

**STATEMENT ON TERMS OF PARTICIPATION AND EXTERNAL ACTIVITIES OF EXPERTS (potential conflict of interest and confidentiality undertaking) WHO ARE INVOLVED IN EUnetHTA Joint Action 3**

***STATEMENT YEAR[[1]](#footnote-1):***

**The undersigned,**

**Name:**

**Organisation/Institute:**

**Address Street:**

**Postal code:**

**Town/city:**

**EUnetHTA Partner/Associate organisation:** Yes/ No

accepts to participate during years 2016-2020 in the work plan of the EUnetHTA Joint Action 3 which I’ve read

and

provides the following information[[2]](#footnote-2) on his/her honour and to the best of his/her knowledge.

**Section 1. Declaration of Interests**

**1a. Main professional activity**

Name of the organisation[[3]](#footnote-3):

Description[[4]](#footnote-4)of the activity:

Period of time (years of start-end)

**1b. I carried out salaried employment for / received remuneration from the following pharmaceutical/medical device/other health-technology developing and/or producing/distributing organisation(s):**

Name of the organisation:

Description of the activities:

Period of time (years of start-end)

**1c. I acted in an advisory capacity for the following organisation(s)[[5]](#footnote-5)** (i.e. patient, HTA, public or private research organisations,…):

Name of the organisation[[6]](#footnote-6):

Description[[7]](#footnote-7) of the advisory capacity:

Honorarium: Yes/ No

Period of time (years of start-end):

**2. I carried out clinical studies in relation to the development of a medicine/medical device/diagnostic / procedure for the following pharmaceutical/medical device/other health technology developing and/or producing/distributing organisation(s):**

Name of the organisation:

Name of the medicine:

Period of time (years of start-end):

**3. I sat in a committee or similar advisory body for the following medical research on behalf of a pharmaceutical/medical device/other health-technology developing and/or producing/distributing organisation**:

Details of the research:

Name of the organisation:

Name of the medicine:

Description of the duties:

Honorarium: Yes/ No

Period of time (years of start-end):

**4a. I received a personal research, study or travel allowance from the following pharmaceutical/medical device/other health-technology developing and/or producing/distributing organisation(s):**

Name of the organisation:

Description of the allowance:

Period of time (years of start-end)

**4b. The following pharmaceutical/medical device/other health-technology developing and/or producing/distributing organisation(s) paid for my congress expenses:**

Name of the organisation:

Description of the congress:

Period of time (years of start-end):

**5. I gave a presentation at meetings organised by the following pharmaceutical/medical device/other health-technology developing and/or producing/distributing organisations and received remuneration for my input:**

Name of the organisation:

Description of the meeting:

Period of time (years of start-end):

**6. I carried out activities or drew up advice for the following pharmaceutical/medical device/other health-technology developing and/or producing/distributing organisations in exchange for personal payment:**

Name of the organisation:

Description of the activities:

Period of time (years of start-end):

**7. I held a managerial position in the following institutes, where medicinal research is carried out that was funded by pharmaceutical/medical device/other health-technology developing and/or producing/distributing organisations:**

Name of the institute:

Description of the duties:

Period of time (years of start-end):

**8. I have financial interests in an organisation involved in the field of medicines/medical device/other health-technology**

Name of the organisation:

Description of the financial interests:

Period of time (years of start-end):

**9. A member of my household[[8]](#footnote-8) has been engaged in activities as described in items 1b-8 above**

Yes/No:

If Yes, description[[9]](#footnote-9):

**10. I have another interest to declare:**

Yes/No:

If Yes, description:

Should there be any change to the above due to the fact that the undersigned acquires additional interests, s/he shall promptly notify the EUnetHTA Directorate and Lead Partner of the relevant Work Package where s/he participates and complete a new declaration of interest detailing the changes. This declaration does not discharge the undersigned from an obligation to declare any potential conflicting interest(s) at the start of and throughout the whole duration of any EUnetHTA Joint Action 3 activity in which s/he participates.

