



WORLD HEALTH ORGANIZATION

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Guidelines on working with the private sector to achieve health outcomes

Report by the Secretariat

1. At its 105th session in January, the Board reviewed progress of work on the establishment of public-private partnerships for health.¹ Members encouraged new and more flexible forms of partnerships and other relationships in order to advance WHO's health agenda. They also stressed the need to be fully transparent and to avoid conflict of interest arising in any relationship.
2. At the same session, the Board endorsed a new policy for extrabudgetary resources, which emphasizes broadening the range of donors to include private sector entities.²
3. In parallel with work on these subjects, a draft set of guidelines on interaction with commercial enterprises,³ was prepared and sent for comment in mid-1999 to Member States and nongovernmental organizations in official relations with WHO, together with a number of other interested bodies. The draft guidelines have also been used in consideration of a range of individual proposals for interaction with the private sector that have arisen over the past year. The guidelines have now been revised on the basis of comments received and of experience in their use.
4. In view of expressions of interest during the discussions at the Board in January 2000, the revised version is now annexed to the present document for the information of the Board.

ACTION BY THE EXECUTIVE BOARD

5. The Executive Board is invited to note the attached guidelines on interaction with the private sector.

¹ Documents EB105/8 and EB105/2000/REC/2, summary record of the second meeting, p. 41.

² Decision EB105(2) and document EB105/2000/REC/1, Annex 8.

³ Defined as the for-profit part of the private sector.



Guidelines on interaction with commercial enterprises to achieve health outcomes

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PURPOSE

1. These guidelines are intended primarily to help WHO staff interact appropriately with commercial enterprises in order to achieve positive outcomes for health. They are posted on WHO's Web site and are available to Member States, organizations and bodies in the public and private sector, and the general public. Procedures for their implementation are appended.

COMMERCIAL ENTERPRISES

2. Commercial enterprises are defined as businesses that are intended to make a profit for their owners. When in doubt, the nature of the organization with which interaction is being contemplated should always be checked with the department in WHO responsible for resource mobilization.

3. Some or all of these guidelines can also apply to a variety of other institutions, including State-run enterprises, associations representing commercial enterprises, foundations not at arms length from their sponsors, and other not-for-profit organizations such as academic institutions. The Office of the Legal Counsel should be consulted at an early stage on establishing relationships of the type referred to in these guidelines with such organizations.

GENERAL CONSIDERATIONS

4. WHO not only serves its membership, but also reaches beyond to collaborate, in the health domain, with other public bodies, civil society and commercial enterprises. The main objective of such interaction is to further WHO's mission and policies.

5. In order to improve health outcomes, WHO regularly interacts with commercial enterprises in various ways, including:

- participation with one or more commercial enterprises in alliances and other relationships (sometimes with other public bodies, governments, nongovernmental organizations and foundations) to address specific health issues;
- exchange of information;
- product research and development aimed at improving health;
- generation of cash and in-kind donations to WHO;
- advocacy for health.

6. In establishing such relationships it should be borne in mind that WHO's activities affect the commercial sector in broader ways, through for example, its public health guidance, its recommendations on regulatory standards, or other work that might influence product costs, market demand, or profitability of specific goods and services.

7. Such activities include setting of norms for quality, safety, and efficacy of pharmaceuticals and related promotional practices, dissemination of information on pharmaceuticals; provision of guidelines for diagnostics and treatment or advice that might affect the market for individual products

and product categories; establishment of chemical safety standards; and formulation of nutritional guidelines.

8. In developing relationships with commercial enterprises, WHO's reputation and values must be ensured. Scientific validity must not be compromised. Staff should thus always consider whether a proposed relationship might involve a real or perceived conflict of interest, either for the staff member or for the work of the Organization. The Staff Rules and Staff Regulations (and the forthcoming ethical framework) should guide decisions on conflict of interest relating to the personal situation of staff. The present guidelines contain provisions relating to conflict of interest for the Organization.

9. A step-by-step evaluation of the commercial enterprise, including an assessment of the company and consultation with the Office of the Legal Counsel, is the best way to identify potential areas of conflict of interest. Relationships should be avoided with commercial enterprises whose activities are incompatible with WHO's work, such as the tobacco or arms industries.

