

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 | Reto |
| Last Name | Caldelari |
| Organisation / Company | University of Bern |
| Country of Organisation / Company | Switzerland |
| Committee | <input type="text" value="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.

| Period | From Month | From Year | To Month | To Year | |
|---------------------------------|--|-----------|----------|---------|---|
| past | 01 | <2016 | 01 | <2016 | X |
| Type | cross product responsibility/involvement | | | | |
| Name of Pharmaceutical Company | CELLnTEC adanced cell sstems | | | | |
| General Role / Area of Activity | Chief Scientific Officer | | | | |

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 |
|--------|-----------------------|---------|--|---------|
| <2016 | Bristol Meyers Squibb | | <i>Services: Development of a rat vaginal epithelium in-vitro model and testing of substance X. Development of a rat bladder epithelium in-vitro model and testing of substance Y.</i> | |
| <2016 | Wyeth (Pfizer) | | <i>Service: 3D rat vaginal epithelium model treated with Estrogen and analysis of gene expression.</i> | |

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.

| Period | Company | Product | Therapeutic Indication <i>General Role / Area of Activity</i> | Funding |
|--------|-----------------------------------|---------|--|---------|
| <2016 | CELLnTEC advanced cell systems AG | | | |
| | | | <i>Co-Founder and Member of the Board of Directors</i> | |

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-imbusement 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.

| | |
|----------------------------------|---|
| <input type="button" value="X"/> | |
| Name of Pharmaceutical Company | CELLnTEC advanced cell systems AG |
| Financial Interest | Sharholder (25'000 shares with nominal value of 1CHF/share) |

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.

SECTION 3: CONFIDENTIALITY UNDERTAKING

In view of the following definitions:

“**Swissmedic Activities**” encompass any meeting (including meeting preparation and follow-up, associated discussion or any other related activity) or work as a member of the Swissmedic Medicines Expert Committees.

“**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 Swissmedic 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 Swissmedic 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 Swissmedic activities and hereby undertake:

- *to treat all Confidential Information and Confidential Documents under conditions of strict confidentiality*
- *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 Swissmedic Activities*
- *to dispose of Confidential Documents as confidential material as soon as I have no further use for them*
- *to comply with the Code of the Swissmedic Medicines Expert Committees*

¹ *third party does not include Swissmedic employees or other SMEC members*

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.

Should there be any change to the above due to the fact that I acquire additional interests, I shall promptly notify Swissmedic 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 Swissmedic Activity in which I participate.

Submit Declaration

I confirm that I allow all my contracting partners of the pharmaceutical industry to announce in the Pharma-Kooperations-Kodex (PKK) any payments falling under the scope of the PKK.

YES

I confirm the information declared on this form is accurate to the best of my knowledge and I consent to my information being stored electronically and published on the Swissmedic website.

YES

I confirm that all mandatory fields are filled and the form is ready for submission.

YES

Date 1. 12. 2025

Signature _____
Caldelari Reto

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