

## DECLARATION OF INTERESTS FOR WHO EXPERTS

### Explanation sheet for the WHO Secretariat

Attached is the Organization's Declaration of Interests. Hopefully, the declaration and instructions are self-explanatory.

#### Use

The Declaration should be used whenever outside expertise is utilised where the expert does not become a staff member with a fixed-term or short term appointment. For example, the Declaration should be used for experts on Expert Committees, Study Groups, Scientific Groups, Steering Committees, Consultations or any other type of expert meetings; temporary advisors; consultants; experts engaged under an APW as well as peer reviewers. In the case of members of expert advisory panels, it does not need to be completed until the member of the panel is requested to serve on a specific committee or perform a particular task.

However, this does not mean that all consultants, persons engaged under APWs or persons invited to meetings need to complete the Declaration of Interest. It is acknowledged that there may at times be some uncertainty when the Declaration should be completed and when it is not necessary. Set forth below is some guidance on when the Declaration should be used and when not. As will be clear from what follows, staff will often need to make a common sense assessment as to the relevance of the Declaration for the particular meeting or activity concerned.

*General Principle:* Generally speaking, consultants, persons engaged under APWs and invitees to meetings should complete the Declaration if the value of their service to the Organization is dependent on their independence and objectivity.

In light of this general principle,

#### A. Meetings

1. Clearly, all **experts** invited to a meeting to develop guidelines or recommendations, as well as assessments of any kind of product, compound, organism or methodology which would in any way be of relevance to a present or future commercial activity or interests, should complete the Declaration.

On the other hand, it should be obvious that some meetings, where the objectivity and independence of the invitees is either irrelevant or inconsequential to the purposes of the meeting, do not require use of the Declaration. For example, persons attending a WHO training course would normally not need to complete the Declaration.

Meetings which consist solely of representatives of other entities would presumably not call for use of the Declaration since the attendees are not invited to advise WHO on the basis of them being experts independent of commercial and financial interests, but rather because they represent another entity with which WHO wishes to have contact/hold discussions or collaborate. Admittedly, an argument can be made that it would still be relevant to know whether these representatives themselves have commercial or financial conflicts of interest which might affect their representative function, or it might be relevant to know whether even the entities themselves might have a financial or commercial conflict of interest. However, this concern is in most cases probably marginal or indirect, since the Organization will not normally be taking the outcome of the meeting as an independent and objective statement of scientific merit, but rather as an outcome of a group of interested entities. It is thus considered to be in most cases either irrelevant or at least too disruptive to the performance of the Organization's business to warrant using the Declaration. In some cases, the various vested interests of the entities themselves will already be known in any event.

Of course, it follows from the above that the Declaration should not be used for meetings of representatives of governments, such as the Meetings of Interested Parties and the programmatic “governing” bodies of HRP, TDR, OCP and APOC.

It should also be borne in mind that there are a wide range of meetings at the global, regional and national levels which are focused on operational, co-ordination or project implementation issues and which have little or nothing to do with WHO’s normative functions of developing guidelines and recommendations or with WHO’s assessment activities described earlier which have a commercial interest. In the case of these other types of meetings, it would normally be unnecessary to use the Declaration. It should be noted, in this respect, that the attendees of many of these types of meetings would in fact be representatives and thus not require use of the Declaration in any event.

2. It follows from the above general principle that **observers** to meetings would never complete the form, since their attendance is not based on them being objective and independent. Rather, they attend because they represent other entities interested in the proceedings. Furthermore, as observers, they are not formally responsible for formulating the outcome of the meeting. In many cases, such observers will expressly be representing commercial interests.

Persons from UN agencies or NGOs would presumably be observers in most WHO meetings and thus they should not be expected to complete the Declaration. If that is not the case, rather if they are participants and the purpose of the meeting is to provide "expert advice" to WHO (e.g., where the value of the advice is dependent on their independence and objectivity), then they should complete the Declaration.

#### B. Consultants and persons hired under APWs

Persons hired (or even persons involved on a volunteer basis) to perform an assessment or analysis which is intended to lead to the development of guidelines, recommendations or assessments of products, etc. as described above in the case of meetings, should normally complete the Declaration. Thus, peer reviewers and consultants engaged to write background reports for meetings involving the development of – or leading to the development of – guidelines, recommendations or assessments should complete the Declaration.

However, persons hired to perform a task for which such objectivity and independence is either irrelevant or inconsequential need not complete the Declaration, even if the work is part of a larger project for which others have completed the Declaration. For example, someone hired to edit or translate a text, regardless of the level of his/her "expertise", would usually not need to complete the Declaration, since their independence and objectivity from commercial and financial interests would presumably in most cases be of limited relevance to the performance of their work. The same could be said for someone engaged as a professional moderator/trainer for a training course or workshop. However, if the subject matter of the course has significant commercial implications, e.g., a course involving instruction on the use of different types of commercially produced equipment in which preference for one brand of equipment versus another could be manifested, then it would be advisable to require completion of the Declaration.

