

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	Paola
Last Name	Luciani
Organisation / Company	University of Bern
Country of Organisation / Company	Switzerland
Committee	<input type="text" value="both (HMEC & VMEC)"/>

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.

Period	Company	Product	Therapeutic Indication General Role / Area of Activity	Funding
04/2020 - TODAY	Lipoid GmbH		<i>Preclinical Research on liver protection / Investigating the impact of different phospholipids on liver diseases by using in vitro and in vivo models</i>	
02/2020 - TODAY	Sanofi-Aventis Deutschland GmbH	Essentiale	Liver diseases	
12/2022 - 12/2024	DSM-Firmenich		<i>Vitamins for pharmaceutical use</i>	
06/2016 - 12/2016	biolitech Recherche GmbH		<i>Liposomes</i>	
03/2016 - 07/2016	Sanofi Aventis Groupe	Essentiale	Educational training of gastroenterologists in Russia	

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.

<input type="button" value="X"/>	
Name of Pharmaceutical Company	Sanofi-Aventis Deutschland GmbH
Subject Matter	Investigate the role of essential phospholipids in hepatosteatosis
Amount of Money (CHF)	280'000
Funding paid into an institutional account with shared power of disposition?	yes

<input type="button" value="X"/>	
Name of Pharmaceutical Company	Lipoid GmbH
Subject Matter	nvestigating the role of phospholipids as hepatoprotectant
Amount of Money (CHF)	60'000
Funding paid into an institutional account with shared power of disposition?	yes

<input type="button" value="X"/>	
Name of Pharmaceutical Company	DSM Nutritional Products Ltd
Subject Matter	Compound testing for anti-fibrotic effects in human hepatic stellate cells
Amount of Money (CHF)	47'000
Funding paid into an institutional account with shared power of disposition?	yes

Name of Pharmaceutical Company

Subject Matter

Amount of Money (CHF)

Funding paid into an institutional account with shared power of disposition?

Name of Pharmaceutical Company

Subject Matter

Amount of Money (CHF)

Funding paid into an institutional account with shared power of disposition?

Name of Pharmaceutical Company

Subject Matter

Amount of Money (CHF)

Funding paid into an institutional account with shared power of disposition?

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.

X

Please specify

In the period September 2015 - March 2019, Paola Luciani was Professor for Phospholipids in Drug Development at the University of Jena, Germany, position made possible thanks to an endowment from the phospholipid company Lipoid GmbH.
Since July 2019 Prof. Luciani is a member of the Scientific Advisory Council of the Phospholipid Research Center, not-for-profit organisation founded in 2006 by international scientists and the phospholipid companies Lipoid GmbH and PHOSPHOLIPID GmbH.
Prof. Luciani entered discussion with an international company manufacturing material for primary packaging (March 2021); with an international company specialized in pharmaceutical products for gastrointestinal diseases (December 2018, at the University of Jena); established a professional relationships with an early clinical stage company dedicated to developing peptide therapeutics (June 2022); entered discussion with an multinational pharmaceutical company about training modules on drug product development (October 2022); entered discussion with a multinational pharmaceutical company about subcutaneous administration (March 2024); entered discussions with Contract Development and Manufacturing Organization about vaginal drug delivery (Aug 2024); entered discussions with a company specialized in the delivery of nucleic acids for women's health (Aug 2025). A group member of the Luciani group has started entrepreneurial activities related to the patent application DendriXAL Technology (see below) and Prof. Luciani signed many CDAs with companies interested in this technology for the treatment of musculoskeletal disorders (July 2024 - present).

X

Please specify

Prof. Luciani is co-inventor in two patent applications:
1) TIF-Gel, International Patent Application No PCT/EP2023/076606, filed on 26 September 2023
2) DendriXAL Technology, International Patent Application No PCT/EP2024/070641, filed on 20 July 2024
3) TILD (for veterinary and human medicines), European Patent Application No EP25186092.0, filed on 27 June 2025