**Declaration of Interests**

**for call for expression of interest from the European Commission**

**INSTRUCTIONS**

This form consists of two parts: your **Personal Details** and **Declaration of Interests**. All parts must be duly completed. You are responsible for the accuracy and completeness of the submitted information.

**SECTION 1: PERSONAL DETAILS**

First name: …

Last name: …

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

Organisation / company1: …

Country: …

E-mail address: …

Type of activity: EMA Expert (nominated for involvement in EMA activities)

1 Patients not part of any organisation or company can leave this field blank.

**SECTION 2: 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 maintenance 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

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)

Title or role within the company: …

Lead role in the development of a medicinal product (at any stage of your career)

| **Product name** | **Therapeutic indication** |
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Cross product responsibility other than executive role (in the last 3 years)

Title or role within the company: …

Individual product responsibility other than lead role in the development of a medicinal product (in the last 3 years)

| **Product name** | **Therapeutic indication** |
| --- | --- |
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For additional employment, please copy the above section and complete it for each employment.

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 maintenance 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 manufacturers 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) 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

Time period1:  Current  Past

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

Name of pharmaceutical company2: …

Individual product related3:

| **Product name** | **Therapeutic indication** |
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Cross product related/ general (non product related)4

General role / Area of activity: …

For additional consultancy, please copy the above section and complete it for each consultancy.

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 manufacturers 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

Time period1:  Current  Past

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

Name of pharmaceutical company2: …

Individual product related3:

| **Product name** | **Therapeutic indication** |
| --- | --- |
|  |  |
|  |  |

Cross product related/ general (non product related)4

General role / Area of activity: …

For additional strategic advisory role, please copy the above section and complete it for each role.

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.

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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

| **Name of pharmaceutical company** | **Financial interest** |
| --- | --- |
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**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

Time period1:  Current  Past

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

Name of pharmaceutical company2: …

Product name3: …

Therapeutic indication: …

For additional principal investigator roles, please copy the above section and complete it for each role.

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.

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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

Time period1:  Current  Past

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

Name of pharmaceutical company2: …

Product name3: …

Therapeutic indication: …

For additional investigator roles, please copy the above section and complete it for each role.

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 manufacturers 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

| **Name of pharmaceutical company1** | **Subject matter** |
| --- | --- |
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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 manufacturers 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).

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).

| **Name of pharmaceutical company1** | **Type of interest declared** |
| --- | --- |
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|  |  |

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 manufacturers 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

Time period1:  Current  Past

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

Product name2: …

Therapeutic indication: … 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.

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**2.11 Interests in the biotechnology and the medical device sector 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

Time period1:  Current  Past

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

Name of company2: …

Function3:

Cross product responsibility (in the last 3 years)

Title or role within the company: …

Individual product responsibility (in the last 3 years)

| **Product name** | **Indication/use** |
| --- | --- |
|  |  |
|  |  |

For additional employment, please copy the above section and complete it for each employment.

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.

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**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

Time period1:  Current  Past

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

Name of company2: …

Individual product related3:

| **Product name** | **Indication/use** |
| --- | --- |
|  |  |
|  |  |

Cross product related/ general (non product related)4

General role / Area of activity: …

For additional consultancy, please copy the above section and complete it for each consultancy.

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.

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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.

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STRATEGIC ADVISORY ROLE

Time period1:  Current  Past

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

Name of company2: …

Individual product related3:

| **Product name** | **Indication/Use** |
| --- | --- |
|  |  |
|  |  |

Cross product related/ general (non product related)4

General role / Area of activity: …

For additional strategic advisory role, please copy the above section and complete it for each role.

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.

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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

| **Name of company** | **Financial interest** |
| --- | --- |
|  |  |
|  |  |

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**2.11.5 Clinical investigator No  Yes**

Clinical investigator for the medical device sector means: an investigator involved in a clinical medical device sector instigated/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

Time period1:  Current  Past

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

Name of company2: …

Product name3: …

Indication/use: …

For additional principal investigator roles, please copy the above section and complete it for each role.

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).

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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

| **Name of company1** | **Subject matter** |
| --- | --- |
|  |  |
|  |  |

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**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).

| **Name of company1** | **Subject matter** |
| --- | --- |
|  |  |
|  |  |

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**2.11.8 Any other interests or facts No  Yes**

**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.

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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.

FULL NAME:

SIGNATURE:

DATE: