7 November 2024
EMA/CVMP/456565/2024
Committee for Veterinary Medicinal Products (CVMP)

Committee for Veterinary Medicinal Products (CVMP) Work Plan 2025

Chairpersons	Status
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Table of contents

Introduction

The Committee for Veterinary Medicinal Products (CVMP) is responsible for preparing the European Medicines Agency (EMA) opinions on all questions concerning veterinary medicines, in accordance with Regulation (EC) No 726/2004 and Regulation (EU) 2019/6 of the European Parliament and of the Council. This includes: evaluating applications for marketing authorisation of new veterinary medicines; supervising the quality, safety and efficacy of veterinary medicines following their introduction to the market; evaluating veterinary medicines authorised at national level that are referred to the EMA for a harmonised position across the EU; and recommending safe limits for residues of veterinary medicines used in food-producing animals. In addition to the various product assessment-related activities, the CVMP together with a number of expert working groups supports veterinary medicinal product development through the provision of scientific advice to companies researching and developing new veterinary medicines and by generating technical guidance for the pharmaceutical industry.

This workplan is not intended to provide an exhaustive list of all activities of CVMP but is intended to highlight those specific areas which will be the subject of particular focus during 2025, taking into account:

- The consolidated 3-year Work Plan of the Veterinary Domain for 2025-2027
- The recommendations of the EMA Regulatory Science to 2025 and the strategic goals for veterinary medicines;
- The European Medicines Agencies Network strategy to 2025.
- Any further work regarding the implementation of Regulation (EU) 2019/6 of the European Parliament and of the Council on veterinary medicinal products.

The CVMP and its Working Parties will focus on the main activities related to the authorisation of veterinary medicines and the establishment of MRLs, providing guidance for industry, and on activities around antimicrobial resistance.

The Agency's work programme provides workload forecasts for the various procedures managed by the Agency for centralised marketing authorisations for veterinary medicinal products, maximum residue limits and referrals, which are the core activities of the CVMP. For these activities, the CVMP is committed to strengthening the quality of the scientific review process, and to ensuring consistency of CVMP assessment reports and other scientific outputs. The CVMP will continue to review assessment procedures with a view to identifying opportunities for process improvement, whilst maintaining the quality and scientific robustness of assessments.

1. Evaluation activities for veterinary medicines

1.1. Support for product development

1.1.1. Emerging therapies and technologies

One of the EMA's strategic goals is to promote development of innovative veterinary medicines and new technologies. In addition, stimulating innovation and promoting new product development is one of the main objectives of Regulation (EU) 2019/6.

When reviewing and updating the technical annex to the Regulation (Commission Delegated Regulation (EU) 2021/805), the CVMP proposed new technical requirements for biological veterinary medicinal products (VMPs) other than immunologicals and for novel therapy VMPs, with the aim of providing predictability for the development of new products and thus promoting innovation. The newly established Novel Therapies and Technologies Working Party (NTWP) and its Operational Expert Groups (OEGs) are committed to foster innovation by facilitating authorisation of non-immunological biologicals and novel therapy VMPs.

Reflecting the limited experience and the large range of novel therapy VMPs, as well as the uncertainty regarding types of products that may be developed in the future, the requirements for novel therapy products are presented in the Commission Delegated Regulation (EU) 2021/805 mostly in a general manner allowing flexibility on a case-by-case basis. Additional guidance on specific topics will support applicants and the efficient evaluation for timely marketing authorisation of novel veterinary treatments. Intensified horizon scanning activities will provide a better overview on emerging needs for targeted and efficient regulatory support.

CVMP topic lead: J. Poot, S. Casado

Key objective

- Promote innovation and use of new approaches in the development of novel veterinary medicines.

Activities

Specific activity	Responsible group[1]	Prio[2]	Start date	Cons.[3]	Completion date
Contribute to VICH[4] guidance on target animal safety evaluation for veterinary monoclonal antibody products	NTWP	2	Ongoing	No	December 2025 (to be determined)
Develop guidance on safety data requirements for products issued from nanotechnologies	NTWP (SWP-V, IWP, QWP, ERAWP)	1	November 2022	Yes	Q1 2026
In collaboration with Quality Innovation Group (QIG) advance key areas for technical developments including novel manufacturing approaches and advanced manufacturing technologies	NTWP	2	January 2024	No	Ongoing
Consider the need for and produce further quality, safety and efficacy guidance to complement Annex II to Regulation (EU) 2019/6 that defines technical standards for novel therapy veterinary medicinal products	NTWP	2	Q1 2025	No	Beyond 2025
With a view to determining where there is a need for future guidance, and to foster expertise in the network, analyse future applications and its associated innovative technologies with input from the veterinary pharmaceutical industry	NTWP	2	Q1 2025	No	Beyond 2025
Explore how post-authorisation evidence generation (including real-world data) may be used to supplement pre-authorisation data in support of an ongoing benefit risk	NTWP	3	Q1 2024	Yes	Q4 2025

