Background document to support discussion of WHO’s engagement with non-State actors

NOTE BY THE SECRETARIAT

1. As part of the WHO governance reform process the Executive Board mandated the Secretariat to develop a framework of engagement with non-State actors. This will include separate policies and operational procedures for both WHO’s engagement with nongovernmental organizations and for WHO’s engagement with the private sector.¹

2. The Board agreed that there would be a further consultation with Member States on the draft framework, policies and operational procedures. This consultation is scheduled for 27–28 March 2014. Unlike the previous consultation it is a consultation for Member States only.

3. Based on the guidance that Member States provide during the informal consultation, the Director-General will revise the draft policies and operational procedures and submit them for the consideration of the Sixty-seventh World Health Assembly in May 2014 through the Programme, Budget and Administration Committee of the Executive Board.

4. This document includes the following elements for review and consultation by Member States:

   • The draft framework of engagement with non-State actors, including a glossary of the key terminology, a description of the rationale for engagement and the overarching principles guiding WHO’s engagement with non-State actors.

   • The draft WHO policy and operational procedures on engagement with nongovernmental organizations.

   • The draft WHO policy and operational procedures on engagement with private sector entities.

   • The draft WHO policy and operational procedures on management of engagement with non-State actors, defining the common policies and processes applied in the management of WHO’s engagement with all non-State actors.

5. The draft framework and the policies have been developed on the basis of the process conducted so far on WHO engagement with non-State actors, including the informal consultations in October 2013.

¹ See decision EB132(11).
Background document to support discussion of WHO’s engagement with non-State actors

and discussion by the Executive Board at its session in January 2014. It builds on the experience in the implementation of the Principles governing relations between the World Health Organization and nongovernmental organizations (adopted in resolution WHA40.25, 1987)\(^1\) and the Guidelines on working with the private sector to achieve health outcomes (document EB107/20, 30 November 2000).\(^2\)


OVERARCHING FRAMEWORK FOR ENGAGEMENT WITH NON-STATE ACTORS

RATIONALE

1. Today’s health landscape has become more complex in many respects, including the increase in players in global health governance. Non-State actors play a major role in all aspects of global health and in order to fulfil its leadership and coordinating role WHO will need to increase the breadth of its engagement with such actors. However, although this engagement is essential for the achievement of global public health goals, it also carries inherent risks. This requires a robust framework for engagement that encourages and increases engagement but serves also as an instrument to identify the risks and balances them against the expected benefits, while protecting and preserving WHO’s integrity and reputation. To this end, WHO manages its engagements with non-State actors actively and transparently.

PRINCIPLES

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

(a) demonstrate a clear benefit to public health;
(b) respect the intergovernmental nature of WHO;
(c) support and enhance the scientific and evidence-based approach that underpins WHO’s work;
(d) be actively managed so as to reduce any form of risk to WHO (including conflicts of interest);
(e) be conducted on the basis of transparency, openness and inclusiveness.

BOUNDARIES

3. WHO’s engagement with non-State actors is limited by four clear boundaries.

(a) Decision-making by the governing bodies is the exclusive prerogative of Member States.
(b) WHO’s processes in setting norms and standards must be protected from any undue influence.
(c) WHO does not engage with industries making products that directly harm human health, such as tobacco or arms.
(d) Engagement with non-State actors must not compromise WHO’s reputation.
TYPES OF INTERACTION

4. The following are categories of interaction in which WHO engages with non-State actors:

• participation
• resources
• evidence
• advocacy
• technical collaboration.¹

5. Each of these interactions can take different forms, be subject to different levels of risk and can involve different levels and types of engagement by the Organization. The draft policy and operational procedures on engagement with nongovernmental organizations and with private sector entities below each propose provisions relating to these interactions.

¹ In document EB134/8 the term “technical cooperation” was used. Based on further analysis the Secretariat proposes to use the term “technical collaboration” instead.
WHO POLICY AND OPERATIONAL PROCEDURES ON ENGAGEMENT WITH NONGOVERNMENTAL ORGANIZATIONS

1. This section describes the draft policy and operational procedures that relate to interactions with nongovernmental organizations. The provisions of the draft overarching framework of engagement with non-State actors and the draft policy and operational procedures for management of engagement with non-State actors also apply to engagement with nongovernmental organizations.

