16 December 2022
EMA/CVMP/SAWP/827784/2022
Committee for Veterinary Medicinal Products (CVMP)

Work plan for the Committee for Veterinary Medicinal Products (CVMP) Scientific Advice Working Party (SAWP-V) for 2023

Chairpersons	Status
Chair: F. Hasslung Wikström Vice-chair: S. Louet	Adopted by CVMP in December 2022

The activities outlined in the work plan for 2023 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 2023

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

Monday, 16 January 2023 (remote)
Friday, 10 February 2022 (remote)
Monday, 20 March 2023 (remote)
Friday, 14 April 2023 (remote)
Friday, 12 May 2023 (remote)
Monday, 12 June 2023 (in-person)
Monday, 10 July 2023 (remote)
Friday, 1 September 2023 (remote)
Monday, 2 October 2023 (remote)
Monday, 6 November 2023 (remote)
Monday, 4 December 2023 (in-person)

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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, 10 January 2023
Tuesday, 7 February 2023
Tuesday, 14 March 2023
Tuesday, 11 April 2023
Monday, 8 May 2023
Tuesday, 6 June 2023
Tuesday, 4 July 2023
Tuesday, 29 August 2023
Tuesday, 26 September 2023
Tuesday, 31 October 2023
Tuesday, 28 November 2023

Other meetings:

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

Depending on the circumstances, some of the plenary meetings may need to be held in the form of virtual meetings.

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 eligible for Article 23, 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 SME veterinary companies 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 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

Continue liaison with FDA Center for Veterinary Medicines for parallel scientific advice requests and continue dialogue in relation to modification of the procedure in order to 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 2018; to be updated in 2023.

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). It is envisaged to amend this document in 2023 due to changes brought about by the Regulation EU) 2019/6, as well as if there are any changes in the parallel scientific advice procedure resulting from the discussions with the FDA counterparts.

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

- Timings of procedures for 2024 (for SAWP-V members)
- Deadlines for submission of SA requests in 2024 (for applicants)
- Timings of procedures for 2025 (for SAWP-V members)
- Deadlines for submission of SA requests in 2025 (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.