

Rules of the Swissmedic Medicines Expert Committees (SMECs)

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

having regard to

Article 68 paragraph 5 of the Therapeutic Products Act of 15 December 2000 (TPA)¹
and Article 5 of the Organisational Rules of Swissmedic dated 23 November 2018,²

hereby resolves:

1 Principle

The following expert committees (Swissmedic Medicines Expert Committees, SMECs) are employed to advise Swissmedic on scientific issues:

- a. Human Medicines Expert Committee (HMEC)
- b. Veterinary Medicines Expert Committee (VMEC)

2 Composition

¹ The SMECs are constituted of ordinary members, extraordinary members and advisory members.

² The HMEC consists of a maximum of nine, the VMEC of a maximum of seven ordinary members. There is no limit on the number of extraordinary or advisory members, this being determined by Swissmedic's need for specialist knowledge in the case in question.

³ When selecting members and the specialist disciplines they represent, care must be taken to ensure that the SMECs are endowed with the high standard of scientific competence necessary to assess issues relating to the quality, safety and efficacy of medicinal products. To this end, Swissmedic will also liaise with the relevant scientific associations.³

⁴ The *ordinary members* are appointed on the basis of the following criteria:

- a) Demonstrable professional qualifications and expertise in the specialist fields listed under b below, accompanied by broad scientific knowledge and generally a postdoctoral qualification. An additional area of expertise is beneficial. Clinical members must be active clinical practitioners; ideally, they should combine this with research activity.
- b) The following specialist fields should be represented on the HMEC (list not exhaustive):
 - 1st General internal medicine
 - 2nd Clinical pharmacology and toxicology
 - 3rd Preclinical discipline (e.g. pathology or pharmacology)

¹ SR 812.21

² SF201_00_003e

³ Amended in accordance with AC decision of 13 February 2009

- c) To be represented on the VMEC: The specialist disciplines and target animal species listed in the *VMEC directory of members*.⁴

⁵ The *extraordinary members* are appointed on the basis of the following criteria:

- a) Demonstrable professional qualifications and expertise in the requisite specialist field. Clinical members must possess extensive experience of clinical practice and of conducting clinical studies (e.g. as an investigator).
- b) Representation of specialist fields that are not adequately covered by ordinary SMEC members and Swissmedic staff.
 1. In the preclinical context, this includes, but is not limited to, the following specialist knowledge: Knowledge of modes of action, drug interactions and risk assessments, including extrapolation to humans and the environment.
 2. For the clinical contexts, the following fields, among others, should be included (where not already covered by ordinary members): Allergology and clinical immunology, anaesthesiology, dermatology and venereology, endocrinology and diabetes, gastroenterology, gynaecology and obstetrics, infectious diseases, haematology, cardiology, angiology, cardiothoracic vascular surgery, intensive care medicine, neurology, nephrology, medical oncology, ophthalmology, paediatric and adolescent medicine, pulmonology, psychiatry and psychotherapy, radiology, rheumatology, dentistry and specialist areas of complementary medicine.
 3. Statistics

This list is not exhaustive and is subject to change, for example as new specialist fields emerge and in line with the expertise possessed by the ordinary members of the SMEC and the preclinical/clinical reviewers.

- c) To be represented on the VMEC: The specialist disciplines and target animal species listed in the *VMEC directory of members*.⁵

⁶ The *advisory members* are appointed using the same professional and scientific qualification criteria as *ordinary members*. They are retained primarily for specialist fields where experience shows it is difficult to find experts who do not have vested interests incompatible with ordinary or extraordinary membership.

⁷ *Extraordinary and advisory members* may also be elected to provide specialist support to Swissmedic in medical devices surveillance and the authorisation and market surveillance of transplant products. The provisions of the SMEC Rules are applicable to them *mutatis mutandis* and they are similarly subject to the SMEC Code of Conduct.⁶

3 Election

¹ The Agency Council elects the Chairpersons and members for a four-year period of office. Vacancies are refilled for the remainder of the current period of office.

² Individuals who have reached the age of 70 may not be elected or re-elected as members.

³ The Agency Council can revoke the election of any member at any time with effect from the end of the month.

⁴ The current compositions of the SMECs are as given in the HMEC directory of members and VMEC directory of members.

⁴ New in accordance with AC decision of 13 February 2009

⁵ New in accordance with AC decision of 13 February 2009

⁶ New in accordance with AC decision of 25 November 2016

4 Incompatibility

¹ The following are **incompatible** with **ordinary membership** of an SMEC:

- a) An existing position of employment with a company in the therapeutic products industry or therapeutic products trade or with associated organisations, foundations or associations that have commercial interests.
- b) Existing membership of a management or supervisory body of a company within the meaning of section 4 paragraph 1 letter a, specifically membership of a board of directors.
- c) An existing personal consultancy contract with a company within the meaning of section 4 paragraph 1 letter a, specifically in connection with membership of an advisory board or similar body.
- d) Any financial holding or investment in a company within the meaning of section 4 paragraph 1 letter a. Units in investment funds where the holders cannot exert any influence on the fund's investment strategy are exempt from this provision.
- e) Income from the ownership of patents on therapeutic products that are available on the market or in development.
- f) Financing ongoing research activities by a company within the meaning of section 4 paragraph 1 letter a, the grants for which are paid into an account under the sole control of the SMEC member.
- g) Acting as a principal investigator or investigator in an ongoing clinical study if the compensation for such activity is paid into an account under the sole control of the SMEC member.

