Code of Conduct for dealing with Conflicts of Interest for the Swissmedic Medicines Expert Committees

The Agency Council of the Swiss Agency for Therapeutic Products (Swissmedic),

having regard to Art. 68 para. 5 of the Therapeutic Products Act of 15 December 2000 (TPA, SR 812.21) and Art. 10 of the Organisation Ordinance of Swissmedic dated 28 September 2001 (SR 812.216)
and supplementing and transposing numbers 9 and 10 of the Agency Council's official decision of 5 December 2008 concerning the deployment of the Swissmedic Medicines Expert Committees,

hereby resolves:

Preamble

The members of the Swissmedic Medicines Expert Committees (hereinafter *SMECs*) have a special role to play in the authorisation, market surveillance and approval of medicinal products and thus for public health in Switzerland. The Agency Council of Swissmedic therefore deems it necessary to safeguard their impartiality and integrity in the context of their advisory work for Swissmedic by means of suitable measures.

In particular, these include consciously addressing conflicts of interests that may arise primarily as a result of the personal situation or parallel professional activity of SMEC members (hereinafter *member*). In the present context, conflicts of interest are understood to mean circumstances under which a risk arises of secondary interests influencing an SMEC member's capacity for professional judgement or action in relation to the public health interests pursued by the awarding of the assignment (primary interests). Conflicts of interest have many different sources. Applied to the activities of the SMECs, they arise when a member's secondary material, social or intellectual interests affect that member's capacity for judgement and thus the integrity and objectivity of the services provided for Swissmedic.

Disclosure of secondary interests is essential for dealing with conflicts of interest. To ensure transparency, SMEC members are therefore required to disclose all interests that could lead to a conflict of interest in the sense defined above. Furthermore, there should be specific rules for dealing with conflicts of interest. The vested interests that SMEC members declare to Swissmedic are published. The Agency Council regards a publicly transparent and trust-building approach to conflicts of interest as crucial to maintaining and strengthening Swissmedic's good reputation, credibility and authority.

By signing the declaration in Annex 1, members undertake to abide by the rules below and consent to the publication of their vested interests in the scope mentioned above. These rules supplement and transpose the abstention rules set out in section 11 of the official decision of the Agency Council of 5 December 2008 appointing the SMECs. The pertinent legal provisions, particularly those on corruption (Art. 322ter et seq. of the Swiss Criminal Code; cf. Annex 3), are not affected.

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I. Conflicts of interest

Each member is required to avoid situations in which secondary personal or institutional interests could affect their interest in providing impartial and objective advice and assessments for Swissmedic and constitute grounds for abstention.

A conflict of interest arises whenever secondary interests of a member or secondary interests of the institution in which that member is employed or for which the member works in any other capacity could affect the objectivity and impartiality of the assessment and advice provided for Swissmedic. Conflicts of interest are frequently, but not exclusively, the result of financial relationships with companies in the therapeutic products industry or therapeutic products trade, or with associated organisations, foundations or associations that have commercial interests. Conflicts of interest do not necessarily affect the capacity for judgement or actions of an individual. However, they do present the risk of clouding that person's perception. In many cases, individuals are largely or completely unaware that conflicts of interest are affecting their judgement. The effect that a conflict of interest has on an individual's judgement is thus frequently not the result of a conscious (or even malicious) decision, but the result of clouded perception.

II. Duties of disclosure

1. Declaration of interests

Each member must submit a declaration concerning potential conflicts of interest. Specifically, the following categories of secondary interest must be disclosed[1]:

(a) Financial interests

Financial interests of any kind in the pharmaceuticals industry, such as ownership of securities, book-entry securities or derivatives, partnership shares[2] in a company within the meaning of section I, one of that company's subsidiaries or a firm in which that company holds a share of the capital. Units in equity or bond funds where the holders cannot exert any influence on the fund's investment strategy are not classified as financial interests for the purposes of this Code of Conduct.