[1] Group to support the CVMP in delivering on the specific activity.
[2] Prio = priority. Activities are prioritised (1 – high; 2 – medium; 3 – low) taking account of the date for completion, the extent of work required and criticality of activity (for example, issues not considered essential and/or for which existing guidance can be applied (temporarily) have been given lower priority taking into account the scale of the overall work required).
[3] Cons. = stakeholder consultation required? (yes or no)
[4] VICH: International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products.

Specific activity	Responsible group[1]	Prio[2]	Start date	Cons.[3]	Completion date
assessment for novel therapies – develop guidance as necessary					
Prepare guidance on post-authorisation measures to monitor the safety and/or efficacy of specific novel therapy products according to the requirement in section V.1.1.6 of Annex II of Regulation (EU) 2019/6	NTWP/PhVWP-V	1	Q1 2025	No	Q4 2025

1.1.2. Limited markets

In order to promote the availability of VMPs within the Union for minor species or for the treatment or prevention of diseases that occur infrequently or in limited geographical areas, recital 30 of Regulation (EU) 2019/6 acknowledges that, in some cases, it should be possible to grant marketing authorisations without a complete application dossier (*reduced safety and efficacy dataset)* having been submitted, on the basis of a benefit-risk assessment of the situation and, where necessary, subject to specific obligations. The EMA/CVMP will consider how the 'limited markets' (LM) provision in the Regulation can best be implemented to increase availability of VMPs.

CVMP topic lead: F. Hasslung Wikström

Key objective

- Provide support and guidance to develop new medicines for limited markets.

Activities

Specific activity	Responsible group	Prio	Start date	Cons.	Completion date
Considerations on the revision of the Reflection Paper on limited markets[5]	EMA/CVMP	2	Ongoing	No	Q2 2025

1.1.3. Scientific advice and support to product innovation

In order to facilitate the development of new veterinary medicines, the Scientific Advice Working Party (SAWP-V) of the CVMP provides scientific advice (SA) to applicants on aspects relating to quality, safety or efficacy of these products, on the establishment of maximum residue limits (MRLs), including requests for status of substances as not falling within the scope of Regulation No 470/2009, or on bioequivalence of generic VMPs, as well as preliminary risk profile assessments of new antimicrobial substances for veterinary use or new antimicrobial veterinary medicinal products. The SAWP-V, the Scientific Advice Working Party of the CHMP and the Agency's 'Innovation Task Force' (ITF) also provide specific SA (SAWP-V/SAWP) and informal advice (ITF) on 3Rs-compliant test methods (e.g. 'New Approach Methodologies' [NAMs]) to foster the uptake of alternatives to experiments on animals in the testing of medicines.

CVMP topic lead: F. Hasslung Wikström

Key objective

- Provide support for the development of new medicines.

[5] Reflection paper on classification of a product as intended for a limited market according to Article 4(29) and/or eligibility for authorisation according to Article 23 (Applications for limited markets)

Activities

Specific activity	Responsible group	Prio	Start date	Cons.	Completion date
Continue ongoing core business of providing scientific advice	SAWP-V	1	Ongoing	No	Ongoing
Continue ongoing activity of providing early advice via ITF briefing meetings	ITF	1	Ongoing	No	Ongoing

1.2. Authorisation activities

The CVMP is responsible for preparing the Agency's opinions on all questions concerning veterinary medicines, including evaluation of applications for marketing authorisation of new veterinary medicines. A critical element of the evaluation process is a robust and consistent approach to benefit/risk assessment.

CVMP topic lead: G. J. Schefferlie/F. Hasslung Wikström

Key objectives

- Efficient procedures to support the authorisation of safe and effective veterinary medicines of good quality;
- Ensure a consistent approach to benefit/risk assessment and taking decisions on classification.

Activities

Specific activity	Responsible group	Prio	Start date	Cons.	Completion date
Reflection paper on the application of Article 40(5) of Regulation (EU) 2019/6 for certain categories of variations	Dedicated group	2	Ongoing	Done	Q1 2025
Concept paper for the development for guidance on demonstration of biosimilarity of VMPs	New CVMP Drafting Group	2	Q1 2025	Yes	Q3 2025

1.3. Post-authorisation activities

1.3.1. Pharmacovigilance

Pharmacovigilance is the science and activities relating to the detection, assessment, understanding and prevention of adverse events following use of VMPs, or any other problem related to a medicinal product. It aims to ensure that post-authorisation safety monitoring and effective risk management are continuously applied to VMPs throughout the EU.

