**Declaration of Interests and Confidentiality Undertaking**

**INSTRUCTIONS**

This form consists of three parts: your **Personal Details**, **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.

**SECTION 1: PERSONAL DETAILS**

First name: …

Last name: …

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 INTEREST**

*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/medical device company in an executive role or lead role in the development of a medicinal product/medical devices (see section 2.1.1 and 2.2.1) 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 2.1.9), 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*](https://www.ema.europa.eu/en/documents/other/policy-44-european-medicines-agency-policy-handling-competing-interests-scientific-committees_en-0.pdf)*and the*[*procedural guidance on inclusion of declared interests in the European Medicines Agency's electronic declaration of interests form*](https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/procedural-guidance-inclusion-declared-interests-european-medicines-agencys-electronic-declaration_en.pdf)

**SECTION 2.1: PHARMACEUTICAL INDUSTRY**

Pharmaceutical company means: any legal or natural person whose focus is to research, develop, manufacture, maintain, market and/or distribute medicinal products. This definition 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 contractual 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, shall be 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. 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.

**2.1.1 Employment No**  **Yes**

**Employment** with a pharmaceutical company means any form of occupation, part-time or full-time, paid or unpaid, in the company.

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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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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)

| **Medicinal product name** | **Therapeutic indication** |
| --- | --- |
|  |  |
|  |  |

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)

| **Medicinal product name** | **Therapeutic indication** |
| --- | --- |
|  |  |
|  |  |

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).

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. 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.

In case of **employment in a CRO or consultancy company**, please mention the name of the CRO or consultancy company under section 2.1.1 Employment and include in section 2.1.2 Consultancy the list of all medicinal 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 respective therapeutic indications.

1. **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. 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. 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. Create a new entry for the next role/responsibility and provide details on the period and responsibility/involvement, while mentioning the same company name.

**2.1.2 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.

**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 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 Employment. Include in this section all medicinal products, with respective therapeutic indication, and individual name of the pharmaceutical companies to which CRO or consultancy services were provided.

CONSULTANCY

Time period1:  Current  Past

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

Name of pharmaceutical company2: …

Individual product related3:

| **Medicinal product name** | **Therapeutic indication** |
| --- | --- |
|  |  |
|  |  |

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.

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1. 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.
2. 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.

**2.1.3 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 or executive committee or executive 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.

**Note:** Involvement in Data Monitoring Committees is not included in this category. Such involvement should be recorded under Principal investigator. Involvement in clinical research should be listed under Principal investigator or 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:

| **Medicinal 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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1. 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.
2. Participation in (scientific) advisory board/steering committee, providing advice on general strategies: Please indicate the role or area in which you were involved.

**2.1.4 Financial interests No  Yes**

**Financial interests in a pharmaceutical company**: means any economic stake in a pharmaceutical company including:

* **CURRENT** holding of stocks and shares, stock options, stock warrants, equities, bonds, ownership 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. 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) are not considered as financial interests.
* **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 the time of completion of the form)

CURRENT FINANCIAL INTERESTS

| **Name of pharmaceutical company1** | **Financial interest2** |
| --- | --- |
|  |  |
|  |  |

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2 Do not disclose amounts. Please describe the activity for which you received the compensation/fees/honorarium/etc. Please provide the name of the medicinal product for which you hold the intellectual property right.

**2.1.5 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 clinical trial or the leading investigator of a monocentre pharmaceutical company instigated/sponsored clinical 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 ‘Any other interests or facts’.

PRINCIPAL INVESTIGATOR

Time period1:  Current  Past

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

Name of pharmaceutical company2: …

Medicinal 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

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1. 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.

**2.1.6 Investigator No  Yes**

**Investigator**: means an investigator involved in a pharmaceutical company instigated/sponsored clinical trial at a specific trial site which 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 ‘Any other interests or facts’.

INVESTIGATOR

Time period1:  Current  Past

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

Name of pharmaceutical company2: …

Medicinal 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

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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.

**2.1.7 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 ‘Any Other Interests or Facts’.

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

CURRENT GRANT OR OTHER FUNDING

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

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**2.1.8 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 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 nonmarital partners.

Interests to be declared include **CURRENT**employment, consultancy, strategic advisory role, repurposing as a champion or collaborating with a champion and financial interests.