(b) Activities for companies within the meaning of section I

All activities undertaken in the preceding five years for or in the interests of a company within the meaning of section I[3], regardless of whether for regular or occasional financial payment or benefits in kind, including:

- Participation in the internal decision-making processes of a company within the meaning of section I (e.g. membership of the Board of Directors or holding an executive operational role).
- Permanent or sporadic membership of the staff of a company within the meaning of section I. Other activities in a company within the meaning of section I (e.g. internships) are also subject to the duty of disclosure.
- Consultancy and other assignments performed for companies within the meaning of section I.Membership of the Board of Directors or holding an executive operational role in a pharmaceutical company of a party related to the member[4].

[1] Based on the EMA Code of Conduct (updated on 16 March 2011)

[2] If the declaration of financial interests includes securities, for example, the name of the company must be given.

[3] A clear and accurate description of the company name, member's position and activities must be provided. If the activities involve a particular product or products, the name of the product and nature of the activities must be stated in the declaration.

[4] Spouse or life partner of the member, related individuals, including in-laws, who live in the same household as the member.

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(c) Other relationships with companies within the meaning of section I

Any form of support from or for companies within the meaning of section I during the preceding five years in the form of financial support, contributions in kind or intellectual services, including:

- Funding for studies or research (third-party funding, grants)
- Bursaries or sponsorship (e.g. in the form of assistantships)
- Acting as a principal investigator or investigator in a preclinical or clinical study
- Intellectual property rights associated with the development or sale of medicinal products or medical devices

2. Publication in the Pharma Cooperation Code

Ordinary, extraordinary and advisory members of the SMECs undertake to permit industrial partners with whom they have a contract to publish the remuneration received in the Pharma Cooperation Code.

3. Ambiguities

In case of doubt, members must consult the Chairperson of the SMEC of which they are a member to determine whether a particular secondary interest should be disclosed.

III. Procedure for disclosing vested interests

1. It is the responsibility of each member to disclose their personal and institutional interests in full, comprehensibly and promptly in accordance with the *Public Declaration of Interests and Confidentiality Undertaking of Swissmedic Medicines Expert Committee Members* form (FO PDoI; see Annex 2).

2. Members being appointed to a committee for the first time must disclose their vested interests prior to their election by the Agency Council. The Head of the Authorisation sector will determine whether any of the disclosed vested interests are incompatible with membership. If no incompatibilities are found, the Head of the Authorisation sector will submit the forms referred to in section III/1 to the Executive Director as part of the election file for decision by the Agency Council's *Committees* committee and as a recommendation for the election by the Agency Council.

3. The FO PDoIs collected from members are used for case-related reviews of vested interests.

4. Each expert must update their FO PDoI annually even if they have no relevant vested interests at that time. Each autumn, the person responsible for experts in the Authorisation sector asks all members to update their FO PDoI and return them no later than 31 December. Any member who does not submit their FO PDoI by this date will not be asked to produce expert opinions until they have done so.

5. If a member's vested interests change significantly during the year, that member must voluntarily and immediately notify the person responsible for experts in the Authorisation sector or the Chairperson of the SMEC of which they are a member. In addition, they must update and submit their FO PDoI. Any member who is uncertain whether they have a duty of disclosure or abstention or is unclear about the scope of such a duty must contact the person responsible for experts on their own initiative.

6. FO PDoIs are filed in the SMEC secretary's office. In addition, each expert's FO PDoI is published on the Swissmedic website. The link to the relevant page will be sent to the Chairperson of the HMEC or VMEC.
   To ensure clarity, the vested interests declared in the FO PDoIs are collated in an Excel table which is also published on the Swissmedic website.

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7. If there are suspicions that the Code may have been breached, the person responsible for experts will check the declarations made by the expert in question in their FO PDoI. As part of this, they will contact that expert. Entries in the Pharma Cooperation Code or databases derived from the Code, for example, will also be checked. The expert in question will not be given any further assignments until the situation has been resolved.

8. SMEC experts must actively and continually report all activities on behalf of a company within the meaning of section I for which they have received financial remuneration or remuneration in kind that exceeds a value of CHF 1,000. The rule applies to all activities not explicitly disclosed in the member's FO PDoI (e.g. speaking at congresses or training events). The SMEC secretary's office will keep a list of these notifications. If the total amount of such remuneration exceeds the value of CHF 5,000 by the end of the year, the associated activities are published and included in the annual report submitted to the AC.