#### **Distribution**

In most cases the Declaration should be distributed with the invitation to attend the meeting or to undertake the work concerned and the invitation should make clear that it is provisional pending receipt by the technical unit of the completed Declaration by a certain date (chosen sufficiently in advance of the meeting date or commencement of the work, e.g. four weeks, to permit the Organization to evaluate, notify the respondent and invite substitute experts, should that become necessary). Since the Declaration already notifies the respondent of potential outcomes (see page 2), it is not necessary to repeat this explanation in the invitation.

Until the standard Consultant’s contract and Agreement for the Performance of Work have been duly modified, the following statement should be added to these forms: “This agreement is subject to completion of the Declaration of Interests for WHO Experts and notification by the Secretariat that the information disclosed in the Declaration does not require modification or cancellation of the agreement. No work or action in reliance of

the agreement should therefore be undertaken until such notification in writing is received. In the case of such cancellation of the agreement by WHO, no payments shall be due hereunder. In case of such modification, payments will be made solely in accordance with the agreement as modified by mutual consent of the parties.”

In the case of meetings, if an earlier distribution has not been possible, the Declaration should at the very latest be distributed and collected prior to commencement of the substance of a meeting. However, this should only be in exceptional circumstances since it may not provide sufficient time to deal with disclosures raising difficult issues (see also the following section). It may also result in WHO unnecessarily paying for an expert to travel to the meeting venue and then not be able to participate.

### **Analysis of the Information Disclosed**

The Team Coordinator or equivalent person responsible for the meeting should collect and review all completed Declarations, and make the initial assessment (based on the information contained on the Declaration) that:

- (i) there is no appreciable conflict of interest;
- (ii) a declared interest reveals the existence of such a significant conflict of interest that the expert should not participate at all in the meeting or the work concerned, thus requiring the withdrawal of the invitation or cancellation of the contract as the case may be;
- (iii) a declared interest reveals the existence of a significant conflict of interest so as to warrant limiting the expert's participation with respect to part of the meeting or of the work concerned, thus requiring a modification of the invitation or of the contract as the case may be; or
- (iv) notwithstanding the declared interest, the nature of a conflict of interest so revealed is such that – or other circumstances exist whereby - it is considered appropriate to continue with the expert's participation in the meeting or work involved, but that the interest be publicly declared, thus requiring the Secretariat to obtain the expert's permission to such public disclosure.

It should be remembered that there are no hard and fast rules when reviewing a declared interest. Not every financial or other declared interest – even one relating to the subject-matter of the meeting or work concerned - will necessarily create such an unacceptable conflict of interest that participation of the expert is precluded. Set forth below is further guidance on how to deal with this issue:

- In part, the decision on how to treat a declared interest will depend on the nature of the interest. For example, the existence of one consultancy with a company having an interest in the outcome of the meeting or work (particularly relatively distant in time) would not necessarily create an appearance of the expert being so biased that his/her participation would be precluded. On the other hand, several consultancies, particularly involving the specific issue on which the meeting or work is to come to an independent judgement, might well render it unwise to permit the continued participation of the expert.
- However, the decision on how to treat a declared interest will also depend in part on the context in which the work is to be performed. For example, the existence of alternative experts could well affect the final decision. In this respect, it is recognised that in many fields it is difficult to find experts who have not been involved in consultancies or other types of work with companies having an interest in the subject matter of the meeting or work. In these cases, there may be little alternative but to obtain the agreement of the expert to have the interest publicly declared (at the meeting and/or in any resulting report). In the case of meetings, or work involving a number of experts, the overall balance of experts can also affect the type of decision to be made. For example, in the case of a meeting of ten experts, in which one or two have declared extensive consultancies constituting a conflict of interest, it might well be reasonable to consider the overall independence of the meeting is assured by the preponderance of the other experts without conflicts of interests, provided however there is a public disclosure of the declared interests of the two experts concerned. This would be a particularly reasonable approach when the presence of the two experts is either necessary or highly desirable in order to ensure an appropriate interdisciplinary balance or geographic representation.

- However, the existence of stock holdings in a company having an interest in the subject matter of the meeting or work would be more difficult to justify the continued involvement of the expert, unless the expert has disclosed the value of the holdings and they are clearly of minimal value (under US\$10,000, for example). Nevertheless, unless the value is specifically disclosed, declared stock holdings must be presumed to be appreciable.

