



Brussels, XXX  
[...] (2024) XXX draft

ANNEXES 1 to 2

## ANNEXES

*to the*

**COMMISSION IMPLEMENTING REGULATION (EU) .../...**

**laying down rules for the application of Regulation (EU) 2021/2282 of the European Parliament and of the Council as regards the management of conflicts of interest in the joint work of the Member State Coordination Group on Health Technology Assessment and its subgroups**

**ANNEX I**

**Declaration of interests form for the participation in the joint work carried out under Regulation (EU) 2021/2282**

*Please answer each of the questions below. If the answer to any of the questions is “yes”, please provide further requested details on relevant interests, as appropriate.*

*If you do not do so, your declaration of interests form will be considered incomplete and, therefore, you will be excluded from joint work carried out in line with Regulation (EU) 2021/2282.*

First name:

Family name:

Organisation/company (*where applicable*):

Country:

Job title in the organisation/company:

Type of activity (*choose one or several, as appropriate*):

Representative in the Coordination Group

Representative in the subgroup on joint clinical assessments

Representative in the subgroup on joint scientific consultations

Representative in the subgroup on emerging health technologies

Representative in the subgroup on development of methodological and procedural guidance

Patient expert

Clinical expert

Other relevant expert

## 1. EMPLOYMENT

<p><b>Q1.1. Are you or were you employed by a health technology developer:</b></p> <ul style="list-style-type: none"> <li>- within the past 5 years in an executive role, such as president/vice president, chief executive officer, chief scientific officer, executive director/director/associate director (Question 1.1a);</li> <li>- within the past 3 years in a role involving cross product responsibility other than executive role (Question 1.1b);</li> <li>- within the past 3 years in a role involving individual product responsibility (Question 1.1c)?</li> </ul> <p><i>'employed by a health technology developer'</i> means any form of occupation, part-time or full-time, paid or unpaid, in a health technology developer.</p> <p><i>'cross product responsibility'</i> means support activities for multiple health technologies across one or several therapeutic areas/full product range, such as pharmacovigilance, regulatory affairs, statistical methodology.</p>	<b>yes</b>	<b>no</b>
	<input type="checkbox"/>	<input type="checkbox"/>

Function	Time period (from... until month/year)	Name of the health technology developer	Role/area of activity
Q1.1a. Executive role (within the past 5 years)			
Q1.1b. Cross product responsibility other than executive role (within the past 3 years)			

Function	Time period (from... until month/year)	Name of the health technology developer	Name and therapeutic indication of the health technology
Q1.1c. Individual product responsibility (within the past 3 years)			

<p><i>Q1.2. Are you or were you within the past 3 years employed in a role involving individual product responsibility by a company or organisation, to which a health technology developer has outsourced its activities on a contractual basis, such as clinical research, regulatory affairs or health technology assessment?</i></p> <p><i>'employed by a company or organisation' means any form of occupation, part-time or full-time, paid or unpaid, in a company or organisation.</i></p>	<p><b>yes</b></p>	<p><b>no</b></p>
	<p><input type="checkbox"/></p>	<p><input type="checkbox"/></p>

<p><b>Name of the company /organisation of employment</b></p>	<p><b>Time period (from... until month/year)</b></p>	<p><b>Name of the health technology developer</b></p>	<p><b>Name and therapeutic indication of the health technology</b></p>

## 2. CONSULTANCY

<p><i>Q2. Do you currently, or did you within the past 3 years, provide advice to or conduct research for a health technology developer regardless of contractual arrangements or any form of remuneration?</i></p> <p><i>This question does <b>not</b> cover:</i></p> <ul style="list-style-type: none"> <li><i>- advice provided to a health technology developer on behalf of a national or regional authority or body. Such activity is <b>not</b> to be declared;</i></li> <li><i>- employment in consultancy companies or contract research organisations providing advice to health technology developers. Such activity is to be declared under <b>Question 1.2</b> ("Employment");</i></li> <li><i>- participation in an advisory board, steering committee, executive committee in the role of providing advice/expressing opinions on the (future) strategy, direction or development activities of a health technology developer. Such activity is to be declared under <b>Question 3</b> ("Strategic advisory role");</i></li> <li><i>- providing presentations or training courses. Such activity is to be declared under <b>Question 4.2</b> ("Financial interests") under the conditions specified therein;</i></li> <li><i>- conducting clinical trials, clinical investigations or clinical performance evaluations where you acted as a principal investigator or investigator. Such activity is to be declared under <b>Question 5</b> ("Principal investigator and investigator").</i></li> </ul>	<p><b>yes</b></p>	<p><b>no</b></p>
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	<input type="checkbox"/>	<input type="checkbox"/>
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Type of consultancy	Time period (from... until month/year)	Name of the health technology developer	Name and therapeutic indication of the health technology
Q2a. Individual product related			

