EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Overview on available guidance for antiparasitic veterinary medicines

EMA Veterinary Medicines Info Day, 14-15 March 2024

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Overview

- Guidance for anthelmintics
- Guidance for ectoparasiticides
- Guidance for the SPC of antiparasitic products
- Reduction in (the risk of) antiparasitic resistance
- Lack of expected efficacy

Available guidance for anthelmintics

VICH guidelines on efficacy of anthelmintics (link)

- VICH GL7: general requirements
- VICH GL12: specific recommendations for bovines
- VICH GL13: specific requirements for ovines
- VICH GL14: specific requirements for caprines
- VICH GL15: specific recommendations for equines
- VICH GL16: specific requirements for porcines
- VICH GL19: specific recommendations for canines
- VICH GL20: specific recommendations for felines
- VICH GL21: specific recommendations for poultry

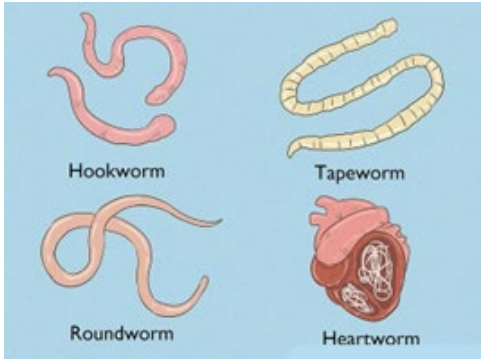
VICH guidelines on efficacy of anthelmintics

- Revision of the general requirements + 8 species-specific GLs began in 2016
- Draft revised guidelines published for consultation between June–November 2022
- 236 comments received from 8 stakeholders
- Currently the comments are being addressed
- Final revised GLs expected to be published in 2024

VICH guidelines on efficacy of anthelmintics

Main revisions:

- Standards of effectiveness: new approach for calculation and evaluation of percent efficacy for DD, DC and persistent effectiveness studies (GM & AM);
- Adequacy of infection in control animals: statistical justification, adequate infection *a priori*, minimum helminth numbers in various target animal species, experimental unit (pen);
- DC studies: scarcity of naturally infected dogs and cats;
- Age of field isolates and laboratory strains;
- Persistent effectiveness studies;
- Approach to new indications.

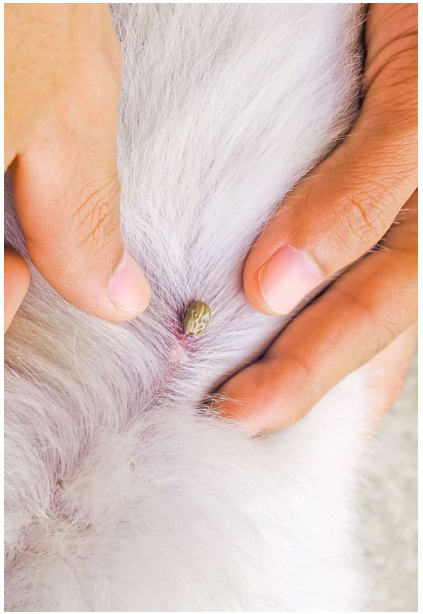


Reflection paper on anthelmintic resistance

- Published in 2017;
- Describes the current resistance situation in Europe for different helminths and anthelmintic classes;
- Current knowledge on known resistance mechanisms;
- Monitoring systems and methods for detecting resistance;
- Currently applied management strategies to delay resistance development;
- Provides recommendations on measures that might delay resistance development.
- More information: link

Available guidance for ectoparasiticides

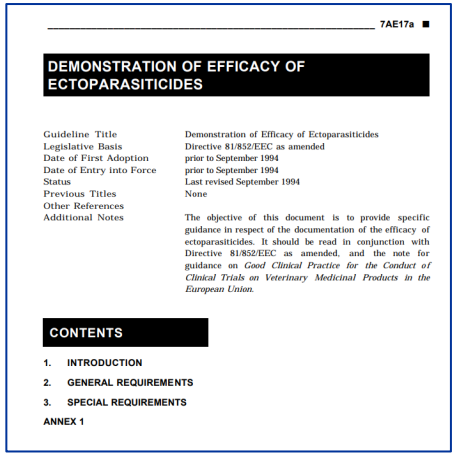
- **Guidelines** (link):
  - Demonstration of efficacy of ectoparasiticides – *under revision*
  - Testing and evaluation of the efficacy of antiparasitic substances for the treatment and prevention of tick and flea infestations in dogs and cats
  - Specific efficacy requirements for ectoparasiticides in cattle
  - Specific efficacy requirements for ectoparasiticides in sheep
  - Veterinary medicinal products controlling *Varroa destructor* parasitosis in bees – *under revision*
  - Data requirements for veterinary medicinal products intended to reduce the risk of transmission of vector-borne pathogens in dogs and cats
- **Reflection paper** on resistance in ectoparasites (link)



Guideline for the demonstration of efficacy of ectoparasiticides (7AE17a)

Currently under revision to:

- align with current legislation and up-to-date terminology;
- update to reflect current scientific knowledge and 3Rs principles;
- harmonise thresholds for efficacy with other guidelines;
- clarify approaches to calculate and assess efficacy;
- recommend a consistent approach to the wording of indications;
- include guidance for ectoparasiticide fixed combinations;
- add general guidance on factors that may affect risk for antiparasitic resistance development.



