



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

14 July 2016
EMA/CVMP/EWP/706095/2015
Committee for Medicinal Products for Veterinary Use (CVMP)

Concept paper for the revision of the guideline on anticoccidials used for the therapy of coccidiosis in chickens, turkeys and geese (7AE15a; 1993)

Agreed by Efficacy Working Party (EWP-V)	June 2016
Adopted by Committee for Medicinal Products for Veterinary Use (CVMP) for release for consultation	July 2016
Start of public consultation	July 2016
End of consultation (deadline for comments)	31 October 2016

The proposed guideline will replace the current guideline on “Anticoccidials used for the Therapy of Coccidiosis in Chickens, Turkeys and Geese” (NtA Volume 7, 7AE15a, May 1993).

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

Keywords	guideline, veterinary medicinal product, anticoccidial, efficacy
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1. Introduction

The guideline providing specific requirements with respect of the documentation of the efficacy of new veterinary medicinal products developed for therapy of coccidiosis came into effect in 1993.

In 2014, a review of current CVMP guideline outlined in the 'Draft concept paper on review and update of European Medicines Agency 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) took place.

Following the review, some issues on behalf of the 3R's principles were considered necessary to address in the guideline. The opportunity should also be taken to revise the guideline in line with recent knowledge on efficacy of anticoccidials. In this respect, it should be considered to expand the scope of this guideline to include also anticoccidials in cattle, sheep, pigs and ducks.

2. Problem statement

Since last revision of the guideline, increased knowledge has been gained on several areas relating to the efficacy of anticoccidials against *Eimeria* species in poultry and development of anticoccidial resistance (Holdsworth P. A. et al., 2004).

Moreover, veterinary medicinal products with anticoccidial effect have been applied and authorised in cattle, sheep, pigs and ducks. Hence it is considered necessary to expand the scope of this guideline to include also efficacy requirements for anticoccidials in these target animals.

The guideline also needs to be re-evaluated in a 3R perspective.

3. Discussion (on the problem statement)

The guideline should be reviewed in line with recent scientific progress and experience. For example:

- The relevance of existing target animals should be reviewed, including pigeons. It is proposed to expand the guideline to include efficacy requirements also for cattle, sheep, pigs and ducks.
- The relevance of the listed coccidia species should be reviewed.
- A section on specific requirements for pharmacodynamics and pharmacokinetics properties of the active substance(s) should be considered.
- The guideline should provide more information regarding the characteristics of the inoculum intended for experimental infection studies.
- The guideline should provide more information on evaluation of the efficacy parameters.
- More advice could be given on criteria for the statistical evaluation.
- More focus should be given to the requirements for evaluation of resistance development, including cross-resistance between active substances used for therapeutic purposes and active substances used for preventive purposes.
- The timing of medication in days after the artificial infection may need consideration.
- The guideline also needs to be reviewed in regards to the 3R principles, especially in regards to refinement of study design.

4. Recommendation

The Efficacy Working Party (EWP-V) recommends a revision of the current guideline in view of the issues raised above.

5. Proposed timetable

July 2016	Concept paper adopted by CVMP for release for consultation
31 October 2016	Deadline for comments from interested parties
Q2-3 2018	Expected date for adoption of the revised draft guideline by EWP
Q3-4 2018	Expected date for adoption of the revised draft guideline by CVMP for release for consultation

A focus group meeting with interested parties might be required.

6. Resource requirements for preparation

Preparation of the revision would involve one rapporteur assisted by two co-rapporteurs.

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

7. Impact assessment (anticipated)

The revision of the guideline is not intended to introduce additional data requirements, rather to update the existing guidance in line with recent scientific progress and experience. It is expected to provide clearer guidance to applicants, as well as to regulatory authorities, and might have an impact on the design of clinical trials, positive impact on animal welfare through refinement of study design and provision of better information on dosing regimens and anticoccidial resistance.

8. Interested parties

Veterinary pharmaceutical industry and consultants.

Regulatory authorities (EFSA).

Scientific veterinary associations, e.g. World Association for the Advancement of Veterinary Parasitology (WAAVP), World Veterinary Poultry Association (WVPA), World Poultry Science Association (WPSA), International sheep Veterinary association, World association for Buiatrics (WAB), European College of Porcine Health Management (ECPHM), International Pig Veterinary Society (IPVS).

9. References to literature, guidelines, etc.

Anticoccidials used for the therapy of coccidiosis in chickens, turkeys and geese (NtA Volume 7, 7AE15a Vol 7, May 1993).

Draft concept paper on review and update of European Medicines Agency 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).

84 Holdsworth P. A. et al. (2004): WAAVP guidelines for evaluating the efficacy of anticoccidial drugs in
85 chickens and turkeys. *Veterinary Parasitology*, 121, 189-212.