2. Nongovernmental organizations engaging with WHO are expected to conform to WHO public health policies.

3. Nongovernmental organizations engaging with WHO shall not influence the Organization’s policy making, which is the prerogative of Member States, nor the setting of technical standard and norms, which is the responsibility of the Secretariat.

TYPES OF INTERACTION

Participation

**Participation by nongovernmental organizations in WHO meetings**

4. Nongovernmental organizations in official relations can participate in WHO’s governing body meetings in accordance with the applicable procedures and practice.

5. WHO can hold informal consultations with nongovernmental organizations in the preparation of policies. Consultations can be electronic or in person, including in the form of hearings where nongovernmental organizations can present their views. The format of such consultations is decided on a case-by-case basis.

6. WHO can invite nongovernmental organizations that are not in official relations to participate in WHO’s meetings. Such participation would be on the basis of discussion of an item in which the nongovernmental organization has a particular interest and where its participation adds value to the outcome of the meeting.

*Operational procedures*

7. The Executive Board can grant the status of “in official relations” to nongovernmental organizations that have a sustained and systematic engagement in the interest of the Organization. The conditions and modalities are regulated in the draft policy on management of engagement with non-State actors outlined below.

8. Nongovernmental organizations participating in WHO meetings shall designate a head of their delegation and declare the affiliations of their delegates. This declaration shall include the function of each delegate within the nongovernmental organizations itself and where appropriate the function of that delegate within any affiliated organization.
Participation by the Secretariat in meetings organized by nongovernmental organizations

9. WHO staff can participate in nongovernmental organization meetings, WHO can organize joint meetings, or cosponsor meetings organized by nongovernmental organizations, as long as the integrity and independence of the Organization is preserved, and as long as this participation furthers WHO’s objectives as expressed in the General Programme of Work.

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

11. In cases where private sector entities cosponsor a nongovernmental organization meeting, the emblem of WHO shall be separated from those of the private sector cosponsors. If a private sector commercial organizer organizes the logistics of such a meeting, the private sector entity shall make no contribution to the scientific or other content of the meeting.

12. WHO does not cosponsor commercial exhibitions.

Resources

13. 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 and are managed in accordance with the draft framework, and comply with other relevant WHO regulation, rules and policies.

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

Specific policies and operational procedures

15. Any acceptance of resources from a nongovernmental organization is handled in accordance with the provisions of the draft policy on management of engagement and relevant other rules such as the Staff Regulations and Rules, the Financial Regulations and Rules and the policies governing procurement by WHO.

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

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

18. Contributions received from all sources, including nongovernmental organizations, are listed in the Financial Report and Audited Financial Statements of WHO.

19. Any contribution received by WHO that is subsequently discovered to be noncompliant with this draft framework for engagement with non-State actors shall be returned to the donor.
20. Acceptance of financial or in-kind resources from nongovernmental organizations must be approved in accordance with the draft framework for engagement with non-State actors and based on a signed agreement.

21. Nongovernmental organizations may not capitalize on their donation by using the results of WHO’s work to promote themselves. However, they may make reference to the contribution in their annual reports or similar documents.

Seconded personnel

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

(a) The overall policy of secondment of personnel applies and the secondment is cleared by the Department for Human Resources.

(b) There is no conflict of interest between the person’s proposed activities for WHO and his or her activities for the employer nongovernmental organization.

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

(d) The seconded person is expected to follow the same rules of conduct as other staff members of WHO and will report only to WHO.

(e) Failure of the seconded person to abide by WHO’s standards of conduct may result in disciplinary measures and ultimately in termination of the secondment.

Evidence

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

Advocacy

24. WHO collaborates on advocacy for health and increasing awareness of health issues; for changing behaviours in the interest of public health; and for fostering collaboration and greater coherence between non-State actors where joint action is required. WHO favours independent monitoring functions and therefore engages with nongovernmental organizations working in this field. Nongovernmental organizations are expected to disseminate WHO policies, guidelines and other tools through their networks so as to extend WHO’s individual reach.

Technical collaboration

25. The Secretariat is encouraged to undertake technical collaboration with nongovernmental organizations provided it is in the interest of the Organization and managed in accordance with the draft framework for engagement with non-State actors.
WHO POLICY AND OPERATIONAL PROCEDURE ON ENGAGEMENT WITH PRIVATE SECTOR ENTITIES

1. This section describes the draft policy and operational procedures that relate to interactions with private sector entities. The provisions of the draft overarching framework of engagement with non-State actors and the draft policy and operational procedure on management of engagement with non-State actors also apply to engagement with the private sector.