Type of consultancy	Time period (from... until month/year)	Name of the health technology developer	General role/area of activity
Q2b. Cross product related/general (non-product related)			

### 3. STRATEGIC ADVISORY ROLE

<p><i>Q3. Do you currently, or did you within the past 3 years, participate in a(n) (scientific) advisory board/steering committee/executive committee in the role of providing advice/expressing opinions on the (future) strategy, direction or development activities of a health technology developer, regardless of contractual arrangements or any form of remuneration?</i></p> <p><i>This question does <b>not</b> cover:</i></p> <ul style="list-style-type: none"> <li>- involvement in data monitoring committees. Such activity is to be declared under <b>Question 5</b> (“Principal investigator and investigator”).</li> </ul>	<b>yes</b>	<b>no</b>
	<input type="checkbox"/>	<input type="checkbox"/>

Type of role	Time period (from... until month/year)	Name of the health technology developer	Name and therapeutic indication of the health technology
Q3a. Individual product related			

Type of role	Time period (from... until month/year)	Name of the health technology developer	General role/area of activity
Q3b. Cross product related/ general (non-product related)			

#### 4. FINANCIAL INTERESTS

<i>Q4.1. Do you currently have any of the following financial interests with a health technology developer:</i>	yes	no
<p>- (co)ownership, shares and other stocks, stock options, stock warrants, equities, bonds. This does not cover the holding of financial interests through an investment fund, pension fund and/or interests in non-nominal unit trusts or similar arrangements provided that they are diversified and independently managed;</p> <p>- intellectual property rights owned by you or of which you are directly a beneficiary?</p>		
	<input type="checkbox"/>	<input type="checkbox"/>

Financial interest	Name of the health technology developer and/or the health technology

<i>Q4.2. Do you currently, or did you within the past 3 years, benefit from:</i>	yes	no
<p>- payment by a health technology developer to provide a presentation or training course, attend a conference/seminar/event;</p> <p>- reimbursement by a health technology developer of expenses incurred in relation to providing a presentation or training course, attending a conference/seminar/event?</p> <p><i>This question does <b>not</b> cover:</i></p> <p>- payment/reimbursement of expenses of a value below 1.000 EUR from one health technology developer within the past 3 years. Such interests are <b>not</b> to be declared.</p>		
	<input type="checkbox"/>	<input type="checkbox"/>

Financial interest	Date of payment/reimbursement	Name of the health technology developer	Therapeutic area (where relevant)

#### 5. PRINCIPAL INVESTIGATOR AND INVESTIGATOR

<i>Q5. Do you currently, or did you within the past 3 years, act as a principal investigator or an investigator in a clinical trial, observation study, clinical investigation or clinical performance evaluation?</i>	<b>yes</b>	<b>no</b>
	<input type="checkbox"/>	<input type="checkbox"/>

Time period (from... until month/year)	Name of the sponsor health technology developer (where relevant)	Name and therapeutic indication of the health technology

#### 6. LEAD MEMBER IN AN ORGANISATION/INSTITUTION RECEIVING FUNDING FROM HEALTH TECHNOLOGY DEVELOPERS

<i>Q6. Are you currently (co)chair, president, director, treasurer of an organisation/institution that receives, or within the past 3 years, received direct funding from a health technology developer or several health technology developers?</i>	<b>yes</b>	<b>no</b>
<i>This question does <b>not</b> cover: - funding of national or regional authorities or bodies by fees from health technology developer.</i>		
	<input type="checkbox"/>	<input type="checkbox"/>