10. Relationships should also have specific aims and meet the following basic criteria:

- (a) the relationship should contribute to improving public health;
- (b) the public health gains should be commensurate with the time and expense involved in establishing and maintaining the relationship;
- (c) relationships should be established on the basis of an exchange of clearly written letters or agreements indicating the contribution (financial or otherwise) that each of the parties brings to the relationship.

11. Commercial enterprises working with WHO will be expected to conform to WHO public health policies in the areas of food safety, chemical safety, ethical promotion of medicinal drug products, tobacco control, and others.

12. In addition, evaluation criteria should be applied which are similar to those already in use by a range of public agencies in assessing potential partnerships with commercial enterprises, including: the public image, and financial stability and integrity of the company.

13. WHO should avoid indirect collaboration (particularly if arranged by a third party acting as an intermediary between WHO and a commercial enterprise).

DONATIONS (CASH)

14. Funds may be accepted from commercial enterprises whose business is unrelated to that of WHO, provided they are not engaged in any activity that is incompatible with WHO's work. The department responsible for resource mobilization should be consulted in case of doubt about the activities of multisector companies.

15. Funds may not be sought or accepted from enterprises that 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.

16. Caution should be exercised in accepting financing from commercial enterprises that have even an indirect interest in the outcome of the project (i.e. the activity is related to the enterprise's 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 Office of the Legal Counsel should be consulted 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.

Donations for clinical trials

17. The question of whether it is acceptable to receive cash contributions from a commercial enterprise for a trial arranged by WHO on that company's proprietary product, without there being an agreement of the type referred to in paragraph 39 below, is addressed on a case-by-case basis and should always be referred to the Committee on Private Sector Collaboration (see Appendix), through the Office of the Legal Counsel. 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 initiative;
- (c) if WHO were not involved in the research,
 - it would either not be undertaken, or
 - not be undertaken in conformity with internationally accepted technical and ethical considerations.

18. 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, and that the trial results are free from any inappropriate influence or perceived influence from the company concerned.

Donations for unspecified programme support

19. Subject to the provisions of these guidelines, commercial enterprises may make unspecified donations to WHO programmes. The acceptance of such general support is encouraged, provided that:

- (a) the donation is not to be used to finance activities in which the company has a direct commercial interest. If the donation is to be used for activities in which the company has an indirect commercial interest as defined in paragraph 16 above, financing should be sought from various sources having a similar interest;
- (b) the overall amount of the funds raised should not be so large that the programme would become dependent on support from a single company, or group of commercial enterprises, for its continued operations. The level of dependency of the programme on such support shall be evaluated at regular intervals.

Donations for WHO meetings

20. For meetings convened by WHO, a contribution from a commercial enterprise 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.

21. Contributions may be accepted to support the overall costs of a meeting, subject to the provisions relating to avoidance of conflict of interest.

Donations for WHO staff participating in external meetings

22. An external meeting is one convened by a party other than WHO. Support from commercial enterprises for travel of WHO staff to attend external meetings or conferences may fall into two categories:

(a) meetings held by the company or trade association paying for travel: financing for travel may be accepted if the company 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 company or trade association proposing to pay for the travel): financing for travel may not be accepted from a company or trade association.

Donations for preparation of guidelines or recommendations

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

Donations for financing staff salaries

24. Funds designated to support the salary of specific staff or posts (including short-term consultants) may not be accepted from commercial enterprises or other commercial sources if they could give rise to a real or perceived conflict of interest in relation to WHO's work. All proposals must be referred to the Office of the Legal Counsel at an early stage.

25. The acceptability of contributions from commercial enterprises to projects which have a staffing element should be reviewed in the light of other relevant guidance mentioned in this document.

Donations for publications

26. Funds may be accepted from commercial enterprises for meeting the printing costs of WHO publications, as long as no conflict of interest arises. Such contributions shall be acknowledged in accordance with paragraph 28 below. In no event may commercial advertisements be placed in WHO publications.

Acknowledgements of donations

27. For reasons of transparency, contributions from commercial enterprises must be publicly acknowledged by WHO. The basic and most common approach to such recognition is to insert an acknowledgement in documentation relating to the activity concerned, including in any publication by WHO of the outcome of this activity.

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

29. Contributors may not use the results of WHO’s work for commercial purposes or seek promotion from the fact that they have made a donation. However, they may make reference to donations in their corporate annual reports or similar documents. In order to ensure compliance with the above, letters requesting funds or accepting donations from commercial enterprises should always be drafted in consultation with the Office of the Legal Counsel.