9. Each year, the person responsible for experts will prepare a report for submission to the February meeting of the Agency Council providing information on the experts who have not returned their FO PDoI on time and/or whose FO PDoI disclosures have been examined in response to suspicions. This report lists the nature of the suspected breach of this Code, the action that was taken in response and, if a breach was established, which assignments the experts in question had dealt with as part of their SMEC activities in the preceding year (citing the issue, medicinal product or active substance and the name of the company). The AC uses the report as a basis for a legally enforceable decision on whether to exclude affected SMEC members.

IV. Abstention rules

1. Before a member is given an assessment or advisory assignment, that member's existing vested interests should be reviewed with reference to the case or product in question in order to determine their compatibility with impartial and objective fulfilment of the assignment.

2. SMEC members must voluntarily withdraw from any assignments in which they themselves or a party related to them have a personal interest or on which they may be biased for some other reason.

3. In particular, the following activities or circumstances are incompatible with SMEC assessment or advisory assignments and constitute grounds for abstention.
   a) Advising the applicant on the indication in question in the preceding two years
   b) Holding a strategic advisory role with the applicant in the preceding two years
   c) Holding a current financial interest in the applicant or the preparation in question
   d) Holding intellectual property rights to the preparation in question
   e) Acting as principal investigator in a pivotal trial of the preparation in question at any time before or during the mandate
   f) Applicant is currently funding research activities

4. In particular, the following activities or circumstances are compatible with SMEC assessment or advisory assignments and do not constitute grounds for abstention.
   a) Acting in an advisory capacity for the applicant more than two years ago
   b) Dissolved financial interest in the applicant or the preparation in question
   c) Dissolved intellectual property rights to the preparation in question
   d) Acting as investigator in a pivotal trial of the preparation in question at any time before or during the mandate. However, investigators may only act in an advisory capacity and do not have voting rights.
   e) Applicant has funded research activities (no longer ongoing) in the preceding five years.

5. Members are responsible for promptly providing Swissmedic (when the agenda is distributed) and the Chairperson of the relevant SMEC (at meetings) with sufficient information on the existence of grounds for abstention. In case of doubt, the member must consult the Chairperson of the relevant

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SMEC beforehand. The Chairperson will then decide whether the vested interests constitute grounds for abstention. In cases affecting a Chairperson, the decision rests with the Deputy Chairperson.

6. At the start of each SMEC meeting, members declare whether they have a duty of abstention or relevant doubts in connection with any agenda items.

7. Where a member has a duty of abstention, they must:
   a) Hand back the assignment in question to Swissmedic
   b) Withdraw from the meeting for the duration of deliberations on the agenda item in question

8. Abstentions are recorded in the relevant files and in the meeting minutes, citing the reasons.

V. Other rules

1. Members who are contacted by third parties – specifically applicants – in the course of an ongoing assessment procedure must not provide any information on the content or progress of the procedure. The person making the enquiry must be referred to Swissmedic's Authorisation sector. The member who was contacted must notify the Chairperson and other members of the SMEC of the fact at the next meeting.

2. Members must not take part in promotional activities by companies within the meaning of section I.

3. Members must also ensure that their dealings with companies within the meaning of section I remain objective and correct outside their activities on behalf of Swissmedic. Specifically, members' behaviour in relation to invitations and donations by private individuals must not give rise to doubts about their personal impartiality and integrity. Members must comply with the relevant Swissmedic guidelines[5] and the guidelines on collaboration between medical professionals and industry[6] issued by the Swiss Academy of Medical Sciences.

VI. Procedure for dealing with breaches of this Code of Conduct

1. The SMEC Chairpersons will pursue blatant or suspected breaches of this Code of Conduct in cooperation with Swissmedic.

2. Where a member has breached this Code of Conduct or where there are fundamental misgivings about that member's impartiality, the Executive Director of Swissmedic must be consulted. The Executive Director will inform the Agency Council.

3. The Agency Council will then prescribe the necessary action (extending to excluding the member from the SMEC).

VII. Approval

This Code of Conduct and amendments to it are approved and enacted by the Agency Council.

