EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

26 June 2026
EMA/CVMP/144957/2025
Committee for Veterinary Medicinal Products (CVMP)

CVMP activities related to antimicrobials

Status report on EMA/CVMP activities (2021–2025) and EMANS 2028 Strategic Overview (Theme 4)

Discussion by CVMP	21 May 2026
Adoption by CVMP	18 June 2026

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1. Introduction

Antimicrobial resistance (AMR) is recognised as a major global public health threat that affects human and animal health, food production and the wider environment. The preamble to Regulation (EU) 2019/6 (VMP-Reg) on veterinary medicinal products (VMPs) acknowledges that AMR to medicinal products used in both humans and animals requires urgent, coordinated and intersectoral action in line with the 'One Health' approach, which recognises the close interdependence between human, animal and environmental health.

To address these challenges, VMP-Reg establishes a comprehensive framework to strengthen the prudent and responsible use of antimicrobials in veterinary medicine. The VMP-Reg introduces measures to avoid routine prophylactic use, to restrict metaphylactic use to duly justified circumstances, and to limit the use of antimicrobials in animals that are critical for the prevention or treatment of life-threatening infections in humans. In addition, it provides incentives to stimulate innovation and the development of new antimicrobial VMPs, while requiring that applications for the authorisation of antimicrobial VMPs adequately address their benefits and risks, including the potential for the development and spread of AMR in humans, animals or the risk of spread to the environment.

In the context of limited innovation in the antimicrobial pipeline, the VMP-Reg underlines the need to preserve the effectiveness of existing antimicrobials for as long as possible. This objective can only be achieved through their responsible use and robust surveillance of antimicrobial sales and use, based on harmonised, well-defined methodologies. Such surveillance is a key component of antimicrobial stewardship and provides an essential evidence base to support regulatory, risk-management and policy decisions at European Union (EU) level.

The Committee for Veterinary Medicinal Products (CVMP) plays a central role in the EU regulatory framework for veterinary medicines and is committed to ensuring the availability of effective antimicrobial VMPs for treating infectious diseases in animals. At the same time, the CVMP seeks to minimise the risks to public and animal health arising from AMR associated with the use of these products, while also taking the role of the environment as a potential reservoir and pathway for the transmission of AMR. The CVMP consults with the Antimicrobials Working Party (AWP) on matters concerning antimicrobials and AMR and with the European Sales and Use of Antimicrobials for Veterinary Medicine Working Group (ESUAvet WG) on matters related to the collection and analysis of data on sales volumes of veterinary antimicrobials and the use of antimicrobials in animals in the EU.

The entry into application of the VMP-Reg on 28 January 2022 necessitated recalibrating CVMP guidance and ongoing activities to ensure alignment with the new regulatory framework.

Building on its long-standing work on antimicrobials, the CVMP's activities are now embedded within broader strategic planning instruments, including the consolidated three-year work plan for the veterinary domain (2025–2027) and the European Medicines Agencies Network Strategy to 2028 (EMANS), notably under the strategic theme 4: 'Antimicrobial resistance and other health threats' to better align with the evolving strategic priorities of the European medicines agencies network [comprising national competent authorities (NCAs) and EMA].

This document provides an overview of the CVMP's work in the area of antimicrobials. It follows up on the previous 'CVMP Strategy on Antimicrobials', which ended its cycle in 2025. The first part of this document presents a status report on antimicrobial-related activities undertaken by the CVMP between 2021 and 2025. The second part outlines ongoing and planned activities in this strategic area, in line with EMANS 2028, Theme 4, and the overarching 'One Health' approach.

2. CVMP status report on activities undertaken on antimicrobials between 2021 and 2025

Based on the CVMP Strategy on antimicrobials 2021-2025, a review was conducted across the six aims to assess the activities implemented.

Aim 1 - Provide opinions to support the authorisation of effective antimicrobial VMPs with measures ensuring safe and sustainable use

Objective for Aim 1: To provide opinions for the authorisation of effective antimicrobial veterinary medicinal products, ensuring that the necessary risk management measures are applied so that products can be used safely and sustainably.

CVMP's existing guideline for the demonstration of efficacy for veterinary medicinal products containing antimicrobial substances and guideline on the conduct of efficacy studies for intramammary products for use in cattle were both updated in 2025, in line with the definitions and terminology provided by Article 4 of the VMP-Reg ('antimicrobial', 'antibiotic', 'metaphylaxis', 'prophylaxis'). The respective guidelines have also been aligned with the provisions on the responsible use of antimicrobials set out in Articles 107(3) and 107(4) of the VMP-Reg.

The intended development of a reflection paper regarding the use of antimicrobials for prophylaxis was discontinued due to legal considerations expressed by the European Commission on the scope of the CVMP's activities.

The guideline on the Summary of Product Characteristics (SPC) for veterinary medicinal products containing antimicrobial substances was updated in 2021, and, based on this, an assessor training session was delivered.

Aim 2 - Advise on the risk to public health of the use of veterinary antimicrobials and balance it against the need to protect animal health and welfare

Objective for Aim 2: To consider and advise on the risk to public health that could arise from the use of antimicrobials in animals, and to balance this against the need to protect animal health and welfare. To provide scientific advice in a One Health context, considering the interaction between humans, animals and the environment as sources of antimicrobial resistance determinants.

The final version of the guideline on the assessment of the risk to public health from antimicrobial resistance due to the use of an antimicrobial veterinary medicinal product in food-producing animal species was published. This guideline provides advice on data requirements and methodology for assessing the risk from AMR in marketing authorisation applications and variations, referrals and post-authorisation studies. Following its publication, a dedicated training on the application of the guideline was delivered in September 2025.

The CVMP published a reflection paper on antimicrobial resistance in the environment: considerations for current and future risk assessment of VMP, which has been a basis for more recent work related to the current regulatory framework on a concept paper for a reflection paper on the assessment of public health risks related to antimicrobial resistance acquired through the environment resulting from the use of a VMP. This concept paper is the start of addressing the specific regulatory requirement to consider the role of the environment vis-à-vis the development of AMR and related risk in humans. The eventual reflection paper is considered more appropriate than a guideline at this time, since this is a

nascent scientific field where data and experience are needed before fully defining the regulatory requirements[1].

The CVMP developed a concept paper on guidance for assessing the risk to public health from the use of antimicrobials in non-food-producing animals.

The intention behind the documents mentioned above on the environment and non-food-producing target animals is to ultimately develop a single guidance document, together with the risk assessment guidance for food-producing animals, covering the regulatory requirements under Article 8(2) of the VMP-Reg.

VICH is a trilateral (EU-Japan-USA) programme aimed at harmonising technical requirements for veterinary product registration. A training on the application of VICH GL27 for the authorisation of antimicrobials in the EU was delivered online in 2022 to veterinary NCAs, particularly assessors involved in evaluating safety and efficacy for marketing authorisations of veterinary medicines. A concept paper on the revision of VICH GL27 was submitted to the VICH Steering Committee. This document provides harmonised technical guidance in the EU, Japan and the U.S. for registration of antimicrobial veterinary medicinal products intended for use in food-producing animals.

For the first time, five EU health and environment agencies – European Food Safety Authority (EFSA), European Centre for Disease Prevention and Control (ECDC), European Chemicals Agency (ECHA), European Environment Agency (EEA) and European Medicines Agency (EMA) – supported by the Joint Research Centre (JRC), reviewed how the use of azole substances outside human medicine affects public health. A scientific report on the 'Impact of the use of azole fungicides, other than as human medicines, on the development of azole-resistant *Aspergillus* spp.' was published.

The CVMP developed a guideline on the evaluation of the benefit-risk balance of veterinary medicinal products. This major update to the original guidance, issued almost twenty years ago, now explains the specific regulatory provisions regarding the risk of resistance development from antimicrobial and antiparasitic VMPs.

The CVMP, in collaboration with CHMP, provided the EFSA's GMO Panel with information on the use of specific aminoglycosides in human and veterinary medicine within the EU, to support its assessment of renewal applications for genetically modified maize and cotton that use antimicrobial marker resistance genes.

Aim 3 - Take measures to ensure the on-going availability and effectiveness of authorised veterinary antimicrobials

Objective for Aim 3: To maintain the effectiveness of antimicrobial substances that are already authorised in veterinary medicinal products by encouraging monitoring for changes in susceptibility of target pathogens and reviewing the authorisation of substances and/or products when there is evidence that there may be a change in the benefit-risk of the authorisation.