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

CURRENT CLOSE FAMILY MEMBER INTEREST

| **Name of pharmaceutical company1** | **Type of interest declared2** |
| --- | --- |
|  |  |
|  |  |

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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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2 Do not disclose amounts, names or relationships.

**2.1.9 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 -outside its existing authorised indication(s).

**Champion for the repurposing of a medicinal product** is a non-profit stakeholder gathering or generating evidence, including seeking scientific advice as the main regulatory tool, for the repurposing of a medicinal product, that can be e.g. a patient organisation, academic institution, 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, (c) transparent regarding interactions with relevant pharmaceutical company(ies) and (d) 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: …

Medicinal 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)

For additional repurposing 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 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.

1. 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.

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

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

* + - Involvement in academic trials and publicly funded research/development initiatives on medicinal 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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**2.1.11 Are you a CAT member or alternate? No  Yes**

CAT members and alternates are required to declare interests in the biotechnology sector and in medical device companies where medical devices or active implantable medical devices are used or to be used in combined ATMPs. 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 in medical device companies where medical devices or active implantable medical devices are used or to be used in combined ATMPs I have currently (at the time of completion of the form) or have had (in the last 3 years) are those listed below:**

**2.1.11.1 Employment No  Yes**

**Employment** with the biotechnology sector or with a medical device company where medical devices or active implantable medical devices are used or to be used in combined ATMPs 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 manufacturers 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. 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 performs the above defined activities of the biotechnology sector, shall be considered as biotechnology sector. Staff members of such units, sections, departments or entities are considered to be involved in the biotechnology sector. Other parts of the organisation to which the unit, section, department or entity belongs can be excluded from this definition of biotechnology sector.

M**edical devices or active implantable medical devices used or to be used in combined ATMPs** are defined in article 2, 1(d) of Regulation (EC) No 1394/2007.

Employment in the biotechnology sector and in medical device companies where medical devices or active implantable medical devices are used or to be used in combined ATMPs **IN THE LAST 3 YEARS** should be declared.

EMPLOYMENT

Time period1:  Current  Past

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

Name of company: …

Function2:

Cross product responsibility (in the last 3 years)

Individual product responsibility (in the last 3 years)

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

Title or role within the company: …

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. For activities that are no longer on-going and have been completed, please also provide the end date.

2 **Cross product responsibility/general**: 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** e.g. product development, manufacture or maintenance (quality, clinical, non-clinical): please provide the product name, active substance and as much detail as possible regarding the indication/use, 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. Create a new entry for the next role/responsibility and provide details on the period and responsibility/involvement, while mentioning the same company name.

**2.1.11.2 Consultancy No  Yes**

**Consultancy**: means provision of advice (including training on a one-to-one basis) to the biotechnology sector or to a medical device company where medical devices or active implantable medical devices are used or to be used in combined ATMPs 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 manufacturers 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.   
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 performs the above defined activities of the biotechnology sector, shall be considered as biotechnology sector. Staff members of such units, sections, departments or entities are considered to be involved in the biotechnology sector. Other parts of the organisation to which the unit, section, department or entity belongs can be excluded from this definition of biotechnology sector.

**Medical devices or active implantable medical devices used or to be used in combined ATMPs** are defined in article 2, 1(d) of Regulation (EC) No 1394/2007.

**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 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 company), please declare this under Employment. Include in this section all products, with respective indication/use, and individual name of the companies to which consultancy services were provided.

CONSULTANCY

Time period1:  Current  Past

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

Name of company: …

Individual product related2:

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

Cross product related/general (non product related)3

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. For activities that are no longer on-going and have been completed, please also provide the end date.
2. **Individual product related:** Consultancy on the development of one or more products within one or more indication/use per company: Please provide the product name, active substance and as much details as possible regarding the indication/use, in order to allow evaluation of this declared interest.
3. **Cross product related/general (non product related):** Cross product consultancy for multiple products across one or several indications/uses/full product range or general (non product related) consultancy per company: Please indicate the role or area in which you were involved.

**2.1.11.3 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 or executive committee with the role of providing advice/expressing opinions on the (future) strategy, direction or development activities of the biotechnology sector or medical device companies where medical devices or active implantable medical devices are used or to be used in combined ATMPs, 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 manufacturers 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. 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 performs the above defined activities of the biotechnology sector, shall be considered as biotechnology sector. Staff members of such units, sections, departments or entities are considered to be involved in the biotechnology sector. Other parts of the organisation to which the unit, section, department or entity belongs can be excluded from this definition of biotechnology sector.

**Medical devices or active implantable medical devices used or to be used in combined ATMPs** are defined in article 2, 1(d) of Regulation (EC) No 1394/2007.

STRATEGIC ADVISORY ROLE

Time period1:  Current  Past

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

Name of company: …

Individual product related2:

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

Cross product related/general (non-product related)3

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. For activities that are no longer on-going and have been completed, please also provide the end date (month/year).
2. Participation in (scientific) advisory board, steering committee or executive committee, providing advice on product related strategies: Please provide the product name, active substance and as much details as possible regarding the indication/use, in order to allow evaluation of this declared interest.
3. Participation in (scientific) advisory board, steering committee or executive committee, providing advice on general strategies: Please indicate the role or area in which you were involved.

**2.1.11.4 Financial Interest No  Yes**

**Financial interests** mean any economic stake in the biotechnology sector or medical device companies where medical devices or active implantable medical devices are used or to be used in combined ATMPs including:

- **CURRENT**holding of stocks and shares, stock options, stock warrants, equities, bonds, ownership or partnership interest in the capital of the biotechnology sector or a medical device company where medical devices or active implantable medical devices are used or to be used in combined ATMPs 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 a medical device company where medical devices or active implantable medical devices are used or to be used in combined ATMPs to you in a personal capacity. 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) or not considered as financial interests.

- **CURRENT** intellectual property rights including patents, trademarks, know-how and/or copyrights relating to the biotechnology sector or a medical device used or to be used in combined ATMPs owned by you or of which you are directly a beneficiary.

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

CURRENT FINANCIAL INTERESTS

| **Name of company1** | **Financial interest2** |
| --- | --- |
|  |  |
|  |  |

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 manufacturers 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 organisation 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.   
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 performs the above defined activities of the biotechnology sector, shall be considered as biotechnology sector. Staff members of such units, sections, departments or entities are considered to be involved in the biotechnology sector. Other parts of the organisation to which the unit, section, department or entity belongs can be excluded from this definition of biotechnology sector.

**Medical device companies where medical devices or active implantable medical devices are used or to be used in combined ATMPs** are defined in article 2, 1(d) of Regulation (EC) No 1394/2007.

2 Do not disclose amounts. Please describe the activity for which you received the compensation/fees/honorarium/etc. Please provide the name of the medical device for which you hold the intellectual property right.

**2.1.11.5 Investigator No  Yes**

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

**Note**: Academic trials and publicly funded research/development initiatives should be included under Any other interests or facts.

INVESTIGATOR

Time period1:  Current  Past

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

Name of company2: …

Product name3: …

Indication/use: …

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. For activities that are no longer on-going and have been completed, please also provide the end date.

2 **Medical device companies where medical devices or active implantable medical devices are used or to be used in combined ATMPs** are defined in article 2, 1(d) of Regulation (EC) No 1394/2007.

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

**2.1.11.6 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 medical device companies where medical devices or active implantable medical devices are used or to be used in combined ATMPs 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 medical device companies where medical devices or active implantable medical devices are used or to be used in combined ATMPs by an organisation/institution to which you belong, or for which you perform any kind of activity do not need to be declared.

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

CURRENT GRANT OR OTHER FUNDING

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

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 manufacturers 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. 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 performs the above defined activities of the biotechnology sector, shall be considered as biotechnology sector. Staff members of such units, sections, departments or entities are considered to be involved in the biotechnology sector. Other parts of the organisation to which the unit, section, department or entity belongs can be excluded from this definition of biotechnology sector.

**Medical device companies where medical devices or active implantable medical devices are used or to be used in combined ATMPs** as defined in article 2, 1(d) of Regulation (EC) No 1394/2007.

**2.1.11.7 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 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.

Interests to be declared include **CURRENT**employment, consultancy, strategic advisory role and financial interests.

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

CURRENT CLOSE FAMILY MEMBER INTEREST

| **Name of company1** | **Type of interest declared2** |
| --- | --- |
|  |  |
|  |  |

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 manufacturers 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. 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 performs the above defined activities of the biotechnology sector, shall be considered as biotechnology sector. Staff members of such units, sections, departments or entities are considered to be involved in the biotechnology sector. Other parts of the organisation to which the unit, section, department or entity belongs can be excluded from this definition of biotechnology sector.

