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Committee for Veterinary Medicinal Products (CVMP)

Concept paper on the need for Revision of Note for Guidance on Quality Aspects of Pharmaceutical Veterinary Medicines for administration via drinking water

Agreed by QWP	April 2025
Adopted by CVMP	12 June 2025
Start of public consultation	20 June 2025
End of consultation (deadline for comments)	31 October 2025

The proposed guideline will replace the Note for Guidance on Quality Aspects of Pharmaceutical Veterinary Medicines for administration via drinking water (EMEA/CVMP/540/03 Rev.1).

Comments should be provided using this EUSurvey form. For any technical issues, please contact the EUSurvey Support.

Keywords	Administration via drinking water, administration via milk, administration via milk replacer, liquid feeds, veterinary medicinal products

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1. Introduction

The Regulation (EU) 2019/6 of the European Parliament and of the Council of 11 December 2018 on veterinary medicinal products (repealing Directive 2001/82/EC) entered into force on 28 January 2019 and is applicable from 28 January 2022 onwards. One of the delegated acts arising from this is Regulation (EU) 2024/1159 of 7 February 2024(1), which lays 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. Article 8 of Regulation (EU) 2024/1159 makes specific reference to administration of veterinary medicinal products for oral administration in drinking water and liquid feeds, including milk, or milk replacers. However, currently there is no available guidance on the use of veterinary medicinal products administered in liquid feeds.

This concept paper addresses the need to complement the guideline on Quality Aspects of Pharmaceutical Veterinary Medicines for administration via drinking water (EMEA/CVMP/540/03 Rev.1)(2) with information relating to the administration of veterinary medicinal products in liquid feeds.

2. Problem statement

The parent guideline on Quality aspects of pharmaceutical veterinary medicines for administration via drinking water (EMEA/CVMP/540/03 rev.1) covers characteristics of water such as pH and hardness, which can affect the solubility and/or stability of the active substance, but it does not include any information regarding the quality of liquid or the medicated liquid when veterinary medicinal products are reconstituted for administration in liquids other than water such as milk or milk replacer.

Regulation (EU) 2024/1159 refers to liquid feeds which is defined as 'any feed material or compound feed in a liquid or semi-liquid form, including milk or diluted milk replacers and ready to use for oral animal feeding'. Therefore, the CVMP tasked the QWP with developing guidance to address the issues relating to administration of veterinary medicinal products via liquid feeds. Reconstitution of veterinary medicinal products for administration in milk and milk replacer is common practice, whereas the oral administration of veterinary medicinal products in other liquid feeds is not commonplace. It is therefore proposed to limit the scope of this revision to administration of veterinary medicinal products in milk and milk replacer[1]. Nevertheless, the revision will confirm that the principles within the guideline are also applicable to other liquid feeds.

3. Discussion (on the problem statement)

For young animals, milk and milk replacer, rather than water, are commonly used to administer veterinary medicinal products. However, the current guideline contains no guidance regarding administration in these liquid feeds. The dissolution, solubility and stability of the active substance in the liquid must be investigated and understood in order to give appropriate instructions for preparation and use of the medicated liquid in the product information of the veterinary medicinal product.

Specifically, the following aspects need to be considered:

- The dissolution of the product should be achievable within a reasonable time at a suitable temperature.

[1] Applicable EDQM standard terms are 'Powder for use in drinking water/milk' and 'In drinking water/milk use', both of which include milk replacer within their scope.

- The formulation should be developed so that the product is freely soluble in the liquid at the concentrations at which it is to be used.
- The medicated liquid should be demonstrated to be stable for the duration of its intended use.

This concept paper aims to introduce quality requirements to ensure the safety and efficacy of medicines administered in milk or milk replacer, into the current guideline. In addition, several other minor revisions to the guideline may be included in this revision, such as incorporation of existing related Q&A's [3], position papers [4], reference to Annex II [5] of the guideline into the text of the guideline and to align with the current EMA template for Guidance.

4. Recommendation

The CVMP recommends the revision of the existing guideline EMEA/CVMP/540/03 Rev.1 in order to provide clearer guidance and to align the guideline with current scientific and regulatory requirements, taking into account the issues identified above.

5. Proposed timetable

July 2025	Concept paper released for public consultation
31 October 2025	Deadline for comments from interested parties
Q2 2026	Expected date for adoption of the draft revised guideline by CVMP for release for consultation
Q4 2026	Expected end of consultation on the draft revised guideline
Q2 2027	Expected date for adoption by CVMP and publication of the revised guideline

6. Resource requirements for preparation

Revision of the guideline will involve one QWP-V rapporteur, and a drafting group. Other relevant working parties may also be consulted if required.

7. Impact assessment (anticipated)

The revision of the guideline is expected to improve the guidance for applicants as well as for regulatory authorities. It is not intended to increase the requirements for marketing authorisation applications for veterinary medicinal products.

8. Interested parties

- Veterinary pharmaceutical industry and consultants;
- EU regulatory authorities involved in the assessment of marketing authorisation applications for veterinary medicinal products;
- Veterinary organisations and professional bodies;
- Scientific veterinary associations.

9. References to literature, guidelines, etc.

(1) 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 has been published in the Official Journal of the EU (https://eur-lex.europa.eu/eli/reg_del/2024/1159/oj).

(2) Guideline on quality aspects of pharmaceutical veterinary medicines for administration via drinking water-EMEA/CVMP/540/03-Rev 1 (2005)

(3) Q&A-Is it possible to grant a marketing authorisation for a product which is not soluble over the pH ranges described in the guideline on quality aspects of pharmaceutical veterinary medicines for administration via drinking water (EMEA/CVMP/540/03 Rev. 1)?

(4) Position paper on the maximum in-use shelf-life for medicated drinking water-EMEA/CVMP/1090/02-FINAL (2002)

(5) Guideline on Quality Aspects of Pharmaceutical Veterinary Medicines for administration via drinking water - Annex on compatibility studies between veterinary medicinal products and biocidal products. EMA/CVMP/QWP/592906/2022

(6) Advice on implementing measures under Article 106 (6) of Regulation (EU) 2019/6 on veterinary medicinal products – scientific problem analysis and recommendations to ensure a safe and efficient administration of oral veterinary medicinal products via routes other than medicated feed – EMA/CVMP/508559/2019 – 20 August 2020 –Committee for Medicinal Products for Veterinary Use.