

Annex 4: Declaration of Interests and confidentiality (To be filled and provided in the bid by the tenderer)



Declaration of Interests and confidentiality undertaking of the European Directorate for the Quality of Medicines and HealthCare (EDQM) Group of Experts, Working parties, Committees and staff.

Instructions

The document consists of three parts:

- 1- your Personal Details,
- 2- the Declaration of Interests and
- 3- the Confidentiality Undertaking.

All parts must be duly completed. You are responsible for the accuracy and completeness of the submitted information.

1. Personal Details

Enter your full name, your organisation/company name, country of organisation/company, the e-mail address on which you would like to be contacted regarding this declaration and the identification of the EDQM Group(s) / Committee(s) / Meeting(s) you are willing to take part.

Your e-mail address will be kept confidential and will not be published.

2. Declaration of Interests

This section asks you to declare any interests in a concerned commercial entity (*) that you currently have or have had within the past 3 years. If you have interests to declare, please tick 'Yes' to the relevant questions. All questions in this section must be answered. Your declaration will not be accepted if any fields are left empty.

You may also provide information on interests over 3 years ago. This information could be useful in the context of increased transparency regarding previous interests. If this should be the case, please declare under §2.6.

(*) The expression “Concerned commercial entity” is used throughout this document and includes any commercial business, industry association, research institution or other enterprise whose funding is significantly derived from commercial sources with an interest related of the meeting or work.

3. Confidentiality Undertaking

Read carefully the confidentiality undertaking agreement. Signing this Declaration of Interests and confidentiality undertaking implies that you adhere to the information declared in this part.

1: PERSONAL DETAILS

First name:

Last name:

Institution / Company:

Country:

Contact e-mail address:

Identification of EDQM Group/Committee/Meeting:

I do hereby declare on my honor that, to the best of my knowledge, the only direct or indirect interests I have in concerned commercial entity are those listed below:

Please specify the interests that you currently have (at the time of completion of the form) or have had within the past 3 years.

2: DECLARATION OF INTERESTS

2.1. Employment in a concerned commercial entity

No

Yes

→If NO, please go to section 2.2.

EMPLOYMENT¹

Period²: Current Past

From Month: From Year: To Month: To Year:

Name of concerned commercial entity³:

EMPLOYMENT¹

Period²: Current Past

From Month: From Year: To Month: To Year:

Name of concerned commercial entity³:

¹ Please indicate any form of occupation, part time or full-time, paid or unpaid, in a concerned commercial entity.

² Please select the appropriate response (Current or Past).

For current ongoing activities, indicate starting date (month/year).

Note: current is interpreted as at the time of completion of this form. Should you engage in future activities of this nature, you will need to update your Declaration of Interest form accordingly. For activities that are no longer ongoing and that have been completed within the specified time, please indicate starting and end date (month / year).

³ Also includes supply or service companies which contribute to the research, development, manufacturing, control, marketing and/or distribution in the concerned commercial entity.

2.2. Consultancy* No Yes

* Any activity where you provide(d) consultancy services/business advice to a concerned commercial entity regardless of contractual arrangements or any form of remuneration.

→If NO, please go to section 2.3.

CONSULTANCY¹

Period²: Current Past

From Month: From Year: To Month: To Year:

Name of the concerned commercial entity:

CONSULTANCY¹

Period²: Current Past

From Month: From Year: To Month: To Year:

Name of the concerned commercial entity:

¹ Please indicate any activity in which you provide or have provided consultancy services/business advice regardless as to whether or not you received a fee for this activity.

² Please select the appropriate response (Current or Past). Please indicate activities which are currently ongoing. Indicate starting date (month / year).

Note: current is interpreted as at the time of completion of the form. Should you engage in future activities of this nature, you will need to update your Declaration of Interest form accordingly. For activities that are no longer ongoing and that have been completed within the specified time, please indicate starting and end date (month / year).

2.3. Financial Interests* No Yes

*Financial interests relate to:

Any current economic stake in concerned commercial entity including:

- Holding of stocks and shares, stock options, equities, bonds and or partnership interest in the capital of the concerned commercial entity(ies). The holding of financial interests through an investment fund, pension fund and/or interests in non-nominal unit trusts or similar arrangements would not need to be declared provided that they are diversified (i.e. not exclusively based on the concerned sector) and they are independently managed (i.e. the individual has no influence on their financial management).
- Intellectual property rights including patents, trademarks, know-how and/or copyrights relating to a product owned by the individual or of which the individual is directly a beneficiary. (current is interpreted as at the time of completion of this form).

