4 December 2025
EMA/CVMP/210842/2025
Veterinary Medicines Division

CVMP work plan 2026

adopted by the committee on 4 December 2025

Table of contents

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

1. Evaluation activities for veterinary medicines

1.1. Pre-authorisation activities

1.1.1. Support for product development

In line with the European medicines agencies network strategy to 2028 (link), the consolidated 3-year Work Plan of the Veterinary Domain for 2025-2027 and the EMA Final programming document 2024-2026 (link), one of the CVMP's strategic goals is to promote development of innovative veterinary medicinal products (VMPs) and new technologies. Stimulating innovation and promoting new product development is one of the main objectives of Regulation (EU) 2019/6, which gives the legal basis for these CVMP activities. In order to facilitate the development of new VMPs, the Scientific Advice Working Party (SAWP-V) of the CVMP provides scientific advice to applicants on request, 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 antimicrobials.

Key objectives

- Promote innovation and use of new approaches in the development of VMPs.

Activities in 2026

- Set up specific Operational Expert Groups of Working Parties to provide guidance on new technologies.
- Set up a European Specialised Expert Community on new technologies.
- Provide scientific advice and contribute to Innovation Task Force meetings.
- Support applicants in obtaining classification of VMPs e.g. biological or immunological.
- Continue promotion of availability of veterinary medicinal products, especially of vaccines, by e.g. implementation of approaches and facilitating applications under exceptional circumstances, vaccine antigen master files, vaccine platform technology master files and multi-strain dossiers.
- Develop guidance for veterinary biosimilar medicinal products. For this task the CVMP has established a temporary Drafting Group (tDG) to deal with the procedural aspects and the development of relevant guidelines.
- In collaboration with Quality Innovation Group (QIG) advance key areas for technical developments including novel/advanced manufacturing approaches.

EMA topic leader: Noemi Garcia; CVMP topic leader: Jacqueline Poot

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, Article 23 of Regulation (EU) 2019/6 acknowledges that, in some cases, it should be possible to grant marketing authorisations based on a customised 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 post-authorisation

measures. The EMA/CVMP will support the availability of VMPs for limited markets, by applying Article 23 of Regulation (EU) 2019/6 as further clarified in the Guidance to Applicants[1].

Key objectives

- Provide support and guidance to develop new medicines for limited markets.
- Support developers of vaccines (and other VMPs) to translate research and development activities into marketing authorisations.

Activities in 2026

- Provide a Q&A on eligibility criteria for limited markets for stakeholders.
- Improve working practice and streamline working practices for the assessment of limited market applications.
- Provide recommendations to applicants on classification of products as limited markets and eligibility to Article 23.

EMA topic leader: Alberto Contreras; CVMP topic leader: Frida Hasslung Wikström

1.2. Authorisation activities

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

Key objectives

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

Activities in 2026

- Review ways to improve the efficiency, robustness, consistency and soundness of outputs throughout the evaluation process.
- Streamline the template for 'List of questions' to ensure consistency of questions in the evaluation reports.

EMA topic leader: Jordi Torren, Emily Drury; CVMP topic leader: Johan Schefferlie, Frida Hasslung Wikström

[1] https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52024XC01443

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. It aims at ensuring that post-authorisation safety monitoring and effective risk management are continuously applied to VMPs throughout the EU.

Regulation (EU) 2019/6 includes several provisions which support the operation of the EU pharmacovigilance system. One of the pillars of the EU pharmacovigilance system is the 'signal management process', which consists of signal detection, validation, analysis and prioritisation, assessment and recommendation for action. Signal management is considered the 'gold standard' for post-authorisation safety monitoring and for effective continuous evaluation of benefit-risk balance.

Key objectives

- Maintain efficient and effective conduct of pharmacovigilance, including surveillance and signal management, by providing the necessary guidance, systems, and refining processes.
- Collaborate with stakeholders to further develop and advance veterinary pharmacovigilance.
- Coordinate with the Coordination Group for Mutual Recognition and Decentralised procedures for veterinary medicinal products (CMDv) on pharmacovigilance issues related to VMPs authorised through national procedures.
- Ensure effective communication of new safety-related information arising from pharmacovigilance activities for VMPs and provide regular updates on emerging issues.

Activities in 2026

- See the Work Plan of the Pharmacovigilance Working Party.
- Provide oversight for the continued implementation of efficient and effective methodology and procedures for post-authorisation surveillance following their implementation in 2025.

EMA topic leader: Camelia Mihaescu; CVMP topic leader: James Mount[2]

1.3.2. Other post-authorisation activities

Referrals and related procedures

All referrals on veterinary medicines are assessed by the CVMP.

The CVMP is undertaking initiatives to provide scientific advice on the use of antimicrobials in animals, aiming to minimise the occurrence of resistance in the Union. One such initiative is the 'Dosage Review and Adjustment of established veterinary Antibiotics (ADRA)', which focuses on reassessing and optimising the dosages of selected combinations of *'antimicrobial active substance/pharmaceutical form/route of administration/target species/disease'*. A rapporteur and a co-rapporteur will be appointed for each scientific advice issued under Article 141(1)(i) of Regulation (EU) 2019/6 related to the ADRA project, who will assume a coordination role and be responsible for ensuring the overall quality of the final report. In addition, a temporary Working Party (ADRA tWP) has been established to

[2] Chair of the PhVWP-V

provide the CVMP with relevant expertise and input on matters related to the ADRA project, including ad-hoc support to the (co-)rapporteurs and expert advice on specific questions raised by the CVMP.