Regulation (EU) 2019/6 includes several provisions aimed at improving the operation of the pharmacovigilance system. Chief amongst those is the move towards the 'signal management process' (consists of tasks of signal detection, validation, confirmation, analysis and prioritisation, assessment and recommendation for action) as the 'gold standard' for post-authorisation safety monitoring and the continuous evaluation of the benefit-risk balance. In addition, the Regulation requires that a pharmacovigilance database is established to record and integrate information of suspected adverse events for all VMPs authorised in the Union, noting that this database should facilitate pharmacovigilance surveillance, improve the detection of product-related adverse events, allow for effective work-sharing and communication between the competent authorities, and ensure that information on the safety of authorised VMPs is available to the general public.

CVMP topic leads: J. Mount

Key objectives

- Maintain efficient and effective conduct of pharmacovigilance, including surveillance and signal management, whilst implementing the new system by providing the necessary guidance, systems, and refining processes;
- Collaborate with stakeholders to further develop and advance veterinary pharmacovigilance;
- Improve communication of new safety-related information arising from pharmacovigilance for VMPs and provide regular updates on emerging and topical issues.

Activities

Specific activity	Responsible group	Prio	Start date	Cons.	Completion date
Implement efficient and effective methodology and procedures for post-authorisation surveillance taking into account the outcome and recommendations from the pilot signal management expert group (P-SMEG) initiative concluding in 2024	PhVWP/ Dedicated Expert group in consultation with EMA, CVMP, and CMDv/HMA	1	Q1 2025	No	Q4 2025
Prepare guidance on post-authorisation measures to monitor the safety and/or efficacy of specific novel therapy products according to the requirement in section V.1.1.6 of Annex II of Regulation (EU) 2019/6	NTWP/PhVWP -V	1	Q1 2025	No	Q4 2025
Provide further guidance for industry, such as on signal submissions, as necessary	PhVWP	1	Q3 2024	Yes	Q4 2025
Improve communication of veterinary pharmacovigilance to veterinarians and other healthcare professionals and the general public	PhVWP/EMA	2	Ongoing	No	Ongoing
Collaborate with stakeholders to further develop and advance veterinary pharmacovigilance	PhVWP	2	Q1 2025	No	Ongoing

1.4. Specialised areas

1.4.1. Quality non-biologicals

The CVMP scientific guidelines on the quality of veterinary medicines help applicants prepare marketing authorisation applications. Guidelines reflect a harmonised approach of the EU Member States and the Agency on how to interpret and apply the requirements for the demonstration of quality set out in the Union legislation.

CVMP topic lead: M. O'Grady/M. H. Sabinotto

Key objective

- Review and revise existing guidelines

Activities

Specific activity	Responsible group	Prio	Start date	Cons.	Completion date
Revise the guideline on quality aspects of pharmaceutical veterinary medicines for administration via drinking water – concept paper for public consultation	QWP	2	2024	Yes	Q3 2025
Update of existing guidelines and Q&As to implement revisions required arising from changes to the variations requirements and Annex II in Regulation (EU) 2019/6	QWP	2	Ongoing	No	Q4 2025
Finalise the revision the reflection paper on risk management requirements for elemental impurities in veterinary medicinal products to convert into a guideline and to include IVMPs within its scope	QWP/IWP/NTWP	2	March 2022	Yes	Q2 2025
Question and answer on co-processed excipients	QWP/GMDP IWG	3	Ongoing	Yes	Q1 2025
Finalise the guideline on synthetic peptides	QWP	3	March 2022	Yes	Q4 2025
Development of the guideline on synthetic oligonucleotides – publication of final guideline	QWP	3	2024	Yes	Q2 2026
Contribute to ongoing revision of VICH GL8 on stability testing of medicated premixes	QWP	2	Ongoing	Yes	Beyond 2025
Contribute to the development of VICH GL on between strength biowaiver	QWP/EWP	2	Ongoing	Yes	Beyond 2025
Contribute to the development of VICH GL60 on GMP for APIs	QWP/GMDP IWG	2	Ongoing	Yes	Beyond 2025
Contribute to the development of VICH GL61 (guideline parallel to ICH Q8)	QWP	2	Ongoing	Yes	Beyond 2025
Consider the ongoing work of the EMA on the risk of nitrosamine formation or presence during the manufacture of human medicines and the implications of this activity for the quality/safety evaluation of VMPs	Dedicated quality/safety Expert group	2	Q1 2022	No	2025
Follow up activities on replacement of TiO2	QWP	2	Ongoing	No	2025
Revision of CHMP/CVMP Annex 1 to ICH/VICH GLs on residual solvents – concept paper for public consultation	QWP	3	2024	Yes	Q3 2025

1.4.2. User Safety

The CVMP scientific guidelines on the user safety of veterinary medicines help applicants prepare marketing authorisation applications. Guidelines reflect a harmonised approach of the EU Member States and the Agency on how to interpret and apply the requirements for the demonstration of user safety set out in the Union legislation.