VIII. Effective date

This Code of Conduct comes into effect on 1 June 2014.

Bern, 9 May 2014

[5] The ban on offering and accepting material benefits in accordance with Article 33 of the Therapeutic Products Act, with particular reference to pharmaceutical industry support for the continuous education of medical professionals; Swissmedic Journal 1/2006

[6] https://www.samw.ch/en.html

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The Agency Council of the Swiss Agency for Therapeutic Products, Swissmedic
The President
Christine Beerli

Change history

Version	Valid and binding as of:	Description, comments (by author)	Author's initials
3.2	01.01.2023	Annex 3: Changes based on the Swiss Criminal Code	ski
3.1	21.10.2021	Metadata modified (author and approver)	dei
3.0	22.11.2019	Clarifications on procedure for disclosing vested interests	ze
2.0	01.01.2017	Declaration to PCC added to Public Declaration of Interests Form	abb
1.0	12.09.2014	▪ Document assigned to different process Old: ZA300_00_001e_SD_SMEC_Kodex.docx New: ZL003_00_001en_SD_SMEC_Kodex.docx ▪ New change history inserted	sel, its

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Annex 1:

Declaration

I hereby declare that I will comply with the rules set out in the Code of Conduct for dealing with Conflicts of Interest for Members of the Swissmedic Medicines Expert Committees dated 1 June 2014.

Name:

.....
(Date / signature)

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Annex 2: Public Declaration of Interests and Confidentiality Undertaking of Swissmedic Medicines Expert Committee Members

(Please use the active pdf form: ZL003_00_004e_FO_SMEC_Public_Declaration_of_Interests.pdf)

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 (version 1)

INSTRUCTIONS

The document consists of three parts, your Personal Details, the Public Declaration of Interests and the Confidentiality Undertaking. All parts must be duly completed. The form is designed to be completed electronically for electronic storage of the data entered. It is your responsibility to ensure that the information
in the form is accurate and complete. Data from the form is sent by e-mail to hmec@swissmedic.ch or vmec@swissmedic.ch. Please print, sign and send a hard copy of the document to Swissmedic, Expertenwesen, Hallerstrasse 7, CH-3012 Bern.
The last page of the document includes the address to which the signed form should be sent.
You may fold the pages and put them – with the last page in front – into a window envelope.

1. Personal Details

Enter your full name, the name of your organisation, country in which your organisation is based and the e-mail address at which you would like to be contacted regarding this declaration.

2. Public Declaration of Interests

This section asks you to declare any interests in the pharmaceutical industry that you currently have or have had within the past 5 years. If you have interests to declare, please click 'Yes' in reply to the relevant questions. All questions in this section must be answered. Your declaration will not be accepted if any fields are left empty.

You may also provide information on interests over 5 years ago. This information will not be used in the evaluation of declared interests but will be useful in the context of increased transparency regarding previous interests.

3. Confidentiality Undertaking

Read carefully the confidentiality undertaking agreement and confirm the information declared on this form by entering your full name.

The document consists of three parts, your Personal Details, the Public Declaration of Interests and the Confidentiality Undertaking. <u>All parts should be duly completed.</u>

SECTION 1: PERSONAL DETAILS

First Name:

Last Name:

Organisation / Company:

Country:

Committee:

I 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 you complete the form) or have had within the past 5 years.

SECTION 2: PUBLIC DECLARATION OF INTERESTS

2.1 Employment [ii]

No ◯ Yes ◯

[ii] Employment in a pharmaceutical company.
(Pharmaceutical company includes supply or service companies which contribute to the research, development, production and maintenance of a medicinal product)

Employment[1]

Period:[2] ◯ Current ◯ Past

From Month: From Year: To Month: To Year:

Name of Pharmaceutical Company:[3]

◯ Individual product responsibility / involvement[4] ◯ Cross product responsibility / involvement[5]

Product Name	Therapeutic Indication

General Role / Area of Activity:

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

2 Please select the appropriate response (Current or Past). For current ongoing activities, indicate starting date (month/year). Note: Current means the time at which you complete the form. Should you engage in activities of this nature in the future, you will need to update your Declaration of Interest form accordingly. For activities that are no longer ongoing and that have been completed within the specified time, please indicate the start and end date (month / year).

