



Public Declaration of Interests and Confidentiality Undertaking

INSTRUCTIONS

This form consists of three parts: your **Personal Details**, **Public Declaration of Interests** and **Confidentiality Undertaking**. All parts must be duly completed. **The form is designed to be completed electronically and the data entered stored electronically**. You are responsible for the accuracy and completeness of the submitted information. Please be advised that once you have submitted and signed the form, the Agency will publish your declaration of interests on its website.

WARNING - If you are already registered in the EMA's Experts database, you should not fill in a blank form but rather ask the Agency for your previous declaration for update.

SECTION 1: PERSONAL DETAILS Please click on any of the footnotes for further information.

First name:

Jan

NOTE: Please write your full first and last name as mentioned on your identity card/passport.

Last name:

Peeters

Organisation / company¹:

ARBXD Institute

Country²:

Belgium

E-mail address:

jan.peeters@arbx.be

Type of activity³:

EMA Expert (nominated for involvement in EMA activities)

SECTION 2: PUBLIC DECLARATION OF INTERESTS

If you have interests to declare, please click 'Yes' to the relevant questions and provide further information. All questions in this section must be answered. Your declaration will not be accepted if any fields are left empty.

All current and/or past interests from the last 3 years should be declared. In the case of previous employment in a pharmaceutical company in an executive role or lead role in the development of a medicinal product (see section 2.1) or in the case of involvement in the repurposing of a medicinal product where your organisation is acting as the champion of the repurposing (see section 2.9), please declare all such past interests from your entire career.

For more information on which interests to declare, please see the [European Medicines Agency policy on the handling of competing interests of scientific committees' members and experts](#) and the [procedural guidance on inclusion of declared interests in the European Medicines Agency's electronic declaration of interests form](#).

I do hereby declare on my honour that, to the best of my knowledge, the only direct or indirect interests in the pharmaceutical industry I have currently (at the time of completion of the form) or have had (in the last 3 years and in case of previous employment in an executive role or lead role in the development of a medicinal product at any stage of my career) are those listed below:

2.1 Employment

No Yes

Employment with a pharmaceutical company means any form of occupation, part-time or full-time, paid or unpaid, in the company. A pharmaceutical company means any legal or natural person whose focus is to research, develop, manufacture, maintain, market and/or distribute medicinal products. This includes companies to which activities relating to the research, development, manufacturing, maintenance, marketing and/or distribution of medicinal products (which might also be carried out in house) are outsourced on a contract basis. CROs or consultancy companies providing advice or services relating to the above activities, or to activities linked with marketing authorisation or other regulatory procedures (e.g. initial applications, variations), also fall under the definition of a pharmaceutical company. Independent researchers and research organisations including universities and learned societies are excluded from the scope of the definition of a pharmaceutical company.

Employment in a pharmaceutical company in an **executive role** and/or a **lead role** in the development of a medicinal product **AT ANY STAGE OF YOUR CAREER** should be declared. **Cross product** responsibility other than an executive role and/or **individual product** responsibility other than lead role in the development of a medicinal product **IN THE LAST 3 YEARS** should be declared.

EMPLOYMENT *Please click on any of the footnotes for further information.*

Time period¹: Current Past

From month: From year: To month: To year:

Name of pharmaceutical company²:

Function³:

- Executive role (at any stage of your career)
- Lead role in the development of a medicinal product (at any stage of your career)
- Cross product responsibility other than executive role (in the last 3 years)
- Individual product responsibility other than lead role in the development of a medicinal product (in the last 3 years)

Product name	Therapeutic indication
<input type="text" value="Product A"/>	<input type="text" value="HIV"/>
<input type="text" value="Product B"/>	<input type="text" value="Epilepsy"/>

EMPLOYMENT *Please click on any of the footnotes for further information.*

Time period¹: Current Past

From month: From year: To month: To year:

Name of pharmaceutical company²:

Function³:

- Executive role (at any stage of your career)
- Lead role in the development of a medicinal product (at any stage of your career)
- Cross product responsibility other than executive role (in the last 3 years)
- Individual product responsibility other than lead role in the development of a medicinal product (in the last 3 years)

Title or role within the company:

1 Please select the appropriate response: Current or Past. For activities which are currently on-going (current is interpreted as the time of completion of the form), please provide the starting date (month/year). For activities that are no longer on-going and have been completed, please also provide the end date (month/year).

Please declare all employment in a pharmaceutical company in an executive role and/or a lead role in the development of a medicinal product that occurred at any stage of your career. Please declare cross product responsibility and/or individual product responsibility that occurred in the last 3 years (other than an executive role and/or lead role in the development of a medicinal product).

2 **Pharmaceutical company:** means any legal or natural person whose focus is to research, develop, manufacture, maintain, market and/or distribute medicinal products. This includes companies to which activities relating to the research, development, manufacturing, maintenance, marketing and/or distribution of medicinal products (which might also be carried out in house) are outsourced on a contract basis. CROs or consultancy companies providing advice or services relating to the above activities, or to activities linked with marketing authorisation or other regulatory procedures (e.g. initial applications, variations), fall under the definition of a pharmaceutical company. Legal or natural persons which do not fall within the scope of the above definition but (i) control (i.e. own a majority stake in, or otherwise exercise a significant influence in the decision-making processes of the relevant pharmaceutical company), (ii) are controlled by or (iii) are under common control of a pharmaceutical company are also considered as pharmaceutical companies.

In case of **employment in a CRO or consultancy company**, please mention the name of the CRO or consultancy company under pharmaceutical company and list all products (including the names of the pharmaceutical companies to which CRO or consultancy services were provided, e.g. product A (pharmaceutical company X), product B (pharmaceutical company Y), etc. and therapeutic indications.

Independent researchers and research organisations including universities, hospitals and learned societies, are excluded from the scope of the present definition. However, any unit department section or entity within such organisation, that manufactures medicinal products, including ATMPs under hospital exemption, or is a marketing authorisation applicant/holder, shall be considered as a pharmaceutical company for the purpose of this policy. Staff members of such units, sections, departments or entities are considered to be equivalent to staff members of a pharmaceutical company. Other parts of the organisation to which the unit, section, department or entity belongs can be excluded from this definition of a pharmaceutical company.

3 **Executive role within a pharmaceutical company** means responsibility for the strategic and operational direction of a pharmaceutical company, and as a consequence a key role in decision-making at strategic and operational level for the pharmaceutical company. For more information, please see the procedural guidance on inclusion of declared interests in the European Medicines Agency's electronic declaration of interests form. Please provide your job title.

Lead role in the development of a medicinal product means direct responsibility for the development of a medicinal product, other than support provided to the development of a medicinal product which should be reported under individual product responsibility. For more information, please see the procedural guidance on inclusion of declared interests in the European Medicines Agency's electronic declaration of interests form. Please provide the product name, active substance and as much detail as possible regarding the therapeutic indication, in order to allow evaluation of this declared interest.

Cross product responsibility or involvement in support activities for multiple products across one or several therapeutic areas/full product range, other than executive role: this option should only be chosen where it is not possible to list all of the products with which you were involved. Examples of such cross product responsibility might include areas such as Pharmacovigilance, Regulatory Affairs, Statistical Methodology. Please provide your job title, as well as the role or area in which you were involved.