**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.

2 Do not disclose amounts, names or relationships.

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

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

* Involvement in academic trials and publicly funded research/development initiatives involving ATMPs or medical device/active implantable medical devices used or to be used in combined ATMPs.
* 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 to medical device companies where medical devices or active implantable medical devices are used or to be used in combined ATMPs, 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 a medical device company where medical devices or active implantable medical devices are used or to be used in combined ATMPs (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 to medical device companies where medical devices or active implantable medical devices are used or to be used in combined ATMPs (not one particular company) in a specific area.
* Expert opinion or testimony in judicial proceedings against or by the biotechnology sector or a medical device company where medical devices or active implantable medical devices are used or to be used in combined ATMPs.
* Participation as a patient in a clinical trial.

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**SECTION 2.2: MEDICAL DEVICE INDUSTRY**

**2.2.1 Employment No  Yes**

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

**Medical device company**: means any legal or natural person whose focus is to research, develop, manufacture, maintain, market and/or distribute medical devices (Regulation (EU) 2017/745) or *in vitro* diagnostic medical devices (Regulation (EU) 2017/746). This includes companies to which activities relating to the research, development, manufacturing, maintenance, marketing and/or distribution of medical devices or *in vitro*diagnostic medical devices (which might also be carried out in house) are outsourced on a contractual basis.   
Notified bodies, CROs and consultancy companies providing advice or services relating to the above activities, or to activities linked with certification or other regulatory procedures, fall under the definition of a medical device 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 medical device company), (ii) are controlled by or (iii) are under common control of the medical device company, shall be considered as medical device company. 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 develops or manufactures medical devices, shall be considered as a medical device company. Staff members of such units, sections, departments or entities are considered to be equivalent to staff members of a medical device company. Other parts of the organisation to which the unit, section, department or entity belongs can be excluded from this definition of a medical device company.

Employment in a medical device company in an **executive role** and/or a **lead role** in the development of a medical device **AT ANY STAGE OF YOUR CAREER** should be declared.

**Cross medical device/general** other than an executive role and/or **individual medical device** involvement other than lead role in the development of a medical device **IN THE LAST 3 YEARS**should be declared.

EMPLOYMENT

Time period1:  Current  Past

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

Name of medical device company2: …

Function3:

Executive role (at any stage of your career)

Title or role within the company: …

Lead role in the development of a medical device (at any stage of your career)

| **Medical device name** | **Intended purpose** |
| --- | --- |
|  |  |
|  |  |

Cross medical device/general role other than executive role (in the last 3 years)

Title or role within the company: …

Individual medical device involvement other than lead role in the development of a medical device (in the last 3 years)

| **Medical device name** | **Intended purpose** |
| --- | --- |
|  |  |
|  |  |

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 medical device company in an executive role and/or a lead role in the development of a medical device that occurred at any stage of your career. Please declare cross medical device/general role and/or individual medical device involvement that occurred in the last 3 years (other than an executive role and/or lead role in the development of a medical device).

1. Medical device company: means any legal or natural person whose focus is to research, develop, manufacture, maintain, market and/or distribute medical devices (Regulation (EU) 2017/745) or in vitro diagnostic medical devices (Regulation (EU) 2017/746). This includes companies to which activities relating to the research, development, manufacturing, maintenance, marketing and/or distribution of medical devices or in vitro diagnostic medical devices (which might also be carried out in house) are outsourced on a contractual basis. Notified bodies, CROs and consultancy companies providing advice or services relating to the above activities, or to activities linked with certification or other regulatory procedures, fall under the definition of a medical device 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 medical device company), (ii) are controlled by or (iii) are under common control of the medical device company, shall be considered as medical device company. 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 develops or manufactures medical devices, shall be considered as a medical device company. Staff members of such units, sections, departments or entities are considered to be equivalent to staff members of a medical device company. Other parts of the organisation to which the unit, section, department or entity belongs can be excluded from this definition of a medical device company.

In case of **employment in a notified body, CRO or consultancy company**, please mention the name of the notified body, CRO or consultancy company under section 2.2.1 Employment and include in section 2.2.2 Consultancy the list of all medical devices (including the names of the medical device companies to which notified body, CRO or consultancy services were provided, e.g. medical device A (medical device company X), medical device B (medical device company Y), etc. and intended purposes.

