

Strategic document

Rules of the Swissmedic Medicines Expert Committees (SMECs)

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Rules of the Swissmedic Medicines Expert Committees (SMECs)

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

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 ordinary HMEC panel and the ordinary VMEC³ panel each consist of a maximum of nine 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 SMEC members are endowed with the high standard of scientific competence necessary to assess issues relating to the quality, safety and efficacy of medicinal products.

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

- a) Demonstrable professional qualifications and expertise accompanied by broad scientific knowledge in a specialist field and generally a postdoctoral qualification. An additional area of expertise is beneficial. Clinical HMEC members must possess experience of clinical practice and of conducting clinical studies (e.g. as an investigator).
- b) To be represented on the HMEC: Specialist fields according to *HMEC directory of members*.⁴
- c) To be represented on the VMEC: The specialist disciplines and target animal species listed in the *VMEC directory of members*.⁵

¹ SR 812.21

² SF201_00_003e

³ New in accordance with AC decision of 22 November 2024

⁴ New in accordance with AC decision of 22 November 2024

⁵ New in accordance with AC decision of 13 February 2009

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 HMEC members must possess experience of clinical practice and of conducting clinical studies (e.g. as an investigator).
- b) To be represented on the HMEC: Specialist fields according to *HMEC directory of members*.⁶
- c) To be represented on the VMEC: The specialist disciplines and target animal species listed in the *VMEC directory of members*.⁷

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 it is difficult to find experts who do not have vested interests incompatible with extraordinary membership.

- a) To be represented on the HMEC: Specialist fields according to *HMEC directory of members*.
- b) To be represented on the VMEC: The specialist disciplines and target animal species listed in the *VMEC directory of members*.

3 Election

¹ The Agency Council elects the Chairperson and members for a four-year period of office. If necessary, during the period of office SMEC members can be elected 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 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.

⁶ New in accordance with AC decision of 22 November 2024

⁷ New in accordance with AC decision of 13 February 2009

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 relating to the authorisation, market surveillance and approval of medicinal products as well as on the market surveillance of medical devices. ⁸

^{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. ⁹

² Providing expert opinions and advice involves:

- a) Dealing with specific specialist questions that arise independently of a particular pending procedure
- b) Dealing with specific specialist questions connected with a pending procedure
- c) Comprehensive evaluation of specified documentation
- d) Commenting on draft assessment reports

³ Individual ordinary or extraordinary members can be tasked with providing expert opinions and advice in accordance with letters a–d 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.

⁴ These assignments are documented in writing and billed in accordance with section 12. ¹⁰

6 Meetings of ordinary SMEC panels

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

⁸ New in accordance with AC decision of 25 November 2016

⁹ New in accordance with AC decision of 25 November 2016

¹⁰ New in accordance with AC decision of 13 February 2009

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

³ Swissmedic and the SMEC members handle the scientific preparation work for agenda items.

7 Decisions

¹ The SMECs decide on their recommendations for submission to Swissmedic by a simple majority. In the event of a tie, the Chairperson's vote counts twice. Only ordinary members participating in the meeting have the right to vote.

² Meetings result in a consolidated recommendation 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 at least five ordinary members in the case of the VMEC. If fewer members are present, Swissmedic in consultation with the Chairperson may cancel the meeting and may convene an additional meeting.

³ The recommendations of the ordinary SMEC panel to Swissmedic and any abstentions by individual members are recorded in the minutes and accompanied by the associated reasons.

8 Swissmedic's right of use to copyrighted works and procedures

¹ Swissmedic 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 12 if Swissmedic makes commercial use of the property.

9 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.¹¹

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

10 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.

¹¹ SR 812.215.4

11 Secretarial services

Swissmedic provides secretarial services for the SMECs. It deals with the SMECs' administrative affairs and assists the Chairperson in their work. Minutes will be taken for each ordinary panel meeting that contain the panel's recommendations and the corresponding justifications.

12 Compensation

¹ Swissmedic 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.¹² 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 assignments¹³ in accordance with section 5 paragraph 2 letters a – d.

³ *Extraordinary members* receive compensation:

- a) in the form of an attendance fee of CHF 1,000 per day for **attending meetings** in accordance with section 6. Half the daily allowance will be paid if attendance is less than four hours.¹⁴
- 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 – d 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.

13 Effective date

¹ These Rules come into force on 1 January 2025.

Bern, 22 November 2024

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

The President

Lukas Bruhin

¹² Amended in accordance with AC decision of 13 February 2009

¹³ Amended in accordance with AC decision of 13 February 2009

¹⁴ Amended in accordance with AC decision of 13 February 2009

Change history

Version	Valid and binding as of:	Change	sig
15.0	01.01.2025	Formal changes and clarifications Number of ordinary VMEC members increased from 7 to 9	ski, ber, hcr, wan
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