² The following are **incompatible** with **extraordinary membership** of an SMEC:

- a) An existing position of employment with a company within the meaning of section 4 paragraph 1 letter a.
- b) Existing membership of a management or supervisory body of a company within the meaning of section 4 paragraph 1 letter a, specifically membership of a board of directors.
- c) An existing personal consultancy contract with a company within the meaning of section 4 paragraph 1 letter a, specifically in connection with membership of an advisory board or similar body.

³ The following is **incompatible** with **advisory membership**:

- a) An existing position of employment with a company within the meaning of section 4 paragraph 1 letter a.

5 Assignments

¹ The SMECs support Swissmedic by providing expert opinions and advice on the scientific assessment of documentation relating to the authorisation, market surveillance and approval of medicinal products and transplant products as well as on the market surveillance of medical devices.⁷

^{1-bis} SMEC members may be invited to attend official activities such as inspections as external experts. However, their role in such cases is purely advisory. They must not be entrusted with official duties.⁸

² Providing expert opinions and advice involves:

- a) Dealing with specific specialist questions that arise independently of a particular pending procedure (individual expert opinions)
- b) Dealing with specific specialist questions connected with a pending procedure (individual expert opinions)
- c) Comprehensive evaluation of specified documentation (expert opinion in the sense of an assessment)
- d) Commenting on draft evaluation reports (expert opinion as SMEC expert)

⁷ New in accordance with AC decision of 25 November 2016

⁸ New in accordance with AC decision of 25 November 2016

e) Commenting on safety-related issues

³ Individual ordinary or extraordinary members can be tasked with providing expert opinions and advice in accordance with letters a–e above. Extraordinary members may only be asked to carry out an assessment in accordance with letter c above if they do not meet any of the incompatibility conditions set out in section 4 paragraph 1. Advisory members may only be assigned advisory tasks in accordance with letters a and b (individual expert opinions) and must always submit their individual expert opinions to Swissmedic in writing.

⁴ Assessment and advisory assignments can be issued by the managers of the relevant divisions (generally division heads or their deputies).⁹

⁵ Specifically, assignments can be issued for:

- a) Applications for new active substances (NAS)
- b) Other applications if a specialist issue has provoked debate within the sectors in question or if a second opinion on a question that has been answered internally or on a completed assessment is required
- c) Independent assessments by an SMEC expert if the Authorisation and Market Surveillance sectors cannot provide the specialist resources needed to conduct the assessment or cannot provide those resources within the appropriate timeframe.¹⁰

⁶ The Chairperson of the committee in question will be notified of the assignment. The cost of assignments is billed in accordance with section 13.¹¹

⁷ Depending on the complexity of the issue at hand, advice in accordance with paragraph 2 letters a, b and e may be issued in the form of an individual expert opinion without discussion at SMEC meetings. Advice in accordance with letters c and d is generally formulated at SMEC meetings.

6 Meetings

¹ In general, all ordinary members of a particular SMEC may attend its meetings. Extraordinary members who are specifically qualified to deal with a case at hand may, if appropriate, also be invited to attend the meeting at which that case is discussed or to be present for the agenda item.

² The HMEC generally meets once a month, the VMEC once every two months. If necessary, the Chairpersons can convene additional meetings by arrangement with the responsible sector heads.

³ The Agency and SMEC experts handle the scientific preparation work for agenda items.

⁴ With the consent of the Chairperson, the Agency employee responsible for the agenda item may also invite external experts to attend the meeting to answer questions concerning highly specialist fields or make an evaluation.¹²

⁵ The SMECs will be notified of products authorised by the Agency under Article 13 TPA¹³.

⁹ New in accordance with AC decision of 13 February 2009

¹⁰ New in accordance with AC decision of 13 February 2009

¹¹ New in accordance with AC decision of 13 February 2009

¹² Amended in accordance with AC decision of 13 February 2009

¹³ New in accordance with AC decision of 13 February 2009

7 Decisions

¹ The SMECs approve responses for submission to the Agency by a simple majority. In the event of a tie, the Chairperson's vote counts twice. Only ordinary members attending the meeting have the right to vote.

² Meetings are quorate only if attended by at least four ordinary members who are clinical specialists and one ordinary member who is a preclinical specialist in the case of the HMEC; and three ordinary members who are clinical specialists and one ordinary member who is a preclinical specialist in the case of the VMEC. If fewer members are present, the Chairperson may cancel the meeting or convene an additional meeting.

³ The SMECs' recommendations to the Agency and any abstentions by individual members are recorded in the minutes and accompanied by the associated reasons.

8 SMEC business regulations

Each SMEC may issue regulations governing the way it conducts its business. These regulations take effect on approval by the Agency Council.