Individual product responsibility or involvement in one or more products within one or more therapeutic areas, e.g. product development, manufacture or maintenance (quality, clinical, non-clinical), other than lead role in the development of a medicinal product: please provide the product name, active substance and as much detail as possible regarding the therapeutic indication, in order to allow evaluation of this declared interest.

Where your role within a company changed during the period of employment, please provide this information as individual entries. Click on 'Add employment' to create a new entry for the next role/responsibility and provide details on the period and responsibility/involvement, while mentioning the same company name.

2.2 Consultancy

No Yes

Consultancy means provision of advice (including training on a one to one basis or involvement in the repurposing of a medicinal product) to a pharmaceutical company regardless of contractual arrangements or any form of remuneration. A pharmaceutical company means any legal or natural person whose focus is to research, develop, manufacture, maintain, market and/or distribute medicinal products. This includes companies to which activities relating to the research, development, manufacturing, maintenance, marketing and/or distribution of medicinal products (which might also be carried out in house) are outsourced on a contract basis.

Note i: Scientific advice provided by the NCA of a Member State is not considered a consultancy activity. Conference/Seminar attendance is not considered as consultancy but should be mentioned under section 2.4 Financial Interests if subject to a fee/honoraria and if current.

Note ii: If you are or have been an employee of a CRO or consultancy company (i.e. a professional business offering advice or services to pharmaceutical companies), please declare this under Section 2.1 Employment.

Consultancy *Please click on any of the footnotes for further information.*

Time period¹: Current Past

From month: From year: To month: To year:

Name of pharmaceutical company²:

Individual product related³ Cross product relates/ general (non product related)⁴

Product name:

Therapeutic indication:

Consultancy Please click on any of the footnotes for further information.

Time period¹: Current Past

From month: From year: To month: To year:

Name of pharmaceutical company²:

Individual product related³ Cross product relates/ general (non product related)⁴

General role / Area of activity:

- 1 Please select the appropriate response: Current or Past. For activities which are currently on-going (current is interpreted as the time of completion of the form), please provide the starting date (month/year). For activities that are no longer on-going and have been completed, please also provide the end date (month/year).
- 2 Pharmaceutical company: means any legal or natural person whose focus is to research, develop, manufacture, maintain, market and/or distribute medicinal products. This includes companies to which activities relating to the research, development, manufacturing, maintenance, marketing and/or distribution of medicinal products (which might also be carried out in house) are outsourced on a contract basis. CROs or consultancy companies providing advice or services relating to the above activities, or to activities linked with marketing authorisation or other regulatory procedures (e.g. initial applications, variations), fall under the definition of a pharmaceutical company. Legal or natural persons which do not fall within the scope of the above definition but (i) control (i.e. own a majority stake in, or otherwise exercise a significant influence in the decision-making processes of the relevant pharmaceutical company), (ii) are controlled by or (iii) are under common control of a pharmaceutical company are also considered as pharmaceutical companies.
- Independent researchers and research organisations including universities, hospitals and learned societies, are excluded from the scope of the present definition. However, any unit, department, section or entity within such organisation, that manufactures medicinal products, including ATMPs under hospital exemption, or is a marketing authorisation applicant/holder, shall be considered as a pharmaceutical company for the purpose of this policy. Staff members of such units, sections, departments or entities are considered to be equivalent to staff members of a pharmaceutical company. Other parts of the organisation to which the unit, section, department or entity belongs can be excluded from this definition of a pharmaceutical company.
- 3 Consultancy on the development of one or more products within one or more therapeutic areas per pharmaceutical company: Please provide the product name, active substance and as much details as possible regarding the therapeutic indication, in order to allow evaluation of this declared interest.
- 4 Cross product consultancy for multiple products across one or several therapeutic areas/full product range or general (non-product related) consultancy per pharmaceutical company: Please indicate the role or area in which you were involved.

2.3 Strategic advisory role

No Yes

Strategic advisory role means participation (with a right to vote on/influence the outputs) in a(n) (scientific) advisory board/steering committee with the role of providing advice/expressing opinions on the (future) strategy, direction or development activities of a pharmaceutical company, either in terms of general strategy or product related strategy, regardless of contractual arrangements or any form of remuneration. A pharmaceutical company means any legal or natural person whose focus is to research, develop, manufacture, maintain, market and/or distribute medicinal products. This includes companies to which activities relating to the research, development, manufacturing, maintenance, marketing and/or distribution of medicinal products (which might also be carried out in house) are outsourced on a contract basis.

Note: Involvement in Data Monitoring Committees is not included in this category. Such involvement should be recorded under section 2.5 Principal investigator. Involvement in clinical research should be listed under section 2.5 Principal investigator or 2.6 Investigator as appropriate.

Strategic advisory role Please click on any of the footnotes for further information.

Time period¹: Current Past

From month: From year: To month: To year:

Name of pharmaceutical company²:

Individual product related³ Cross product related/ general (non-product related)⁴

Product name:

Therapeutic indication:

Strategic advisory role Please click on any of the footnotes for further information.

Time period¹: Current Past

From month: From year: To month: To year:

Name of pharmaceutical company²:

Individual product related³ Cross product related/ general (non-product related)⁴

General role / Area of activity:

- 1 Please select the appropriate response: Current or Past. For activities which are currently on-going (current is interpreted as the time of completion of the form), please indicate the starting date (month/year). For activities that are no longer on-going and have been completed, please also provide the end date (month/year).
- 2 Pharmaceutical company: means any legal or natural person whose focus is to research, develop, manufacture, maintain, market and/or distribute medicinal products. This includes companies to which activities relating to the research, development, manufacturing, maintenance, marketing and/or distribution of medicinal products (which might also be carried out in house) are outsourced on a contract basis. CROs or consultancy companies providing advice or services relating to the above activities, or to activities linked with marketing authorisation or other regulatory procedures (e.g. initial applications, variations), fall under the definition of a pharmaceutical company. Legal or natural persons which do not fall within the scope of the above definition but (i) control (i.e. own a majority stake in, or otherwise exercise a significant influence in the decision-making processes of the relevant pharmaceutical company), (ii) are controlled by or (iii) are under common control of a pharmaceutical company are also considered as pharmaceutical companies. Independent researchers and research organisations including universities, hospitals and learned societies, are excluded from the scope of the present definition. However, any unit, department, section or entity within such organisation, that manufactures medicinal products, including ATMPs under hospital exemption, or is a marketing authorisation applicant/holder, shall be considered as a pharmaceutical company for the purpose of this policy. Staff members of such units, sections, departments or entities are considered to be equivalent to staff members of a pharmaceutical company. Other parts of the organisation to which the unit, section, department or entity belongs can be excluded from this definition of a pharmaceutical company.
- 3 Participation in (scientific) advisory board/steering committee, providing advice on product related strategies: Please provide the product name, active substance and as much details as possible regarding the therapeutic indication, in order to allow evaluation of this declared interest.
- 4 Participation in (scientific) advisory board/steering committee, providing advice on general strategies: Please indicate the role or area in which you were involved.

2.4 Financial interests

No Yes

Financial interests mean any economic stake in a pharmaceutical company including:

- **CURRENT** holding of stocks and shares, stock options, stock warrants, equities, bonds and or partnership interest in the capital of a pharmaceutical company with the exclusion of 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 (i.e. not exclusively based on the pharmaceutical sector) and they are independently managed (i.e. the individual has no influence on their financial management).
- **CURRENT** compensation, fees, honoraria, salaries, grant or other funding (including rents, sponsorships and fellowships) paid by a pharmaceutical company to you in a personal capacity, other than payment for or reimbursement of expenses incurred with research work or reimbursement of reasonable expenses directly related to conference/seminar attendance (i.e. accommodation and travel costs).
- **CURRENT** intellectual property rights including patents, trademarks, know-how and/or copyrights relating to a medicinal product owned by you or of which you are directly a beneficiary.

