EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

15 September 2023
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Committee for Veterinary Medicinal Products (CVMP)

Concept paper on the revision of the Guideline on user safety of topically administered veterinary medicinal products (EMA/CVMP/SWP/721059/2014)

Agreed by Safety Working Party (SWP-V)	August 2023
Adopted by CVMP for release for consultation	7 September 2023
Start of public consultation	15 September 2023
End of consultation (deadline for comments)	30 November 2023

The proposed guideline will revise and replace 'Guideline on user safety of topically administered veterinary medicinal products' (EMA/CVMP/SWP/721059/2014)

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

Keywords	user safety, topically administered veterinary medicinal products

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1. Introduction

The Guideline on user safety of topically administered veterinary medicinal products (EMA/CVMP/SWP/721059/2014) was published in May 2018. This guideline was written to provide specific guidance and advice on how user risk assessments should be conducted for topically administered products. The guideline is to be used in conjunction with the 'Guideline on user safety for pharmaceutical veterinary medicinal products' (EMA/CVMP/543/03-Rev.1).

2. Problem statement

The Guideline on user safety of topically administered veterinary medicinal products is planned to be revised in relation to the possible inclusion of reference to current EU-standards in the assessment of dermal absorption, i.e. 'EFSA guidance on dermal absorption' (EFSA Journal 2017; 15(6):4873) and to updated OECD 'Guidance notes on dermal absorption' No. 156.

The revision could also include developments on the toxicological reference values, defaults and exposure calculations (e.g. absorption factors, appropriateness of the default values and of the wipe test) and risk mitigation measures.

3. Discussion (on the problem statement)

The Guideline on user safety of topically administered veterinary medicinal products is planned to be revised in relation to:

- the possible inclusion of reference to current EU-standards in the assessment of dermal absorption, i.e. 'EFSA guidance on dermal absorption' (EFSA Journal 2017; 15(6):4873) and to updated OECD 'Guidance notes on dermal absorption' No. 156.
- provide more clarity, where necessary, on the establishment of appropriate toxicological reference values to be used in the risk characterization.
- the possible inclusion of reference to in vitro tests when considering local tolerance.
- the wipe test; provide more guidance on situations for which wipe tests are required and re-evaluate whether the nominal defaults for transferable residue fraction used in the absence of a wipe test are considered adequate.
- provide more guidance on adequate risk mitigation measures; which user safety warnings are appropriate and practicable.
- provide more guidance on the assessment relevant for pregnant women, in case of substances that cause developmental toxicity.
- provide some clarity on the risk characterization of generic products; for example qualitative and quantitative differences in excipients may result in different exposures, e.g. when spilling the product or when stroking the treated animal.

4. Recommendation

The Working Party/Committee recommends revising the 'Guideline on user safety of topically administered veterinary medicinal products' taking into account the issues identified above, in order to include the latest insights and provide more clarity, when necessary, on the risk characterization of these products.

5. Proposed timetable

7 September 2023	Concept paper released for consultation
30 November 2023	End of consultation of the concept paper (deadline for comments)
March 2024 – June 2024	Discussion of the draft guideline in SWP-V
September 2024	Draft guideline adopted by CVMP and released for 2-month consultation
November 2024	End of consultation of the guideline (deadline for comments)
December 2024- March 2025	Re-discussion of the draft guideline in SWP-V
April 2025	Final guideline adopted by CVMP and published

6. Resource requirements for preparation

The revision of the guideline above will involve the SWP-V (including a drafting group composed of SWP-V members(s) including rapporteur, and expert(s)) and the CVMP.

The guideline is foreseen to be discussed at two plenary meetings of the SWP-V. Ad-hoc meetings may take place as needed.

7. Impact assessment (anticipated)

The revision will refine and update some steps of the assessment.

No adverse impact on industry or regulators with respect to either resources or costs is foreseen.

8. Interested parties

Pharmaceutical Industry, EU Competent Authorities, Consultants

9. References to literature, guidelines, etc.

1. CVMP Guideline on user safety of topically administered veterinary medicinal products (EMA/CVMP/SWP/721059/2014) https://www.ema.europa.eu/en/documents/scientific-guideline/guideline-user-safety-topically-administered-veterinary-medicinal-products_en.pdf
2. CVMP Guideline on user safety for pharmaceutical veterinary medicinal products (EMA/CVMP/543/03-Rev.1) (http://www.ema.europa.eu/docs/en_GB/document_library/Scientific_guideline/2010/03/WC500077971.pdf)
3. EFSA Guidance on dermal absorption' (EFSA Journal 2017; 15(6):4873). https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/j.efsa.2017.4873
4. OECD Guidance notes on dermal absorption' No. 156. https://www.oecd.org/chemicalsafety/testing/48532204.pdf