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Committee for Veterinary Medicinal Products (CVMP)

Concept paper for the development of a guideline on the assessment of the risk to public health from antimicrobial resistance due to the use of an antimicrobial veterinary medicinal product in non-food-producing animal species

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1. Introduction

Since there is close contact between companion animals and humans, the use of antimicrobial veterinary medicinal products (VMPs) in pets constitutes a potential risk for direct transfer of antimicrobial-resistant bacteria (ARB), including relevant antimicrobial resistance genes (ARG), between companion animals and humans.

Regulation (EU) 2019/6 ('the Regulation') (Official Journal of the European Union, 2019) governing the authorisation of veterinary medicinal products (VMPs) in the European Union, outlines under Article 8(2) further dossier data requirements for the authorisation of antimicrobial VMPs in addition to the ones listed in Article 8(1). The following will be addressed by the guideline to be developed:

> Article 8(2)(a): Documentation on the direct or indirect risks to public or animal health, or to the environment, associated with the use of the antimicrobial veterinary medicinal product in animals;

Details regarding the above requirements specifically for companion animals are further addressed in Section II.3A.4.3. of Annex II of the Regulation ('Development of resistance and related risk in humans'), in which it is stated:

> (2) For companion animals, consideration of risk to human or public health shall address:
>
> > (a) the identification of resistant bacteria or resistance determinants that could be associated with human illness and are selected by the use of the antimicrobial VMP in target animals;
> >
> > (b) an estimate of exposure of zoonotic and commensal bacteria in the target animal species based on the conditions of use of the VMP under consideration;
> >
> > (c) consideration of subsequent human exposure to antimicrobial resistance (AMR), and the resulting consequences to human health.

In contrast to food-producing animals, no guidance documents are currently available to address these data requirements.

Therefore, among the activities of the CVMP's work plan for 2025 (EMA/CVMP, 2024) the development of a guideline is foreseen on the assessment of the risk to public health from AMR due to the use of an antimicrobial VMP in companion animal species. This activity is also included in the CVMP's Strategy on Antimicrobials 2021–2025 (EMA/CVMP, 2021) under 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).

In view of the experience and knowledge with antimicrobials for pets, the intended guideline will be developed with a focus on companion animals, although all non-food-producing animals are in scope.

2. Problem statement

For antimicrobial VMPs in food-producing animals, international and European guidance is available related to data requirements concerning AMR (EMEA/CVMP, 2004), as well as for the assessment of the public health risk associated with the transfer of AMR (EMA/CVMP/AWP, 2025). Since these guidelines apply only to antimicrobial VMPs for food-producing animal species, they focus on relevant food-borne pathogens and commensal organisms that may be transmitted by food of animal origin or by direct contact.

Similarly, for companion animals, the transmission risk of ARB, including their ARGs, to humans has been identified, which may also impact human health. In this context, the CVMP/AWP published a

'Reflection paper (RP) on the risk of antimicrobial resistance transfer from companion animals' in 2015 (EMA/CVMP/AWP, 2015; Pomba et al., 2016).

This reflection paper reviewed the public health risks associated with the transfer of AMR from companion animals by considering the use of antimicrobials in these animal species, the prevalence of drug-resistant bacteria of concern among companion animals, risk factors for colonisation of companion animals with resistant bacteria, and the transmission of ARB/ARG between animals and humans. Methicillin-resistant *Staphylococcus aureus* (MRSA), methicillin-resistant *Staphylococcus pseudintermedius* (MRSP), vancomycin-resistant enterococci (VRE), as well as extended-spectrum beta-lactamase (ESBL) and carbapenemase-producing Gram-negative bacteria were identified as potential hazards of concern that may cause direct or indirect adverse health effects in humans.

The reflection paper also identified knowledge gaps concerning risk factors, transmission routes, the extent and patterns of antimicrobial usage in companion animals, the ecology of drug-resistant bacteria in companion animals and their environment, and the relative importance of such bacteria in contributing to the burden of human disease. Despite the limited knowledge available at that time, it was concluded that close contact between companion animals and their owners presents an opportunity for the transfer of AMR that may be underestimated. Consequently, one of the CVMP recommendations resulting from that reflection paper was to develop a risk assessment guideline to address the public health risk from AMR associated with the use of antimicrobial VMPs in companion animals.

A decade has passed since the reflection paper was published, and additional knowledge has since then been acquired regarding the gaps outlined (Bhat, 2021; Caddey et al., 2025; Jin et al., 2023; Kaspar et al., 2019). This will be further elaborated on in the discussion section.

3. Discussion (on the problem statement)

Since the publication of the reflection paper in 2015 (EMA/CVMP/AWP, 2015), several new scientific insights have been gained. To begin with, advances in whole-genome sequencing and metagenomics have provided a greater understanding of the dissemination of AMR via mobile genetic elements between bacteria. The mobility of resistance genes between bacteria influences transmission between animals and humans.

Recent developments in AMR in companion animals include, for example, an increased understanding of the risks associated with AMR transmission within households. One such example is the carriage of ESBL-producing bacteria, primarily by dogs, which can have similarities with ESBL-carriage in the owners (Van den Bunt et al., 2020). In the case of MRSA, transmission between pets and humans within households also plays a significant role (Caddey et al., 2025).

