13 December 2024
EMA/CVMP/ESUAVET/339175/2024
Committee for Veterinary Medicinal Products (CVMP)

2025 Work plan for the European Sales and Use of Antimicrobials in veterinary medicine Working Group (ESUAvet WG)

Co-chairpersons:	**Status of the workplan**
EMA co-chair: Cristina Ribeiro-Silva, EMA CVMP co-chair: Sara Sacristán, AEMPS	Adopted by CVMP in December 2024

1. Meetings scheduled for 2025

Plenary meetings 2025

- 6 + 7 February 2025, mornings (virtual meeting)
- 6 +7 May 2025, mornings (virtual meeting)
- 4 + 5 September 2025, mornings (virtual meeting)
- 13 (pm) + 14 (am) November 2024 (in-person meeting)

Other meetings

- A minimum of 3-4 meetings of each ESUAvet WG sub-group per task, virtual, 6-12 participants.
- 1 stakeholder (virtual) meeting in Q3-4 2025 to introduce the ESUAvet report on 2023 data and the changes compared to the ESVAC reports.

2. Priority areas for advice

The ESUAvet WG was established in June 2023 to provide strategic guidance and recommendations to the Agency and the CVMP on matters related to Article 57 of Regulation (EU) 2019/6. This includes advice on collection and analysis of data, liaison with the relevant national bodies involved in these activities and supporting the Agency to meet its obligations with regards to the surveillance and monitoring of antimicrobial sales and use in the EU.

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The ESUAvet WG's remit includes the following tasks:

- Provision of scientific advice to CVMP, in support of activities under Article 57 of Regulation (EU) 2019/6.
- Strategic and operational advice to the Agency on technical matters related to the collection, reporting and analysis of data on volumes of sales and on use of antimicrobials in animals, and the development and maintenance of relevant IT systems.
- Contribute to identifying Member States' needs for support from the Agency in terms of scientific, technical assistance, training and best practice sharing activities and foster technical and scientific collaboration within and between Member States.

The work of the ESUAvet WG will be progressed through sub-groups where the required expertise is available amongst the WG membership.

2.1. Advice on data analysis and reporting

2.1.1. Agency reports on sales of veterinary antimicrobials and on use of antimicrobials in animals

Action: Draft the reports on the 2023 data for publication by March 2025 and on the 2024 data for publication by December 2025

Expected output:

- two reports

Expected delivery timelines:

2023 data report

- ESUAvet WG sub-group work started in 2024
- adoption by the ESUAvet WG by January 2025
- CVMP adoption by March 2025

2024 data report

- ESUAvet WG sub-group work to start after receipt of data in Q2 2025
- first draft for discussion by the ESUAvet WG by Q3 2025
- CVMP adoption by December 2025

Comments: The work supports the deliverables of Member States and EMA on antimicrobial sales and use reporting.

Priority 1

2.1.2. Content for the future public ASU interactive database that will replace the current public ESVAC interactive database (carry-over from the 2023/2024 workplan)

Action: Agree on content for the future public ASU interactive database that will replace the current public ESVAC interactive database.

The work, building on the action 2.1.1, should consider

- the elements to be delivered in the annual reports and whether they should be replicated in the interactive data base,
- additional analyses only to be displayed in the public interactive data base, if needed, including country-specific analyses and reports
- consideration of the need to transfer the ESVAC interactive database content into the public ASU interactive database.

Expected output:

- Mock-up for the proposed content of the public ASU interactive database

Expected delivery timeline:

- ESUAvet WG subgroup to start on this task in Q1 2025
- first draft for discussion by the ESUAvet WG by Q3 2025
- CVMP adoption by end 2025

Comments: The work contributes to the mandate of EMA and Member States under Article 57 of Regulation 2019/6, and will benefit policy-makers, research scientists and the general public by optimising availability of data.

Priority 2

2.1.3. Reporting by DDDvet and DCDvet (continued from the 2023/2024 workplan)

Action: Review the current methodology for the calculation of DDDvet and DCDvet values.

- To determine whether a revision of the methodology is necessary (to be concluded in 2024).
- If yes, proceed to develop a concept paper to updating the established methodology
- After CVMP approval and public consultation update the methodology accordingly.