1. **Executive role within a medical device company** means responsibility for the strategic and operational direction of a medical device company, and as a consequence a key role in decision-making at strategic and operational level for the company. Please provide your job title.

**Lead role in the development of a medical device** means direct responsibility for the development of a medical device, other than support provided to the development which should be reported under individual medical device involvement. Please provide the medical device name, nature of the device and as much detail as possible regarding the intended purpose, in order to allow evaluation of this declared interest.

**Cross medical device/general role other than executive role**: this option should only be chosen where it is not possible to list all of the medical devices with which you were involved. Examples of such cross medical device/general role might include areas such as post-market surveillance, Regulatory Affairs, Statistical Methodology. Please provide your job title, as well as the role or area in which you were involved.

**Individual medical device involvement other than lead role in development of medical device**, e.g. device development, manufacture or maintenance (safety and clinical performance), other than lead role in the development of a medical device: please provide the medical device name, nature of the device and as much detail as possible regarding the intended purpose, 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. Create a new entry for the next role/responsibility and provide details on the period and responsibility/involvement, while mentioning the same company name.

**2.2.2 Consultancy No  Yes**

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

**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 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 medical device companies), please declare this under Employment. Include in this section all medical devices, with respective intended purpose, and individual name of the medical device companies to which notified body, CRO or consultancy services were provided.

CONSULTANCY

Time period1:  Current  Past

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

Name of medical device company2: …

Individual medical device related3:

| **Medical device name** | **Intended purpose** |
| --- | --- |
|  |  |
|  |  |

Cross medical device related/general (non-medical device 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).

**Medical device company**: means any legal or natural person whose focus is to research, develop, manufacture, maintain, market and/or distribute medical devices (Regulation (EU) 2017/745) or in vitro diagnostic medical devices (Regulation (EU) 2017/746). This definition includes companies to which activities relating to the research, development, manufacturing, maintenance, marketing and/or distribution of medical devices or in vitro diagnostic medical devices (which might also be carried out in house) are outsourced on a contract basis. Notified bodies, CROs and consultancy companies providing advice or services relating to the above activities, or to activities linked with certification or other regulatory procedures, fall under the definition of a medical device 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 medical device company), (ii) are controlled by or (iii) are under common control of the medical device company, shall be considered as medical device company. 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 develops or manufactures medical devices, shall be considered as a medical device company. Staff members of such units, sections, departments or entities are considered to be equivalent to staff members of a medical device company. Other parts of the organisation to which the unit, section, department or entity belongs can be excluded from this definition of a medical device company.

1. Consultancy on the development of one or more medical devices per medical device company: Please provide the device name, nature of the device and as much details as possible regarding the intended purpose, in order to allow evaluation of this declared interest.
2. Cross medical device or general (non-medical device related) consultancy per medical device company: Please indicate the role or area in which you were involved.

**2.2.3 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 or executive committee with the role of providing advice/expressing opinions on the (future) strategy, direction or development activities of a medical device company, either in terms of general strategy or product related strategy, regardless of contractual arrangements or any form of remuneration.

STRATEGIC ADVISORY ROLE

Time period1:  Current  Past

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

Name of medical device company2: …

Individual medical device related3:

| **Medical device name** | **Intended purpose** |
| --- | --- |
|  |  |
|  |  |

Cross medical device related/general (non-medical device 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. **Medical device company**: means any legal or natural person whose focus is to research, develop, manufacture, maintain, market and/or distribute medical devices (Regulation (EU) 2017/745) or *in vitro* diagnostic medical devices (Regulation (EU) 2017/746). This definition includes companies to which activities relating to the research, development, manufacturing, maintenance, marketing and/or distribution of medical devices or *in vitro* diagnostic medical devices (which might also be carried out in house) are outsourced on a contractual basis. Notified bodies, CROs and consultancy companies providing advice or services relating to the above activities, or to activities linked with certification or other regulatory procedures, fall under the definition of a medical device 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 medical device company), (ii) are controlled by or (iii) are under common control of the medical device company, shall be considered as medical device company. 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 develops or manufactures medical devices, shall be considered as a medical device company. Staff members of such units, sections, departments or entities are considered to be equivalent to staff members of a medical device company. Other parts of the organisation to which the unit, section, department or entity belongs can be excluded from this definition of a medical device company.
3. Participation in (scientific) advisory board/steering committee, providing advice on medical device related strategies: Please provide the medical device name, nature of the device and as much details as possible regarding the intended purpose, 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.