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

4 **Individual product responsibility** for (**involvement** in) one or more products within one or more therapeutic areas. e.g. product development (quality, clinical, non-clinical) or line management responsibility for such individuals. Please indicate trade name and active substance. Please provide as much detail as possible in order to allow evaluation of this declared interest with respect to any products in which you may be involved as part of Swissmedic activity.

5 **Cross product responsibility** for (**involvement** in) support activities for multiple products across one or several therapeutic areas / full product range. Examples of such cross product responsibility might include areas such as Pharmacovigilance, Regulatory Affairs, Statistical Methodology. Please indicate your job title and role.
This option should only be chosen where it is not possible to list all of the products with which you were involved. Where you had both Individual and Cross product responsibility during the same time period, please choose the option - Individual product responsibility / Involvement.

2.2 Consultancy [iii] No ◯ Yes ◯

iii 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)

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

Consultancy[1]

Period:[2] ◯ Current ◯ Past

From Month: ☐ From Year: ☐ To Month: ☐ To Year: ☐

Name of Pharmaceutical Company:[3] ☐

◯ Product-related[4] ◯ General (non-product-related)[5]

Product Name: ☐

Therapeutic Indication: ☐

General Role / Area of Activity: ☐

1 Please indicate 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.

2 Please select the appropriate response (Current or Past). Please indicate activities which are currently ongoing. Indicate starting date (month / year). Note: Current means the time at which you complete the form. Should you engage in activities of this nature in the future, you will need to update your Declaration of Interest form accordingly. For activities that are no longer ongoing and that have been completed within the specified time, please indicate the start and end date (month / year).

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

4 Consultant on the **development of one or more products** within one or more therapeutic areas. Please indicate trade name and active substance. Please provide as much detail as possible in order to allow evaluation of this declared interest with respect to any products in which you may be involved as part of Swissmedic activity.

5 **General consultancy** (non-product-related). Please indicate the general area in which you were involved.

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2.3 Strategic Advisory Role [iv]

No ◯ Yes ◯

[iv] 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 2.6 Principal Investigator Involvement in clinical research should be listed under section 2.6 or 2.7 as appropriate.

Strategic Advisory Role[1]

Period:[2] ◯ Current ◯ Past

From Month: ☐ From Year: ☐ To Month: ☐ To Year: ☐

Name of Pharmaceutical Company:[3] ☐

◯ Product-related[4] ◯ General (non-product-related)[5]

Product Name: ☐

Therapeutic Indication: ☐

General Role / Area of Activity: ☐

1 Please indicate 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 / influence the outcomes of that body.

2 Please select the appropriate response. Please indicate activities which are currently ongoing. Indicate starting date (month / year). Note: Current means the time at which you complete the form. Should you engage in activities of this nature in the future, you will need to update your Declaration of Interest form accordingly. For activities that are no longer ongoing and that have been completed within the previous 5 years, please indicate the start and end date (month / year).

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

4 Participation in (Scientific) Advisory Board / Steering Committee, providing advice on product-related strategy. Please indicate trade name and active substance. Please provide as much detail as possible in order to allow evaluation of this declared interest with respect to any products in which you may be involved as part of Swissmedic activity.

5 Participation in (Scientific) Advisory Board / Steering Committee, providing advice on general strategy. Please indicate the general area in which you were involved.

2.4 Current Financial Interests [v]

No ◯ Yes ◯

[v] Financial interests relate to:

CURRENT shareholdings in a pharmaceutical company with the exception of independently managed investment/pension funds. Compensation, fees, honoraria, salaries **CURRENTLY** being paid directly to you by a pharmaceutical company, other than payment for expenses incurred for research work or reimbursement of reasonable expenses incurred in relation to conference/seminar attendance (i.e. accommodation and travel costs).

(**CURRENT** means the time at which you complete this form).

