8 December 2016
EMA/CVMP/EWP/707299/2015
Committee for Medicinal Products for Veterinary Use (CVMP)

Concept paper for the revision of the guideline on veterinary medicinal products for fluid therapy in case of diarrhoea

Agreed by the CVMP's Efficacy Working Party (EWP-V)	September 2016
Adopted by the Committee for Medicinal Products for Veterinary Use (CVMP) for release for consultation	8 December 2016
Start of public consultation	16 December 2016
End of consultation (deadline for comments)	31 March 2017

The proposed guideline will replace the "Guideline on veterinary medicinal products for fluid therapy in case of diarrhoea" (NtA Volume 7, 7AE14a)

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

Keywords	veterinary medicinal product, fluid therapy, rehydration, electrolyte imbalances

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1. Introduction

The guideline on veterinary medicinal products for fluid therapy in case of diarrhoea (7AE14a) was adopted in March 1992 and has been in force since September 1992.

Following the review of current CVMP guidelines outlined in the 'review and update of European Medicines Agency guideline to implement best practice with regard to 3Rs (replacement, reduction and refinement) in regulatory testing of medicinal products' (EMA/CHMP/CVMP/JEG-3Rs/704685/2012), an issue for review was noted in the guideline on veterinary medicinal products for fluid therapy in case of diarrhoea (7AE14a; 1992) with regards to the 3Rs' principles. Besides this issue, several other points were noted.

2. Problem statement

The current guideline recommends that an untreated control group is included in clinical studies. However, this may not always be possible for animal welfare reasons. Changes to the text could be made to reflect this fact.

There have been very few applications for authorisation of new medicinal products for fluid therapy indicated for diarrhoea, although dehydration can be caused by many other factors. The scope of the guideline is narrow and some parts of the guideline are outdated. The guideline contains references to the Directive and guidelines that have since been amended or replaced (e.g. Directive 81/852/EEC and Good Clinical Practices, VICH GL 9).

3. Discussion (on the problem statement)

In the current guideline it is mentioned that for efficacy evaluation the test products could be compared with a product approved in accordance with requirements of Directive 81/852/EEC. In addition to this, there is a request for comparison to an untreated control group, unless justified. The inclusion of a negative control is beneficial to ensure internal validity. However, this design may for animal welfare reasons not be an option for severely affected animals. The text could be revised to better reflect appropriate study design options taking study quality as well as animal welfare into account. Furthermore, a broadening of the scope of this guideline is considered to include recommendations on clinical efficacy and safety evaluation for different types of fluid therapy and for different disease conditions and not only for animals suffering from diarrhoea. However, the purpose of fluid therapy as stated in the guideline will remain: to correct dehydration and/or electrolyte imbalances and/or metabolic imbalances and, if need be, energy losses. Such broadening of the scope of the guideline may form incentives for future applications of new veterinary medicinal products.

4. Recommendation

The CVMP recommends revising the current guideline to provide more detailed and relevant information regarding the selection of control groups, taking quality aspects of the study as well as animal welfare into consideration. Furthermore, a broadening of the scope could be considered to include recommendations on clinical efficacy and safety evaluation for different types of fluid therapy and for different disease conditions.

5. Proposed timetable

8 December 2016 Concept paper adopted by CVMP for release for consultation

31 March 2017	Deadline for comments from interested parties
Q2-Q3 2018	Expected date for adoption of the revised guideline by EWP-V
Q3-Q4 2018	Expected date for adoption of the revised guideline by CVMP for release for consultation

6. Resource requirements for preparation

Preparation of the revision would involve one rapporteur assisted by co-rapporteur(s).

Preparation of the draft guideline will require discussion at EWP-V plenary meetings, and drafting group meetings (virtual), as needed.

7. Impact assessment (anticipated)

The revised guideline is not intended to increase the requirements for marketing authorisation applications. The review and update of existing guideline might be more appropriate for authorization of medicinal products for fluid therapy.

8. Interested parties

Veterinary pharmaceutical industry and consultants.

Regulatory authorities.

Scientific veterinary associations, e.g. FVE (Federation of Veterinarians of Europe), European College of Veterinary Internal Medicine Companion Animals (ECVIM CA), European Veterinary Emergency and Critical Care Society (EVECCS), European College of Equine Internal Medicine (ECEIM).

9. References to literature, guidelines, etc.

Concept paper on review and update of EMA guidelines to implement best practice with regard to 3Rs (replacement, reduction and refinement) in regulatory testing of medicinal products (EMA/CHMP/CVMP/JEG-3Rs/704685/2012).