The AWP reflected on a guidance document on the circumstances and requirements for post-authorisation studies for antimicrobial veterinary medicines, to be considered at the time of granting a marketing authorisation, to ensure that the benefit-risk remains positive, given the potential for the development of AMR [Article 36(2) of Regulation (EU) 2019/6]. The AWP concluded that the accumulated experience in the matter was limited and that the volume of initial marketing authorisations containing new antimicrobials did not justify the development of a guidance document in the absence of practical experience. It was proposed to include information in the existing Questions

[1] With regard to Article 8(2) of Regulation (EU) 2019/6 and section II.3A.4.3 of Annex II of that Regulation.

and Answers document instead. This approach was presented to the CVMP in February 2025 and was endorsed by the Committee.

The CVMP published and took forward the recommendations from its reflection paper on dose review and adjustment of established veterinary antibiotics in the context of SPC harmonisation. The CVMP initiated the dosage review and adjustment of the selected veterinary antibiotics (ADRA) project and adopted a priority list of candidate antimicrobial substances for dosage review and adjustment. The main goals of this initiative are to minimise AMR in the EU and to ensure the continued availability, efficacy and safety of first-line veterinary antibiotics for treatment. In May 2025, EMA hosted an information session on the ADRA project facilitating a direct dialogue between EMA and veterinary industry stakeholders. The Dosage Review and Adjustment of Established Veterinary Antibiotics temporary Working Party (ADRA tWP) was established in October 2025 to provide ad-hoc support to the CVMP rapporteurs on matters related to the preparation of the respective scientific advice under article 141(1)(i) of the VMP-Reg. The first procedure has begun as a review of veterinary medicines containing amoxicillin as a single active substance for use in drinking water or feed in pigs, specifically for respiratory indications.

The CVMP started reviewing its reflection paper on Macrolides, Lincosamides and Streptogramins (MLS) to update its recommendations, as required, to reflect recent developments in AMR and the importance of these antibiotic classes to animal and human health. The updated reflection paper provides a comprehensive review of the use of MLS within the EU, examining their pharmacological properties, patterns of use, the development of resistance, and the resulting public, animal, and environmental health implications. It also identifies the need for animal and environmental risk management measures, highlights knowledge gaps, and suggests areas for further research. As the first step, the concept paper was published, and based on the feedback received from stakeholders and interested parties during the period of public consultation, the reflection paper is currently being revised.

The CVMP conducted a Union interest referral procedure under Article 82 of Regulation (EU) 2019/6 for VMPs containing procaine benzylpenicillin as a single active substance presented as suspensions for injection to review the dosage regimens and withdrawal periods of these products, due to an identified increased risk of AMR development. The CVMP considered it essential to provide practising veterinarians with the necessary tools to use procaine benzylpenicillin as a first-choice antimicrobial and recommended changes to the indications, dosage regimen, warnings on the effective use of VMPs, and withdrawal periods. This recommendation ensures the effective use of these medicines and contributes to reducing the development of AMR.

The CVMP also started a scientific advice procedure under Article 141(1)(i) on whether quarter-based selective dry cow therapy with antibiotic intramammary veterinary medicines (medicines applied into the udder) could be considered consistent with the latest scientific knowledge aimed at reducing antibiotic use, without compromising animal health. At present, antimicrobial use recommendations for mastitis may include treatment of all four quarters. If quarter-based selective antibiotic dry cow therapy is deemed an effective strategy to reduce antibiotic use, the CVMP was asked to advise on how this approach could be reflected in the product information of the relevant intramammary antibiotic veterinary medicines. This would enable veterinarians and farmers to practice quarter-based selective antibiotic dry cow therapy in accordance with the terms of the marketing authorisation.

Aim 4 - Encourage the development of antimicrobial veterinary medicinal products and foster the development of products that can help to reduce the use of antimicrobials [2]

Objective for Aim 4: To encourage the development of new and existing antimicrobial veterinary medicinal products. To encourage the development of alternatives to antimicrobials.

Vaccines are the primary tool for prevention of infections and infectious diseases, making them an effective strategy in the fight against AMR. They can help to reduce the use of antimicrobials, either due to their primary indication or because of complications arising from secondary bacterial infections in non-vaccinated animals. The availability of master files, such as the platform technology master file (PTMF) and vaccine antigen master file (VAMF), further streamlines the approval of vaccines with similar structures, enabling a faster authorisation procedure. The first vaccine platform technology master file (vPTMF) and VAMF were authorised in 2024. As of the end of 2025, a total of 3 vPTMF and 12 VAMF have been certified.

Between 2021 and 2025, the CVMP authorised 46 vaccines and 3 antiparasitic products that reduce the risk of infection with protozoans. Viruses are the most prominent target pathogens of the vaccines, with 33 vaccines targeting viral infections. Additionally, 2 new antimicrobial veterinary products were authorised, one antifungal and one combination of an antibiotic and an antifungal. These products can have a role in reducing the use of antimicrobials.

Under the VMP-Reg, authorisation pathways with customised data requirements (limited markets, exceptional circumstances) are available to facilitate the authorisation of new VMPs. In 2024 and 2025, a total of 7 vaccines were authorised under exceptional circumstances (Article 25 of VMP-Reg), intended for use against avian influenza, bluetongue disease or epizootic haemorrhagic disease.

Six Innovation Task Force (ITF) meetings were held with applicants aiming to develop antimicrobials or products that can reduce the use of antimicrobials, and the CVMP has provided 38 initial scientific advice reports on new antimicrobial VMPs or products that may help reduce the use of antimicrobials.

Guidelines and respective dedicated trainings to support the authorisation of antimicrobial VMPs or products that can help to reduce the use of antimicrobials were published, e.g. on:

- quality, safety and efficacy of bacteriophages
- evaluation of benefit-risk balance of veterinary VMPs
- clinical trials with immunological VMPs
- requirements for the production and control of immunological VMPs
- data requirements for vPTMF
- data requirements for VAMF
- data requirements for multi-strain dossiers for inactivated veterinary vaccines
- data requirements for authorisation of immunological VMPs in exceptional circumstances
- data requirements for adjuvants in vaccines for veterinary use

The Novel Therapies Working Party (NTWP) conducted two horizon-scanning surveys on novel therapies and held pipeline meetings with several companies to identify areas requiring further

[2] The original wording of Aim 4 was 'Encourage the development of antimicrobial veterinary medicinal products and foster the development of alternatives to antimicrobials'

regulatory guidance and to gain insights into upcoming developments, including antimicrobial VMPs and products that may help reduce antimicrobial use.

The reflection paper on promoting the authorisation of alternatives to antimicrobials (products that can help to reduce the use of antimicrobials) in the EU was finalised and published in 2021. This reflection paper was developed at that time to perform a gap analysis and identify additional measures that could be implemented to promote the authorisation of alternatives to antimicrobials in the EU. Recommendations to address the identified needs are presented. Some aspects/recommendations in the reflection paper have been superseded because the generalised goals that covered a variety of products became targeted towards preparing guidance on specific types of products e.g. the guideline on quality, safety and efficacy of bacteriophages as veterinary medicines. Additionally, experience has been gained in the area of indications for the reduction of antimicrobial resistance.

A reflection paper on the application of Article 40(5) of VMP-Reg for certain categories of variations was published in 2025. This paper clarifies the circumstances and types of data required to demonstrate a reduction in AMR and provides guidance on variations to marketing authorisations that could benefit from an additional four years of data protection on the supporting (pre-)clinical data package (Article 40(5) of the VMP-Reg).

International exchange of information on the classification and regulation of products that can help reduce the use of antimicrobials took place during TATFAR meetings.

Aim 5 - Support responsible use of antimicrobials both in accordance with marketing authorisations and under the cascade

Objective for Aim 5: To support the responsible use of antimicrobials both in accordance with marketing authorisations and under the 'cascade'.

The European Surveillance of Veterinary Antimicrobial Consumption (ESVAC) project ran from 2009 to 2023 and reported on the sales of antimicrobial medicines used in animals across the European Union (EU). This type of information was essential to identifying possible risk factors that could lead to the development and spread of AMR in animals. CVMP has consistently supported the ESVAC project and has taken its findings into account. The last ESVAC report showed a 28% reduction in overall antibiotic sales in food-producing animals between 2018 and 2022. This represents significant progress towards the objective of reducing EU sales of antimicrobials.

Since January 2024, the 27 EU Member States, Iceland, and Norway have been required to report data on the volume of sales and use of antimicrobial medicinal products for animals. The legal framework governing the collection and publication of this data is set out in three main legal acts: Article 57 of the VMP-Reg, the Commission Delegated Regulation (EU) 2021/5784, and the Commission Implementing Regulation (EU) 2022/209 (please see below the two reports prepared on the requirements and format for data collection). Additionally, as mentioned in the Introduction, CVMP is now supported by the ESUAvet WG on matters related to the collection and analysis of data on sales volumes of veterinary antimicrobials and the use of antimicrobials in animals in the EU.

To support the work of the Member States for data collection, in 2023, CVMP published a guideline on the reporting of antimicrobial sales and use in animals at the EU level (focusing on denominators and indicators), developed based on comments from stakeholders and interested parties during the public consultation period. The development of the guideline also considered the previous concept paper and the comments received during its public consultation period.

During this period, the ESUAvet WG also developed several manuals to support Member States in transitioning to the new legal framework established by the VMP-Reg. This includes a manual for

reporting the use data denominator to the Agency, by animal category, which was also developed, and a manual for Member States on establishing data quality management plans for the collection of antimicrobial sales and use data under the VMP-Reg and its delegated and implementing regulations.

The first ESUAvet report, based on 2023 data, was published in March 2025. The second ESUAvet report, based on 2024 data, was published in December 2025, together with two Power BI public interactive dashboards – one containing ESUAvet data, and another containing historical ESVAC data.

The EMA works closely with the EFSA and the ECDC to analyse the relationship between antimicrobial consumption in humans and animals and the occurrence of AMR. Their findings are published in the joint inter-agency antimicrobial consumption and resistance analysis (JIACRA) reports. The third JIACRA report was published in 2021, and the fourth in 2024. They are based on data provided by the surveillance and monitoring systems of the 3 agencies. The reports enable monitoring of progress against key outcome indicators for antimicrobial consumption and AMR in both the human and animal sectors. The fourth JIACRA report, covering the period 2019–2021, confirms that sustained reductions in antimicrobial use, particularly in food-producing animals, are associated with favourable trends in AMR for certain pathogen–antimicrobial combinations, and underlines the importance of continued harmonised surveillance across sectors. This report, for the first time, includes a multi-agency analysis of trends in antimicrobial use and resistance in *E. coli* in humans and animals. Work on the 5th report is progressing, with publication anticipated in December 2026. In line with Regulation (EU) 2019/5 amending Regulation (EC) No 726/2004, such joint reporting shall be carried out at least every three years.

As described throughout this document, the VMP-Reg introduces legal requirements to counter AMR, such as reporting data on antimicrobial use in animals (in addition to sales), restricting the use of antimicrobials for the prevention of infections, and reserving critically important antimicrobials for certain conditions in humans. To support this implementation, EMA prepared scientific and technical recommendations regarding antimicrobials and AMR to feed into delegated and implementing acts as part of the implementation of the VMP-Reg. EMA provided these recommendations at the request of the European Commission:

- Advice on implementing measures under Article 57(3) of Regulation (EU) 2019/6 on veterinary medicinal products - Report on specific requirements for the collection of data on antimicrobial medicinal products used in animals. Based on this advice, the Commission Delegated Regulation (EU) 2021/578 was adopted (see above).
- Advice on implementing measures under Article 57(4) of Regulation (EU) 2019/6 on veterinary medicinal products – Report on the format of the data to be collected on antimicrobial medicinal products used in animals. Based on this advice, the Commission Implementing Regulation (EU) 2022/209 was adopted (see above).
- Advice on the designation of antimicrobials or groups of antimicrobials reserved for treatment of certain infections in humans - in relation to implementing measures under Article 37(5) of VMP-Reg ('Human Reserved List'). Based on this advice, the Commission Implementing Regulation (EU) 2022/1255 was adopted. This advice comprises a review of all classes and groups of antimicrobials that could be used in animals, based on the strict application of the criteria for designating certain critically important antimicrobials as reserved for the treatment of specific conditions in humans. Globally, it is the first systematic review of all antimicrobials or antimicrobial classes that might be used in animals, conducted with a view to prohibiting the use of certain substances in animals, which represents the strictest possible risk management measure.
- Scientific advice under Article 107(6) of Regulation (EU) 2019/6 for the establishment of a list of antimicrobials which shall not be used in accordance with Articles 112, 113 and 114 of the same

Regulation or which shall only be used in accordance with these articles subject to certain conditions ('Cascade advice'). Based on this advice, the Commission Implementing Regulation (EU) 2024/1973 was adopted. This advice addresses the conditions and restrictions governing the permitted off-label use of antimicrobials in animals for animal-welfare needs (so-called 'cascade' use), taking into account risks to animal and public health, as well as the impact on agriculture. It provides science-based recommendations for additional measures to reduce AMR development resulting from the use of antimicrobials in animals.

- Scientific advice under Article 115(5) of Regulation (EU) 2019/6, regarding the list of substances which are essential for the treatment of equine species and for which the withdrawal period for equine species shall be six months ('Horse list'). Based on this advice, the Commission Implementing Regulation (EU) 2025/901 was adopted. The objective of this exercise was to develop a proposed list of essential substances with a justification for each substance, together with the corresponding indication, explanation of use and identification of alternatives.
- Scientific advice under Article 114(3) of Regulation (EU) 2019/6 for the establishment of a list of substances used in VMPs authorised in the Union for use in food-producing terrestrial animal species or substances contained in medicinal products for human use authorised in the Union, which may be used in food-producing aquatic species in accordance with Article 114(1) ('Fish list'). Only the substances on this list may be allowed for use in food-producing aquatic species in accordance with Article 114(1).

The CVMP published a concept paper outlining a reflection paper to assess the availability and characteristics of diagnostic tests to improve the responsible use of antimicrobials in animals. The development of the reflection paper, taking into account the comments received during the public consultation, is ongoing. This reflection paper will provide a comprehensive review of diagnostic assays that support the diagnosis or exclusion of bacterial diseases in animals and assess their current and future applicability, with particular focus on European countries.

Aim 6 - Work in partnership with EU/EEA and international human and animal health organisations to tackle the global problem of AMR

Objective for Aim 6: Recognising that AMR is a global problem affecting both animal and human health and the environment, to work in partnership with the European Commission and its agencies, competent authorities in the Member States, international regulatory bodies, human and animal health organisations and the pharmaceutical and livestock industries to provide science-led guidance on the responsible use of antimicrobials in animals.

As mentioned in the section above, the CVMP provided advice to the Commission on the VMP-Reg on VMPs and the Regulation on Medicated Feed (Regulation (EU) 2019/4). The advices were prepared by ad hoc expert groups composed of members of the European experts and EMA staff, in collaboration with other EU bodies, where necessary.

The CVMP has continued open public consultations on guidelines and reflection papers on AMR topics and has received and addressed extensive responses from international organisations and regulatory bodies, professional bodies, academia, the pharma and livestock industry groups.

At EU policy level, the EU One Health Action Plan against AMR, adopted in 2017, highlights the significant social and economic burden of AMR and calls for coordinated action across sectors. This approach has been further reinforced through the establishment of the Cross-Agency One Health Task Force, which brings together the ECDC, the EMA, the EFSA, the EEA and the ECHA. The Task Force's Framework for Action for 2024–2026 sets out shared strategic objectives, including strategic and

research coordination, capacity building, stakeholder engagement and the development of joint activities, to strengthen the EU's capacity to prevent and respond to health threats, including AMR.

The EMA/CVMP has collaborated extensively with ECDC and EFSA on the implementation of the EU One Health Action Plan against AMR, assisting with the compilation of several inter-agency reports (e.g. JIACRA, Azoles reports) and providing advice to the Commission on the new legislation on VMPs and Medicated Feed.

CVMP is represented at the Ad hoc Codex Intergovernmental Task Force on Antimicrobial Resistance (TFAMR) and VICH and provides input to discussions on antimicrobial issues, including revisions to guidance.

VICH hosted its 7th public conference in November 2024 at the EMA.

The Federation of Veterinarians of Europe (FVE) and the EMA, in collaboration with selected CVMP members, run webinars on the VMP-Reg to clarify and deepen understanding of the new prescribing rules for veterinarians, competent authority staff, and officials. Topics included data collection on the sales and use of antimicrobials, the EMA's categorisation of antibiotics for veterinary use, restrictions on the use of certain antimicrobials in animals, and the conditions for using certain antimicrobials under the "cascade".

In October 2024, EMA hosted a training session for EU candidate countries under the Instrument for Pre-accession Assistance programme, focusing on the veterinary aspects of AMR and the One Health approach. More than 60 participants from national competent authorities in Albania, Bosnia and Herzegovina, Kosovo, Montenegro, North Macedonia, Serbia, Turkey, Moldova, Georgia, and Ukraine attended the two-day event. Following this session, representatives from EU candidate countries later joined the ESUAvet WG and AWP meetings as observers.

3. Overview of CVMP's activities in the strategic area of antimicrobials - EMANS 2028 activities overview, Theme 4

Initially published in 2020, EMANS 2025 is the main strategy guiding the delivery of the operational, regulatory and scientific output of the European Medicines Agency and the national competent authorities for medicines in the EU. The strategy sets out goals and priorities for the years 2021 to 2025, providing strategic direction for the work of the European Medicines Regulatory Network.

The strategy was updated in 2026 to cover the period up to 2028 under the overarching theme of 'seizing opportunities in a changing medicines landscape'. EMANS 2028 will guide the network in addressing future opportunities and challenges, including preparing for and responding to public health emergencies and threats such as AMR.

The recently published report describes the network's main achievements in implementing the strategy from January 2021 to the end of 2025.

The EMANS is structured around six thematic areas:

- Theme 1: Accessibility
- Theme 2: Leveraging data, digitalisation and artificial intelligence
- Theme 3: Regulatory science, innovation and competitiveness
- Theme 4: Antimicrobial resistance and other health threats
- Theme 5: Availability and supply
- Theme 6: Sustainability of the network

This section follows the structure of Theme 4 ('Antimicrobial Resistance and other health threats') and provides an overview of the objectives and activities related to antimicrobials and AMR that involve the CVMP.

Theme 4 reinforces the importance of coordinated, cross-network action to tackle AMR. It reinforces the principles of the 'One Health' approach, recognising that the health of humans, animals and the environment are interconnected and that effective AMR mitigation requires efforts across all sectors.

Table 1 below summarises the three goals and the related objectives of Theme 4. For completeness, objectives that pertain to human medicines are also presented in this table. CVMP deliverables are not

associated with those objectives, as they fall under the remit of the CHMP and other committees or activities related to human medicines and public health.

Table 1. Goals for antimicrobial resistance and other health threats (Theme 4 of EMANS)

Goals	How we will achieve them
Contribute to responsible use of antimicrobials and effective antimicrobial stewardship using a One Health approach	Continue to implement the requirements for the mandatory collection and reporting of sales and use data for antimicrobials in animals and for improving access to information and data and communicating the findings
	Modernise the product information of existing antibiotics for veterinary use and consider additional options for guiding prescribing practices in accordance with the terms of their marketing authorisation. For human medicines, take account of ongoing initiatives while incorporating relevant new provisions in the new pharmaceutical legislation
	In collaboration with relevant EU bodies, define a roadmap for point-of-care diagnostics to support the development of improved diagnostic tests
	Develop, update and promote regulatory guidance on antimicrobial use in animals to guarantee therapeutic options and minimise the impact of antimicrobial resistance while also supporting the development, implementation and uptake of guidance for human medicines
Support development of new antimicrobial agents and alternatives to the use of antimicrobials in collaboration with international partners	Provide guidance on regulatory pathways for phages and other innovative products in human and veterinary medicine, engaging with relevant stakeholders
	Engage stakeholders in pipeline discussions with a view to facilitating the development and eventual authorisation of relevant products, including vaccines
	Provide systematic support to developers of new antimicrobials for human use, including vaccines, antibacterials and alternatives to the use of antimicrobials, mainly through the ETF, and for veterinary medicines through the Innovation Task Force (ITF) and veterinary medicines Scientific Advice Working Party