Financial Interests, including shareholdings in a pharmaceutical company[1]

Name of Pharmaceutical Company[2]

1 Please indicate any financial interest currently held in a pharmaceutical company.

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

2.5 Patent [vi]

No ◯ Yes ◯

[vi] Relates to a patent for a medicinal product/competitor product **CURRENTLY** owned by either the individual or the individual's institution, where the individual is a beneficiary. *(**CURRENT** means the time at which you complete this form)*

Patent Ownership[1]

Name of Pharmaceutical Company (if applicable)	Subject Matter

1 Please indicate any patents held for a medicinal product, owned by either yourself or your institution, of which you are a beneficiary.

2.6 Principal Investigator [vii]

No ◯ Yes ◯

[vii] Principal Investigator responsible for coordinating investigators at different centres 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 national coordinating investigators in a multinational trial. Involvement in Data Safety Monitoring Committee should be included in this section.

Principal Investigator[1]

Period:[2] ◯ Current ◯ Past

Funding paid into an institutional account with shared power of disposition:[3] ◯ No ◯ Yes

From Month: ☐ From Year: ☐ To Month: ☐ To Year: ☐

Name of Pharmaceutical Company:[4] ☐

Product Name:[5] ☐

Therapeutic Indication: ☐

1 Please indicate all trials for which you are acting or have acted as **Principal Investigator**.
2 Please indicate activities which are currently ongoing. Indicate the start date (month / year). Note: Current means the time at which you complete the form. Should you engage in activities of this nature in the future, you will need to update your Declaration of Interest form accordingly. For activities that are no longer ongoing and that have been completed within the specified time, please indicate the start and end date (month / year).
3 Please reply 'No' if you are the only person with power of disposition for banking matters.
4 Pharmaceutical company: also includes supply or service companies which contribute to the research, development, production and maintenance of a medicinal product.
5 Please indicate trade name and active substance. Please provide as much detail as possible, in order to allow evaluation of this declared interest with respect to any products in which you may be involved as part of Swissmedic activity.

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2.7 Investigator [viii]

No ◯ Yes ◯

[viii] Investigator involved in a clinical trial at a specific trial site who may 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.

Investigator[1]

Period:[2] ◯ Current ◯ Past

Funding paid into an institutional account with shared power of disposition:[3] ◯ No ◯ Yes

From Month: | From Year: | To Month: | To Year:

Therapeutic Indication:

Product Name:[4]

Name of Pharmaceutical Company:[5]

1 Please indicate all trials for which you are acting or have acted as an **Investigator**.
2 Please indicate activities which are currently ongoing. Indicate starting date (month / year). Note: Current means the time at which you complete the form. Should you engage in activities of this nature in the future, you will need to update your Declaration of Interest form accordingly. For activities that are no longer ongoing and that have been completed within the specified time, please indicate the start and end date (month / year).
3 Please reply 'No' if you are the only person with power of disposition for banking matters.
4 Please indicate trade name and active substance. Please provide as much detail as possible in order to allow evaluation of this declared interest with respect to any products in which you may be involved as part of Swissmedic activity.
5 Pharmaceutical company: also includes supply or service companies which contribute to the research, development, production and maintenance of a medicinal product.

2.8 Grant / Funding to Institution [ix]

No ◯ Yes ◯

[ix] 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.

Grant or other Funding[1]

Funding paid into an institutional account with shared power of disposition:[2] ◯ No ◯ Yes

Name of Pharmaceutical Company[3]	Subject Matter	≥ CHF 500k	
		◯ No	◯ Yes

1 Please indicate any grants or other funding received by your institutional unit from a pharmaceutical company without personal gain yourself; 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.
2 Please indicate 'No' if you are the only person with power of disposition for banking matters.
3 Pharmaceutical company: also includes supply or service companies which contribute to the research, development, production and maintenance of a medicinal product.

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Further to the interests declared above, I hereby declare on my honour that I have no other interests or facts that should be disclosed to Swissmedic, the Swiss Agency for Therapeutic Products and the public.

In case of any other facts or interests of related parties, please specify:

Should any of the above information change owing to the acquisition of additional interests, I shall promptly notify **Swissmedic** and complete a new Declaration of Interests form 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.

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.

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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 party[1] 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.***

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.

I confirm that I allow all my contracting partners of the pharmaceutical industry to publish in the Pharma Cooperation Code (PCC) any payments that fall within the scope of the PCC.

I confirm that 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.

