



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Public Declaration of Interests and Confidentiality Undertaking

INSTRUCTIONS

This form consists of three parts: your **Personal Details**, **Public Declaration of Interests** and **Confidentiality Undertaking**. All parts must be duly completed. **The form is designed to be completed electronically, printed and sent to the MB Secretariat in pdf format.** You are responsible for the accuracy and completeness of the submitted information.

Please be advised that once you have signed and submitted the form, the Agency will publish your declaration of interests on its website.

You will be asked to provide an updated Curriculum Vitae which must be submitted simultaneously to your declaration.

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:

Role³:

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 (where applicable) should be declared.

You may also provide information on interests over 3 years ago. This information, to be recorded under Section 2.10, Any other interests or facts, will not be used in the evaluation of declared interests.

For more information on which interests to declare, please see the [European Medicines Agency policy on the handling of competing interests of Management Board members](#).

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) are those listed below.

I further declare on my honour that, to the best of my knowledge, personal interests, other than interests in pharmaceutical industry, which I have currently (at the time of completion of the form) 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.

2.2 Consultancy

No Yes

Consultancy to a pharmaceutical company means any activity where the Management Board member provides advice (including training on a one-to-one basis) 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.

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 for a pharmaceutical company means any activity where the Management Board member is participating (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 and 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 fall outside the scope of this definition. Such involvement should be recorded under section 2.5 Principal Investigator. Involvement in research for a pharmaceutical company should be listed under section 2.5 Principal Investigator or 2.6 Investigator as appropriate.

2.4 Financial interests

No Yes

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

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

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

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

Note: Attendance at courses and conferences funded by pharmaceutical industry (including attendance at accredited courses or conferences with respect to CPD (Continuing Professional Development)/CME (Continuing Medical Education) acquisition) whereby the MB member receives payment by pharmaceutical industry going beyond reimbursement of reasonable expenses (i.e. accommodation and travel costs) directly related to a conference/seminar attendance need to be declared if current.

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

2.5 Principal investigator

No Yes

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

Note: Involvement in academic trials and publicly funded research/development initiatives involving pharmaceutical products as well as membership of an ethics committee, should be included under section 2.10 Any other interests or facts.

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

2.6 Investigator

No Yes

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

Note: Involvement in academic trials and publicly funded research/development initiatives involving pharmaceutical products as well as membership of an ethics committee, should be included under section 2.10 Any other interests or facts.

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

2.7 Grant / Funding to organisation/institution

No Yes

Grant or other funding to an organisation/institution means any **CURRENT** funding received from a pharmaceutical company by an organisation/institution to which the Management Board member belongs, or for which he/she performs any kind of activity, and which is used to support any activity of the Management Board member whether or not it is related to research work.

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

2.8 Close family member interest

No Yes

Close family member means first-line members of your family (i.e. a spouse or a partner, children and parents).

Partner shall mean: a natural person with whom the Management Board member is registered as having a stable non-marital partner legally by an EU member state or any competent authority of a member state, acknowledging their status as non-marital partners.

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

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

2.9 Personal interests, other than interests in a pharmaceutical company

No Yes

MB members should declare the following current personal interests:

- Interests in other entities possibly providing services to the Agency (i.e. in the areas of IT, infrastructure, catering), as well as interests in other areas such as medical devices/diagnostics/reagents not linked with medicinal products which may be discussed at the Management Board.
- Positions (either a managerial role or other influential roles) in a governing body (irrespective if such position is paid or not) of a professional organisation with an interest in the field of pharmaceuticals other than a pharmaceutical company.

Note: If you belong to organisations such as patients', consumers' or healthcare professionals' organisations and your organisation receives grants or other funding from a pharmaceutical company please declare this under section 2.7 "Grant or other funding to an organisation/institution".

2.10 Any other interests or facts

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 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.

Please declare any other interests below:

None.

SECTION 3: CONFIDENTIALITY UNDERTAKING

In view of the following definitions:

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

"Confidential Information" means all information, facts, data and any other matters of which I acquire knowledge, either directly or indirectly, as a result of my EMA Activities.

"Confidential Documents" mean all drafts, preparatory information, documents and any other material, together with any information contained therein, to which I have access, either directly or indirectly, as a result of my participation in EMA Activities. Furthermore, any records or notes made by me relating to Confidential Information or Confidential Documents shall be treated as Confidential Documents.

I understand that I may be invited to participate either directly or indirectly in certain EMA activities and hereby undertake:

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

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.

I confirm I have read and understood the European Medicines Agency policy on the handling of competing interests of Management Board members and I agree to abide by the policy. I have read and understood the training material which has been provided to me.

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.

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

Full name:

Andrej Janžič

Date:

24-Feb-2022

Signature:

Signature on file.