2. Private sector entities engaging with WHO are expected to conform to WHO public health policies.

3. Private sector entities engaging with WHO shall not influence the Organization’s policy making, which is the prerogative of Member States, nor the setting of technical standard and norms, which is the responsibility of the Secretariat.

4. When other non-State actors, such as nongovernmental organizations, philanthropic foundations and academic institutions receive funding from private sector entities they will not automatically be considered as being themselves a private sector entity. The relevant provisions of the private sector policy may apply subject to an assessment of the relevant circumstances such as the level of funding provided by the private sector entity, and the nature and purpose of the engagement.

TYPES OF INTERACTION

Participation

Participation by private sector entities in WHO meetings

5. International business associations in official relations can participate in WHO’s governing body meetings in accordance with the applicable procedures and practice.

6. WHO can hold hearings with private sector entities. Hearings can be electronic or in person. All interested private sector entities should be invited on the same basis or all interested international business associations are invited to propose participants. The participants and positions presented during hearings shall be documented.

7. Private sector entities can be invited to informal consultations, if these consultations are not related to the elaboration of policies, norms and standards.

Operational procedures

8. The Executive Board can grant the status of “in official relations” to international business associations that have a sustained and systematic engagement in the interest of the Organization. The conditions and modalities are regulated in the draft policy on management of engagement with non-State actors outlined below.

9. International business associations participating in WHO meetings shall designate a head of their delegation and declare the affiliations of their delegates. This declaration shall include the
function of each delegate within the business association itself and where appropriate within an affiliated private sector entity.

10. There shall be no commercial exhibitions at WHO meetings (whether of WHO’s governing bodies or technical programmes, and whether held on WHO premises or elsewhere).

**Participation by the Secretariat in meetings organized by private sector entities**

11. WHO staff can participate in meetings of a private sector entity as long as the integrity and independence of the Organization is preserved and as long as this participation furthers WHO’s objectives as expressed in the General Programme of Work. The private sector entity shall not misrepresent WHO’s participation as official WHO support for the meeting, and shall agree not to use WHO’s participation for commercial and/or promotional purposes.

12. WHO shall not co-organize or cosponsor meetings or exhibitions organized by private sector entities.

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

**Resources**

14. Any acceptance of financial, personnel or in-kind contribution from private sector entities shall be managed in accordance with the draft framework for engagement with non-State actors.

15. 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.

16. Funds may not be sought or accepted from private sector entities that have themselves or through their affiliated companies have a direct commercial interest in the outcome of the project toward which they would be contributing, unless approved in conformity with the provisions on clinical trials or product development, set out below.

17. 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 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 donation 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.

18. Unspecified financial and in-kind contributions from private sector entities to WHO programmes are only acceptable under 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 to clearly 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.

19. The acceptance of donations (whether in cash or in kind) should be made subject to the following conditions:

(a) The acceptance of the donation does not constitute an endorsement by WHO of the private sector entity, its activities, products or services.

(b) The donor may not use the results of WHO’s work for commercial purposes or seek promotion of its donation.

(c) The acceptance of the donation does not award the donor with any privilege or advantage.

(d) The acceptance of the donation does not offer the donor any possibility for advising, influencing, participating in, or being in command of the management or implementation of operational activities. WHO keeps its discretionary right to decline a donation, without any further explanation.

20. The Director-General can set up mechanisms of pooled donations from multiple sources, if the mechanisms are designed in such a manner as to avoid any perceived influence from the donors on WHO’s work; the mechanism is open to all interested donors; and is subject to the conditions in paragraph (19) above.

Specific policies and operational procedures

21. For reasons of transparency, contributions and donations from private sector entities must be publicly acknowledged by WHO in accordance with its policies and practices.

22. Acknowledgements shall usually be worded along the following lines: “The World Health Organization gratefully acknowledges the financial contribution of [private sector entity] towards [description of the outcome or activity].”

23. Contributions received from all sources, including private sector entities, are listed in the Financial Report and Audited Financial Statements of WHO.

24. Any contribution received by WHO that is subsequently discovered to be noncompliant with this draft framework for engagement with non-State actors shall be returned to the donor.

25. Acceptance of financial or in-kind resources from private sector entities must be approved in accordance with the draft framework for engagement with non-State actors and based on a signed agreement.