CVMP topic leads: C. Bergman

Key objective

- Ensure the safe use of veterinary medicines in regard to their potential impact on users.

Activities

Specific activity	Responsible group	Prio	Start date	Cons.	Completion date
Revision of the CVMP Guideline on user safety of topically administered veterinary medicinal products	SWP-V	2	Ongoing	Yes	2025
Revision of the CVMP Guideline on user safety for pharmaceutical veterinary medicinal products	SWP-V	2	Q42024	Yes	2026

1.4.3. Environmental risk assessment (ERA)

Regulation (EU) 2019/6 includes several provisions with the specific objective of ensuring the highest level of environmental protection. In addition, the EC 'Strategic Approach to Pharmaceuticals in the Environment[6]' outlines a set of actions addressing the multifaceted challenges that the release of pharmaceuticals poses to the environment.

CVMP topic leader: R. Carapeto Garcia

Key objective

- To ensure that potential risks to the environment associated with the use of VMPs are evaluated and that the environmental risk assessment methodology is updated in accordance with international best practice.

Activities

Specific activity	Responsible group	Prio	Start date	Cons.	Completion date
Development of a guideline on the environmental risk assessment of veterinary medicinal products intended for use in aquaculture	ERAWP	2	Ongoing	Yes	Q2 2026
Review of the "Reflection paper on risk mitigation measures related to the environmental risk assessment of veterinary medicinal products" (EMA/CVMP/ERAWP/409328/2010)	ERAWP	2	Ongoing	Yes	Q2 2025
Development of a concept paper for the development of a reflection paper on the assessment on public health risks related to antimicrobial resistance acquired via the environment, resulting from the use of a VMP	ERAWP/AWP	2	Q1 2023	Yes	Q1 2025
Development of a reflection paper on the assessment on public health risks related to antimicrobial resistance acquired via the environment, resulting from the use of a VMP	ERAWP/AWP	2	Q3 2025	Yes	Q4 2026
Development of a concept paper for the development of a guideline on the methodology of environmental risk assessment for ectoparasiticidal VMPs for cats and dogs	ERAWP	2	Q1 2024	Yes	Q1 2025
Development of a guideline on the methodology of environmental risk	ERAWP	2	Q3 2025	Yes	Q4 2027

[6] https://ec.europa.eu/environment/water/water-dangersub/pdf/strategic_approach_pharmaceuticals_env.PDF

Specific activity	Responsible group	Prio	Start date	Cons.	Completion date
assessment for ectoparasiticidal VMPs for cats and dogs					
Consider the need for revision of the Reflection Paper on article 18(7) of Regulation 2019/6	Dedicated group	3	Q1 2025	Yes	Q4 2025

1.4.4. Maximum Residue Limits (MRLs) and consumer safety

Safeguarding human health by establishing MRLs of veterinary medicines for food-producing animals continues to be a key task. While the consumer safety evaluation of conventional pharmaceutics is well established and the methodology currently used by the EMA/CVMP is considered adequate to ensure consumer safety, alternative methodologies or approaches are used by other EU/International agencies and, consequently, it is appropriate to consider the need to harmonise approaches. Further, when reviewing and updating the technical annex to the Regulation (Commission Delegated Regulation (EU) 2021/805), the CVMP proposed new technical requirements for biological VMPs other than immunologicals and for novel therapy VMPs. According to Commission Regulation (EU) 2018/782, evaluations of "chemical-unlike" biologicals shall be conducted on a case-by-case basis. The respective procedures have not yet been developed.

CVMP topic leads: C. Bergman

Key objective

- Ensure that the establishment of MRLs support the safe use of veterinary medicines in regard to their potential impact on consumer health.

