10 December 2020
EMA/CVMP/SAWP/564965/2020
Committee for Medicinal Products for Veterinary Use (CVMP)

Work plan for the Committee for Medicinal Products for Veterinary Use (CVMP) Scientific Advice Working Party (SAWP-V) for 2021

Chairpersons	**Status**
Chair: F. Hasslung Wikström Vice-chair: S. Louet	Adopted by CVMP in December 2020

The activities outlined in the work plan for 2021 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 2021

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

If remote:	**If face-to-face:**
18 January 2021	19 January 2021
15 February 2021	16 February 2021
15 March 2021	16 March 2021
12 April 2021	13 April 2021
7 May 2021	10 May 2021
14 June 2021	15 June 2021
12 July 2021	13 July 2021
6 September 2021	7 September 2021
4 October 2021	5 October 2021

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29 October 2021	3 November 2021
6 December 2021	7 December 2021

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).

12 January 2021
9 February 2021
9 March 2021
6 April 2021
4 May 2021
8 June 2021
6 July 2021
31 August 2021
28 September 2021
26 October 2021
30 November 2021

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. It is also responsible for the provision of advice within the agreed framework for free scientific advice under the MUMS/limited market policy (EMA/308411/2014).

SAWP-V will be involved in the provision of scientific advice regarding dossier requirements for applications classified as MUMS/limited market by CVMP, in line with the adopted CVMP guidelines on dossier requirements for quality, safety, efficacy and immunologicals for MUMS products.

SAWP-V will 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 the expected number per year of contributions (number of involvements in dossier) for scientific advice and product assessment, including pre- and post-authorisation issues.

Expected contribution in Scientific Advice	Expected contribution in Product Assessment
25 (11 Standard, 6 MUMS, 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.

Preparation for potential requests for scientific advice for variations qualifying for application of Article 40(5) of Regulation (EU) 2019/6. To be finalised by January 2022.

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.

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) – updated in 2018.

Revised Guidance for Applicants has been published on the web page of veterinary scientific advice (https://www.ema.europa.eu/en/veterinary-regulatory/research-development/scientific-advice) in October 2020. This document underwent consultation following the update related to the incorporation of the PRP assessment procedure within the SA procedure and was adopted by CVMP in 2019. Also, appropriate changes have been made in 2020 due to the transition to IRIS, a secure online platform for handling product-related scientific and regulatory procedures.

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

- Timings of procedures for 2021 (for SAWP-V members)

- Deadlines for submission of SA requests in 2021 (for applicants)

- Timings of procedures for 2022 (for SAWP-V members)

- Deadlines for submission of SA requests in 2022 (for applicants)

- Revised *Mandate, objectives and rules of procedure for the CVMP Scientific Advice Working Party* document will be released for internal consultation within the CVMP after the update related to the incorporation of the PRP assessment procedure within the SA procedure.

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.