reports including the risk assessment shall be made available in public domain**

### **Risk management**

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. **The decision and the related information of the risk management will be made publicly available.**

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

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

~~Type 1: Information gathering~~

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

~~Type 3: Implementation.~~

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

### **Engagement with particular industries**

44. WHO does not engage with the tobacco or arms industries. In addition, WHO will exercise particular caution when engaging with other industries affecting human health or affected by WHO's norms and standards, **in particular aiming to get compliance with WHO's public health mandate, norms, standards, guideline or policy.**

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

47. The implementation of the framework for engagement with non-state actors is coordinated with the following related policies, which remain valid. **In the case of conflict this framework shall prevail over the policies listed below.**

### **OFFICIAL RELATIONS**

49. **“Official relations”** is a privilege that the Executive Board may grant to nongovernmental organizations, ~~international business associations and philanthropic foundations that have had and continue to have a sustained and systematic engagement<sup>†</sup> in the interest of the Organization. The whose~~ aims and activities of all these entities shall be are 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.

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

(Bolivia is the view that a set of rules for accreditation of NGOs should be developed.)

### **DRAFT WHO POLICY AND OPERATIONAL PROCEDURES ON ENGAGEMENT WITH NON-GOVERNMENTAL ORGANIZATIONS**

#### **PARTICIPATION**

##### **Participation by nongovernmental organizations in WHO meetings**

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 expertise, information or 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.

#### **RESOURCES**

7. WHO can accept funds, ~~personal~~, 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.

##### **Specific policies and operational procedures**

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 contributing NGO shall disclose the source of its contribution and the Secretariat shall make this information publicly available.

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

~~3. In engaging with private sector entities, WHO will aim to operate on a competitively neutral basis.~~

## **PARTICIPATION**

### **Participation by private sector entities in WHO meetings**

4. WHO can hold consultations with private sector entities, as well as non-State actors with links to private sector entities, if there is a mandate from the governing bodies. ~~in the preparation of policies.~~ Consultations can be electronic or in person, and may take the form of hearings at which private sector entities can present their views. The format of such consultations is decided on a case-by-case basis either by the governing body at the session at which a hearing or consultation is mandated or in other cases by the Secretariat.

5. WHO can invite private sector entities as well as non-State actors with links to private sector entities to participate in other WHO meetings, if there is a mandate from the governing bodies and if those meetings are not involved in the formulation or setting of policies, norms, standards or guidelines. In absence of such a mandate, applicable rules, policies and procedures of the organization shall apply. 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.

New paragraph 5.bis

The information with regard to participation of private sector entities as well as non-State actors with links to private sector entities, in consultation or hearing or any other WHO meeting including inputs of the private sector entities as well as non-State actors with links to private sector entities in such meetings such as presentation or oral or written submission shall be made publicly available.

~~8. WHO does not cosponsor meetings organized by specific private sector entities. It may, however, cosponsor a meeting for which the scientific initiators have hired a commercial conference organizer to deal with the logistical aspects, provided that the commercial organizer makes no contribution to the scientific content of the meeting.~~

## **RESOURCES**

12. The level of risk associated with the acceptance of resources from private sector entities depends on the field of activity of the private sector entity, the WHO activity for which the resources are used and the modalities of the contributions

New paragraph (d)

WHO shall not receive financial resources from private sector entities as well as non-State actors with links to private sector entities whose activities or advocacy are

**undermining the mandate of WHO as stated in its Constitution or decisions and resolutions of governing bodies**

(New Paragraphs)

**17bis Anonymous donations: Anonymous donations may not be accepted under any circumstances.**

**18bis Return of donations: Any donation received by WHO which is subsequently discovered to be noncompliant with this Framework shall be returned to the donor.**

*Financial contributions for clinical trials*

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

(New paragraphs)

(b) **The clinical trial data shall be made available for public scrutiny**

(c) **The clinical trial follows the ethical standards laid down in the Helsinki Protocol**

(d) **The final product shall be made accessible and affordable to the patients, in particular in developing countries.**

*Contributions for WHO staff participating in external meetings*

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

- a) meetings held by the private sector entity paying for travel: financing for travel ~~may~~ **will not** 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;~~

*Contributions for financing staff salaries*

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

**contribution from private sector entities to support the salary of staff including short-term consultancy.**

**EVIDENCE**

32. Individuals working for interested private sector entities **as well as non-State actors with links to private sector entities** are excluded from participating in advisory groups, expert committee, working groups etc.; however, expert groups need to be able, where appropriate, to conduct hearings with such individuals in order to access their knowledge. **Inputs provided by such individuals should be made public.**

**TECHNICAL COLLABORATION**

36. Technical collaboration with the private entities **as well as non-State actors with links to private sector entities** 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.

*Product development*

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

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

**PARTICIPATION**

**Participation by philanthropic foundations in WHO meetings**



3. WHO can hold consultations with philanthropic foundations **if there is a mandate from the governing bodies.** ~~in the preparation of policies.~~ Consultations can be electronic or in person, and may take the form of hearings at which philanthropic foundations can present their views. The format of such consultations is decided on a case-by-case basis either by the governing body at the session at which a hearing or consultation is mandated or in other cases by the Secretariat. **Inputs from philanthropic foundations shall be publicly available.**

4. WHO can invite philanthropic foundations to participate in other WHO meetings **if there is a mandate from the governing bodies.** Such participation is on the basis of discussion of an item in which the philanthropic foundation has a particular **expertise, information or 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 available in public.**

#### *Operational procedures*

6. The participation of WHO in meetings organized by philanthropic foundations as co-organizers, cosponsors, panellists or speakers shall be managed according to the provisions of the framework for engagement with non-State actors. **Any decision with regard to the participation of WHO staff in the meeting can be done only after proper risk assessment including the actual or perceived conflict of interest. This risk assessment report shall be made public.**

## **RESOURCES**

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

#### *Specific policies and operational procedures*

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**

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

### **PARTICIPATION**

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

4. WHO can hold consultations with academic institutions **if there is a mandate from the governing bodies.** ~~in the preparation of policies.~~ Consultations can be electronic or in person, and may take the form of hearings at which academic institutions can present their views. The format of such consultations is decided on a case-by-case basis either by the governing body at the session at which a hearing or consultation is mandated or for other cases by the Secretariat. **Inputs received from academic institutions shall be made publicly available**

5. WHO can invite academic institutions to participate in other WHO meetings **if there is a mandate from the governing bodies requiring such meetings.** Such participation is on the basis of discussion of an item in which the academic institution has a particular interest and where its participation adds value to the deliberations of the meeting. Such participation is also for the exchange of information and views, but not for the formulation of any advice. **Inputs received from academic institutions shall be made publicly available**

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

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

## **EVIDENCE**

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 shall ensure that the intellectual property arising from collaboration with academic institutions are freely accessible for further research and development or studies as well as other non-commercial uses.**

## **TECHNICAL COLLABORATION**

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

---