Key objectives

- Support the network in overseeing reviews of benefit/risk for classes of active substance or veterinary medicinal products.
- Facilitate the prudent use of antimicrobials and other classes of veterinary medicinal products.

Activities in 2026

- Proceeding with the referrals and related procedures initiated by NCAs, EC or MAH issuing high-quality and consistent CVMP documents.
- Provide scientific advice/opinions in cases listed in Article 141(1) of Regulation (EU) 2019/6.
- For the ADRA project, see the work plan of the ADRA temporary Working Party (ADRA tWP).

EMA topic leader: Emily Drury; CVMP topic leader: Johan Schefferlie

2. Horizontal activities and other areas

2.1. Specific activities

2.1.1. Maximum Residue Limits

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. Following a June 2025 update to Commission Regulation (EU) 2018/782 relating to "chemical-unlike" biologicals, the respective guidance and procedure are to be reviewed.

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 in 2026

- Collaborate with other EU Agencies to establish a common approach to consumer exposure assessment.
- See the work plan of the Safety Working Party (SWP-V).

EMA topic leader: Nicholas Jarrett; CVMP topic leader: Carina Bergman

2.1.2. Environmental Risk Assessment

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'[3] outlines a set of actions addressing the multifaceted challenges that the release of pharmaceuticals poses to the environment.

Key objectives

- To ensure that potential risks to the environment associated with the use of VMPs are evaluated and mitigated.
- To update the environmental risk assessment methodology/guidance in accordance with current scientific knowledge.

Activities in 2026

- Consider the comments from the Concept Paper on the environmental risk assessment for specific groups of companion animal products and discuss the next steps.
- See the work plan of the Environmental Risk Assessment Working Party (ERAWP).

EMA topic leader: Michael Empl; CVMP topic leader: Ricardo Carapeto, Mark Montforts[4]

2.1.3. Antimicrobial resistance

2.1.3.1. AMR 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.

The EMA, the European Food Safety Authority (EFSA) and the European Centre for Disease Prevention and Control (ECDC) jointly publish the Joint Inter-Agency Antimicrobial Consumption and Resistance Analysis (JIACRA) reports. Following the amendment of Regulation (EU) No 726/2004 by Regulation (EU) 2019/5, these joint reports on antimicrobial consumption and resistance in human and veterinary

[3] https://ec.europa.eu/environment/water/water-dangersub/pdf/strategic_approach_pharmaceuticals_env.PDF
[4] Chair of the ERAWP

medicine are now legally mandated at least every three years. 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.

Key objectives

- Facilitate the prudent and responsible use of antimicrobials and promote their alternatives and contribute to maintaining the efficacy of established antimicrobials.
- Contribute to the minimisation of the risk to man and animals from AMR due to the use of antimicrobials in veterinary medicine.

Activities in 2026

- Provide scientific opinions on existing antibiotics, focussing on the review of the posology.
- See the work plan of the Antimicrobials Working Party (AWP).
- Work in partnership with the European Commission, other EU Agencies and regulators and international bodies to promote the responsible use of antimicrobials and their alternatives.
- Contribute to the development and finalization of the 5th JIACRA report. As part of this work, the EMA collaborates closely with EFSA and ECDC to analyse the potential relationship between antimicrobial use in humans and food-producing animals and the occurrence of antimicrobial resistance.
- Provide pre-authorisation support (e.g. via early pre-submission discussions, scientific advice) to develop and obtain a marketing authorisation for new antimicrobial VMPs and for VMPs that can assist in the reduction of use of antimicrobials, initiating the development of scientific guidance, as appropriate.

EMA topic leader: Zoltan Kunsagi; CVMP topic leader: Damien Bouchard[5]

2.1.3.2. Antimicrobial sales and use data-related activities

Regulation (EU) 2019/6 requires the collection of sales and use data for antimicrobial VMPs. Member States collect these data, and the EMA and a dedicated working group of the CVMP (ESUAvet) analyse the data in combination with data on the use of antimicrobials in humans and data on antimicrobial-resistant organisms found in animals, humans and food. The working group collaborates with EMA on supporting Member States regarding the quality of data collected on sales and use of antimicrobials in veterinary medicine by developing guidance to ensure the appropriate quality, analysis and publication of data reported to EMA by Member States.

Key objectives

- Ensure appropriate analysis and annual reporting of data on sales and the use of antimicrobials in veterinary medicines (ESUAvet reports).

[5] Chair of the AWP

- Ensure appropriate integrated analysis between ESUAvet data with relevant data from humans and resistance in relevant zoonotic organisms transmitted via food together with relevant other Union agencies (JIACRA reports).

Activities in 2026

- See the work plan of the European Sales and Use of Antimicrobials for Veterinary Medicine Working Group (ESUAVET)

EMA topic leader: Cristina Ribeiro

2.1.4 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. 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.