To the extent possible, the Team Coordinator should make a reasonable determination whether the declared interest poses a risk of actually affecting the expert's objectivity (or creating the perception thereof), and consult with his/her Director in case of any doubt. If both the Team Coordinator and the Director are uncertain on this issue or are uncertain of the action to be taken in an individual case, the Declaration should be sent to LEG, which may in turn consult the Committee on Private Sector Collaboration.

The process of analysing individual situations should be carried out as follows:

Has the expert declared an interest relating to the subject matter of the meeting or work?

1. If no, there is no impact on participation in the meeting or involvement in the work.
2. If yes, is the declared interest:
  - (a) insignificant?
  - (b) perhaps significant, or significant in the opinion of some individuals?
  - (c) clearly significant?

If the answer is (a), no limitation on participation or involvement is necessary and in most cases no public disclosure would be necessary.

If the answer is (c), do one of the following:

- (i) if notwithstanding the declared interest, the nature of the interest or particular circumstances exist whereby it is considered appropriate to continue with the expert's involvement in the meeting or work, but that the interest be publicly declared, obtain the expert's permission to such public disclosure, which would appear as part of the proceedings of the meeting, peer review or otherwise published in a suitable way.
- (ii) limit the expert's involvement so as to exclude him/her from that portion of the meeting or work where a significant conflict of interest has been identified;
- (iii) if limitation of the expert's involvement to only a portion of the meeting or work is not feasible because the nature of the conflict of interest is too significant vis-à-vis the overall objective and/or duration of the meeting or work (thereby rendering the person's involvement for the remainder of the meeting or work of relatively little or no value or otherwise not feasible), then exclude the expert's involvement in the meeting or work altogether;

As an aide in performing the assessment under (c) on whether participation of the expert in the meeting or work with public disclosure of the expert's declared interest is possible, one should assess the situation through the eyes of a hypothetical "person on the street". If it is felt that there is a reasonable likelihood that such a person might conclude the proceedings or work as a whole were tainted, unfair or otherwise influenced by this expert's interest in the outcome, then the expert's involvement should be limited as described in (c)(ii) or (iii) above.

If the answer is (b), review the declared interest through the same eyes of a hypothetical "person on the street". If it is felt that there is a reasonable likelihood that such a person might conclude that the expert concerned is biased, then proceed as in the case for (c) above to see whether the expert's participation is still possible or must be excluded in whole or in part.

In the event that an employment or association with the tobacco industry is declared, the Coordinator should first consider whether the meeting or work concerned could in any way have an impact, even indirectly, on the interests of the industry (e.g., on whether certain insecticides, which may be used on crops - including tobacco plants - could have carcinogenic qualities). If so, then the relationship should be considered in the same manner as a conflict of interest. Furthermore, all declared relationships should be reported promptly to the Tobacco Free Initiative (TFI).

### **Release of the Declarations**

All completed Declarations will be kept confidential and will normally only be used to evaluate whether an expert's declared interests constitute an appreciable real, potential or apparent conflict of interest that may impinge the technical integrity and impartiality of the conclusions reached at the subject meeting. Nevertheless, if the objectivity of persons involved in the meeting or work is questioned, Coordinators should consult LEG in order to determine whether it is in the best interests of the Organization to release the content of one or more declarations. Such release would only occur after consultation with the experts concerned.

### **Retention of the Declarations**

Declarations should be retained by the Department for at least ten years. The Declarations should be filed and maintained in a manner consistent with the Department's general procedures for the retention of confidential documents. If none currently exist, the documents should remain in the custody of a senior officer of the Department in segregated files kept in a locked cabinet.

Any written requests by Member Governments for access to certain Declarations, and any questions with respect to the implementation of these procedures or this Declaration, should be directed to LEG/CCM.



## DECLARATION OF INTERESTS FOR WHO EXPERTS

**Title of meeting or work to be performed, including description of subject-matter, substance (compounds and organisms), technology or process to be considered:** \_\_\_\_\_

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Public health considerations have a primary importance in all WHO technical work. Measures need to be taken to ensure that the best possible assessment of scientific evidence is achieved in an independent atmosphere free of either direct or indirect pressures. Thus, to assure the technical integrity and impartiality of WHO's work, it is necessary to avoid situations in which financial or other interests might affect the outcome of that work.

Each expert is therefore asked to declare any interests that could constitute a real, potential or apparent conflict of interest, with respect to his/her involvement in the meeting or work, between (1) commercial entities and the participant personally, and (2) commercial entities and the administrative unit with which the participant has an employment relationship. "Commercial entity" refers to any company, association (e.g., trade association), organization or any other entity of any nature whatsoever, with commercial interests.