30. Contributions received from all sources, including commercial enterprises, are listed in the Financial Report and Audited Financial Statements of WHO.

Anonymous donations

31. Anonymous donations may not be accepted under any circumstances.

Return of donations

32. Any donation received by WHO which is subsequently discovered to be noncompliant with these guidelines shall be returned to the donor.

CONTRIBUTIONS IN KIND

33. The acceptability of donations in kind is covered in the WHO Manual, part VI, section 3, paragraphs 10 to 110. In summary, these paragraphs provide that such contributions may be accepted if they “can be utilized and [if] any conditions which may be attached to them are consistent with the objective and policies of the Organization”.¹ However, pursuant to paragraph VI.3.30, the Office of the Legal Counsel should be consulted in the case of contributions in kind from commercial enterprises.

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

¹ WHO Manual, part VI, section 3, paragraph 20.

- (a) sound evidence exists of the safety and efficacy of any drug in the indication for which it is being donated. The drug is approved by the recipient country for use in that indication; it should preferably appear on the WHO model list of essential drugs 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 onto 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 drug donation is not of a promotional nature, either with regard to the company itself, or by creating a demand for the drug which 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 drug reactions has been set up with the participation of the donating company.
35. WHO programmes should consult the Office of the Legal Counsel with a view to negotiating and drafting an appropriate agreement with the donor. They should also consult the financial services of WHO with a view to determining the value at which the donation will be recorded in WHO's financial records.
36. Arrangements involving provision of expertise for a WHO project or activity by a commercial enterprise should always be referred to the Committee on Private Sector Collaboration through the Office of the Legal Counsel, at an early stage.

SECONDED PERSONNEL

37. Secondments from commercial enterprises to WHO are acceptable provided that:
- (a) personnel are not seconded from industries whose activities clearly conflict with WHO's mandate;
 - (b) there is no conflict of interest between the person's proposed activities for WHO and his or her activities for the employer company. Particular care should be taken when it is proposed to second persons from health-related enterprises. Such secondment should therefore be considered only in consultation with the Office of the Legal Counsel and may need to be referred to the Committee on Private Sector Collaboration;
 - (c) the person being proposed for secondment has the skills, experience and language abilities to carry out the proposed tasks. The skills and experience provided by the secondment should meet time-limited needs;

- (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 company is involved, or which could promote the commercial interests of this company. The seconded person should furthermore 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 company;
- (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) the secondment is for a limited period of time, to be determined in advance by agreement between WHO, the employer company and the seconded person;
- (g) secondment agreements with commercial enterprises must be negotiated in consultation with the Office of the Legal Counsel and the department responsible for human resources. The contract with the seconded person should be cleared by the Office of the Legal Counsel in order to ensure that it includes all the above-mentioned safeguards and accurately reflects the terms of WHO's agreement with the employer company.

38. 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.

PRODUCT DEVELOPMENT

39. WHO collaborates with commercial enterprises in the development of new 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 company concerned have concluded an agreement which ensures that the final product will ultimately be made widely available, including to the public sector of developing countries at a preferential price. If such an agreement is concluded, financing may be accepted from the commercial enterprise for a trial arranged by WHO on the product in question, since contractual commitments obtained from the company 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, without having concluded the kind of agreement referred to above.

40. Collaborative research and development agreements should always be drafted and negotiated in consultation with the Office of the Legal Counsel.

41. 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 commercial enterprises known to have an interest in such a product are invited to collaborate with WHO in the same way.

COST RECOVERY

42. 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 enterprises for such services on the basis of cost recovery. For example, pesticide manufacturers pay for having their product tested under the WHO Pesticide Evaluation Scheme (WHOPES). It should be noted, however, that the purpose of WHO's evaluation schemes is always to provide advice to governments and/or organizations, such as UNICEF, for procurement. Evaluation does not constitute endorsement by WHO of the product(s) in question.

MEETINGS (see also paragraphs 20 and 21 for donations for WHO meetings)

Cosponsored meetings

43. WHO may not cosponsor a meeting being held by specific commercial enterprises. It may, however, cosponsor a meeting for which the scientific initiators have hired a commercial conference organizer to deal with the logistical aspects, the commercial organizer making no contribution to the scientific content of the meeting.

