EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

18 September 2026
EMA/CVMP/AWP/381531/2025
Committee for Veterinary Medicinal Products (CVMP)

Concept paper on the revision of the CVMP Guideline on the summary of product characteristics (SPC) for veterinary medicinal products containing antimicrobial substances (EMA/CVMP/383441/2005-Rev.1 Corr.[1])

Agreed by Antimicrobials Working Party (AWP) and Efficacy Working Party (EWP-V)	6 July 2026
Adopted by CVMP for release for consultation	10 September 2026
Start of public consultation	18 September 2026
End of consultation (deadline for comments)	31 December 2026

Comments should be provided using this template. The completed comments form should be sent to awpsecretariat@ema.europa.eu .

Keywords	Antimicrobial, antibiotic, summary of product characteristics, veterinary medicinal products, responsible use, antimicrobial resistance, prophylaxis, metaphylaxis

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. Introduction

The guideline on the summary of product characteristics (SPC) for veterinary medicinal products (VMPs) containing antimicrobial substances (EMA/CVMP/383441/2005-Rev.1 Corr.[1]) provides specific guidance on the information to be included in the SPC of such products (EMA, 2021). Since its first publication in 2003, the guideline has been revised several times to improve the consistency of SPCs for antimicrobial products and to align with the requirements and definitions included in Regulation (EU) 2019/6 ('the Regulation') (Official Journal of the European Union, 2019).

The Regulation lays down a comprehensive framework to address the serious and growing public health threat posed by antimicrobial resistance (AMR) within the Union. It calls for urgent and coordinated intersectoral action in accordance with the 'One Health' approach. These measures include, *inter alia*, promoting prudent and responsible antimicrobial use and avoiding routine administration for prophylactic or metaphylactic purposes.

Following the previous revision of the guideline, it is necessary to reinforce that antimicrobial VMPs, when used for prophylaxis or metaphylaxis, are subject to specific provisions under Articles 107(3) and 107(4) of the Regulation. These provisions must be strictly observed to ensure compliance and to support the Union's overarching objective of combating AMR.

2. Problem statement and discussion

In light of the identified need to reinforce to veterinarians and animal owners that the use of antimicrobial VMPs for prophylaxis or metaphylaxis is subject to specific provisions, as laid down in Articles 107(3) and 107(4) of the Regulation, it is considered necessary to include further statements on this matter in the product information of such VMPs. These statements would highlight the applicable restrictions in practice, support prudent antimicrobial use, and help mitigate the risk of AMR.

In order to accurately reflect the specific provisions set out in Articles 107(3) and 107(4) of the Regulation, additional standard sentences should be introduced. In particular, the following points should be addressed:

- The use of antimicrobials for prophylaxis is only allowed under the conditions laid down in Article 107(3) of Regulation (EU) 2019/6, i.e. in exceptional cases, for administration to an individual animal (for antibiotics) or a restricted number of animals (for antimicrobials other than antibiotics) when the risk of an infection or of an infectious disease is very high and the consequences are likely to be severe.
- The use of antimicrobials for metaphylaxis is only permitted under the conditions laid down in Article 107(4) of Regulation (EU) 2019/6, i.e. when the risk of spread of an infection or of an infectious disease in a group of animals is high and where no appropriate alternatives are available.

In addition, the guideline should include references to the latest relevant scientific guidance and legislation.

Lastly, a need to ensure consistency in the translations of the standard sentences included in the guideline across Member States was identified. To tackle this need, it is suggested to include the translations of those standard sentences in all EU/EEA languages as a separate Annex to the guideline, in collaboration with Member States.

3. Recommendation

The Committee for Veterinary Medicinal Products (CVMP) recommends revising the existing guideline, taking into account the points mentioned above.

4. Proposed timetable

Q3 2026: Concept paper adopted by CVMP and released for public consultation

Q4 2026: Deadline for comments from interested parties

Q1 2027: Expected date for adoption of the draft revised guideline by CVMP for release for consultation

Q2 2027: Expected end of consultation on the draft revised guideline

Q4 2027: Expected date for adoption by CVMP and publication of the final revised guideline

5. Resource requirements for preparation

The Antimicrobials Working Party (AWP) and the Efficacy Working Party (EWP-V) would jointly revise the guideline. Each working party will nominate a rapporteur. Adequate time for discussions at both working parties will be required. EMA will coordinate consultations and communication between the working parties as well as public consultations.

6. Impact assessment (anticipated)

The proposed revision of the current guideline would contribute to improved clarity of SPCs for antimicrobial VMPs regarding the provisions applicable for their use for prophylaxis and metaphylaxis, thereby ensuring clear communication of relevant information to veterinarians, animal owners, industry and other interested parties. General benefits would include improved prudent use of antimicrobials and thus a decreased risk of AMR. The proposed annex containing translations of the standard sentences included in the guideline is expected to ensure consistency of the SPCs for antimicrobial VMPs across Member States. The revised guideline is not intended to increase the requirements for marketing authorisation applications for VMPs.

7. Interested parties

Veterinary pharmaceutical industry and consultants, EU regulatory authorities, veterinary organisations and professional bodies, consumers, animal owners as well as other interested parties that might be concerned with the use of antimicrobials and with AMR resulting from the use of antimicrobials in veterinary medicine.

8. References to literature, guidelines, etc.

- EMA/CVMP (2021). Guideline on the summary of product characteristics (SPC) for veterinary medicinal products containing antimicrobial substances (EMA/CVMP/383441/2005-Rev.1 Corr.[1]). Available at: https://www.ema.europa.eu/en/guideline-summary-product-characteristics-spc-veterinary-medicinal-products-containing-antimicrobial-substances-scientific-guideline.

- Official Journal of the European Union (2019). Regulation (EU) 2019/6 of the European Parliament and of the Council of 11 December 2018 on veterinary medicinal products and repealing Directive 2001/82/EC.
- EMA (2024). QRD veterinary product-information annotated template (English) version 9.1. Available at: https://www.ema.europa.eu/en/veterinary-regulatory-overview/marketing-authorisation-veterinary-medicines/product-information-requirements-veterinary-medicines/veterinary-product-information-qrd-templates.
- Official Journal of the European Union (2024). Commission Delegated Regulation (EU) 2024/1159 of 7 February 2024 supplementing Regulation (EU) 2019/6 of the European Parliament and of the Council by laying down rules on appropriate measures to ensure the effective and safe use of veterinary medicinal products authorised and prescribed for oral administration via routes other than medicated feed and administered by the animal keeper to food-producing animals.
- EMA/CVMP (2026). Scientific advice of the Committee for Veterinary Medicinal Products pursuant to Article 141(1)(i) of Regulation (EU) 2019/6, for Quarter-based selective antibiotic dry cow therapy (EMA/CVMP/44250/2026). Available at: https://www.ema.europa.eu/en/medicines/veterinary/referrals/quarter-based-selective-dry-cow-therapy.