**2.2.4 Financial Interests No  Yes**

**Financial interests in a medical device company**: means any economic stake in a medical device company including:

- **CURRENT** holding of stocks and shares, stock options, stock warrants, equities, bonds, ownership and/or partnership interest in the capital of a medical device 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 medical device 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 medical device company to you in a personal capacity. 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) are not considered as financial interests.

- **CURRENT** intellectual property rights including patents, trademarks, know-how and/or copyrights relating to a medical device owned by you or of which you are directly a beneficiary.

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

CURRENT FINANCIAL INTERESTS

| **Name of medical device company1** | **Financial interest2** |
| --- | --- |
|  |  |
|  |  |

1 **Medical device company**: means any legal or natural person whose focus is to research, develop, manufacture, maintain, market and/or distribute medical devices (Regulation (EU) 2017/745) or *in vitro* diagnostic medical devices (Regulation (EU) 2017/746). This definition includes companies to which activities relating to the research, development, manufacturing, maintenance, marketing and/or distribution of medical devices or *in vitro* diagnostic medical devices (which might also be carried out in house) are outsourced on a contractual basis. Notified bodies, CROs and consultancy companies providing advice or services relating to the above activities, or to activities linked with certification or other regulatory procedures, fall under the definition of a medical device 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 medical device company), (ii) are controlled by or (iii) are under common control of the medical device company, shall be considered as medical device company. 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 develops or manufactures medical devices, shall be considered as a medical device company. Staff members of such units, sections, departments or entities are considered to be equivalent to staff members of a medical device company. Other parts of the organisation to which the unit, section, department or entity belongs can be excluded from this definition of a medical device company.

2 Do not disclose amounts. Please describe the activity for which you received the compensation/fees/honorarium/etc. Please provide the name of the medical device for which you hold the intellectual property right.

**2.2.5 Principal Investigator No  Yes**

**Principal investigator**: means an investigator with the responsibility for the coordination of investigators at different centres participating in a multicentre medical device company instigated/sponsored clinical trial, clinical investigation or performance study or the leading investigator of a monocentre medical device company instigated/sponsored clinical trial, clinical investigation or performance study, or the coordinating (principal) investigator signing the clinical study report.

This definition does not include a national coordinating investigator in a multinational trial.

**Note:** Involvement in academic investigations and publicly funded research/development initiatives on medical devices should be included under ‘Any other interests or facts’.

PRINCIPAL INVESTIGATOR

Time period1:  Current  Past

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

Name of medical device company2: …

Medical device name3: …

Intended purpose: …

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. **Medical device company**: means any legal or natural person whose focus is to research, develop, manufacture, maintain, market and/or distribute medical devices (Regulation (EU) 2017/745) or *in vitro* diagnostic medical devices (Regulation (EU) 2017/746). This definition includes companies to which activities relating to the research, development, manufacturing, maintenance, marketing and/or distribution of medical devices or *in vitro* diagnostic medical devices (which might also be carried out in house) are outsourced on a contractual basis. Notified bodies, CROs and consultancy companies providing advice or services relating to the above activities, or to activities linked with certification or other regulatory procedures, fall under the definition of a medical device 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 medical device company), (ii) are controlled by or (iii) are under common control of the medical device company, shall be considered as medical device company. 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 develops or manufactures medical devices, shall be considered as a medical device company. Staff members of such units, sections, departments or entities are considered to be equivalent to staff members of a medical device company. Other parts of the organisation to which the unit, section, department or entity belongs can be excluded from this definition of a medical device company.
3. Please indicate the medical device name, nature of the device and as much details as possible regarding the intended purpose, in order to allow evaluation of this declared interest.

**2.2.6 Investigator No  Yes**

**Investigator**: means an investigator involved in a medical device company instigated/sponsored clinical trial, clinical investigation or performance study at a specific trial site which can be the responsible lead investigator of the trial, investigation or study at that specific site or a member of the clinical trial, clinical investigation or performance study team who performs critical trial, investigation or study related procedures and makes important trial, investigation or study related decisions.

