1 6 November 2014
2 EMA/CVMP/EWP/309734/2014
3 Committee for Medicinal Products for Veterinary Use (CVMP)

4 Concept paper for a guideline on data requirements 5 regarding veterinary medicinal products for the 6 prevention of transmission of canine and feline vector- 7 borne diseases

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Agreed by Efficacy Working Party (EWP-V)	October 2014
Adopted by CVMP for release for consultation	4-6 November 2014
Start of public consultation	18 November 2014
End of consultation (deadline for comments)	28 February 2015

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1. Introduction

Vectors are living organisms – such as diptera (mosquitoes, sand flies, muscid flies), ticks, fleas and lice – that transmit a disease from an infected animal to a human or another animal. Vector-borne diseases (VBDs) are caused by a wide range of infectious agents including viruses, bacteria and parasites (protozoa and helminths). VBDs may be highly pathogenic in dogs and cats, and diseased animals may have persistent infections and act as reservoirs for several zoonoses (leishmaniosis, Lyme disease, bartonellosis etc.). The threat of VBDs may increase based on a combination of factors like changing social and economic conditions, globalised travel and trade, increased urbanisation, climatic changes, environmental and ecosystem changes.

Prevention of transmission of VBDs is fundamentally based on ectoparasite control. Ectoparasite management in dogs and cats is important not only for the health and well-being of the individual companion animal but for public health in general.

2. Problem statement

Across Europe many ectoparasiticides are authorised as veterinary medicinal products (VMPs) in dogs and cats. Many of these products were assessed on the basis of existing guidelines, especially the CVMP guideline for the testing and evaluation of the efficacy of antiparasitic substances for the treatment and prevention of tick and flea infestations in dogs and cats (EMEA/CVMP/EWP/005/2000-Rev.2). However, this guideline does not give any recommendation for specific study designs to demonstrate the prevention of transmission of VBDs due to the complex nature of this issue.

Therefore, a separate guidance document is considered necessary. Stakeholders are also expected to welcome specific recommendations for studying the prevention of VBDs transmission.

3. Discussion

The prevention of VBD transmission involves disruption of the vector–host interaction by targeting the infestation with ectoparasites. The mechanisms of pathogen transmission differ widely between vectors and specific pathogens. Therefore, information on the active substance(s), pharmacodynamic properties of the formulation, pathogen transmission time, and time from attachment until transmission of pathogen(s), including the dynamics of pathogen transmission is considered necessary.

A conclusion on the prevention of transmission of VBDs requires adequately designed clinical studies, and appropriate guidance is necessary on how to design and evaluate such specific studies.

Such guidance is intended to apply to any new application for a VMP, as well as for new claims of an already authorised VMP, for which a relevant dossier to support an indication of prevention of transmission of VBDs will be provided by the marketing authorisation holder.

4. Recommendation

It is recommended to initiate the drafting of a new guideline on dossier requirements for VMPs for the prevention of transmission of VBDs in cats and dogs.

Proposed timetable

November 2014 Concept paper adopted by CVMP for release for consultation

February 2015	Deadline for comments
3-4 Q 2016	Expected date for adoption of the revised guideline by EWP-V
4Q 2016/1Q 2017	Revised draft guideline for discussion and adoption by CVMP for release for consultation

5. Resource requirements for preparation

Rapporteur in cooperation with co-rapporteur(s) to prepare the draft guideline.

Member states to provide input via EWP-V.

Preparation of the draft guideline will require discussions at a minimum of 2 – 3 EWP-V plenary meetings, and possibly some drafting group meetings using web technology (or something similar; we used to call them virtual meetings).

6. Impact assessment (anticipated)

This new guideline is expected to have an impact on animal health and public health in relation to transmission of VBDs. The anticipated benefit both to stakeholders and regulatory authorities is due to the specific recommendations for the testing of antiparasitic products for use as prevention of transmission of VBDs. A harmonised guidance document is likely to increase the interest for stakeholders in applying for marketing authorisations for such antiparasitic products, and would also be beneficial to regulators in assessing such dossiers.

7. Interested parties

Veterinary pharmaceutical industry and consultants.

Regulatory authorities.

Scientific committees.

8. References to literature, guidelines, etc.

EFSA (2014): Infographic: Vector-borne diseases http://www.efsa.europa.eu/en/press/news/140729.htm?utm_source=newsletter&utm_medium=email&utm_content=hl&utm_campaign=20140731

Mencke N. (2013): Future challenge for parasitology: vector control and “One health” in Europe. The veterinary medicinal view on CVBDs such as tick borreliosis, rickettsiosis and canine leishmaniosis. Veterinary Parasitology, 195 (3-4), 256-71

CVMP 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)