26. Private sector entities may not use the results of WHO’s work for commercial purposes or seek promotion from the fact that they have made a financial contribution. However, they may make reference to contribution in their corporate annual reports or similar documents.
Seconded personnel

27. Secondments from private sector entities to WHO are acceptable provided that:

(a) The overall policy of secondment of personnel applies and the secondment is cleared by the Department for Human Resources.

(b) Personnel are not seconded from entities whose activities clearly conflict with WHO’s mandate.

(c) There is no conflict of interest between the person’s proposed activities for WHO and his or her activities for the employer company.

(d) The terms of reference of the seconded person are designed to ensure that he or she will not, during the secondment, participate in activities in which the employer private sector entity is involved, or which could promote the commercial interests of this entity. The seconded person should further more be clearly informed of his or her obligations of confidentiality (both during and after the secondment). The said person should not seek or accept any instructions from, nor report to, any authority or entity external to WHO during the secondment including, specifically, the employer entity.

(e) The seconded person is expected to follow the same rules of conduct as other staff members at WHO and will report only to WHO.

(f) Failure of the seconded person to abide by WHO’s standards of conduct may result in disciplinary measures and ultimately in termination of the secondment.

Donations of medicines

28. In determining the acceptability of large-scale donations of medicines, the following criteria should be met:

(a) Sound evidence exists of the safety and efficacy of any medicine in the indication for which it is being donated. The medicine is approved or otherwise authorized by the recipient country for use in that indication; it should preferably appear in the WHO model list of essential medicines for that indication.

(b) Objective and justifiable criteria for the selection of recipient countries, communities or patients have been determined.

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

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

(e) A donation of medicines is not of a promotional nature, either with regard to the company itself, or by creating a demand for the medicine that is not sustainable once the donation has ended.
(f) A phase-out plan for the donation has been agreed upon with recipient countries.

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

29. In consultation with the financial services of WHO, the value of donations of medicines is determined and is formally recorded in the audited statements.

Donations for clinical trials

30. Except as provided in the paragraph on product development, cash contributions from a commercial enterprise for a trial arranged by WHO of that company’s proprietary product is addressed on a case-by-case basis and always decided by the Senior Management Committee on Engagement. In this connection, it should be ensured that:

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

(b) the research is conducted at WHO’s request;

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

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

Donations for WHO meetings

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

33. Contributions may be accepted to support the overall costs of a meeting, subject to the provisions of this draft framework for engagement with non-State actors.

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

Donations for WHO staff participating in external meetings

35. An external meeting is one convened by a party other than WHO. Support from private sector entities for travel of WHO staff 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 as per WHO rules if the private sector entity or trade association is also supporting the travel and ancillary expenses of other participants at the meeting, and the risk of a conflict of interest has been assessed;
(b) meetings held by a third party (i.e. a party other than the private sector entity or trade association proposing to pay for the travel): financing for travel may not be accepted from a private sector entity.

*Donations for publications*

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

*Donations for financing staff salaries*

37. Funds designated to support the salary of specific staff 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.

38. The acceptability of contributions from private sector entities to projects that have a staffing element should be reviewed in the light of other relevant guidance provided in this document.

*Cost recovery*

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

*Evidence*

40. 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 strictly managed.

41. 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 to access their knowledge.

*Advocacy*

42. WHO encourages private sector entities to implement and advocate for the implementation of WHO norms and standards.

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

44. Technical collaboration with the private sector is welcomed if potential risks of engagement are managed or mitigated, provided that there are clear firewalls around the normative work of WHO and there is no interference with WHO’s advisory function to Member States.

Specific policies and operational procedures

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

Product development

46. WHO collaborates with private sector entities in the development of health-related technology, either by conducting research and development on their products, or by licensing its intellectual property to such enterprises. Collaborative research and development should, as a general rule, be undertaken only if WHO and the entity concerned have concluded an agreement cleared by the Legal Counsel, which ensures that the final product will ultimately be made widely available, 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 trial arranged by WHO on the product in question, since 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 trial arranged by WHO on a proprietary product.
WHO POLICY AND OPERATIONAL PROCEDURES ON MANAGEMENT OF ENGAGEMENT WITH NON-STATE ACTORS

BENEFITS AND RISKS OF ENGAGEMENT

1. In the main, WHO’s engagement with non-State actors brings important benefits to global public health and to WHO itself. Therefore WHO engages extensively with non-State actors in the types of engagement described in the draft policy on engagement with nongovernmental organizations and the draft policy on engagement with the private sector. Engagements range from major, longer-term collaborations to smaller, briefer interactions.