Activities

Specific activity	Responsible group	Prio	Start date	Cons.	Completion date
Revise procedural and technical guidance on MRL evaluation for chemical-unlike biologicals, as needed by update of Regulation (EU) 2018/782	EMA, SWP-V, NTWP	1	tbd	Yes	tbd
Provide scientific advice to the European Commission to confirm that the substances currently on the list of chemical-unlike biological substances not requiring an MRL evaluation do not pose any risk to public health and that their inclusion in Table 1 of the Annex to Regulation (EU) No 37/2010 with a 'no MRL required' classification is appropriate	CVMP	1	Q4 2024	No	Q1 2025
Together with EFSA, develop a tool for the calculation of exposure of consumers to residues of veterinary medicines in food of animal origin	SWP-V	1	Q42024	Yes	November 2026
Contribute to ongoing revision of VICH safety guidance: GL 22, GL 23 and GL 49.	SWP-V	1	Ongoing	Yes	Beyond 2025
Concept paper for the development of a guideline on consumer safety of active substances of IVMPs acting against endogenous targets	SWP-V, IWP, NTWP	2	Ongoing	Yes	Q1 2025
Prepare EU position at Codex Alimentarius on issues related to safety of residues	SWP-V	1	Ongoing	No	Ongoing

1.4.5. Efficacy

The CVMP scientific guidelines on the efficacy of veterinary medicines help applicants prepare marketing authorisation applications. Guidelines reflect a harmonised approach of the EU Member States and the Agency on how to interpret and apply the requirements for the demonstration of efficacy set out in the Union legislation.

CVMP topic lead: C. Muñoz Madero

Key objectives

- Support the continued availability of effective antimicrobial and antiparasitic veterinary medicines;
- Review and revise existing guidelines.

Activities

Specific activity	Responsible group	Prio	Start date	Cons.	Completion date
Review the intramammary and antimicrobials efficacy guidelines and revise as appropriate	EWP (AWP)	2	Ongoing	No	Q1 2025
Contribute to the ongoing development of a new VICH guideline on fixed combination products	EWP	2	Ongoing	Yes	Beyond 2025
Revision of guideline on products controlling *Varroa destructor* parasitosis in bees	EWP	2	Q1 2025	Yes	Q2 2026
Revision of the guideline on anticancer products for dogs and cats	EWP/QWP/ SWP	3	Q1 2025	Yes	Q2 2026
Finalise revision of the guideline for the demonstration of efficacy for veterinary medicinal products containing anticoccidial substances	EWP	2	Ongoing	Yes	Q2 2025
Revision of the guideline on the conduct of bioequivalence studies for veterinary medicinal products	EWP/QWP	1	Q1 2025	Yes	Q2 2026
Provide guidance on what is considered a new indication within the context of Article 38(3) of Regulation (EU) 2019/6	EWP/IWP	1	Q1 2025	Yes	Q4 2025
Consider the need to develop guidance on using owner assessment as primary efficacy parameter in companion animals	EWP	2	Q1 2025	Yes	Q4 2025

2. Horizontal activities and other areas

2.1. Antimicrobial resistance (AMR)

2.1.1. AMR scientific guidance-related topics

The preamble to Regulation (EU) 2019/6 acknowledges that antimicrobial resistance to medicinal products both for human and veterinary use has become a global public health concern that affects the whole of society and requires urgent and coordinated inter-sectoral action in accordance with the 'One Health' approach. Accordingly, the Regulation includes provisions aimed at strengthening the prudent use of antimicrobials, avoiding their routine prophylactic use and limiting metaphylactic use, restricting the use in animals of antimicrobials that are of critical importance for preventing or treating life-

threatening infections in humans and encouraging and incentivising the development of new antimicrobials. It is also stated that the rules for the authorisation requirements of antimicrobial VMPs should sufficiently address the risks and benefits of these products and, in particular, an application for an antimicrobial VMP should contain information about the potential risk that use of that medicinal product may lead to the development of antimicrobial resistance in humans or animals or in organisms associated with them. The preamble to Regulation (EU) 2019/6 also recognises that, given the limited innovation in developing new antimicrobials, it is essential that the efficacy of existing antimicrobials be maintained for as long as possible. This requires that antimicrobial VMPs should be used responsibly and surveillance of antimicrobial sales and use according to a harmonised and defined methodology is a valuable tool for monitoring progress in antimicrobial stewardship.

CVMP seeks to balance the continued need for antimicrobials to treat infectious diseases in animals with the need to minimise the risk of antimicrobial resistance arising from the use of these classes of products in veterinary medicine.

CVMP topic lead: D. Bouchard

Key objectives

- Facilitate the prudent and responsible use of antimicrobials;
- Contribute to the minimisation of the risk to man and animals from AMR due to the use of antimicrobials in veterinary medicine.