Full Name: _____

Date: _____

Signature: _____

[1] Third party does not include Swissmedic employees or other SMEC Members.

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Annex 3:

Excerpt from the Swiss Criminal Code:

Title Nineteen: Bribery

1. Bribery of Swiss public officials. Bribery

Art. 322ter Bribery

Any person who offers, promises or gives a member of a judicial or other authority, a public official, an officially-appointed expert, translator or interpreter, an arbitrator, or a member of the armed forces an undue advantage, or offers, promises or gives such an advantage to a third party in order to cause the public official to carry out or to fail to carry out an act in connection with his official activity which is contrary to his duty or dependent on his discretion,

shall be liable to a custodial sentence not exceeding five years or to a monetary penalty.

Art. 322quater Acceptance of bribes

Any person who as a member of a judicial or other authority, as a public official, officially-appointed expert, translator or interpreter, or as an arbitrator demands, secures the promise of or accepts an undue advantage for that person or for a third party in order that he carries out or fails to carry out an act in connection with his official activity which is contrary to his duty or dependent on his discretion,

shall be liable to a custodial sentence not exceeding five years or to a monetary penalty.

Art. 322quinquies Granting an advantage

Any person who offers, promises or gives a member of a judicial or other authority, a public official, an officially-appointed expert, translator or interpreter, an arbitrator or a member of the armed forces an undue advantage for that person or for a third party in order that the person carries out his official duties,

shall be liable to a custodial sentence not exceeding three years or to a monetary penalty.

Art. 322sexies Acceptance of an advantage

Any person who as a member of a judicial or other authority, as a public official, officially-appointed expert, translator or interpreter, or as an arbitrator, demands, secures the promise of, or accepts an undue advantage for that person or for a third party in order that he carries out his official duties,

shall be liable to a custodial sentence not exceeding three years or to a monetary penalty.

2. Bribery of foreign public officials

Art. 322septies

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Any person who offers, promises or gives a member of a judicial or other authority, a public official, an officially-appointed expert, translator or interpreter, an arbitrator, or a member of the armed forces who is acting for a foreign state or international organisation an undue advantage, or gives such an advantage to a third party, in order that the person carries out or fails to carry out an act in connection with his official activities which is contrary to his duties or dependent on his discretion,

any person who as a member of a judicial or other authority, a public official, an officially-appointed expert, translator or interpreter, an arbitrator, or a member of the armed forces of a foreign state or of an international organisation demands, secures the promise of, or accepts an undue advantage for himself or for a third party in order that he carries out or fails to carry out an act in connection with his official activity which is contrary to his duty or dependent on his discretion,[264]

shall be liable to a custodial sentence not exceeding five years or to a monetary penalty.

3. Bribery of private individuals

Art. 322^octies Bribery

[1] Any person who offers, promises or gives an employee, partner, agent or any other auxiliary of a third party in the private sector an undue advantage for that person or a third party in order that the person carries out or fails to carry out an act in connection with his official activities which is contrary to his duties or dependent on his discretion shall be liable to a custodial sentence not exceeding three years or to a monetary penalty.

[2] In minor cases, the offence is only prosecuted on complaint.

Art. 322^novies Accepting bribes

[1] Any person who as an employee, partner, agent or any other auxiliary of a third party in the private sector demands, secures the promise of, or accepts an undue advantage for himself or for a third party in order that the person carries out or fails to carry out an act in connection with his official activities which is contrary to his duties or dependent on his discretion shall be liable to a custodial sentence not exceeding three years or to a monetary penalty.

[2] In minor cases, the offence is only prosecuted on complaint.

4. General provisions

Art. 322^decies

1. The following are not undue advantages:
    a. advantages permitted under public employment law or contractually approved by the third party;
    b. negligible advantages that are common social practice.

264 Paragraph inserted by Art. 2 No 2 of the Federal Decree of 7 Oct. 2005 on the Approval and Implementation of the Criminal Law Convention and the Additional Protocol of the Council of Europe on Corruption, in force since 1 July 2006 (AS 2006 2371 2374; BBl 2004 6983).

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2. Private individuals who fulfil official duties are subject to the same provisions as public officials.

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