7AE17a ■

DEMONSTRATION OF EFFICACY OF ECTOPARASITICIDES

Guideline Title	Demonstration of Efficacy of Ectoparasiticides
Legislative Basis	Directive 81/852/EEC as amended
Date of First Adoption	prior to September 1994
Date of Entry into Force	prior to September 1994
Status	Last revised September 1994
Previous Titles	None
Other References	
Additional Notes	

The objective of this document is to provide specific guidance in respect of the documentation of the efficacy of ectoparasiticides. It should be read in conjunction with Directive 81/852/EEC as amended, and the note for guidance on *Good Clinical Practice for the Conduct of Clinical Trials on Veterinary Medicinal Products In the European Union.*

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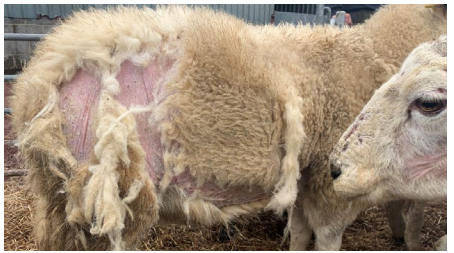
1. INTRODUCTION
2. GENERAL REQUIREMENTS
3. SPECIAL REQUIREMENTS

ANNEX 1



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

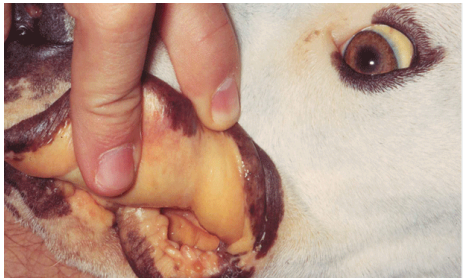
Guidelines on specific efficacy requirements for ectoparasiticides in cattle

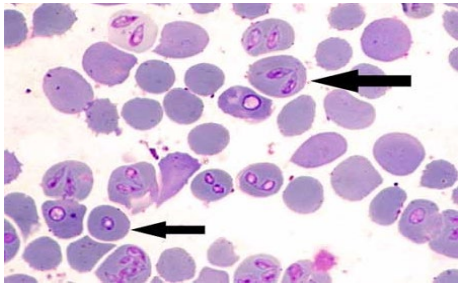
Guidelines on specific efficacy requirements for ectoparasiticides in sheep

Guideline on veterinary medicinal products controlling *Varroa destructor* parasitosis in bees

Guideline on data requirements for veterinary medicinal products intended to reduce the risk of transmission of vector-borne pathogens in dogs and cats

- New guideline, effective from 1 January 2023
- Such indications already approved by the CVMP





Guideline on data requirements for veterinary medicinal products intended to reduce the risk of transmission of vector-borne pathogens in dogs and cats

Table of contents

Reflection paper on resistance in ectoparasites

- Published in 2023;
- Provides an overview of the currently known resistance situation in ectoparasites to active substances used in VMPs;
- Focused on European situation;
- Includes a review of the current knowledge on resistance mechanisms;
- Methods of detecting resistance are discussed;
- Management strategies to delay resistance development;
- Recommendations for reducing the risk for resistance development.

Guidance for SPC for antiparasitic products

Guideline on the summary of product characteristics for antiparasitic veterinary medicinal products

- Revision 1 came into effect on **1 July 2022**;
- Scope extended to **other antiparasitic VMPs** besides anthelmintics;
- Scope extended to other target animal species (ruminants, horses + **pigs, poultry, companion animals**;
- Provides guidance on the content of the different SPC sections, mainly in relation to the management of antiparasitic resistance or the risk thereof;
- Where appropriate, standard statements/warnings are proposed.

SPC

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Summary of Product Characteristics

Questions and answers on the 'Guideline on the summary of product characteristics for antiparasitic veterinary medicinal products'

- Published in December 2022
- One Q&A on how the onset of persistent efficacy should be mentioned in the SPC of ectoparasiticides with no established immediate efficacy

Prevention of re-infestations with <parasite name, parasite species> through a <type of effect> ***from X days to*** *X weeks after treatment.*

or

Persistent <type of effect> activity ***from X days to*** *X weeks after treatment for <parasite name, parasite species>.*

Reduction in (the risk of) antiparasitic resistance

Reflection paper on the application of Art. 40(5) of Reg. 2019/6 for certain categories of variations

- Final RP to be shortly finalised and published (end of Q2 2024);
- Provides details on the potential approaches to demonstrate a reduction in (the risk of development of) antiparasitic resistance;
- If this is successfully demonstrated, the concerned studies will benefit from 4 years of data protection.

Article 40

Prolongation and additional periods of the protection of technical documentation

5. If a variation to the terms of the marketing authorisation approved in accordance with Article 67 involves a change to the pharmaceutical form, administration route or dosage, which is assessed by the Agency or the competent authorities referred to in Article 66 to have demonstrated:

(a) a reduction in the antimicrobial or antiparasitic resistance; or

(b) an improvement of the benefit-risk balance of the veterinary medicinal product,

the results of the concerned pre-clinical studies or clinical trials shall benefit from four years protection.

Lack of expected efficacy

- **Develop an infographic on lack of expected efficacy for antiparasitic veterinary medicinal products** (EWP-V & PhVWP-V)

  - identify information that should be provided when cases of lack of efficacy of antiparasitics are reported through the pharmacovigilance system;
  - give further details on the relevant data to be collected to make it easier to identify possible reasons for the lack of expected efficacy.

Any questions?

Further information

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