(**CURRENT** is interpreted at time of completion of this form).

Current financial interests *Please click on any of the footnotes for further information.*

Name of pharmaceutical company ¹	Financial interest
Company F	Shares

¹ Pharmaceutical company: means any legal or natural person whose focus is to research, develop, manufacture, maintain, market and/or distribute medicinal products. This includes companies to which activities relating to the research, development, manufacturing, maintenance, marketing and/or distribution of medicinal products (which might also be carried out in house) are outsourced on a contract basis. CROs or consultancy companies providing advice or services relating to the above activities, or to activities linked with marketing authorisation or other regulatory procedures (e.g. initial applications, variations), fall under the definition of a pharmaceutical company. Legal or natural persons which do not fall within the scope of the above definition but (i) control (i.e. own a majority stake in, or otherwise exercise a significant influence in the decision-making processes of the relevant pharmaceutical company), (ii) are controlled by or (iii) are under common control of a pharmaceutical company are also considered as pharmaceutical companies. Independent researchers and research organisations including universities, hospitals and learned societies, are excluded from the scope of the present definition. However, any unit, department, section or entity within such organisation, that manufactures medicinal products, including ATMPs under hospital exemption, or is a marketing authorisation applicant/holder, shall be considered as a pharmaceutical company for the purpose of this policy. Staff members of such units, sections, departments or entities are considered to be equivalent to staff members of a pharmaceutical company. Other parts of the organisation to which the unit, section, department or entity belongs can be excluded from this definition of a pharmaceutical company.

2.5 Principal investigator

No Yes

Principal investigator means an investigator with the responsibility for the coordination of investigators at different centres participating in a multicentre pharmaceutical company instigated/sponsored trial or the leading investigator of a monocentre pharmaceutical company instigated/sponsored trial, or the coordinating (principal) investigator signing the clinical study report. This definition does not include a national coordinating investigator in a multinational trial. Involvement in Data Monitoring Committees should be included in this section.

Note: Academic trials and publicly funded research/development initiatives involving pharmaceutical products should be included under section 2.10 Any other interests or facts.

Principal investigator *Please click on any of the footnotes for further information.*

Time period¹: Current Past

From month: From year:

Name of pharmaceutical company²:

Product name³:

Therapeutic indication:

- 1 Please select the appropriate response: Current or Past. For activities which are currently on-going (current is interpreted as the time of completion of the form), please provide the starting date (month/year). For activities that are no longer on-going and have been completed, please also provide the end date (month/year).
- 2 Pharmaceutical company: means any legal or natural person whose focus is to research, develop, manufacture, maintain, market and/or distribute medicinal products. This includes companies to which activities relating to the research, development, manufacturing, maintenance, marketing and/or distribution of medicinal products (which might also be carried out in house) are outsourced on a contract basis. CROs or consultancy companies providing advice or services relating to the above activities, or to activities linked with marketing authorisation or other regulatory procedures (e.g. initial applications, variations), fall under the definition of a pharmaceutical company. Legal or natural persons which do not fall within the scope of the above definition but (i) control (i.e. own a majority stake in, or otherwise exercise a significant influence in the decision-making processes of the relevant pharmaceutical company), (ii) are controlled by or (iii) are under common control of a pharmaceutical company are also considered as pharmaceutical companies. Independent researchers and research organisations including universities, hospitals and learned societies, are excluded from the scope of the present definition. However, any unit department section or entity within such organisation, that manufactures medicinal products, including ATMPs under hospital exemption, or is a marketing authorisation applicant/holder, shall be considered as a pharmaceutical company for the purpose of this policy. Staff members of such units, sections, departments or entities are considered to be equivalent to staff members of a pharmaceutical company. Other parts of the organisation to which the unit, section, department or entity belongs can be excluded from this definition of a pharmaceutical company.
- 3 Please indicate the product name, active substance and as much details as possible regarding the therapeutic indication, in order to allow evaluation of this declared interest.

2.6 Investigator

No Yes

Investigator means an investigator involved in a pharmaceutical company instigated/sponsored trial at a specific trial site who can be the responsible lead investigator of the trial at that specific site or a member of the clinical trial team who performs critical trial related procedures and makes important trial related decisions.

Note: Academic trials and publicly funded research/development initiatives involving pharmaceutical products should be included under section 2.10 Any other interests or facts.

Investigator *Please click on any of the footnotes for further information.*

Time period¹: Current Past

From month: From year: To month: To year:

Name of pharmaceutical company²:

Product name³:

Therapeutic indication:

- 1 Please select the appropriate response: Current or Past. For activities which are currently on-going (current is interpreted as the time of completion of the form), please provide the starting date (month/year). For activities that are no longer on-going and that have been completed, please also provide the end date (month/year).
- 2 Pharmaceutical company: means any legal or natural person whose focus is to research, develop, manufacture, maintain, market and/or distribute medicinal products. This includes companies to which activities relating to the research, development, manufacturing, maintenance, marketing and/or distribution of medicinal products (which might also be carried out in house) are outsourced on a contract basis. CROs or consultancy companies providing advice or services relating to the above activities, or to activities linked with marketing authorisation or other regulatory procedures (e.g. initial applications, variations), fall under the definition of a pharmaceutical company. Legal or natural persons which do not fall within the scope of the above definition but (i) control (i.e. own a majority stake in, or otherwise exercise a significant influence in the decision-making processes of the relevant pharmaceutical company), (ii) are controlled by or (iii) are under common control of a pharmaceutical company are also considered as pharmaceutical companies. Independent researchers and research organisations including universities, hospitals and learned societies, are excluded from the scope of the present definition. However, any unit, department, section or entity within such organisation, that manufactures medicinal products, including ATMPs under hospital exemption, or is a marketing authorisation applicant/holder, shall be considered as a pharmaceutical company for the purpose of this policy. Staff members of such units, sections, departments or entities are considered to be equivalent to staff members of a pharmaceutical company. Other parts of the organisation to which the unit, section, department or entity belongs can be excluded from this definition of a pharmaceutical company.
- 3 Please indicate the product name, active substance and as much details as possible regarding the therapeutic indication, in order to allow evaluation of this declared interest.

2.7 Grant / Funding to organisation/institution

No Yes

Grant or other funding to an organisation/institution means any **CURRENT** funding (other than compensation for services provided, as requested by National Competent Authorities) received from a pharmaceutical company by an organisation/institution to which you belong, or for which you perform any kind of activity, and which is used to support any of your activities whether or not they are related to research work. Any other funding received from a pharmaceutical company by an organisation/institution to which you belong, or for which you perform any kind of activity do not need to be declared. If you want to declare such funding for transparency purposes, please report under 2.10 Any Other Interests or Facts.

(**CURRENT** is interpreted at time of completion of this form).

Current grant or other funding Please click on any of the footnotes for further information.