In addition, as a result of WHO's strong stance against tobacco use, it is considered relevant for the Organization to know whether experts working with it have, or have had, any relationship with any part of what may be called "the tobacco industry". Nevertheless, declaration of such an interest would not necessarily be considered a reason to disqualify an expert.

### **What is a conflict of interest?**

Conflict of interest means that the expert or his/her partner ("partner" includes a spouse or other person with whom s/he has a similar close personal relationship), or the administrative unit with which the expert has an employment relationship, has a financial or other interest that could unduly influence the expert's position with respect to the subject-matter being considered. An apparent conflict of interest exists when an interest would not necessarily influence the expert but could result in the expert's objectivity being questioned by others. A potential conflict of interest exists with an interest which any reasonable person could be uncertain whether or not should be reported.

Different *types of financial or other interests*, whether personal or with the administrative unit with which the expert has an employment relationship, can be envisaged and the following list, which is not exhaustive, is provided for your guidance. For example, the following types of situations should be declared:

1. a current proprietary interest in a substance, technology or process (e.g. ownership of a patent), to be considered in - or otherwise related to the subject-matter of - the meeting or work;
2. a current financial interest, e.g. shares or bonds, in a commercial entity with an interest in the subject-matter of the meeting or work (except share holdings through general mutual funds or similar arrangements where the expert has no control over the selection of shares);
3. an employment, consultancy, directorship, or other position during the past 4 years, whether or not paid, in any commercial entity which has an interest in the subject-matter of the meeting/work, or an ongoing negotiation concerning prospective employment or other association with such commercial entity;
4. performance of any paid work or research during the past 4 years commissioned by a commercial entity with interests in the subject-matter of the meetings or work;
5. payment or other support covering a period within the past 4 years, or an expectation of support for the future, from a commercial entity with an interest in the subject-matter of the meetings or work, even if it does not convey any benefit to the expert personally but which benefits his/her position or administrative unit, e.g. a grant or fellowship or other payment, e.g. for the purpose of financing a post or consultancy.

With respect to the above, an interest in a competing substance, technology or process, or an interest in or association with, work for or support by a commercial entity having a direct competitive interest must similarly be disclosed.

**How to complete this Declaration:** Please complete this Declaration and submit it to the Secretariat. Any financial or other interests that could constitute a real, potential or apparent conflict of interest should be declared (1) with

respect to yourself or partner, as well as (2) with respect to the administrative unit with which you have an employment relationship. Only the name of the commercial entity and the nature of the interest is required to be disclosed, no amounts need to be specified (though they may be, if you consider this information to be relevant to assessing the interest). With respect to items 1 and 2 in the list above, the interest should only be declared if it is current. With respect to items 3, 4 and 5, any interest during the past 4 years should be declared. If the interest is no longer current, please state the year when it ceased. With respect to item 5, the interest ceases when a financed post or fellowship is no longer occupied, or when support for an activity ceases.

**Assessment and outcome:** The information submitted by you will be used to assess whether the declared interests constitute an appreciable real, potential or apparent conflict of interest. Such conflict of interest will, depending on the situation, result in (i) you being asked not to take part in the portion of the discussion or work affecting that interest, (ii) being asked not to take part in the meeting or work altogether, or (iii) if deemed by WHO to be appropriate to the particular circumstances, and with your agreement, you taking part in the meeting or work and your interest being publicly disclosed.

Information disclosed on this Form may be made available to persons outside of WHO only when the objectivity of the meeting or work has been questioned such that the Director-General considers disclosure to be in the best interests of the Organization, and then only after consultation with you.

**Declaration:** Have you or your partner any financial or other interest in the subject-matter of the meeting or work in which you will be involved, which may be considered as constituting a real, potential or apparent conflict of interest?

Yes:  No:  **If yes, please give details in the box below.**

Do you have, or have you had during the past 4 years, an employment or other professional relationship with any entity directly involved in the production, manufacture, distribution or sale of tobacco or any tobacco products, or directly representing the interests of any such entity? Yes:  No:  **If yes, please give details in the box below.**

Type of interest, e.g. patent, shares, employment, association, payment (including details on any compound, work, etc.)	Name of commercial entity	Belongs to you, partner or unit?	Current interest? (or year ceased)

Is there anything else that could affect your objectivity or independence in the meeting or work, or the perception by others of your objectivity and independence?

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I hereby declare that the disclosed information is correct and that no other situation of real, potential or apparent conflict of interest is known to me. I undertake to inform you of any change in these circumstances, including if an issue arises during the course of the meeting or work itself.

\_\_\_\_\_  
Signature

\_\_\_\_\_  
Date

\_\_\_\_\_  
Name

\_\_\_\_\_  
Institution