9 Agency's right of use to copyrighted works and procedures

¹ The Agency shall have the right to use all work performed by members in the course of their committee work in the context of performing its tasks. This right of use also extends to any intellectual property belonging to members and applies in particular to the duplication, publication, dissemination, translation and archiving of such property.

² The originator of the intellectual property shall only be entitled to compensation beyond that provided for in section 13 if the Agency makes commercial use of the property.

10 Duty of confidentiality

¹ Members are subject to a duty of confidentiality in accordance with Article 61f. TPA and to the obligation to maintain professional, business and official secrecy in accordance with Article 45 of the Ordinance on the Personnel of the Swiss Agency for Therapeutic Products.¹⁴

² All SMEC deliberations and the documents provided to members for the purpose of providing assessments and advice are confidential.

11 Disclosure of conflicts of interest and duty of abstention

¹ Disclosure of conflicts of interest and members' duty of abstention are subject to the rules set out in the Code of Conduct for dealing with Conflicts of Interest for the Swissmedic Medicines Expert Committees dated 9 May 2014 and section 7 paragraph 3 of these Rules.

² Abstention rules for court proceedings are not affected by these provisions.

12 Secretarial services

The Agency provides secretarial services for the SMECs. It deals with the SMECs' administrative affairs and assists the Chairpersons in their work. It produces minutes of every meeting on the basis of the written contributions of the Swissmedic employees and the experts.¹⁵

¹⁴ SR 812.215.4

¹⁵ Amended in accordance with AC decision of 13 February 2009

13 Compensation

¹ The Agency provides funding for committee activities.

² Ordinary members receive compensation:

- a) in the form of a flat-rate base payment of CHF 12,000 annually or CHF 1,000 per month for members of the HMEC and CHF 6,000 annually or CHF 500 per month for members of the VMEC.
- b) in the form of a daily allowance for **preparing for and attending meetings** in accordance with section 6. This is CHF 3,500 for Chairpersons and 3,000 for members. Half the daily allowance will be paid if attendance is less than four hours.¹⁶ Members who do not attend a meeting will not be entitled to a daily allowance.
- c) In the form of an hourly fee of CHF 200 for additional assessment and advisory assignments¹⁷ in accordance with section 5 paragraph 2 letters a – e.

³ Extraordinary members receive compensation:

- a) in the form of an attendance fee of CHF 1,000 for **attending meetings** in accordance with section 6. Half the daily allowance will be paid if attendance is less than four hours.¹⁸
- b) in the form of an hourly fee of CHF 200 for assessment and advisory assignments in accordance with section 5 paragraph 2 letters a – e and for preparing for meetings in accordance with section 6.

⁴ Advisory members receive compensation:

- a) in the form of an hourly fee of CHF 200 for advisory assignments in accordance with section 5 paragraph 2 letters a and b.

⁵ The amounts stated are gross. Statutory pension and unemployment insurance contributions will be paid by Swissmedic. Members of the SMECs will not be enrolled in the PUBLICA pension fund. Swissmedic does not pay contributions to an occupational pension scheme.

14 Effective date

¹ These Rules come into force on 1 June 2014.

Bern, 9 May 2014

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

¹⁶ Amended in accordance with AC decision of 13 February 2009

¹⁷ Amended in accordance with AC decision of 13 February 2009

¹⁸ Amended in accordance with AC decision of 13 February 2009

Change history

| Version | Valid and binding as of: | Description, comments (by author) | Author's initials |
|---------|--------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------|
| 14.1 | 07.03.2023 | Chapter 2: Formal adjustments | ski |
| 14.0 | 19.04.2021 | Section 10 "Duty of confidentiality" amended following the full revision of the Swissmedic Personnel Ordinance and Swissmedic Organisational Rules of 23 November 2018 | ski |
| 13.3 | 11.12.2020 | Formal adaptation pages 3/4 (a–e) | stb |
| 13.2 | 30.04.2020 | Formal update | ze |
| 13.1 | 28.04.2020 | Formal aspects updated | ze |
| 13.0 | 26.03.2018 | Number of ordinary HMEC members increased from 8 to 9. Various linguistic modifications (particularly use of FMH terminology). | ze |
| 12.0 | 01.05.2017 | Annex 1 and 2 deleted from the Rules and separate directory of members created. | ze |
| 11.0 | 25.11.2016 | <i>Section 2 para. 7 (new), section 5 para. 1 (modified) and section 5 para. 1-bis (new)</i> | abb |
| | | Departure of R. Bolli with effect from 30 November 2016 | ze, abe |
| | | 2017 – 2020 period of office: Annex updated on the basis of the Agency Council's election decisions 16.09.16: Ordinary SMEC members elected 25 November 2016: Extraordinary and advisory SMEC members elected | ze, abe |
| 10.0 | 16.09.2016 | First-time election of M. Borner, K. Buser and A.-P. Sappino as extraordinary members of HMEC First-time election of A. Angelillo as advisory member of HMEC | anj, abe |
| 9.0 | 13.05.2016 | First-time election of M. von Wolff and M. Arand as extraordinary members of HMEC First-time election of R. Hunger as advisory member of HMEC | anj, abe |