Expected output:

- If a need for review is identified, develop a concept paper to review the 'Principles on assignment of defined daily dose for animals (DDDvet) and defined course dose for animals (DCDvet)' (EMA/710019/2014)' document.
- Update the 'Principles on assignment of defined daily dose for animals (DDDvet) and defined course dose for animals (DCDvet)' (EMA/710019/2014)' in line with the concept paper and comments received during the consultation on the concept paper.

Expected delivery timeline:

- Q4 2025

Comments: The work contributes to the mandate of EMA and Member States under Article 57 of Regulation 2019/6, and will be of interest to research scientists, veterinarians and the general public.

Priority 2

2.1.4. Consideration of refinement of the use data denominators (if feasible in 2025)

Action: Consider the advice given in the EMA Guideline on reporting antimicrobial sales and use data at the EU level: denominators and indicators.

- to determine whether a revision of the methodology for determining the denominator is desirable for animal species or categories living less than one year.

Expected output:

- If a need for refinement is identified, develop a concept paper to review the 'Guideline on reporting antimicrobial sales and use data at the EU level: denominators and indicators' (EMA/CVMP/882931/2022)'.
- Update the Guideline on reporting antimicrobial sales and use data at the EU level: denominators and indicators' (EMA/CVMP/882931/2022)' in line with the concept paper and any comments received.

Expected delivery timeline:

- Start: Q4 2025, if possible; otherwise 2026

Comments:	The work contributes to the mandate of EMA under Article 57 of Regulation 2019/6.
Priority	2

3. ESUAvet WG sub-groups

3.1. 'Data analysis and reporting' sub-group

Scope:	This group will advise on matters related to data analysis and reporting
Composition and expertise:	The group consists of a minimum of six up to twelve experts from Member States and the Agency with a background in the analysis and presentations of data on sales of veterinary antimicrobials and on use of antimicrobials in animals. This subgroup is expected to be a permanent subgroup that will guide the writing of the EMA annual reports. Participation will be renewable.
Estimated workload:	4-6 virtual meetings of 2-hour duration for each task, potentially more Additional time for drafting of the text for appointed coordinator of the task

3.1.1. Coordinator(s)

One or two ESUAvet members or alternates will be nominated as coordinators for this sub-group.

3.1.2. Tasks

- Develop the Agency reports on sales data for veterinary antimicrobials and on use data for antimicrobials used in animals within the terms described under 2.1.1.
- Develop the content of the future public ASU interactive database that provides public access to aggregated data on sales of veterinary antimicrobials and on use of antimicrobials in animals within the terms described under 2.1.2.
- Consider the advice given in the EMA Guideline on reporting antimicrobial sales and use data at the EU level: denominators and indicators within the terms described under 2.1.4.

3.2. 'DDDvet/DCDvet methodology' sub-group

Scope:	This sub-group will advise on the revision of the methodology for designating DDDvet and DCDvet values, established by the ESVAC project.
Composition and expertise:	The group consists of a minimum of six up to twelve experts from Member States and the Agency with hands on experience in the analysis of use data and on the collection, management and reporting of ASU-data, and experts from the AWP with experience in PK/PD.
Estimated workload:	6-8 virtual meetings of 2-hour duration per task, more if needed Additional time for drafting of the text for appointed coordinator of the task

3.2.1. Coordinator(s)

One or two ESUAvet members or alternates will be nominated as coordinators for this sub-group.

3.2.2. Tasks

- If not concluded in 2024, to finalise the development of a concept paper to review the 'Principles on assignment of defined daily dose for animals (DDDvet) and defined course dose for animals (DCDvet)' (EMA/710019/2014)' document and the evaluation of comments received during the public consultation.
- To update the 'Principles on assignment of defined daily dose for animals (DDDvet) and defined course dose for animals (DCDvet)' (EMA/710019/2014)' in line with the Concept Paper and the comments received, if necessary.

4. Activities with external parties

4.1. Meeting with interested parties

Stakeholder meeting in Q3-4 2025 to introduce the first annual report on antimicrobial sales and use data

4.2. Regulatory authorities outside the EU

Swiss Medic of Switzerland and the Veterinary Medicines Directorate of the United Kingdom who both collaborated in the EVAC project as well as the FDA of the United States of America and Health Canada/Public Health Agency of Canada and representatives of the World Organisation for Animal Health (WOAH) shall be invited to the Stakeholder meeting.