



Public Declaration of Interests

INSTRUCTIONS

This form consists of two parts: your **Personal Details** and **Public Declaration of Interests**. All parts must be duly completed. You are responsible for the accuracy and completeness of the submitted information. Please be advised that once you have submitted and signed the form, the Agency will publish your declaration of interests on its website.

SECTION 1: PERSONAL DETAILS

First name:

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

Last name:

Organisation / company¹:

Country²:

E-mail address:

Type of activity³ :

SECTION 2: PUBLIC DECLARATION OF INTERESTS

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

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

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

2.1 Employment

No Yes

Employment with a pharmaceutical company means any form of occupation, part-time or full-time, paid or unpaid, in the company. A pharmaceutical company means any legal or natural person whose focus is to research, develop, manufacture, market and/or distribute medicinal products. This includes companies to which activities relating to the research, development, manufacturing, marketing and maintenance 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, also fall under the definition of a pharmaceutical company. Independent researchers and research organisations including universities and learned societies are excluded from the scope of the definition of a pharmaceutical company.

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

Cross product responsibility other than an executive role and/or **individual product** responsibility other than lead role in the development of a medicinal product **IN THE LAST 3 YEARS** should be declared.

Employment

Please click on any of the footnotes for further information.

Time period¹: Current Past

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

Name of pharmaceutical company²:

Function³:

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

Employment

Please click on any of the footnotes for further information.

Time period¹: Current Past

From month: From year:

Name of pharmaceutical company²:

Function³:

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

1 Please select the appropriate response: Current or Past. For activities which are currently on-going (current is interpreted as the time of completion of the form), please provide the starting date (month/year). For activities that are no longer on-going and have been completed, please also provide the end date (month/year). Please declare all employment in a pharmaceutical company in an executive role and/or a lead role in the development of a medicinal product that occurred at any stage of your career. Please declare cross product responsibility and/or individual product responsibility that occurred in the last 3 years (other than an executive role and/or lead role in the development of a medicinal product).

2 **Pharmaceutical company:** means any legal or natural person whose focus is to research, develop, manufacture, market and/or distribute medicinal products. This includes companies to which activities relating to the research, development, manufacturing, marketing and maintenance 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, fall under the definition of a pharmaceutical company. Legal or natural persons which do not fall within the scope of the above definition but (i) control (i.e. own a majority stake in, or otherwise exercise a significant influence in the decision-making processes of the relevant pharmaceutical company), (ii) are controlled by or (iii) are under common control of a pharmaceutical company are also considered as pharmaceutical companies.

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

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

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

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

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

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

2.2 Consultancy

No Yes

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

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

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

2.3 Strategic advisory role

No Yes

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

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

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). If the strategic advisory role is current and is subject to a fee/honoraria (paid directly to you), please also declare this activity under section 2.4 Current financial interests. 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, market and/or distribute medicinal products. This includes companies to which activities relating to the research, development, manufacturing, marketing and maintenance 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, 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.

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

2.4 Financial interests

No Yes

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

- **CURRENT** holding of stocks and shares, stock options, equities, bonds and or partnership interest in the capital of a pharmaceutical company with the exclusion of the holding of financial interests through an investment fund, pension fund and/or interests in non-nominal unit trusts or similar arrangements provided that they are diversified (i.e. not exclusively based on the pharmaceutical sector) and they are independently managed (i.e. the individual has no influence on their financial management).

- **CURRENT** compensation, fees, honoraria, salaries, grant or other funding (including rents, sponsorships and fellowships) paid by a pharmaceutical company to you in a personal capacity, other than payment for or reimbursement of expenses incurred with research work or reimbursement of reasonable expenses directly related to conference/seminar attendance (i.e. accommodation and travel costs).

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

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

2.5 Principal investigator

No Yes

Principal investigator means an investigator with the responsibility for the coordination of investigators at different centres participating in a multicentre pharmaceutical industry instigated/sponsored trial or the leading investigator of a monocentre pharmaceutical industry instigated/sponsored trial, or the coordinating (principal) investigator signing the clinical study report.

This definition does not include a national coordinating investigator in a multinational trial. Involvement in Data Monitoring Committees should be included in this section.

Note: Academic trials and publicly funded research/development initiatives involving pharmaceutical products should be included under section 2.9 Any other interests or facts.

2.6 Investigator

No Yes

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

Note: Academic trials and publicly funded research/development initiatives involving pharmaceutical products should be included under section 2.9 Any other interests or facts.

2.7 Grant / Funding to organisation/institution

No Yes

Grant or other funding to an organisation/institution means any **CURRENT** funding (other than compensation for services provided, as requested by National Competent Authorities) received from a pharmaceutical company by an organisation/institution to which you belong, or for which you perform any kind of activity, and which is used to support any of your activities whether or not they are related to research work. Any other funding received from a pharmaceutical company by an organisation/institution to which you belong, or for which you perform any kind of activity do not need to be declared. If you want to declare such funding for transparency purposes, please report under 2.9 Any Other Interests or Facts.

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

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

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

2.9 Any other interests or facts

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

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

Other interest or facts

Member of the Pharmaceutical Users Software Exchange (PhUSE) Data De-Identification Working Group

Should there be any change to the above due to the fact that I acquire additional interests, I shall promptly notify the **European Medicines Agency** and complete a new Declaration of Interests detailing the changes. This declaration does not discharge me from my obligation to declare any potential conflicting interest(s) at the start of any EMA activity in which I participate.

I confirm that the information declared on this form is accurate to the best of my knowledge and I acknowledge that my information will be stored electronically and published on the EMA website.

Full name:

Lukasz Kniola

Date:

27/4/2017

Signature:

A handwritten signature in black ink, appearing to read 'Lukasz Kniola', is written inside a rectangular box.