Name of pharmaceutical company¹:

Subject matter :

1 Pharmaceutical company: means any legal or natural person whose focus is to research, develop, manufacture, maintain, market and/or distribute medicinal products. This includes companies to which activities relating to the research, development, manufacturing, maintenance, marketing and/or distribution of medicinal products (which might also be carried out in house) are outsourced on a contract basis. CROs or consultancy companies providing advice or services relating to the above activities, or to activities linked with marketing authorisation or other regulatory procedures (e.g. initial applications, variations), fall under the definition of a pharmaceutical company. Legal or natural persons which do not fall within the scope of the above definition but (i) control (i.e. own a majority stake in, or otherwise exercise a significant influence in the decision-making processes of the relevant pharmaceutical company), (ii) are controlled by or (iii) are under common control of a pharmaceutical company are also considered as pharmaceutical companies. Independent researchers and research organisations including universities, hospitals and learned societies, are excluded from the scope of the present definition. However, any unit, department, section or entity within such organisation, that manufactures medicinal products, including ATMPs under hospital exemption, or is a marketing authorisation applicant/holder, shall be considered as a pharmaceutical company for the purpose of this policy. Staff members of such units, sections, departments or entities are considered to be equivalent to staff members of a pharmaceutical company. Other parts of the organisation to which the unit, section, department or entity belongs can be excluded from this definition of a pharmaceutical company.

2.8 Close family member interest

No Yes

Close family member means first-line member of your family (i.e. a spouse or a partner, children and parents). Partner means a natural person with whom the committee member, alternate or expert is registered as having a stable non-marital partner legally by an EU member state or any competent authority of a member state, acknowledging their status as non-marital partners. Interests to be declared include **CURRENT** employment, consultancy, strategic advisory role and financial interests.

(**CURRENT** is interpreted at time of completion of this form).

Current interest of close family member Please click on any of the footnotes for further information.

Name of pharmaceutical company ¹	Type of interest declared
<input type="text" value="Company J"/>	<input type="text" value="Employee"/>
<input type="text" value="Company H"/>	<input type="text" value="Shares"/>

1 Pharmaceutical company: means any legal or natural person whose focus is to research, develop, manufacture, maintain, market and/or distribute medicinal products. This includes companies to which activities relating to the research, development, manufacturing, maintenance, marketing and/or distribution of medicinal products (which might also be carried out in house) are outsourced on a contract basis. CROs or consultancy companies providing advice or services relating to the above activities, or to activities linked with marketing authorisation or other regulatory procedures (e.g. initial applications, variations), fall under the definition of a pharmaceutical company. Legal or natural persons which do not fall within the scope of the above definition but (i) control (i.e. own a majority stake in, or otherwise exercise a significant influence in the decision-making processes of the relevant pharmaceutical company), (ii) are controlled by or (iii) are under common control of a pharmaceutical company are also considered as pharmaceutical companies. Independent researchers and research organisations including universities, hospitals and learned societies, are excluded from the scope of the present definition. However, any unit, department, section or entity within such organisation, that manufactures medicinal products, including ATMPs under hospital exemption, or is a marketing authorisation applicant/holder, shall be considered as a pharmaceutical company for the purpose of this policy. Staff members of such units, sections, departments or entities are considered to be equivalent to staff members of a pharmaceutical company. Other parts of the organisation to which the unit, section, department or entity belongs can be excluded from this definition of a pharmaceutical company.

2.9 Repurposing of a medicinal product

No Yes

Repurposing of a medicinal product means the process of identifying a new use for an existing medicinal product - out of regulatory protection - in an indication that is not registered in its marketing authorisation.

Champion for the repurposing of a medicinal product is a non-profit stakeholder developing or gathering evidence, including the use of scientific advice as the main regulatory tool, for the repurposing of a medicinal product, that can be e.g. a patient organisation, academia, collaborative groups or European Reference Networks. A champion is typically (a) able to coordinate and/or foster the research programme up until the point of full engagement by a pharmaceutical company, (b) initially responsible for liaising and leading the interactions with regulatory authorities and pharmaceutical companies/other stakeholders and (c) transparent regarding interactions with relevant pharmaceutical company(ies) in charge of filing the initial request for scientific/regulatory advice on the basis of the available data.

(i) Involvement in the repurposing of a medicinal product where **your organisation is acting as the champion** of the repurposing **AT ANY STAGE OF YOUR CAREER** should be declared.

(ii) Involvement in the repurposing of a medicinal product where **your organisation is collaborating with the champion** of the repurposing **IN THE LAST 3 YEARS** should be declared.

(iii) Involvement of **your organisation** in the repurposing of a medicinal product where your organisation is acting as the champion of the repurposing or is collaborating with the champion of the repurposing, but where **you as an individual are not involved** yourself **IN THE LAST 3 YEARS** should be declared.

REPURPOSING OF A MEDICINAL PRODUCT Please click on any of the footnotes for further information.

Time period¹: Current Past

From month: From year: To month: To year:

Product name:²

Product G

Therapeutic indication:

Dravet syndrome

Involvement in the repurposing:

- Involvement in the repurposing of a medicinal product where my organisation is acting as the champion of the repurposing (at any stage of your career)
- Involvement in the repurposing of a medicinal product where my organisation is collaborating with the champion of the repurposing (in the last 3 years)
- Involvement of my organisation in the repurposing of a medicinal product where the organisation is acting as the champion of the repurposing or is collaborating with the champion of the repurposing, but where I as an individual am not involved in the repurposing (in the last 3 years)

¹ Please select the appropriate response: Current or Past. For activities which are currently on-going (current is interpreted as the time of completion of the form), please provide the starting date (month/year). For activities that are no longer on-going and have been completed, please also provide the end date (month/year).

The **end date for the repurposing** of a medicinal product is the **date of the Commission Decision** for a new marketing authorisation or variation of the medicinal product.

Please declare all your individual involvement in the repurposing of a medicinal product where your organisation is/was acting as the champion for the repurposing, that occurred at any stage of your career.

Please declare all your individual involvement in the repurposing of a medicinal product where your organisation is/was collaborating with the champion for the repurposing, that occurred in the last 3 years.

Please declare all repurposing of a medicinal product where your organisation is/was acting as the champion for the repurposing or collaborating with the champion of the repurposing, but where you as an individual are/were not involved in the repurposing, that occurred in the last 3 years.

² Please indicate the product name, active substance and as much details as possible regarding the therapeutic indication, in order to allow evaluation of this declared interest.

2.10 Any other interests or facts

For transparency purposes, please also provide information on the following activities in this section:

- Academic trials and publicly funded research/development initiatives involving pharmaceutical products.
- Membership of an Ethics Committee (you do not need to state a list of trials you were involved in).
- If you work in an organisation/institution where your colleagues provide consultancy advice to pharmaceutical companies, but you are not directly involved in the provision of such advice. Examples include employees of Official Medicines Control Laboratories, staff members of academic departments, etc.
- Participation in European societies/research foundations/strategy boards/treatment groups/focus groups, which may be funded in full or in part from unrestricted grants from pharmaceutical companies (not from one single company), with or without involvement of industry participants and which may provide general advice (on development programmes, clinical study design, strategy, etc.) to several pharmaceutical companies (not one particular company) in a specific therapeutic area.
- Expert opinion or testimony in judicial proceedings against or by a pharmaceutical company relating to a medicinal product.
- Participation as a patient in a clinical trial.

Member of Ethics Committee of University Hospital

2.11 Are you a CAT member or alternate?

No Yes

CAT members and alternates are required to declare interests in the biotechnology sector and the medical device sector. Only CAT members and alternates need to complete this section of the declaration of interests.