→If NO, please go to section 2.4.

Financial Interests, including holding of shares in a concerned commercial entity and receipt of any other fees / honoraria

Name of concerned commercial entity	Financial Interest
1.	
2.	

3.	
----	--

Patent Ownership

Name of concerned commercial entity	Subject Matter
1.	
2.	
3.	
4.	
5.	

2.4. Grant / Funding to Institution/Organisation* No Yes

*Refers to any funding received from a concerned commercial entity by the organisation/institution to which you belong, or for which you perform any kind of activity, and which is used to support any of your activity whether or not it is related to research work.

→If NO, please go to section 2.5.

Grant or Other Funding

Name of concerned commercial entity	Subject Matter
1.	
2.	
3.	

2.5. Close Family Member Interests* No Yes

* Means known interests from first-line members of your family (i.e. spouse or partner, children and parents).

Interest of Close Family Member¹

Name of concerned commercial entity	Type of Interest Declared
1.	
2.	
3.	

¹ Please indicate known interests currently held by first-line members of your family (i.e. spouse or partner, children and parents). In order to maintain privacy, neither the relationship nor the name need be declared. Interests to be declared include all current Direct Interests (i.e. Employment, Consultancy, Current Financial interests or current Patent Ownership).

2.6. Any other matters that might be of interest for transparency purposes* No Yes

* Means any other matters that might be of interest for transparency purposes e.g. working for or providing expert advice to another standardisation body (e.g. ISO, CEN etc.), Pharmacopoeia, a former employment in a concerned commercial entity, etc.

Work for or provide expert advice to non-European pharmacopoeias:

No Yes

If Yes, please specify the non-European pharmacopoeia(s):

International Ph. USP Chinese Ph. Indian Ph.

Other pharmacopoeia:

Any other matters that might be of interest for transparency purposes

Further to the interests (direct and indirect) declared above, I do hereby declare on my honor that I do not have any other interests or facts that should be made known to the EDQM and the public.

Should there be any change to the above due to the fact that I acquire additional interests, I shall promptly notify the EDQM and complete a new Declaration of Interests detailing the changes. This declaration does not discharge me from my obligation to declare any potential conflicting interest(s) at the start of any EDQM Activity or meeting/session in which I participate.

3: CONFIDENTIALITY UNDERTAKING

In view of the following definitions:

“EDQM Activities” encompass any meeting (including meeting preparation and follow-up, associated discussion or any other related activity) of the EDQM, Committees, Working Parties, Expert Groups, or any other such meeting; work as an expert on guidance development.

“Confidential Information” means all information, facts, data and any other matters of which I acquire knowledge, either directly or indirectly, as a result of my EDQM Activities.

“Confidential Documents” mean all drafts, preparatory information, documents and any other material, together with any information contained therein, to which I have access, either directly or indirectly, as a result of my participation in EDQM activities. Furthermore, any records or notes made by me relating to Confidential Information or Confidential Documents shall be treated as Confidential Documents.

Note: the confidentiality status does not apply where the individual has a legitimate access to the data from sources other than the EDQM confidential documents or where EDQM provides public access to a document (for example: Technical Guides, Rules of Procedure, Guide for Work).

I understand that I may be invited to participate either directly or indirectly in certain EDQM activities and hereby undertake:

- ✓ to treat all Confidential Information and Confidential Documents under conditions of strict confidentiality,
- ✓ not to disclose (or authorise any other individual to disclose) in any way to any third party any Confidential Information or Confidential Document,

- ✓ not to use (or authorise any other individual to use) any Confidential Information or Confidential Document other than for the purposes of my work in connection with EDQM activities,
- ✓ to dispose of Confidential Documents as confidential material as soon as I have no further use for them and take all measures to protect them especially when handled in public area (e.g. airport, train etc.).

I also understand that in case I do involve other persons in the work for the EDQM where this is useful for the conduct of the work, I am responsible for ensuring that these persons are aware of the confidential nature of the information and document/data provided and that the results of the work shall be used by the EDQM only.

This undertaking shall not be limited in time, but shall not apply to any document or information that I can reasonably prove was known to me before the date of this undertaking or which becomes public knowledge other than as a result of a breach of any of the above undertakings.

I confirm the information declared on this form is accurate to the best of my knowledge and I consent to my information being made available to public in case of request.

Full name:

Date:

Signature: