1 11 October 2012
2 EMA/CVMP/EWP/290691/2012
3 Committee for Medicinal Products for Veterinary Use (CVMP)

4 Concept paper for the revision of the Guideline for the 5 testing and evaluation of the efficacy of antiparasitic 6 substances for the treatment and prevention of tick and 7 flea infestations in dogs and cats 8 (EMEA/CVMP/EWP/005/2000-Rev.2)

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Agreed by Efficacy Working Party (EWP-V)	September 2012
Adopted by CVMP for release for consultation	11 October 2012
Start of public consultation	30 October 2012
End of consultation (deadline for comments)	31 January 2013

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11 The proposed guideline will replace the CVMP Guideline for the testing and evaluation of the efficacy of
12 antiparasitic substances for the treatment and prevention of tick and flea infestations in dogs and cats'
13 (EMEA/CVMP/EWP/005/2000-Rev.2).

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1. Introduction

The last revision of the current guideline came into effect in June 2008. Since that time new aspects for guidance came up which were addressed in a Question and Answer (Q&A-) document (EMA/CVMP/EWP/82829/2009-Rev.2). In the meantime a further issue regarding the justification of a claim for the treatment and prevention of parasite species which are exotic to Europe arose which also needs to be discussed. Additionally, consideration should be given to the potential inclusion of guidance for systemic acaricides based on their likely introduction to the market place.

2. Problem statement

In the aftermath of the last revision the content of the current guideline has been supplemented by a Q&A-document which addresses two areas: to provide clarification and harmonisation with regard to requirements 1) for generic ectoparasiticides for topical use and 2) for calculation of clinical efficacy under controlled conditions (Abotts's formula). Furthermore it has been noted that the listed tick species, which are considered acceptable for the demonstration of clinical efficacy for veterinary medicinal products intended for the EU market, may need reconsideration. The potential use of systemic acaricides needs to be considered.

3. Discussion (on the problem statement)

It is suggested to include the following points for the revision of the guideline:

- The current guideline does not cover requirements for generic or hybrid applications (according to Art. 13 (3) of Directive 2001/82/EC as amended) and can only be used partly for such applications. Therefore, to cope with this situation a Q&A-document (EMA/CVMP/EWP/82829/2009-Rev.2) on the above guideline was compiled in order to provide guidance for the determination of efficacy and safety for generic ectoparasiticidal products for external/topical use in dogs and cats. This guidance should be integrated into the existing guideline.

- In addition, based on the record of previous applications for ectoparasiticidal products a need was identified to clarify the calculation of efficacy in laboratory studies with regard to the kind of mean value to be used in Abbott's formula. Experiences from simulated as well as real data indicate that there is no clear substantiation for the use of geometric mean. The arithmetic mean is considered the only appropriate tool for estimating efficacy of ectoparasiticides in the treatment and prevention of tick and flea infestations in controlled clinical studies in dogs and cats (see Q&A-document, EMA/CVMP/EWP/82829/2009-Rev.2). Therefore, a respective modification of the relevant sections in the existing guideline is considered reasonable to improve the guidance

- In the meantime a further issue regarding the justification of a claim for the treatment and prevention of parasite species which are exotic to Europe arose which also needs to be discussed. It is agreed that the current guideline is in first line directed to the most relevant tick species on dogs and cats common in the EU. Tick species not-endemic within the EU are not explicitly addressed. Taking into account global marketing strategies it should be checked if there is a need for changing the recommendations in place.

- Consideration should be given to the potential inclusion of guidance for systemic acaricides based on their likely introduction to the market place.

4. Recommendation

The EWP/CVMP recommends the revision of the existing guideline.

5. Proposed timetable

October 2012	Concept paper adopted by CVMP for release for consultation
January 2013	Deadline for comments
Q3-4 2014	Expected date for adoption of the draft guideline by EWP
Q4 2014	Draft guideline for discussion and adoption by CVMP for release for consultation

6. Resource requirements for preparation

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

Preparation of the draft guideline will require discussions at 3-4 EWP plenary meetings.

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 usual requirements for veterinary dossiers.
It will also provide for a more homogeneous assessment of dossiers.

8. Interested parties

Veterinary pharmaceutical industry and consultants, regulatory medicines agencies, scientific committees.

9. References to literature, guidelines, etc.

- Guideline for the testing and evaluation of the efficacy of antiparasitic substances for the treatment and prevention of tick and flea infestation in dogs and cats (EMEA/CVMP/EWP/005/2000-Rev.2), Nov 2007.
- Questions and answers on the CVMP guideline on the “Testing and evaluation of the efficacy of antiparasitic substances for the treatment and prevention of tick and flea infestation in dogs and cats” (EMA/CVMP/EWP/82829/2009-Rev.2), Nov 2011