I do hereby declare on my honour that, to the best of my knowledge, the only direct or indirect interests in the biotechnology sector and the medical device sector I have currently (at the time of completion of the form) or have had (in the last 3 years) are those listed below:

2.11.1 Employment

No Yes

Employment with the biotechnology sector or the medical device sector means any form of occupation, part-time or full-time, paid or unpaid, in the sector.

Biotechnology sector means any legal or natural person involved in the biotechnology sector whose research, development, manufacturing, maintaining, marketing and/or distribution activities are closely linked to ATMPs, i.e. **Blood, cells and tissues establishments and manufactures of critical starting materials for ATMPs**, e.g. viral vector manufacturers. This includes natural and legal persons to which activities relating to the research, development, manufacturing, maintaining, marketing and/or distribution closely linked with ATMPs (which might also be carried out in house) are outsourced on a contractual basis. Consultancy companies providing advice or services relating to the above activities, or to activities linked with marketing authorisation or other regulatory procedures (e.g. initial applications, variations) for ATMPs, fall under the definition of biotechnology sector. Independent researchers and research organisations including universities, hospitals and learned societies are excluded from the scope of the present definition.

Medical device sector means any legal or natural person involved in the medical device sector whose focus is to research, develop, maintain, manufacture, market and/or distribute **medical devices or active implantable medical devices used or to be used in combined ATMPs** as defined in article 2, 1 (d) of Regulation (EC) No 1394/2007. This includes natural or legal persons to which activities relating to the research, development, manufacturing, maintenance, marketing and/or distribution of medical devices used or to be used in combined ATMPs (which might also be carried out in house) are outsourced on a contractual basis. Consultancy companies providing advice or services relating to the above activities, or to activities linked with the Notified Bodies' procedures (e.g. applications, follow-up) fall under the definition of medical device sector. Independent researchers and research organisations including universities, hospitals and learned societies are excluded from the scope of the present definition.

Employment in the biotechnology sector and the medical device sector **IN THE LAST 3 YEARS** should be declared.

EMPLOYMENT Please click on any of the footnotes for further information.

Time period¹: Current Past

From month: From year: To month: To year:

Name of company²:

Function³:

- Cross product responsibility (in the last 3 years)
 Individual product responsibility (in the last 3 years)

Title or role within the company:

¹ Please select the appropriate response: Current or Past. For activities which are currently on-going (current is interpreted as the time of completion of the form), please provide the starting date (month/year). For activities that are no longer on-going and have been completed, please also provide the end date (month/year).

Please declare all cross-product responsibility and/or individual product responsibility that occurred in the last 3 years.

² **Biotechnology sector:** means any legal or natural person involved in the biotechnology sector whose research, development, manufacturing, maintaining, marketing and/or distribution activities are closely linked to ATMPs, i.e.: Blood, cells and tissues establishments and manufactures of critical starting materials for ATMPs, e.g. viral vector manufacturers. This includes natural and legal persons to which activities relating to the research, development, manufacturing, maintaining, marketing and/or distribution closely linked with ATMPs (which might also be carried out in house) are outsourced on a contractual basis. Consultancy companies providing advice or services relating to the above activities, or to activities linked with marketing authorisation or other regulatory procedures (e.g. initial applications, variations) for ATMPs, fall under the definition of biotechnology sector. Legal or natural persons which do not fall within the scope of the above definition but (i) control (i.e. own a majority stake in, or otherwise exercise a significant influence in the decision-making processes of the relevant biotechnology sector), (ii) are controlled by or (iii) are under common control of the biotechnology sector, shall be considered as biotechnology sector for the purposes of this policy. Independent researchers and research organisations including universities, hospitals and learned societies are excluded from the scope of the present definition.

Medical device sector: means any legal or natural person involved in the medical device sector whose focus is to research, develop, maintain, manufacture, market and/or distribute medical devices or active implantable medical devices used or to be used in combined ATMPs as defined in article 2, 1 (d) of Regulation (EC) No 1394/2007. This includes natural or legal persons to which activities relating to the research, development, manufacturing, maintenance, marketing and/or distribution of medical devices used or to be used in combined ATMPs (which might also be carried out in house) are outsourced on a contractual basis. Consultancy companies providing advice or services relating to the above activities, or to activities linked with the Notified Bodies' procedures (e.g. applications, follow-up) fall under the definition of medical device sector. Legal or natural persons which do not fall within the scope of the above definition but (i) control (i.e. own a majority stake in, or otherwise exercise a significant influence in the decision-making processes of the relevant medical device sector), (ii) are controlled by or (iii) are under common control of the medical device sector, shall be considered as medical device sector for the purposes of this policy. Independent researchers and research organisations including universities, hospitals and learned societies are excluded from the scope of the present definition.

In case of **employment in consultancy company**, please mention the name of the consultancy company under company and list all products (including the names of the companies to which consultancy services were provided, e.g. product A (company X), product B (company Y), etc. and indications or use of the product.

³ **Cross-product responsibility or involvement in support activities for multiple products full product range:** this option should only be chosen where it is not possible to list all of the products with which you were involved. Examples of such cross-product responsibility might include areas such as Materiovigilance, Regulatory Affairs, Statistical Methodology.

Please provide your job title, as well as the role or area in which you were involved.

Individual product responsibility or involvement in one or more products, e.g. product development, manufacture or maintenance (quality, clinical, non-clinical): please provide the product name and as much detail as possible regarding the indication or use of the product, in order to allow evaluation of this declared interest.

Where your role within a company changed during the period of employment, please provide this information as individual entries. Click on 'Add employment' to create a new entry for the next role/responsibility and provide details on the period and responsibility/involvement, while mentioning the same company name.

2.11.2 Consultancy

No Yes

Consultancy means provision of advice (including training on a one to one basis) to the biotechnology sector or the medical device sector regardless of contractual arrangements or any form of remuneration.

Biotechnology sector means any legal or natural person involved in the biotechnology sector whose research, development, manufacturing, maintaining, marketing and/or distribution activities are closely linked to ATMPs, i.e. Blood, cells and tissues establishments and manufactures of critical starting materials for ATMPs, e.g. viral vector manufacturers. This includes natural and legal persons to which activities relating to the research, development, manufacturing, maintaining, marketing and/or distribution closely linked with ATMPs (which might also be carried out in house) are outsourced on a contractual basis. Consultancy companies providing advice or services relating to the above activities, or to activities linked with marketing authorisation or other regulatory procedures (e.g. initial applications, variations) for ATMPs, fall under the definition of biotechnology sector. Independent researchers and research organisations including universities, hospitals and learned societies are excluded from the scope of the present definition.

Medical device sector means any legal or natural person involved in the medical device sector whose focus is to research, develop, maintain, manufacture, market and/or distribute medical devices or active implantable medical devices used or to be used in combined ATMPs as defined in article 2, 1 (d) of Regulation (EC) No 1394/2007. This includes natural or legal persons to which activities relating to the research, development, manufacturing, maintenance, marketing and/or distribution of medical devices used or to be used in combined ATMPs (which might also be carried out in house) are outsourced on a contractual basis. Consultancy companies providing advice or services relating to the above activities, or to activities linked with the Notified Bodies' procedures (e.g. applications, follow-up) fall under the definition of medical device sector. Independent researchers and research organisations including universities, hospitals and learned societies are excluded from the scope of the present definition.