As carbapenemase-producing Enterobacterales (CPE) continue to rise worldwide, reports of companion animals carrying CPE are also increasing (Ramírez-Castillo et al., 2023). The most prevalent CPE-genes (belonging to the New Delhi metallo-beta-lactamase (NDM)- or OXA beta-lactamase-group) appear to be the same in humans, livestock, dogs, cats and horses (Rincón-Real & Suárez-Alfonso, 2022), indicating transmission may occur between these reservoirs. As the development or persistence of AMR can be driven by co-selection, antimicrobial use in companion animals may contribute to its persistence and/or spread. This occurs not only within animal reservoirs but may also result in spill-over and spill-back between animals and humans. In addition to households, veterinary practices also play a role in animal-to-human and human-to-animal transmission, as is described for both MRSA and CPE (Caddey et al., 2025). In general, transmission of multi-drug-resistant organisms between companion animals and humans appears to occur at a low frequency in Europe, although this may be due to limited data,

with only a few or relatively small studies currently available (Dazio et al., 2021; Hackmann et al., 2024; Jin et al., 2023).

In line with the approach taken for 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' (EMA/CVMP/AWP, 2025), the risk assessment methodology for the companion animals guideline could be adapted to the methodology described in the 'Terrestrial Animal Health Code by the World Organisation for Animal Health (WOAH)' (OIE, 2022).

The methodology follows a stepwise approach, incorporating an understanding of the mechanisms of resistance to the antimicrobial in question. This includes the identification of ARB and ARG that may be associated with human illness and are selected based on the use of the concerned antimicrobial substance in the target species (hazard identification); the pathways leading to exposure of ARB and ARG to the antimicrobial in the target animal species, based on the conditions of use of the VMP (release assessment); the subsequent human exposure to ARB and ARG via direct and/or indirect contact through domestic or clinical environments (exposure assessment); and the resulting impact on human health (consequence assessment). Finally, the outcomes of the release, exposure, and consequence assessments are integrated into an overall risk estimate of the AMR risk to public health from the use of the antimicrobial VMP in animals, based on its conditions of use.

Using the WOAH methodology as the basis for the guidance would ensure consistency with models applied in other regulatory jurisdictions. However, compared to food-producing animals, the amount and extent of data available for companion animals may be less favourable, e.g., the absence of harmonised monitoring systems for AMR as a public health hazard in companion animals results in a lack of comparable data at the EU level. In addition, human exposure to potential hazards can vary widely depending on the specific conditions under which companion animal species are kept. In particular, the individual owner-animal relationship, i.e., how close humans allow their companion animals to come into contact with them, as well as the extent to which hygiene measures are taken, will strongly influence exposure, which can hamper the application of a standardised risk assessment approach. These limitations should be taken into consideration, and the development of a new risk assessment methodology that deviates from that applicable to food-producing animals might be necessary for companion animals.

4. Recommendation

The CVMP recommends developing a 'Guideline on the assessment of the risk to public health from antimicrobial resistance due to the use of an antimicrobial veterinary medicinal product in non-food-producing animal species', taking into account the issues identified above. The purpose of the guideline will be to provide guidance on the data required according to section II.3A.4.3. of Annex II of the Regulation and the methodology to be applied for the assessment of the risk to public health from AMR in relation to antimicrobial VMPs for use in non-food-producing animals. The guideline should contain information on:

- Objectives, scope, legal basis, definitions: Clearly define the aims of the guideline, its applicability, the legal framework supporting it, and important definitions to ensure clarity.
- Methodology for the risk assessment: Development of the approach to be used in assessing the risk to public health from AMR.
- Data requirements: The necessary data to identify the resistant bacteria or resistance determinants associated with human illness (including those leading to resistance carriage in humans) and that are selected by the use of the antimicrobial VMP in target animals, the

exposure of zoonotic and commensal bacteria in the target animal species, the subsequent human exposure to antimicrobial resistance (AMR), and the resulting consequences to human health.

- Data sources and quality: Specify the sources of data that will inform the assessment, and the standards of data quality required.
- Limitations and uncertainty in the risk assessment: provide information about the limitations (including the methodology) and the uncertainty related to such assessment

5. Proposed timetable

November 2025	Concept paper released for consultation
May 2026	Deadline for comments from interested parties
Q2 2026	Start guideline development

6. Resource requirements for preparation

The development of the guideline will involve two AWP rapporteurs. Adequate time for discussions at the working party will be required. The EMA will coordinate the public consultation. Time at the CVMP plenary meetings will be needed to discuss and adopt the various drafts of the guideline.

7. Impact assessment (anticipated)

The guideline will provide information on the data requirements to fulfil the obligation of Article 8(2)(a) of the Regulation to address the AMR risk to human health due to the use of the antimicrobial VMP in non-food-producing animals. This will contribute to the effective application of Section II.3A.4.3.(2) of Annex II of the Regulation, taking into account the aims of the Regulation in respect of mitigation of the risks of AMR development in humans. It will facilitate the practical and harmonised application of Article 8(2)(a) for antimicrobial VMPs in non-food-producing animals by regulatory authorities and industry.

8. Interested parties

Veterinary pharmaceutical industry, consultants/policy advisors, EU national competent authorities, veterinarians.

9. References to literature, guidelines, etc.

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