44. WHO may not cosponsor a meeting with one or more health-related enterprises. Other instances of cosponsorship with commercial enterprises should be reviewed on a case-by-case basis and always referred to the Office of the Legal Counsel to determine the risk of a real or perceived conflict of interest.

Exhibitions at WHO meetings

45. There may be no commercial exhibitions at WHO meetings (whether of WHO's governing bodies or technical programmes, and whether held on WHO premises or elsewhere) in order to avoid any perception of conflict of interest or of influence on the outcome of the meeting.

Exhibitions at cosponsored meetings

46. Commercial exhibitions are permissible at WHO cosponsored meetings, but should be held in a location other than the meeting room. It should be noted that WHO does not cosponsor commercial exhibitions, either as part of a cosponsored meeting or as a separate event. If WHO involvement is considered important (for instance, to permit a certain audience to become acquainted with products and/or services) it should, subject to clearance by the Office of the Legal Counsel, be achieved in a way other than cosponsorship or use of WHO's name in relation to the event.

OTHER FORMS OF INTERACTION

47. Proposals for the initiation of work with commercial enterprises on matters not referred to in these guidelines, such as establishment of multiple-party alliances or product pricing, should be referred to the Director-General, after due consideration by the Executive Director or Regional Director concerned and the Office of the Legal Counsel.

USE OF WHO'S NAME OR EMBLEM

48. WHO's name and emblem are recognized symbols of integrity and of assurance to the public. No commercial enterprise shall be authorized to use WHO's name or emblem for the promotion, advertisement or marketing of its products or services. Use of the name or emblem in all other circumstances involving commercial enterprises or trade associations representing commercial enterprises must always be cleared with the Office of the Legal Counsel, in particular when the name or emblem is to be used in conjunction with other names or logos to indicate joint work or ownership.

HOSPITALITY

49. WHO receptions and similar functions may not be paid for by commercial enterprises or trade associations.

CONTROL

50. WHO shall maintain full control over the activity to which a contribution in cash, kind, or personnel relates, including over any report of the activity, its contents, whether it is published or disseminated in any form (e.g. electronically), and timing of such diffusion.

IMPLEMENTATION REVIEW

51. The application and impact of these guidelines shall be periodically reviewed.

APPENDIX

PROCEDURES FOR IMPLEMENTATION

1. Contact between a commercial enterprise and WHO may be initiated by either party. At first contact with a commercial enterprise, the programme concerned should consult the guidelines and decide whether the proposed arrangement may be acceptable. The department responsible for resource mobilization can assist in assessing the commercial enterprise, which would provide a basis for further discussions. The Regional Director or Executive Director concerned should be consulted at this stage.
2. The public health goal underlying the proposed collaboration should be clearly stated.
3. If it is not clear whether the arrangement is acceptable under the guidelines, or where the guidelines require matters to be referred to the Office of the Legal Counsel, that Office should be consulted, through the Regional Director or Executive Director concerned.
4. The Office of the Legal Counsel will review the proposal and if, in the Office's opinion, there is no conflict of interest, the proposed arrangement will be cleared for action.
5. If, in the opinion of the Office of the Legal Counsel, there is doubt as to whether the interaction is acceptable under the guidelines, the Office of the Legal Counsel will, in consultation with the programme concerned, submit the proposed arrangement to the Committee on Private Sector Collaboration.
6. In the case of apparently unacceptable proposals, the programme concerned is invited to work with the Office of the Legal Counsel to determine whether an acceptable arrangement can be defined.
7. The Committee on Private Sector Collaboration will usually meet once a month to review any proposals. In a case of urgency, the proposal will be copied to the members of the Committee for a rapid decision or, in exceptional cases, an ad hoc meeting will be convened. If this is not possible, the Chair of the Committee may take an executive decision, consistent with earlier Committee jurisprudence. If it is felt desirable, the programme may present additional information on its case at the meeting of the Committee on Private Sector Collaboration.
8. The Committee on Private Sector Collaboration will record its decisions and the reasons for such decisions. In the event that a consensus is not reached, the different positions taken will be recorded. All decisions of the Committee will be submitted for endorsement by the Director-General. If appropriate, the present guidelines will be updated (for example, in the event of a change in policy or an unprecedented case).
9. A routine application with a referral to the Committee on Private Sector Collaboration will normally take four weeks to be processed.

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