Organisation/institution	Name of the health technology developer(s)	End of the funding period (until month/year)

7. INTERESTS OF IMMEDIATE FAMILY MEMBERS

<p><i>Q7. Do your immediate family members have interests referred to in Questions 1.1a, 1.1b, 1.1c, 1.2 (“Employment”) and 4.1 (“Financial interests”)?</i></p> <p><i>‘immediate family member’ means the individual’s spouse, children and parents. “Spouse” includes a partner with whom the individual has a registered non marital regime.</i></p> <p><i>‘children’ means the children that the individual and the spouse have in common, the individual’s own children and the spouse’s own children.</i></p>	<p><b>yes</b></p>	<p><b>no</b></p>
	<input type="checkbox"/>	<input type="checkbox"/>

Type of interest declared	Name of the health technology developer and/or the health technology

8. OTHER RELEVANT INFORMATION

<p><i>Do you have any additional information relevant to the joint work that you would like to disclose?</i></p>	<p><b>yes</b></p>	<p><b>no</b></p>
	<input type="checkbox"/>	<input type="checkbox"/>
<p><i>Please provide the description here (please do not provide any personal data of other individuals):</i></p>		



**ANNEX II**

**Exclusions from and limitations of the participation in the joint work based on the declared interests**

<b>Declared interest</b>	<b>Time frame</b>	<b>(Co)Chair</b>	<b>Representative, including (co)assessor</b>	<b>Individual expert (patient, expert, relevant expert) clinical other expert)</b>
<b>1. EMPLOYMENT</b>				
<b>1.1a.</b> Executive role	Current	<b>X</b>	<b>X</b>	<b>X</b>
	Within the past 5 years	<b>XC</b>	<b>X<sub>HTD</sub></b>	<b>X<sub>HTD</sub></b>
<b>1.1b.</b> Cross product responsibility other than executive role	Current	<b>X</b>	<b>X</b>	<b>X</b>
	Within the past 3 years	<b>XC</b>	<b>X<sub>HTD</sub></b>	<b>X<sub>HTD</sub></b>
<b>1.1c.</b> Individual product responsibility	Current	<b>X</b>	<b>X</b>	<b>X</b>
	Within the past 3 years	<b>XC</b>	<b>X<sub>HT</sub></b>	<b>X<sub>HT</sub></b>
<b>1.2.</b> Employment in consultancy company or contract research organisation	Current	<b>X</b>	<b>X</b>	<b>X</b>
	Within the past 3 years	<b>XC</b>	<b>X<sub>HT</sub></b>	<b>X<sub>HT</sub></b>
<b>2. CONSULTANCY</b>				
<b>2a.</b> Individual product related	Current	<b>X</b>	<b>X</b>	<b>X</b>
	Within the past 3 years	<b>XC</b>	<b>X<sub>HT</sub></b>	<b>X<sub>HT</sub></b>
<b>2b.</b> Cross product related/general (non-product related)	Current	<b>X</b>	<b>X</b>	<b>X</b>
	Within the past 3 years	<b>XC</b>	<b>X<sub>HTD</sub></b>	<b>X<sub>HTD</sub></b>
<b>3. STRATEGIC ADVISORY ROLE</b>				
<b>3a.</b> Individual product related	Current	<b>X</b>	<b>X</b>	<b>X</b>
	Within the past 3 years	<b>XC</b>	<b>X<sub>HT</sub></b>	<b>X<sub>HT</sub></b>
<b>3b.</b> Cross product related/general (non-product related)	Current	<b>X</b>	<b>X</b>	<b>X</b>
	Within the past 3 years	<b>XC</b>	<b>X<sub>HTD</sub></b>	<b>X<sub>HTD</sub></b>