2. However, there can be risks in engagement with non-State actors. WHO takes a risk management approach to engagement, entering only when the benefits of the engagement in terms of direct or indirect contributions to the fulfilment of the Organization’s mandate and the public health gains clearly outweigh the time and expense involved in establishing and maintaining the engagement as well as the risk of engagement. The implementation of the draft framework for engagement with non-State actors is coordinated with related policies.

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

   • WHO’s engagement with a non-State actor could lead to undue or improper influence (real or perceived) being exercised by this actor on WHO’s work, especially but not limited to norms and standard setting.

   • WHO’s engagement with a non-State actor could negatively impact WHO’s reputation and credibility including by diminishing the value and integrity of WHO’s name, emblem and work, which would in turn undermine the value of WHO’s work.

   • Collaboration with WHO could be misused by a non-State actor for its own benefits. This includes influence of WHO by a non-State actor to obtain a competitive advantage or undue endorsement; the interaction aiming at achieving the partner’s objectives with limited benefit and/or excessive burden to the Organization or “white washing” of a non-State actor’s image through its association with WHO.

4. Conflict of interest is an important area for consideration of related risk. A conflict of interest is a set of circumstances in which professional judgment or actions regarding a primary interest

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1.-WHO’s involvement in external partnerships is regulated by the policy on WHO’s engagement with global health partnerships and hosting arrangements (endorsed by the World Health Assembly in resolution WHA63.10). For the management of risks of WHO’s engagement in these partnerships the draft framework for engagement with non-State actors applies.

- The management of WHO’s relations with individual experts is regulated by the Regulations for expert advisory panels and committees (see WHO basic documents http://apps.who.int/gb/bd/PDF/bd47/EN/regu-for-expert-en.pdf).

- The procurement of goods and services is not covered by the draft framework for engagement with non-State actors, although pro-bono contributions and collaboration with nongovernmental organizations as implementing partners are covered.

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(WHO’s work) may be unduly influenced by a secondary interest (a vested interest in the outcome of WHO’s work in a given area). This secondary interest may affect or may reasonably be seen to affect the independence and objectivity of WHO’s work.

TRANSPARENCY

5. WHO’s interaction with non-State actors shall be managed transparently. Non-State actors engaging with WHO are required to provide basic information on their organization. WHO provides to the governing bodies annual reports on its engagement with non-State actors and makes basic information on individual engagements publicly available.

DUE DILIGENCE, RISK ASSESSMENT AND RISK MANAGEMENT

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

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

   • Clarify what is in the interest of the actor to engage and what they really expect in return.

   • Establish the “business card” of the entity (general screening).

   • Status, area of activities, governance, sources of funding, constitution, statutes and by-laws, affiliation.

   • Main elements describing the history of the entity: human and labour issues, environment ethical and business issues, reputation and image as well as the financial stability of the examined entity.

   • Identification of “red lines” such as: activities that are incompatible with WHO’s work and mandate (such as activities by the tobacco and arms industries).

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

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

2 WHO’s due diligences are internally conducted in order to exclude any external undue influence and are drawn from readily available information as much as possible. The unit in charge of conducting them proceeds by screening different public and commercial sources of information, including: press and media (newspapers, newsletters, aggregate sources, magazine and journals); companies’ analyst reports, directories and profiles; public and governmental sources (governmental registers, charity commissions, registers of trade and industry).
9. **Risk management** is the management process leading to a decision on engagement, engagement with measures to mitigate risks, non-engagement or disengagement from an ongoing or planned engagement.

**WHO REGISTER OF NON-STATE ACTORS**

10. The WHO register of non-State actors is an electronic tool used by the Secretariat to document engagement with non-State actors. It contains standard information provided by non-State actors and descriptions of the engagement that WHO has with these actors.

**POLICY, NORMS AND STANDARD SETTING**

11. WHO distinguishes three phases of dealing with policies approved by the governing bodies and scientific and technical norms and standards. Reference to specific protection of the norms and standard setting process refers to the second phase.
   1. Information gathering
   2. Preparation for, elaboration of and decision on the normative text, and
   3. Implementation.

