26 January 2024
EMA/CVMP/SAWP/427324/2023
Committee for Veterinary Medicinal Products (CVMP)

Work plan for the Committee for Veterinary Medicinal Products (CVMP) Scientific Advice Working Party (SAWP-V) for 2024

Chairpersons	**Status**
Chair: F. Hasslung Wikström Vice-chair: S. Louet	Adopted by CVMP in January 2024

The activities outlined in the work plan for 2024 have been agreed considering the respective business priorities and may be subject to further review and reprioritisation in accordance with the business plan of the Agency.

1. Meetings scheduled for 2024

Plenary meetings: 11 (per meeting: 15 members, each 0.5 day; additional 6–7 expert-days/year)

Friday, 12 January 2024 (remote)
Friday, 9 February 2024 (remote)
Friday, 8 March 2024 (remote)
Friday, 12 April 2024 (remote)
Friday, 17 May 2024 (remote)
Friday, 14 June 2024 (remote)
Monday, 15 July 2024 (in-person)
Friday, 6 September 2024 (remote)
Friday, 4 October 2024 (remote)
Monday, 4 November 2024 (in-person)
Friday, 29 November 2024 (remote)

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Pre-meetings: These meetings are regarded as complementary to plenary meetings and may be used for prior discussions on specific requests; they will be held remotely and will take place only if required (e.g. by high workload); up to 11 meetings (per meeting: 15 members, each 0.3 day; additional 3-4 expert-days/year).

Tuesday, 9 January 2024
Monday, 5 February 2024
Tuesday, 5 March 2024
Tuesday, 9 April 2024
Tuesday, 14 May 2024
Tuesday, 11 June 2024
Tuesday, 9 July 2024
Tuesday, 3 September 2024
Tuesday, 1 October 2024
Tuesday, 29 October 2024
Tuesday, 26 November 2024

Other meetings:

Drafting / Expert groups	None.
Workshop / Focus group	None.
Training	None.

2. Product-related issues

The Scientific Advice Working Party (SAWP-V) is established to provide scientific advice on all matters relating to development of veterinary medicinal products and establishment of MRLs, including requests for status of substances as not falling within the scope of Regulation No 470/2009, as well as to provide assessment of preliminary risk profile of new antimicrobial substances or veterinary medicinal products, in conjunction with other working parties or groups.

SAWP-V will be involved in the provision of scientific advice for products satisfying the requirements of Article 4(29) of the Regulation (EU) 2019/6, including products that qualify to have their application submitted under Article 23 of the Regulation, in line with the adopted CVMP guidelines on data requirements for veterinary medicinal products intended for limited markets.

SAWP-V will also be involved in the provision of scientific advice at a reduced fee (90% fee waiver) to veterinary companies in possession of an SME status, in accordance with Commission Regulation (EC) No 2049/2005 on assistance to SME companies. This is an area of increased requests, as increasing number of veterinary companies are registered as SMEs with the Agency, to avail of the incentives offered.

The following table provides an estimated number per year of contributions (number of involvements) for scientific advice (including pre- and post-authorisation issues) and preliminary risk profile assessment.

Expected contribution in Scientific Advice	Expected contribution in Preliminary Risk Profile assessment
25 (11 Standard, 6 LM, 8 SME)	None foreseen

3. CVMP guidance documents

3.1. Guidance documents to be finalised after the consultation period

None foreseen.

3.2. Guidance documents to be released for consultation

None foreseen.

3.3. New topics/Concept Papers to be prepared

None foreseen.

4. VICH guidelines and activities

None foreseen.

5. EU regulatory activities

Continuation of provision of the Preliminary Risk Profile (PRP) assessment procedure for new antimicrobial substances and veterinary medicinal products within the Scientific Advice procedure, if requested.

6. Activities with external parties

6.1. Meetings with interested parties

None foreseen.

6.2. Regulatory authorities outside the EU

Continuation of discussions with the FDA Center for Veterinary Medicines in relation to parallel scientific advice with the aim to modify the procedure and make it a more attractive option for the applicants.

7. Organisational matters

7.1. List of adopted organisational documents

Mandate, objectives and rules of procedure for the CVMP Scientific Advice Working Party (EMA/CVMP/SAWP/676117/2010-Rev.6) – last updated in 2017.

Guidance for Applicants, revised in 2020, has been published on the web page of veterinary scientific advice (https://www.ema.europa.eu/en/veterinary-regulatory/research-development/scientific-advice).

7.2. List of organisational documents to be developed in the forthcoming 2 years

- Timings of procedures for 2025 (for SAWP-V members)
- Deadlines for submission of SA requests in 2025 (for applicants)
- Timings of procedures for 2026 (for SAWP-V members)
- Deadlines for submission of SA requests in 2026 (for applicants)

7.3. List of proposed scientific guidelines for the next work plan

None foreseen.

7.4. Procedure evaluation and optimisation

Action:	Continuously review the operation of the scientific advice procedure and optimise where necessary.
Comments:	Feedback received from the applicants, CVMP members and SAWP-V members will be used as a basis for optimisation proposals.