**Note:** Involvement in academic investigations and publicly funded research/development initiatives on medical devices should be included under ‘Any other interests or facts’.

INVESTIGATOR

Time period1:  Current  Past

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

Name of medical device company2: …

Medical device name3: …

Intended purpose: …

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).

1. **Medical device company**: means any legal or natural person whose focus is to research, develop, manufacture, maintain, market and/or distribute medical devices (Regulation (EU) 2017/745) or *in vitro* diagnostic medical devices (Regulation (EU) 2017/746). This definition includes companies to which activities relating to the research, development, manufacturing, maintenance, marketing and/or distribution of medical devices or *in vitro* diagnostic medical devices (which might also be carried out in house) are outsourced on a contractual basis. Notified bodies, CROs and consultancy companies providing advice or services relating to the above activities, or to activities linked with certification or other regulatory procedures, fall under the definition of a medical device 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 medical device company), (ii) are controlled by or (iii) are under common control of the medical device company, shall be considered as medical device company. 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 develops or manufactures medical devices, shall be considered as a medical device company. Staff members of such units, sections, departments or entities are considered to be equivalent to staff members of a medical device company. Other parts of the organisation to which the unit, section, department or entity belongs can be excluded from this definition of a medical device company.

3 Please indicate the medical device name, nature of the device and as much details as possible regarding the intended purpose, in order to allow evaluation of this declared interest.

**2.2.7 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 medical device 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 medical device 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 ‘Any Other Interests or Facts’.

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

CURRENT GRANT OR OTHER FUNDING

| **Name of medical device1** | **Subject matter** |
| --- | --- |
|  |  |
|  |  |

1 **Medical device company**: means any legal or natural person whose focus is to research, develop, manufacture, maintain, market and/or distribute medical devices (Regulation (EU) 2017/745) or *in vitro* diagnostic medical devices (Regulation (EU) 2017/746). This definition includes companies to which activities relating to the research, development, manufacturing, maintenance, marketing and/or distribution of medical devices or *in vitro* diagnostic medical devices (which might also be carried out in house) are outsourced on a contractual basis. Notified bodies, CROs and consultancy companies providing advice or services relating to the above activities, or to activities linked with certification or other regulatory procedures, fall under the definition of a medical device 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 medical device company), (ii) are controlled by or (iii) are under common control of the medical device company, shall be considered as medical device company. 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 develops or manufactures medical devices, shall be considered as a medical device company. Staff members of such units, sections, departments or entities are considered to be equivalent to staff members of a medical device company. Other parts of the organisation to which the unit, section, department or entity belongs can be excluded from this definition of a medical device company.

**2.2.8 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 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 the time of completion of the form).

CURRENT CLOSE FAMILY MEMBER INTEREST

| **Name of medical device company1** | **Type of interest declared2** |
| --- | --- |
|  |  |
|  |  |

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2 Do not disclose amounts, names or relationships.

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

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

## Involvement in academic investigations and publicly funded research/development initiatives involving medical devices.

* + - Membership of an Ethics Committee (you do not need to state a list of investigations you were involved in).
    - If you work in an organisation/institution where your colleagues provide consultancy advice to medical devices, 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 medical device companies (not from one single company), with or without involvement of industry participants and which may provide general advice (on development programmes, clinical investigation or performance study design, strategy, etc.) to several medical device companies (not one particular company) in a specific clinical field.
    - Expert opinion or testimony in judicial proceedings against or by a medical device company or notified body relating to a medical device.
    - Participation as a subject in a clinical investigation or performance study.

|  |
| --- |
|  |

**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 indicate clearly that the views are my own if acting in my own capacity or those of the EMA, Management Board, Committee, Working Party, Expert Group or other group if acting on behalf of 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's policy on the handling of competing interests of scientific committees' members and experts and I agree to abide by the policy.

Please see the specific [European Medicines Agency policy on the handling of competing interests of scientific committees’ members and experts](https://www.ema.europa.eu/en/documents/other/policy-44-european-medicines-agency-policy-handling-competing-interests-scientific-committees_en-0.pdf)

I confirm the information declared on this declaration of interest is accurate and complete to the best of my knowledge and I acknowledge that my information will be stored electronically.

FULL NAME: …

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.