Note i: Advice provided by the NCA of a Member State is not considered a consultancy activity. Conference/Seminar attendance is not considered as consultancy but should be mentioned under section 2.11.4 Financial Interests if subject to a fee/honoraria and if current.

Note ii: If you are or have been an employee of a consultancy company (i.e. a professional business offering advice or services to the biotechnology sector or the medical device sector), please declare this under Section 2.11.1 Employment.

Consultancy *Please click on any of the footnotes for further information.*

Time period¹: Current Past

From month: From year: To month: To year:

Name of company²:

Individual product related³ Cross product relates/ general (non product related)⁴

Product name:

Indication/use:

¹ Please select the appropriate response: Current or Past. For activities which are currently on-going (current is interpreted as the time of completion of the form), please provide the starting date (month/year). For activities that are no longer on-going and have been completed, please also provide the end date (month/year).

² **Biotechnology sector:** means any legal or natural person involved in the biotechnology sector whose research, development, manufacturing, maintaining, marketing and/or distribution activities are closely linked to ATMPs, i.e.: Blood, cells and tissues establishments and manufactures of critical starting materials for ATMPs, e.g. viral vector manufacturers. This includes natural and legal persons to which activities relating to the research, development, manufacturing, maintaining, marketing and/or distribution closely linked with ATMPs (which might also be carried out in house) are outsourced on a contractual basis. Consultancy companies providing advice or services relating to the above activities, or to activities linked with marketing authorisation or other regulatory procedures (e.g. initial applications, variations) for ATMPs, fall under the definition of biotechnology sector. Legal or natural persons which do not fall within the scope of the above definition but (i) control (i.e. own a majority stake in, or otherwise exercise a significant influence in the decision-making processes of the relevant biotechnology sector), (ii) are controlled by or (iii) are under common control of the biotechnology sector, shall be considered as biotechnology sector for the purposes of this policy. Independent researchers and research organisations including universities, hospitals and learned societies are excluded from the scope of the present definition.

Medical device sector: means any legal or natural person involved in the medical device sector whose focus is to research, develop, maintain, manufacture, market and/or distribute medical devices or active implantable medical devices used or to be used in combined ATMPs as defined in article 2, 1 (d) of Regulation (EC) No 1394/2007. This includes natural or legal persons to which activities relating to the research, development, manufacturing, maintenance, marketing and/or distribution of medical devices used or to be used in combined ATMPs (which might also be carried out in house) are outsourced on a contractual basis. Consultancy companies providing advice or services relating to the above activities, or to activities linked with the Notified Bodies' procedures (e.g. applications, follow-up) fall under the definition of medical device sector. Legal or natural persons which do not fall within the scope of the above definition but (i) control (i.e. own a majority stake in, or otherwise exercise a significant influence in the decision-making processes of the relevant medical device sector), (ii) are controlled by or (iii) are under common control of the medical device sector, shall be considered as medical device sector for the purposes of this policy. Independent researchers and research organisations including universities, hospitals and learned societies are excluded from the scope of the present definition.

³ Consultancy on the development of one or more products per company: Please provide the product name and as much details as possible regarding the indication or use of the product, in order to allow evaluation of this declared interest.

⁴ Cross-product consultancy for multiple products /full product range or general (non-product related) consultancy per company: Please indicate the role or area in which you were involved.

2.11.3 Strategic advisory role

No Yes

Strategic advisory role means participation (with a right to vote on/influence the outputs) in a(n) (scientific) advisory board/steering committee with the role of providing advice/expressing opinions on the (future) strategy, direction or development activities of the biotechnology sector or the medical device sector, either in terms of general strategy or product related strategy, regardless of contractual arrangements or any form of remuneration.

Biotechnology sector means any legal or natural person involved in the biotechnology sector whose research, development, manufacturing, maintaining, marketing and/or distribution activities are closely linked to ATMPs, i.e. Blood, cells and tissues establishments and manufactures of critical starting materials for ATMPs, e.g. viral vector manufacturers. This includes natural and legal persons to which activities relating to the research, development, manufacturing, maintaining, marketing and/or distribution closely linked with ATMPs (which might also be carried out in house) are outsourced on a contractual basis. Consultancy companies providing advice or services relating to the above activities, or to activities linked with marketing authorisation or other regulatory procedures (e.g. initial applications, variations) for ATMPs, fall under the definition of biotechnology sector. Independent researchers and research organisations including universities, hospitals and learned societies are excluded from the scope of the present definition.

Medical device sector means any legal or natural person involved in the medical device sector whose focus is to research, develop, maintain, manufacture, market and/or distribute medical devices or active implantable medical devices used or to be used in combined ATMPs as defined in article 2, 1 (d) of Regulation (EC) No 1394/2007. This includes natural or legal persons to which activities relating to the research, development, manufacturing, maintenance, marketing and/or distribution of medical devices used or to be used in combined ATMPs (which might also be carried out in house) are outsourced on a contractual basis. Consultancy companies providing advice or services relating to the above activities, or to activities linked with the Notified Bodies' procedures (e.g. applications, follow-up) fall under the definition of medical device sector. Independent researchers and research organisations including universities, hospitals and learned societies are excluded from the scope of the present definition.

Strategic advisory role *Please click on any of the footnotes for further information.*

Time period¹: Current Past

From month: From year: To month: To year:

Name of pharmaceutical company²:

Individual product related³ Cross product related/ general (non-product related)⁴

General role / Area of activity:

1 Please select the appropriate response: Current or Past. For activities which are currently on-going (current is interpreted as the time of completion of the form), please indicate the starting date (month/year). For activities that are no longer on-going and have been completed, please also provide the end date (month/year).

2 **Biotechnology sector:** means any legal or natural person involved in the biotechnology sector whose research, development, manufacturing, maintaining, marketing and/or distribution activities are closely linked to ATMPs, i.e.: Blood, cells and tissues establishments and manufactures of critical starting materials for ATMPs, e.g. viral vector manufacturers. This includes natural and legal persons to which activities relating to the research, development, manufacturing, maintaining, marketing and/or distribution closely linked with ATMPs (which might also be carried out in house) are outsourced on a contractual basis. Consultancy companies providing advice or services relating to the above activities, or to activities linked with marketing authorisation or other regulatory procedures (e.g. initial applications, variations) for ATMPs, fall under the definition of biotechnology sector. Legal or natural persons which do not fall within the scope of the above definition but (i) control (i.e. own a majority stake in, or otherwise exercise a significant influence in the decision-making processes of the relevant biotechnology sector), (ii) are controlled by or (iii) are under common control of the biotechnology sector, shall be considered as biotechnology sector for the purposes of this policy. Independent researchers and research organisations including universities, hospitals and learned societies are excluded from the scope of the present definition.

Medical device sector: means any legal or natural person involved in the medical device sector whose focus is to research, develop, maintain, manufacture, market and/or distribute medical devices or active implantable medical devices used or to be used in combined ATMPs as defined in article 2, 1 (d) of Regulation (EC) No 1394/2007. This includes natural or legal persons to which activities relating to the research, development, manufacturing, maintenance, marketing and/or distribution of medical devices used or to be used in combined ATMPs (which might also be carried out in house) are outsourced on a contractual basis. Consultancy companies providing advice or services relating to the above activities, or to activities linked with the Notified Bodies' procedures (e.g. applications, follow-up) fall under the definition of medical device sector. Legal or natural persons which do not fall within the scope of the above definition but (i) control (i.e. own a majority stake in, or otherwise exercise a significant influence in the decision-making processes of the relevant medical device sector), (ii) are controlled by or (iii) are under common control of the medical device sector, shall be considered as medical device sector for the purposes of this policy. Independent researchers and research organisations including universities, hospitals and learned societies are excluded from the scope of the present definition.