**ASSOCIATION WITH WHO’S NAME**

12. WHO’s **name and emblem** are recognized symbols of integrity and of quality assurance to the public. WHO’s name, acronym and emblem shall not be used for or in conjunction with commercial and/or promotional purposes. This includes but is not limited to use for the promotion, advertisement or marketing of products or services. Any use of the name or emblem needs an explicit written authorization by the WHO Director-General (delegated to the Legal Counsel).¹

**OVERSIGHT OF ENGAGEMENT**

13. The Executive Board, through its Committee on non-State actors,² oversees the implementation of WHO’s policy on engagement with non-State actors, proposes revisions to the draft framework and can grant the status of official relations to international nongovernmental organizations, philanthropic foundations and international business associations.

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¹ See [http://www.who.int/about/licensing/emblem/en/](http://www.who.int/about/licensing/emblem/en/).

² See the terms of reference of the Committee on non-State actors of the Executive Board in paragraphs 23–26.
PROCESS OF MANAGEMENT OF ENGAGEMENT

14. The WHO Secretariat\(^1\) decides on engagement, continuation of engagement and termination of engagements with non-State actors based on an explicit management decision. No prior decision nor the status of being in official relations automatically confers a qualification for all kinds of engagements. The decisions are based on a standard decision-making process including a due diligence, risk assessment and risk-management decision. A description of the engagement is documented in the WHO register of non-State actors.

15. When WHO decides on an engagement with a non-State actor, the information provided by such a non-State actor is entered by it in the register of non-State actors. The content of this information is the responsibility of the non-State actor and does not constitute any form of endorsement by WHO. Non-State actors described in the register must update their information annually or on the request of WHO.

16. Failure on the part of a non-State actor to comply with the agreed terms of the engagement as set forth in the draft framework for engagement with non-State actors or other applicable WHO policies can lead to the discontinuation of WHO’s engagement with the non-State actor.

\[\text{Specific operational procedures for the initiation, continuation and discontinuation of engagement}\]

17. A Senior Management Committee on Engagement appointed by the Director-General discusses referred proposals of engagement. It can decide on engagement, risk mitigation or non-engagement or refer the case to the Director-General for decision.

18. Decisions on engagement, risk management or non-engagement and the documentation of engagements are facilitated through an electronic workflow,\(^2\) whereby the information provided by the non-State actor on its nature and the description of the proposed engagement is subject to a due diligence procedure and risk assessment. If the risk assessment shows there to be a clearly greater benefit than risk in the engagement then the line manager can decide on the engagement. Any proposal with potentially significant risks shall be referred to the Senior Management Committee on Engagement.

19. Information in the 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”.

20. The Secretariat distinguishes between nongovernmental organizations, private sector entities, philanthropic foundations and academia, based on their nature, objectives, governance, independence and membership and not necessarily on the basis of their legal status or funding. The attribution of a non-State actor to one of these categories can change over time.

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\(^1\) Meaning all three levels of the Organization: global, regional and country level, including hosted partnerships and joint programmes.

\(^2\) The electronic workflow system is closely coordinated with the management of individual conflicts of interest in order to coordinate the implementation of the draft framework with the implementation of the policy on management of individual conflicts of interest for experts.
21. WHO maintains and updates a handbook guiding non-State actors in their interaction with WHO.

22. WHO maintains a guide for staff on the implementation of the draft framework for engagement with non-State actors.

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

23. The Committee on non-State actors shall be composed of six members, one from each region, selected from among Executive Board members during the May session of the Executive Board.

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

   (1) Oversight of WHO’s implementation of the draft framework for engagement with non-State actors including:

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

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

   (2) Non-State actors in official relations with WHO

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

   (b) review of renewals of non-State actors status of official relations

   (3) Proposal when needed of revisions of the framework of engagement with non-State actors.

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

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

27. As a recognition of sustained and systematic engagement\(^1\) by a non-State actor with WHO, WHO can grant the status of “organization in official relations” to international nongovernmental organizations, philanthropic foundations and international business associations whose aims and activities are in conformity with the spirit, purposes and principles of the Constitution of WHO, and who contribute significantly to the advancement of public health.

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

29. International nongovernmental organizations shall be free from concerns that are primarily of a commercial or profit-making nature. Its members shall exercise voting rights in relation to its policies or actions, or the organization shall otherwise be constituted with a non-profit public interest goals. They shall have the authority to speak for their members through their authorized representatives.

30. Philanthropic foundations shall be clearly independent from any private sector entity in their governance and decision making. They shall commit to collaborate with WHO through contributions that include but are not limited to financial support.