4. FINANCIAL INTERESTS				
4.1. (Co)ownership, shares etc., intellectual property rights	Current	<b>X</b>	<b>X</b>	<b>X</b>
4.2. Payment/reimbursement of expenses	Current	<b>X</b>	<b>X<sub>T/HTD</sub><sup>1</sup></b>	<b>X<sub>T/HTD</sub><sup>2</sup></b>
	Within the past 3 years	<b>RC<sub>HTD</sub></b>	<b>X<sub>T/HTD</sub><sup>3</sup></b>	<b>X<sub>T/HTD</sub><sup>4</sup></b>
5. PRINCIPAL INVESTIGATOR AND INVESTIGATOR	Current	<b>XC</b>	<b>X<sub>HTD/HT</sub><sup>5</sup></b>	<b>X<sub>HTD/HT</sub><sup>6</sup></b>
	Within the past 3 years	<b>RC<sub>HTD/HT</sub><sup>7</sup></b>	<b>X<sub>HT</sub></b>	<b>X<sub>HT</sub></b>
6. LEAD MEMBER IN AN ORGANISATION/INSTITUTION RECEIVING FUNDING FROM HEALTH TECHNOLOGY DEVELOPERS	Current funding	<b>X</b>	<b>X<sub>HTD</sub></b>	<b>X<sub>HTD</sub></b>
	Funding ended within the past 3 years	<b>RC<sub>HTD</sub></b>	<b>X<sub>HTD</sub></b>	<b>X<sub>HTD</sub></b>
7. INTERESTS OF IMMEDIATE FAMILY MEMBERS	Current	<b>RC<sub>HTD/HT</sub><sup>8</sup></b>	<b>X<sub>HTD/HT</sub><sup>9</sup></b>	<b>X<sub>HTD/HT</sub><sup>10</sup></b>

<sup>1</sup> T where the presentation, training course, conference/seminar/event was related to a therapeutic area and HTD where the therapeutic area cannot be identified.

<sup>2</sup> T where the presentation, training course, conference/seminar/event was related to a therapeutic area and HTD where the therapeutic area cannot be identified.

<sup>3</sup> T where the presentation, training course, conference/seminar/event was related to a therapeutic area and HTD where the therapeutic area cannot be identified.

<sup>4</sup> T where the presentation, training course, conference/seminar/event was related to a therapeutic area and HTD where the therapeutic area cannot be identified.

<sup>5</sup> HTD if clinical trial is sponsored by a health technology developer and HT if clinical trial is sponsored by other means than by health technology developers.

<sup>6</sup> HTD if clinical trial is sponsored by a health technology developer and HT if clinical trial is sponsored by other means than by health technology developers.

<sup>7</sup> HTD if clinical trial was sponsored by a health technology developer and HT if clinical trial was sponsored by other means than by health technology developers.

<sup>8</sup> HT in case of intellectual property rights and HTD in all other instances.

<sup>9</sup> HT in case of intellectual property rights and HTD in all other instances.

<sup>10</sup> HT in case of intellectual property rights and HTD in all other instances.

## Explanations

<u><i>Interests constituting a conflict of interest deemed incompatible with the participation in the joint work</i></u>	
X	No participation in joint work

<u><i>Interests constituting a conflict of interest deemed incompatible with taking up certain roles and responsibilities in the joint work</i></u>	
XC	Cannot be elected as chair/co-chair

<u><i>Interests constituting a conflict or potential conflict of interest in relation to the health technology developer or to the specific health technologies</i></u>	
RC <sub>HTD</sub>	To be replaced as chair/co-chair with regard to any health technologies from the health technology developer
RC <sub>HT</sub>	To be replaced as chair/co-chair with regard to specific health technologies under assessment or comparator health technologies
X <sub>HTD</sub>	No involvement of the representative as (co)assessor nor in any discussions or decision making in relation to any health technologies from the health technology developer  No involvement of the individual expert in joint work in relation to any health technologies from the health technology developer
X <sub>HT</sub>	No involvement of the representative as (co)assessor nor in any discussions or decision making in relation to specific health technologies under assessment or comparator health technologies  No involvement of the individual expert in joint work in relation to specific health technologies under assessment or comparator health technologies
X <sub>T</sub>	No involvement of the representative as (co)assessor nor in any discussions or decision making in relation to health technologies from the health technology developer within the therapeutic area  No involvement of the individual expert in joint work in relation to health technologies from the health technology developer within the therapeutic area

“**Comparator health technology**” means a health technology identified in the assessment scope for the joint clinical assessment finalised by the subgroup on joint clinical assessments. Comparator health technology that is no longer covered by a patent or supplementary protection is not taken into consideration for the conflict of interest management.