3 Participation in (scientific) advisory board/steering committee, providing advice on product related strategies: Please provide the product name and as much details as possible regarding the indication or use of the product, in order to allow evaluation of this declared interest.

4 Participation in (scientific) advisory board/steering committee, providing advice on general strategies: Please indicate the role or area in which you were involved.

2.11.4 Financial interests

No Yes

Financial interests mean any economic stake in the biotechnology sector or the medical device sector including:

- **CURRENT** holding of stocks and shares, stock options, stock warrants, equities, bonds and or partnership interest in the capital of the biotechnology sector or the medical device sector with the exclusion of 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 (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).
- **CURRENT** compensation, fees, honoraria, salaries, grant or other funding (including rents, sponsorships and fellowships) paid by the biotechnology sector or the medical device sector to you in a personal capacity, other than payment for or reimbursement of expenses incurred with research work or reimbursement of reasonable expenses directly related to conference/seminar attendance (i.e. accommodation and travel costs).
- **CURRENT** intellectual property rights including patents, trademarks, know-how and/or copyrights relating to the biotechnology sector or the medical device sector owned by you or of which you are directly a beneficiary.

(CURRENT is interpreted at time of completion of this form).

Current financial interests *Please click on any of the footnotes for further information.*

Name of company ¹	Financial interest
Company L	Shares

1 Biotechnology sector: means any legal or natural person involved in the biotechnology sector whose research, development, manufacturing, maintaining, marketing and/or distribution activities are closely linked to ATMPs, i.e.: Blood, cells and tissues establishments and manufactures of critical starting materials for ATMPs, e.g. viral vector manufacturers. This includes natural and legal persons to which activities relating to the research, development, manufacturing, maintaining, marketing and/or distribution closely linked with ATMPs (which might also be carried out in house) are outsourced on a contractual basis. Consultancy companies providing advice or services relating to the above activities, or to activities linked with marketing authorisation or other regulatory procedures (e.g. initial applications, variations) for ATMPs, fall under the definition of biotechnology sector. Legal or natural persons which do not fall within the scope of the above definition but (i) control (i.e. own a majority stake in, or otherwise exercise a significant influence in the decision-making processes of the relevant biotechnology sector), (ii) are controlled by or (iii) are under common control of the biotechnology sector, shall be considered as biotechnology sector for the purposes of this policy. Independent researchers and research organisations including universities, hospitals and learned societies are excluded from the scope of the present definition.

Medical device sector: means any legal or natural person involved in the medical device sector whose focus is to research, develop, maintain, manufacture, market and/or distribute medical devices or active implantable medical devices used or to be used in combined ATMPs as defined in article 2, 1 (d) of Regulation (EC) No 1394/2007. This includes natural or legal persons to which activities relating to the research, development, manufacturing, maintenance, marketing and/or distribution of medical devices used or to be used in combined ATMPs (which might also be carried out in house) are outsourced on a contractual basis. Consultancy companies providing advice or services relating to the above activities, or to activities linked with the Notified Bodies' procedures (e.g. applications, follow-up) fall under the definition of medical device sector. Legal or natural persons which do not fall within the scope of the above definition but (i) control (i.e. own a majority stake in, or otherwise exercise a significant influence in the decision-making processes of the relevant medical device sector), (ii) are controlled by or (iii) are under common control of the medical device sector, shall be considered as medical device sector for the purposes of this policy. Independent researchers and research organisations including universities, hospitals and learned societies are excluded from the scope of the present definition.

2.11.5 Clinical Investigator

No Yes

Clinical Investigator for the medical device sector means: an investigator involved in a clinical medical device sector investigated/sponsored trial

Involvement in Data Monitoring Committees should be included in this section.

Note: Academic trials and publicly funded research/development initiatives involving medical devices should be included under section 2.11.8 Any other interests or facts.

Clinical Investigator *Please click on any of the footnotes for further information.*

Time period¹: Current Past

From month: From year: To month: To year:

Name of company²:

Product name³:

Indication/use:

1 Please select the appropriate response: Current or Past. For activities which are currently on-going (current is interpreted as the time of completion of the form), please provide the starting date (month/year). For activities that are no longer on-going and have been completed, please also provide the end date (month/year).

2 Medical device sector: means any legal or natural person involved in the medical device sector whose focus is to research, develop, maintain, manufacture, market and/or distribute medical devices or active implantable medical devices used or to be used in combined ATMPs as defined in article 2, 1 (d) of Regulation (EC) No 1394/2007. This includes natural or legal persons to which activities relating to the research, development, manufacturing, maintenance, marketing and/or distribution of medical devices used or to be used in combined ATMPs (which might also be carried out in house) are outsourced on a contractual basis. Consultancy companies providing advice or services relating to the above activities, or to activities linked with the Notified Bodies' procedures (e.g. applications, follow-up) fall under the definition of medical device sector. Legal or natural persons which do not fall within the scope of the above definition but (i) control (i.e. own a majority stake in, or otherwise exercise a significant influence in the decision-making processes of the relevant medical device sector), (ii) are controlled by or (iii) are under common control of the medical device sector, shall be considered as medical device sector for the purposes of this policy. Independent researchers and research organisations including universities, hospitals and learned societies are excluded from the scope of the present definition.

3 Please provide the product name and as much details as possible regarding the indication or use of the product, in order to allow evaluation of this declared interest.

2.11.6 Grant / Funding to organisation/institution

No Yes

Grant or other funding to an organisation/institution means any **CURRENT** funding (other than compensation for services provided, as requested by National Competent Authorities) received from the biotechnology sector or the medical device sector by an organisation/institution to which you belong, or for which you perform any kind of activity, and which is used to support any of your activities whether or not they are related to research work. Any other funding received from the biotechnology sector or the medical device sector by an organisation/institution to which you belong, or for which you perform any kind of activity do not need to be declared. If you want to declare such funding for transparency purposes, please report under 2.11.8 Any Other Interests or Facts.

(**CURRENT** is interpreted at time of completion of this form).

Current grant or other funding *Please click on any of the footnotes for further information.*

Name of company ¹:

Company L

Subject matter:

Research on syringe

1 Biotechnology sector: means any legal or natural person involved in the biotechnology sector whose research, development, manufacturing, maintaining, marketing and/or distribution activities are closely linked to ATMPs, i.e.: Blood, cells and tissues establishments and manufactures of critical starting materials for ATMPs, e.g. viral vector manufacturers. This includes natural and legal persons to which activities relating to the research, development, manufacturing, maintaining, marketing and/or distribution closely linked with ATMPs (which might also be carried out in house) are outsourced on a contractual basis. Consultancy companies providing advice or services relating to the above activities, or to activities linked with marketing authorisation or other regulatory procedures (e.g. initial applications, variations) for ATMPs, fall under the definition of biotechnology sector. Legal or natural persons which do not fall within the scope of the above definition but (i) control (i.e. own a majority stake in, or otherwise exercise a significant influence in the decision-making processes of the relevant biotechnology sector), (ii) are controlled by or (iii) are under common control of the biotechnology sector, shall be considered as biotechnology sector for the purposes of this policy. Independent researchers and research organisations including universities, hospitals and learned societies are excluded from the scope of the present definition.