31. International business associations shall have the authority to speak for their members through their authorized representatives. Their members shall exercise voting rights in relation to their policies or action. They shall commit to work with their members in order to improve their public health impact and the implementation of WHO policies, norms and standards.

32. 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 report annually on the WHO register of non-State actors on the progress made in implementing the plan of collaboration and other related activities.

33. The Executive Board shall be responsible for deciding on the admission of organizations into official relations with WHO and shall review this status every three years. The Director-General proposes under what title an organization is admitted (International nongovernmental organizations, philanthropic foundations, or international business associations). The Director-General can propose an earlier review based on the experience in the collaboration with the organization.

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

(a) The right to appoint a representative to participate, without right of vote, in WHO’s meetings or in those of the committees and conferences convened under its authority.

\(^1\) Meaning at least for two years of systematic engagement as documented in the WHO register of non-State actors, assessed by both parties to be mutually beneficial. Participation in each other’s meetings alone is not considered to be a systematic engagement.
(b) The right to submit a memorandum to the Director-General, who would determine if this statement should be posted on a dedicated website for statements from non-State actors.

(c) The right to make a statement at the invitation of the Chairperson of the meeting or the Chairperson acceding to a request from an organization during a session of the World Health Assembly, the Executive Board or regional committee, when it discusses an item in which the related nongovernmental organization is particularly interested.

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

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

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

36. 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. Applications for official relations shall be reviewed to ensure that the established criteria and other requirements are fulfilled as set out in the draft framework for engagement. Applications should be transmitted to the Executive Board members by the Secretariat six weeks in advance of the January session of the Executive Board at which they will be considered for admission.

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

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

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

40. The Director-General shall inform each organization of the Board’s decision on its application. The Director-General shall maintain a list of the organizations admitted into official relations, reflect the status in the register of non-State actors and document decisions taken within the Secretariat and by the Executive Board on applications from non-State actors.
41. The Board, through its Committee on non-State actors, shall review collaboration with each non-State actor every three years and shall determine the desirability of maintaining official relations or defer the decision on the review to the following year. The Board’s review shall be spread over a three-year period, one-third of the non-State actors in official relations being reviewed each year.

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

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

GLOSSARY¹

Actors

1. **Non-State actor** is an entity that is not part of any State or public institution. Non-State actors include nongovernmental organizations, private sector entities, philanthropic foundations and academic institutions.

2. **Nongovernmental organizations** are non-profit entities that operate independently of governments. They are usually membership-based with non-profit entities or individuals as members, or are otherwise constituted with non-profit, public interest goals that are not related to any private interest. They include grassroots community organizations, civil society groups and networks, faith-based organizations, professional groups, disease specific groups, and patient groups.

3. **Private sector entities** are commercial enterprises, i.e. businesses that are intended to make a profit for their owners. The term also refers to entities that represent or are governed or controlled by private sector entities. This includes (but is not limited to) business associations representing commercial enterprises, entities not at “arms’ length” of their commercial sponsors, and partially or fully state owned commercial enterprises acting like private sector entities.

4. **Philanthropic foundations** are non-profit entities whose assets are provided by donors and whose income is spent on socially useful purposes. If a philanthropic foundation is under the influence of a private sector entity, it is considered in the same way as a private sector entity.

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

Interactions

6. The following paragraphs provide detailed definitions of the different types of interactions with non-State actors.

Participation

7. Participation is the attendance by non-State actors at WHO-organized meetings. Participation can take different forms including: participation in governing bodies, participation in consultations, hearings, and in other WHO meetings.

(a) **WHO governing bodies** are the World Health Assembly, the Executive Board and the six regional committees. Participation would be in accordance with the bodies’ respective rules of procedure, policies and practices.

¹ The definition of terms provided is for the purposes of this document only.

² The main policy for collaboration with academic institutions remains the Regulations for Study and Scientific Groups, Collaborating Institutions and other Mechanisms of Collaboration (last amended by the Executive Board in resolution EB105 R.7). The draft framework under review also applies to other collaboration with academic institutions.
(b) **Consultations** are any physical or virtual meeting other than governing bodies for the purpose of exchanging information and views.

(c) **Hearings** are meetings where the participants can present their evidence, views and positions and be questioned about them but do not enter into a debate.

**Resources**

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

**Evidence**

9. Evidence includes information gathering, generation and management of knowledge and research.

**Advocacy**

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

**Technical collaboration**

11. For the purpose of this draft framework, technical collaboration refers to other collaboration with non-State actors, as appropriate, in activities which 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.