

Public Declaration of Interests and Confidentiality Undertaking of Swissmedic Medicines Expert Committee Members

This document is aligned to the 'Public Declaration of Interests and Confidentiality Undertaking of European Medicines Agency (EMA) Scientific Committee members and experts' of the EMA.

SECTION 1: PERSONAL DETAILS

First Name	Andrea
Last Name	Cseh Zsoltné Pálos
Organisation / Company	National Center for Public Health and Pharmacy
Country of Organisation / Company	Hungary
Committee	Human Medicines Expert Committee (HMEC)

I do hereby declare on my honour that, to the best of my knowledge, the only direct or indirect interests I have in the pharmaceutical industry are those listed below.

Please specify the interests that you currently have (at the time of completion of the form) or have had within the past 5 years.

SECTION 2: PUBLIC DECLARATION OF INTERESTS**2.1 Employment** No Yes

Please indicate if you are employed / have been employed, either full or part time, either as paid or unpaid employee in pharmaceutical company.

Pharmaceutical company includes supply or service companies which contribute to the research, development, production and maintenance of a medicinal product.

2.2 Consultancy

No Yes

Choose "Yes" if there is any activity in which you provide or have provided advice or services regardless as to whether or not you received a fee for this activity. Please indicate all of them below.

Provision of advice or services to a pharmaceutical company (in a particular field such as the development of a product) regardless of contractual arrangements or any form of remuneration. (Pharmaceutical company includes supply or service companies which contribute to the research, development, production and maintenance of a medicinal product)

Involvement in Data Safety Monitoring Committee should be included in this section.

Note: Conference / Seminar attendance is not considered as consultancy but should be indicated under Financial Interests, if subject to a fee / honoraria.

2.3 Strategic Advisory Role

No Yes

Choose "Yes" if you are participating or have participated in a (Scientific) Advisory Board/Steering Committee of a pharmaceutical company (e.g. board membership / directorship), with a right to vote on / influence the outcome of that body.

Participation (with a right to vote on/influence the outputs) in a (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. Pharmaceutical company includes supply or service companies which contribute to the research, development, production and maintenance of a medicinal product.

Note: Involvement in Data Safety Monitoring Committees is not included in this category. Such involvement should be recorded under section 2.2 Consultancy. Involvement in clinical research should be listed under section 2.6 Principal Investigator or 2.7 Investigator as appropriate.

2.4 Current Financial Interests

No Yes

Choose "Yes" if you have any financial interests currently held in a pharmaceutical company.

Financial interests relate to current holding of shares of a pharmaceutical company with the exclusion of independently managed investment funds/pension. Compensation, fees, honoraria, salaries currently being paid directly to you by a pharmaceutical company, other than payment for expenses incurred with research work or re-imbursment of reasonable expenses incurred in relation to conference/seminar attendance (i.e. accommodation and travel costs).

Current is interpreted at time of completion of this form.

2.5 Patent

No Yes

Choose "Yes" if any patent for a medicinal / competitor product is currently owned by either yourself or your institution and you are a beneficiary.

Current is interpreted at time of completion of this form.

2.6 Principal Investigator No Yes

Choose "Yes" if there are trials for which you are acting or have acted as Principal Investigator

Principal Investigator with the responsibility for the coordination of investigators at different centres participating in a multicentre trial or the leading investigator of a monocentre trial, or the coordinating (principal) investigator signing the clinical study report. This definition does not include a national coordinating investigator in a multinational trial.

2.7 Investigator

No Yes

Choose "Yes" if there are trials for which you are acting or have acted as Investigator.

Investigator involved in a clinical 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.

2.8 Grant / Funding to organisation/institution

No Yes

Choose "Yes" if any grants or other funding is currently received by your institutional unit from a pharmaceutical company and you receive no personal gain; or where your Organisation (e.g. Patient Organisation) receives a grant or other funding from a pharmaceutical company and you (irrespective if you are employed by the Organisation or are a volunteer) receive no personal gain.

Refers to a grant or other funding from a pharmaceutical company, currently being received (as far as the individual is aware) by an institution (please indicate funding to the smallest institutional unit) or an organisation (e.g. patient organisation), irrespective of whether or not the individual is employed or is a volunteer, and the individual receives no personal gain.

2.9 Any other interests or facts

No Yes

Choose "Yes" if further to the interest declared above you have any other interests or facts that should be made known to Swissmedic, the Swiss Agency of Therapeutic Products and the public.

By choosing "No" you declare on your honour that you do not have any other interests or facts to declare accordingly.