Medical device sector: means any legal or natural person involved in the medical device sector whose focus is to research, develop, maintain, manufacture, market and/or distribute medical devices or active implantable medical devices used or to be used in combined ATMPs as defined in article 2, 1 (d) of Regulation (EC) No 1394/2007. This includes natural or legal persons to which activities relating to the research, development, manufacturing, maintenance, marketing and/or distribution of medical devices used or to be used in combined ATMPs (which might also be carried out in house) are outsourced on a contractual basis. Consultancy companies providing advice or services relating to the above activities, or to activities linked with the Notified Bodies' procedures (e.g. applications, follow-up) fall under the definition of medical device sector. Legal or natural persons which do not fall within the scope of the above definition but (i) control (i.e. own a majority stake in, or otherwise exercise a significant influence in the decision-making processes of the relevant medical device sector), (ii) are controlled by or (iii) are under common control of the medical device sector, shall be considered as medical device sector for the purposes of this policy. Independent researchers and research organisations including universities, hospitals and learned societies are excluded from the scope of the present definition.

2.11.7 Close family member interest

No Yes

Close family member means first-line member of your family (i.e. a spouse or a partner, children and parents). Partner means a natural person with whom the committee member or alternate is registered as having a stable non-marital partner legally by an EU member state or any competent authority of a member state, acknowledging their status as non-marital partners. Interests to be declared include **CURRENT** employment, consultancy, strategic advisory role and financial interests.

(**CURRENT** is interpreted at time of completion of this form).

Current interest of close family member [Please click on any of the footnotes for further information.](#)

Name of company ¹	Type of interest declared
Company M	consultancy

1 Biotechnology sector: means any legal or natural person involved in the biotechnology sector whose research, development, manufacturing, maintaining, marketing and/or distribution activities are closely linked to ATMPs, i.e.: Blood, cells and tissues establishments and manufactures of critical starting materials for ATMPs, e.g. viral vector manufacturers. This includes natural and legal persons to which activities relating to the research, development, manufacturing, maintaining, marketing and/or distribution closely linked with ATMPs (which might also be carried out in house) are outsourced on a contractual basis. Consultancy companies providing advice or services relating to the above activities, or to activities linked with marketing authorisation or other regulatory procedures (e.g. initial applications, variations) for ATMPs, fall under the definition of biotechnology sector. Legal or natural persons which do not fall within the scope of the above definition but (i) control (i.e. own a majority stake in, or otherwise exercise a significant influence in the decision-making processes of the relevant biotechnology sector), (ii) are controlled by or (iii) are under common control of the biotechnology sector, shall be considered as biotechnology sector for the purposes of this policy. Independent researchers and research organisations including universities, hospitals and learned societies are excluded from the scope of the present definition.

Medical device sector: means any legal or natural person involved in the medical device sector whose focus is to research, develop, maintain, manufacture, market and/or distribute medical devices or active implantable medical devices used or to be used in combined ATMPs as defined in article 2, 1 (d) of Regulation (EC) No 1394/2007. This includes natural or legal persons to which activities relating to the research, development, manufacturing, maintenance, marketing and/or distribution of medical devices used or to be used in combined ATMPs (which might also be carried out in house) are outsourced on a contractual basis. Consultancy companies providing advice or services relating to the above activities, or to activities linked with the Notified Bodies' procedures (e.g. applications, follow-up) fall under the definition of medical device sector. Legal or natural persons which do not fall within the scope of the above definition but (i) control (i.e. own a majority stake in, or otherwise exercise a significant influence in the decision-making processes of the relevant medical device sector), (ii) are controlled by or (iii) are under common control of the medical device sector, shall be considered as medical device sector for the purposes of this policy. Independent researchers and research organisations including universities, hospitals and learned societies are excluded from the scope of the present definition.

2.11.8 Any other interests or facts

For transparency purposes, please also provide information on the following activities in this section:

- Academic trials and publicly funded research/development initiatives involving the biotechnology sector or the medical device sector.
- Membership of an Ethics Committee (you do not need to state a list of trials you were involved in).
- If you work in an organisation/institution where your colleagues provide consultancy advice to the biotechnology sector or the medical device sector, but you are not directly involved in the provision of such advice (e.g. staff members of academic departments).
- Participation in European societies/research foundations/strategy boards/treatment groups/focus groups, which may be funded in full or in part from unrestricted grants from the biotechnology sector or the medical device sector (not from one single company), with or without involvement of industry participants and which may provide general advice (on development programmes, strategy, etc.) to the biotechnology sector or the medical device sector (not one particular company) in a specific area.
- Expert opinion or testimony in judicial proceedings against or by the biotechnology sector or the medical device sector.
- Participation as a patient in a clinical trial.

Academic trial on combined ATMP

Should there be any change to the above due to the fact that I acquire additional interests, I shall promptly notify the **European Medicines Agency** 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 EMA activity in which I participate.

SECTION 3: CONFIDENTIALITY UNDERTAKING

In view of the following definitions:

"EMA Activities" encompass any meeting (including meeting preparation and follow-up, associated discussion or any other related activity) of the European Medicines Agency's Management Board, Committees, Working Parties, Expert Groups, or any other such meeting; work as an expert on assessments; 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 EMA 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 EMA 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 EMA activities and hereby undertake:

- **to treat all Confidential Information and Confidential Documents under conditions of strict confidentiality as long as the information or document has not been made public/is not in the public domain.**
- **not to disclose (or authorise any other person to disclose) in any way to any third party¹ any Confidential Information or Confidential Document.**
- **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 EMA activities.**
- **to dispose of Confidential Documents as confidential material as soon as I have no further use for them.**
- **when expressing views to clearly indicate that the views are my own if acting in my own capacity or those of the EMA, Committee, Working Party, Expert Group or other group if acting on behalf that group.**
- **not to disclose any commercially confidential information.**

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 I have read and understood the [European Medicines Agency policy on the handling of competing interests of scientific committees' members and experts](#) and I agree to abide by the policy.
- I confirm the information declared on this form is accurate to the best of my knowledge and I acknowledge that my information will be stored electronically and published on the EMA website.

Please see the specific [privacy statement regarding the Experts database and the handling of competing interests of scientific committees' members and experts](#).

- I undertake to submit an up-to-date Declaration of Interests and Curriculum Vitae at least on an annual basis and to update this Declaration of Interests and my Curriculum Vitae promptly should any changes occur, indicating additional interests that should be known to the Agency.

FULL NAME:

Jan Peeters

Date:

¹ 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.

SUBMISSION AND VALIDATION

After completion of this form, please click on the '**Submit by E-mail**' button to send your information to the European Medicines Agency as an e-mail attachment using your local e-mail client. Please do not edit the e-mail address in the To field.

If your submission is successful, you will receive a notification with an attached completed copy of the form showing the information you supplied, together with a web link requesting you to provide or update your electronic curriculum vitae and to validate the submission of the declaration of interests form. For this validation (sign-off electronically), you must use your single sign-on credentials (user name and password) as provided to you by the EMA. Once validated, your electronic declaration of interests form and electronic curriculum vitae will be published automatically on the EMA website.

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