Activities

Specific activity	Responsible group	Prio	Start date	Cons.	Completion date
Finalise the draft guideline on the risk assessment of antimicrobial VMPs following the public consultation	AWP	1	Ongoing	No	Q1 2025
Develop the CVMP Strategy on antimicrobials for 2026–2030	AWP/EMA	1	Q1 2025	Yes	Q4 2025
Article 36(2): Development of a guideline on post-authorisation studies for antimicrobial VMPs to ensure the benefit-risk remains positive given the potential development of antimicrobial resistance	AWP/EWP-V	2	Ongoing	Yes	Q4 2025
Development of a Reflection paper on the availability and characteristics of diagnostic tests to improve the responsible use of antimicrobials in animals	AWP	3	Ongoing	Yes	Q4 2025
Revise the AWP's reflection paper on the use of macrolides, lincosamides and streptogramins in animals in the European Union	AWP (ERAWP, SWP)	2	Ongoing	Yes	Q4 2025
Implement the CVMP's recommendations of the 'Reflection paper on dose review and adjustment of established veterinary antibiotics in the context of SPC harmonisation' (EMA/CVMP/849775/2017)	CVMP	2	Q2 2025	Yes	Beyond 2025
Develop a concept paper for the development of a guideline on the assessment of risk to public health from AMR due to antimicrobial use in companion animals	AWP	2	Q2 2025	Yes	Q4 2026

2.1.2. Antimicrobial sales and use data-related activities

The preamble of Regulation (EU) 2019/6 notes that there is still a lack of sufficiently detailed and comparable data at Union level to determine the trends and identify possible risk factors that could lead to the development of measures to limit the risk from antimicrobial resistance and to monitor the effect of measures already introduced. It is therefore important to continue the collection of such data and further develop it in line with a stepwise approach. These data, when available, should be analysed with data on the use of antimicrobials in humans and data on antimicrobial resistant organisms found in animals, humans and food. To ensure that the data collected can be used effectively, appropriate technical rules should be laid down concerning the collection and the exchange of data. The Member States should be responsible for collecting data on the sales and use of antimicrobials used in animals under the coordination of the Agency. It should be possible to make further adjustments to the obligations on data collection when the procedures in the Member States for the collection of data on sales and use of antimicrobials are sufficiently reliable.

CVMP collaborate with EMA for the technical implementation of relevant IT systems and on supporting Member States regarding the data quality of collected data on sales and use of antimicrobials in veterinary medicine by developing guidance to ensure appropriate quality, analysis and publication of data reported to EMA by Member States, as well as integrated analysis on the use of antimicrobials in humans and data on antimicrobial resistant organisms found in animals, humans and food.

CVMP topic lead: S. Sacristán

Key objectives

- Ensure appropriate analysis and reporting of data on sales and the use of antimicrobials in veterinary medicines, as well as integrated analysis with relevant data from humans and resistance in relevant zoonotic organisms transmitted via food together with relevant other Union agencies;
- Support Member States in data quality management related to the collection and reporting of data on sales and use of antimicrobials in veterinary medicine to EMA.

Activities

Specific activity	Responsible group	Prio	Start date	Cons.	Completion date
Annual report on 2023 antimicrobial sales and use data	ESUAvet WG	1	Q4 2024	No	30 Mar 2025
Annual report on 2024 antimicrobial sales and use data	ESUAvet WG	1	Q3 2025	No	31 Dec 2025
Content of the future public ASU interactive data base	ESUAvet WG	2	Q1 2025	No	End 2025
Article 57: Further consideration of reporting use data as the Defined Daily Doses for animals (DDDvet) or Defined Course Doses for animals (DCDvet) (EMA/224954/2016)	ESUAvet WG	2	Ongoing	Yes	Q4 2025 or early 2026
Consideration of refinement of use data denominators for certain animal species categories living less than 1 year	ESUAvet WG	2	Q4 2025	Yes	Q4 2026

2.2. Antiparasitic resistance

Antiparasitic veterinary medicines are widely used in both livestock and companion animals to treat or prevent parasitic diseases in animals; furthermore, a number of these parasites also have zoonotic potential, and some pose a major health concern in humans. Veterinary antiparasitic medicines are

extensively used, representing one of the largest financial markets for the animal health industry. With the wide (routine) use of antiparasitic substances, concern has been raised about an increase in the development of resistance in parasites. The frequent use of antiparasitics and the observed development of resistance have already resulted in the loss of efficacy of some substances in certain target animals in certain regions, giving rise to concerns about continued availability of effective antiparasitic medicines.

CVMP topic lead: C. Muñoz Madero

Key objective

- Promote the responsible use of antiparasitic veterinary medicines.