Goals	How we will achieve them
	Support the European Commission and Member States in the implementation of new business models for antimicrobials (particularly antibacterial agents), including eligibility assessment
Strengthen regulatory preparedness for health threats	Refine regulatory activities to increase preparedness and harmonise approaches for investigating medicinal products during emergencies, including approaches for conducting timely clinical trials during emergencies
	Respond to health threats that could be related to climate and environmental changes using the One Health approach, as defined by the One Health High-Level Expert Panel (OHHLEP), when applicable, and in close collaboration with other Union agencies
	Expand international alignment on regulatory requirements from quadrilateral (US FDA-Health Canada-PMDA-EMA) agreements to achieve more global consensus
	Adopt necessary regulatory flexibilities to support the development and authorisation of countermeasures for use in emergencies, including those caused by chemical, biological, radiation and nuclear threats
	Explore ways to better inform the public about medicines for health threats to engender trust in medicines and the regulatory system

EMANS activities cover work carried out by both the NCAs and the EMA in relation to human and veterinary medicines. For the purpose of this document, the sections below summarise numerous deliverables expected from the CVMP in this area over the coming years:

The CVMP is expected to deliver a coordinated set of activities in the coming years that support responsible antimicrobial use, strengthen understanding of AMR risks, and prepare the regulatory system for new veterinary technologies. The programme brings together continued surveillance, updated regulatory guidance, targeted scientific advice, and early work on innovative therapies.

The Committee will continue to support EU and national policy-making through the annual ESUAvet report, which tracks antimicrobial sales and use in animals, and the JIACRA report published every three years, which combines data on antimicrobial use and resistance in humans, animals, and food. These reports will remain central for identifying trends and shaping regulatory priorities. In addition, the EMA will ensure that the findings and insights generated through these annual reports are

disseminated to a broader range of stakeholders, with the aim of maximising their uptake and use as a resource to support informed action across sectors.

Several important guidance documents will be revised or newly developed to support prudent antimicrobial use and protect public health. A next revision of the SPC guideline on antimicrobials will ensure product information reflects current scientific knowledge and stewardship principles, particularly as regards restrictions on use that apply to antimicrobials authorised for prophylaxis.

New work will include a guideline on AMR risks from antimicrobial use in non-food-producing animals and a reflection paper on AMR risks acquired via the environment, with the aim of eventually consolidating these into a single guidance document addressing Article 8(2) of the VMP-Reg (See Aim 2 in Section 2 above). The future reflection paper on diagnostic tests is intended to support more targeted and responsible antibiotic use. Together, these documents will strengthen the consistency and quality of AMR-related assessments across the EU.

The CVMP will also expand its role in early scientific dialogue and continue supporting the implementation of EU legislation.

A pilot for the dosage review and adjustment of the selected veterinary antibiotics (ADRA) scientific advice will be launched for selected combinations of active substances, routes of administration, and species thereby providing marketing authorisation holders and NCAs with the latest scientific knowledge as a basis to update authorised dosages (and consequential changes) where necessary (See section 2, Aim 3). In parallel, CVMP will continue to support the European Commission by providing updates on the AMEG categorisation and other scientific and technical recommendations needed for the Veterinary Medicines Regulation: this could include the update of the 'Cascade advice' according to the Commission Implementing Regulation (EU) 2025/901 ('Horse list') (See section 2, Aim 5).

The Committee will continue publishing reflection papers on various antibiotic classes. Following the revision of the paper on the use of macrolides, lincosamides, and streptogramins in animals in the European Union, the CVMP will next examine the use of fluoroquinolones and other quinolones in both food- and non-food-producing animals in the EU.

Looking ahead to new therapeutic platforms, CVMP will publish concept papers outlining quality and safety expectations for RNA interference and RNA antisense therapies, as well as for mRNA vaccines for veterinary use. These papers will form the basis for future guidelines and help prepare the regulatory system for next-generation veterinary medicines.

Together, these planned activities present a balanced, forward-looking agenda that maintains strong surveillance, updates key guidance documents, promotes responsible antimicrobial use, supports EU policy needs, and prepares for innovative therapies. This work contributes to reducing AMR risks while ensuring that veterinary medicines remain safe, effective, and aligned with public-health goals.

Further details on CVMP deliverables are set out in the CVMP Work Plan 2026 and will be incorporated into future Committee work plans.