Furthermore, by signing this statement, I accept and agree to the following:

* Collected declarations are for information of the EUnetHTA Directorate and EUnetHTA JA3 WP Lead and Co-Lead Partners of WP only and it is the responsibility of the EUnetHTA Directorate and Lead and Co-Lead Partners to keep the information confidential.
* Signed declarations will be stored in electronic form, protected by password access only.
* In case of the conflict of interest being identified, the issue of handling this conflict of interest will be between the individual and the EUnetHTA Directorate or (as relevant) the Lead Partner or Co-Lead Partner of a relevant WP. Accuracy of the conclusion is the responsibility of the individual (providing correct information) and the Lead Partner or Co-Lead Partner (as relevant). Details of such conclusions and their consequences will not be made known to any third parties other than the members of the working group/team of the respective project. The process of assessing the conflict of interest and its general outcome will be described in the final report from the project to ensure transparency of the procedures while respecting the privacy rights of any individuals concerned.

**Section 2. Confidentiality undertaking**

**In view of the following definitions:**

**“EUnetHTA Joint Action 3 Activities”** encompass any meeting (including meeting preparation and follow-up), associated discussion or any other related activity of the EUnetHTA Joint Action 3 committees and governance bodies, its Work Packages, expert groups, stakeholder groups, or any other such meeting, work as an expert on assessments, and work as an expert on guidance development.

**“Confidential Information”** means all information, facts, data and any other matters which are indicated as confidential and of which I acquire knowledge, either directly or indirectly, as a result of my EUnetHTA Joint Action 3 Activities.

**“Confidential Documents”** mean all drafts, preparatory information, documents and any other material, together with any information contained therein, which is indicated as confidential and to which I have access, either directly or indirectly, as a result of my participation in EUnetHTA Joint Action 3 Activities. Furthermore, any records or notes made by me relating to Confidential Information or Confidential Documents shall be treated as Confidential Documents.

**I understand that I may be invited to participate either directly or indirectly in certain EUnetHTA Joint Action 3 Activities and hereby undertake:**

1. to treat all Confidential Information and Confidential Documents under conditions of strict confidentiality.

2. not to disclose (or authorise any other person to disclose) in any way to any third party[[10]](#footnote-10) any Confidential Information or Confidential Document.

3. not to use (or authorise any other person to use) any Confidential Information or Confidential Document other than for the purposes of my work in connection with EUnetHTA Joint Action 3 Work Package activities.

4. to dispose of Confidential Documents as confidential material as soon as I have no further use for them.

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 otherwise than as a result of a breach of any of the above undertakings.

Place:

Date:

Signature:

1. Note that the validity of this DOICU is **1 year** starting from date of signature. [↑](#footnote-ref-1)
2. Please provide details on your affiliations as far as 3 years back (and up until now) from the time of filling the form [↑](#footnote-ref-2)
3. Enter ‘none' if you feel this point does not apply. This also applies to subsequent items. [↑](#footnote-ref-3)
4. Please provide a brief description. This also applies to subsequent items. [↑](#footnote-ref-4)
5. Where necessary, additional entries can be made. This also applied to subsequent items. [↑](#footnote-ref-5)
6. Enter ‘none' if you feel this point does not apply. This also applies to subsequent items. [↑](#footnote-ref-6)
7. Please provide a brief description. This also applies to subsequent items. [↑](#footnote-ref-7)
8. Household member is a spouse, partner, or child living at the same address as the individual who signs the conflict of interest declaration. [↑](#footnote-ref-8)
9. Please provide a description following the format of Items 1b-8 of the declaration. Individuals from countries where information on the this persons are legally not allowed to be provided may omit this item – indication of the legal reason of omitting this information need to be explicitly indicated. [↑](#footnote-ref-9)
10. Third party does not include employees of the National Competent Authorities who either have employment contracts that provide confidentiality obligations or are encompassed by confidentiality obligations under national legislation on professional secrecy. [↑](#footnote-ref-10)