Activities

Specific activity	Responsible group	Prio	Start date	Cons.	Completion date
Revision of the guideline on demonstration of efficacy of ectoparasiticides	EWP	2	Ongoing	Yes	Q3 2025
Promote prudent and responsible use of antiparasitics in the EU. Develop infographic on LEE for antiparasitics	EWP/PhVWP	2	Ongoing	No	Q4 2025

2.3. Products that can assist in the reduction of use of antimicrobials ("alternatives to antimicrobials (ATAm)")

The European Union One Health Action Plan against AMR, published in 2017, presents a range of objectives aimed at tackling AMR, with the boosting of research, development and innovation being one of the key underlying pillars. The Action Plan highlights that, in addition to developing new antimicrobials, there is a need to support the development of alternative and novel therapeutic approaches for the treatment or prevention of infectious disease. The use of products that can assist in the reduction of use of antimicrobials ("ATAm") represents one way in which to reduce the use of antimicrobials, particularly antibiotics, in veterinary medicine. The CVMP has developed a reflection paper on promoting the authorisation of alternatives to antimicrobial veterinary medicinal products in the EU (EMA/CVMP/143258/2021) exploring ways by which to ensure that the EU is encouraging the authorisation of ATAm. In this reflection paper a number of recommendations are listed on the measures that could be taken to deliver the objective in the CVMP's Strategy on Antimicrobials related to ATAm.

CVMP topic lead: C. Muñoz Madero

Key objective

- Promote the authorisation of products that can assist in the reduction of use of antimicrobial veterinary medicinal products ("alternatives to antimicrobials")

Activities

Specific activity	Responsible group	Prio	Start date	Cons.	Completion date
Review/Analyse the recommendations of the respective reflection paper (EMA/CVMP/143258/2021) to support the development of products that can assist in the reduction of use of antimicrobial veterinary medicinal products in the EU	CVMP/EMA	2	January 2023	No	Through-out 2025

2.4. Vaccine and other immunologicals availability

Vaccination is one of the most effective tools for preventing animal diseases and for promoting animal health and welfare, safe food production and public health. In addition, veterinary vaccines can be an efficient tool in reducing the need to use antimicrobials in animals, thereby contributing to the fight against antimicrobial resistance. Despite their importance, there are often challenges to ensuring that suitable veterinary vaccines are available in a timely manner on the EU market.

The European Medicines Agencies Network strategy to 2025 identifies increasing the availability of veterinary medicines in general, and those that are needed to control incursions of emerging disease in particular, as a priority area for action by the European medicines regulatory network.

Increasing availability of veterinary medicines is also a key intent of Regulation (EU) 2019/6.

CVMP topic lead: E. Werner

Key objective

- Support the development and availability of veterinary vaccines.

Activities

Specific activity	Responsible group	Prio	Start date	Cons.	Completion date
Contribute to ongoing VICH activities relating to extraneous viruses, mycoplasma contamination (GL34) and replacement of in vivo by in vitro methods for batch potency testing	IWP	1	Ongoing	Yes	Beyond 2025
Continue the collaboration with EDQM on practical implementation of veterinary vaccine monographs and chapters	IWP	2	Ongoing	No	Ongoing
Revision of the Guideline on the requirements for combined vaccines and associations of immunological veterinary medicinal products (IVMPs) EMA/CVMP/IWP/594618/2010	IWP	2	Q1 2025	Yes	Q4 2026
Development of a guideline on quality aspects of mRNA vaccines for veterinary use	IWP	2	Q1 2025	Yes	Q4 2026

2.5. Availability of VMPs for food producing species - use of the cascade

Availability of veterinary medicines is limited in certain food producing species. Legal provisions to allow the use of veterinary medicines outside the marketing authorisations have been established. In addition, the European Commission shall establish lists of substances for equine species and for

aquatic species for which such uses are allowed. The CVMP will assist the European Commission by identifying relevant substances and by assessing them under the different legal provisions.

CVMP topic lead: K. Baptiste, D. Palic

Key objective: Provide scientific advice related to articles 115(5) and 114(3).

Activities

Specific activity	Responsible group	Prio	Start date	Cons.	Completion date
Article 114(3): Provide scientific advice to the European Commission on the list of substances which may be used in food-producing aquatic species in accordance with article 114(1)	CVMP	1	Ongoing	No	Q2 2025

2.6. Application of 3Rs in the regulatory testing of medicinal products

The use of animals in scientific research, including regulatory testing, has been a matter of debate for decades, primarily revolving around ethical and animal welfare considerations. Current animal welfare legislation (Directive 2010/63/EU), which fully applies to the regulatory testing of HMPs and VMPs, unambiguously requires the application of so-called 3Rs principles when considering the choice of test methods to be used, i.e. the Replacement, Reduction and Refinement of animal experiments.