Key objective

- Promote the responsible use of antiparasitic veterinary medicines.

Activities

- See the work plan of the Efficacy Working Party (EWP).

EMA topic leader: Valentin Nicorescu; CVMP topic leader: Cristina Muñoz

2.1.5 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 VMPs (except for veterinary *clinical trials* required for marketing authorisations), 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 (i.e. the experiments used as part of the pre-clinical testing).

Key objective:

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

Activities

- In order to achieve the above-mentioned objective, 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.
- Support the international regulatory acceptance of 3Rs compliant methods through promoting those in the context of the development of VICH guidelines (see 2.1.9).

EMA topic leader: Nicholas Jarrett; CVMP topic leader: Sarah Adler-Flindt

2.1.6 Nitrosamine impurities

EMA has assessed the risk of nitrosamine formation or presence during the manufacture of human medicines and provided guidance to marketing authorisation holders to avoid the presence of nitrosamine impurities.

Key objective:

- Based on the monitoring of the work on the human side to take the necessary actions on the veterinary side, if appropriate.

Activities

- Monitor 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 veterinary medicines.

EMA topic leader: Miguel Llorens; CVMP topic leader: Mary O'Grady

2.1.7 Application of non-conventional sources of data in product-lifecycle

The digital systems used by regulators and companies gather, process and make available crucial data for the regulation of veterinary medicines.

Meanwhile, animal health professionals and users of veterinary medicines increasingly use digital technologies and tools in farm management and animal healthcare practices, which also generates large amounts of real-world data. This reflects a general societal trend, whereby massive amounts of data are generated on a daily basis that could potentially be harnessed to support medicines regulation.

Key objective:

- Promote application of non-conventional sources of data in product-lifecycle.

Activities

- Explore non-conventional sources of data (e.g. real-world evidence, real-world data), advanced analytical methods, and use of AI, to understand their potential use and consider applicability to support product authorisations or ongoing benefit-risk assessments.

EMA topic leader: Lynn Paul Damien; CVMP topic leader: Els Dewaele

2.1.8 Reinforce the scientific and regulatory capacity and capability of the network

The European medicines agencies network strategy 2028 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. In addition, capabilities to assess 3Rs methods such as novel approach methodologies provided as part of authorisation dossiers need to be extended. 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.

Key objectives

- Strengthen the quality of the scientific review process by developing available expertise.
- Support optimal organisation of the available expertise within the network for services provided to CVMP/EMA.
- Identify and enable access to the best expertise across Europe and internationally.

Activities in 2026

- In collaboration with EU network training centre, contribute to the training of assessors on regulatory scientific topics and guidelines for the network.
- Work to increase capability in modelling, simulation and extrapolation within the European Regulatory Network. The CVMP Working Parties 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.
- Consider the need to establish European specialised expert communities (ESECs) in more scientific areas related to veterinary medicinal product development.
- Together with HMA, analyse the current gaps in, and future needs for capacity and capability, in order to ensure sustainable scientific support for the CVMP.
- Streamline evaluation processes to enable more efficient use of resources.
- Liaison with the CHMP Methodological Working Party for scientific advice and potentially during MAAs/variations.
- Collaboration with the CHMP Infectious Diseases Working Party on the development of future guidance documents.

EMA topic leader: Jordi Torren, Emily Drury; CVMP topic leader: Johan Schefferlie

2.1.9 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.

Key objective

- Promote uptake of harmonised standards at international level.

Activities in 2026

- Contribute to development of VICH guidelines.
- Engage with EDQM to discuss issues of mutual interest with regard to the quality of VMPs e.g. on practical implementation of veterinary vaccine monographs and chapters.
- 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 topic leader: Jordi Torren, Emily Drury, Nicholas Jarrett; CVMP topic leader: Johan Schefferlie

2.1.10 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.

Key objective

- Promote stakeholder engagement.

Activities in 2026

- Organisation of a Veterinary Medicines Info Day.
- Organisation of a CVMP Interested Parties Meeting.
- Organisation of focus groups meetings, information sessions, and/or workshops on specific topics, where appropriate.
- Reviewing the content of CVMP agendas and minutes with a view to increasing transparency.

EMA topic leader: Teresa Ferreira, Janos Kovacs; CVMP topic leader: Johan Schefferlie

2.2. Scientific guidance

Predictability of scientific requirements and quality and consistency of dossier assessment across the EU regulatory network is key to foster innovation and maintenance of authorised veterinary medicines. The CVMP provides scientific guidance in various areas related to dossier requirements and assessment for biological and non-biological veterinary medicinal products.

Key objective

Set out strategic goals and priorities for scientific guideline development by the respective working parties.

Activities in 2026

- Keep track of scientific developments (e.g. safety of nanoparticles) and EU policy initiatives that might impact on the authorisation and use of veterinary medicines.
- Ensure that the guidance documents published reflect the current scientific knowledge.
- See the work plans of the CVMP Working Parties.

EMA topic leader: Jordi Torren, Emily Drury; CVMP topic leader: Frida Hasslung Wikström