The European Medicines Agency 'Regulatory Science to 2025' strategy clearly identifies the development as well as the use, where possible and appropriate, of 3Rs-compliant methods as a strategic goal both for the human and veterinary medicines regulatory network.

CVMP topic lead: C. Bergman

Key objective:

- Support and promote the development and application of 3Rs-compliant methods in the regulatory testing of human and veterinary medicinal products.

In order to achieve the above-mentioned objective(s), EMA has instated the Joint CHMP/CVMP Working Party on the Application of the 3Rs in Regulatory Testing of Medicinal Products (3RsWP) under the governance of the Agency's Non-Clinical Domain. Any planned activities of the 3RsWP can be found in the consolidated 3-year work plan of the Non-Clinical Domain.

Activities

Specific activity	Responsible group	Prio	Start date	Cons.	Completion date
Application of section I.1.7. of Annex II to Regulation (EU) 2019/6	Dedicated working group from: CVMP/ CMDv/3RsWP	2	Ongoing	Yes	Q4 2025
Contribution to the revision of various CVMP guidelines (e.g. on user safety) to include references to relevant 3Rs approaches	3RsWP	3	Ongoing	No	According to timelines for relevant individual guidance documents

2.7. Reinforce the scientific and regulatory capacity and capability of the network

The European medicines agencies network strategy to 2025 acknowledges the advances in science and technology that expand the possibilities for development of medicines and their use, increasing the demands on regulatory advice and assessment. In addition to having the capacity to deal with these increasing demands, it is recognised that there is a need to continue to strengthen the quality of the scientific review process and outputs and to acquire the necessary skills/competencies to support the development of, and appropriately regulate, novel products/technological innovations. An important tool in building regulatory capacity and capability is the provision of training. Much of the training in the Network is facilitated by the 'EU Network Training Centre' (EU NTC), a joint HMA and EMA initiative with the mission to ensure the exchange of good scientific and regulatory practices across the EU regulatory network, by harmonising training standards and offering high quality and relevant training opportunities.

CVMP topic lead: G.J. Schefferlie

Key objectives

- Strengthen the quality of the scientific review process by developing available expertise;
- Ensure optimal organisation of the available expertise within the network for services provided to EMA.

Activities

Specific activity	Responsible group	Prio	Start date	Cons.	Completion date
In collaboration with EU network training centre, contribute to the training of assessors on regulatory scientific topics and guidelines for the network	Veterinary Domain	1	Ongoing	No	All 2025
Implement the recommendations of the EMA Management Board Task Force on Working Parties with a focus on: - Establishment of ESECs - Stakeholder engagement	Veterinary Domain	2	Ongoing	N/A	All 2025
Work to increase capability in modelling, simulation and extrapolation within the European Regulatory Network. The WP will identify the most relevant models potentially used in their areas of dossier assessment and identify if the network could benefit from further trainings in using models, for example, by seeking out and developing relevant training materials.	AWP, SWP-V and ERAWP	2	Ongoing	N/A	All 2025

2.8. International cooperation and harmonisation of requirements for authorisation

Authorisation of veterinary medicines takes place within a global context and CVMP seeks to harmonise the requirements for authorisation at an international level, wherever possible.

CVMP topic lead: G.J. Schefferlie

Key objective

- Promote uptake of harmonised standards at international level.

Activities

Specific activity	Responsible group	Prio	Start date	Cons.	Completion date
Contribute to development of VICH guidelines	Relevant working party	1/2	Ongoing	No	All 2025
Engage with EDQM to discuss issues of mutual interest with regard to the quality of VMPs	IWP/QWP	2	Ongoing	No	All 2025
Continue cooperation with EC, EU Agencies, other international agencies/organisations to discuss issues of mutual interest in particular but not limited to environmental risk assessment	EMA	2	Ongoing	No	All 2025

2.9. Stakeholder engagement

Stakeholder engagement is important for transparency and for maintaining effective regulatory procedures and guidance, appropriately adapted to the specific needs in the veterinary field.

CVMP topic lead: G.J. Schefferlie

Key objective

- Promote stakeholder engagement.

Activities

Specific activity	Responsible group	Prio	Start date	Cons.	Completion date
Organisation of a Veterinary Medicines Innovation Day	EMA	1	Q1 2025	No	13-14 March 2025
Organisation of a CVMP Interested Parties Meeting	EMA	1	Q2 2025	No	14 May 2025