

Anthelmintic Expert Working Group

Chairperson: Aimee Phillippi-Taylor

Introduction

Nine guidelines related to the evaluation of efficacy of anthelmintics were implemented in 2001 and 2002: General Requirements (GL7), and species-specific guidelines for Bovines (GL12), Ovines (GL13), Caprines (GL14), Equine (GL15), Swine (GL16), Canine (GL19), Feline (GL20), and Poultry (GL21). In 2015, a Task Force recommended revisions to these guidelines, and this Expert Working Group was formed. The revised draft guidelines were published in November 2022, for public comment. These comments were considered in the final revisions, and the final guidelines are to be implemented October 2024.

Guidelines adopted

- Efficacy of Anthelmintics: General Requirements (GL 7, Revision 1)
- Efficacy of Anthelmintics: Specific Recommendations for Bovines (GL 12, Rev. 1)
- Efficacy of Anthelmintics: Specific Recommendations for Ovines (GL13, Rev. 1)
- Efficacy of Anthelmintics: Specific Recommendations for Caprines (GL14, Rev. 1)
- Efficacy of Anthelmintics: Specific Recommendations for Equines (GL15, Rev. 1)
- Efficacy of Anthelmintics: Specific Recommendations for Porcines (GL16, Rev. 1)
- Efficacy of Anthelmintics: Specific Recommendations for Canines (GL19, Rev. 1)
- Efficacy of Anthelmintics: Specific Recommendations for Felines (GL 20, Rev. 1)
- Efficacy of Anthelmintics: Specific Recommendations for Chickens (GL21, Rev. 1)

Key scientific issues resolved

Major revisions included updates to considerations for dose confirmation studies (including both statistical design considerations and determination of percent efficacy), information regarding field studies in grazing species, fecal egg count reduction testing, the potential use of two induced-infection studies in companion animals with appropriate justification, definition of adequacy of infection, clarification regarding field isolate and laboratory strain characterization including sensitivity/resistance characterization of field isolates, and the statistical methods to consider when the experimental unit is a group of animals.

The use of arithmetic vs. geometric means when calculating percent efficacy in dose confirmation studies has been under scientific discussion since the early creation of these guidelines. The Revised Guideline 7 provides a method for evaluating efficacy using both means, including decision criteria for interpreting results.

Key benefits of the harmonized guidelines

These updates serve to promote consistency between member countries regarding the evaluation of efficacy of anthelmintic products. Recent scientific discussion was leading towards divergence from the existing guidelines, and these updated guidelines aim to maintain consistency between regulators such that there is a predictable path forward, and fewer animal studies are necessary to support global authorizations of veterinary medicinal products.

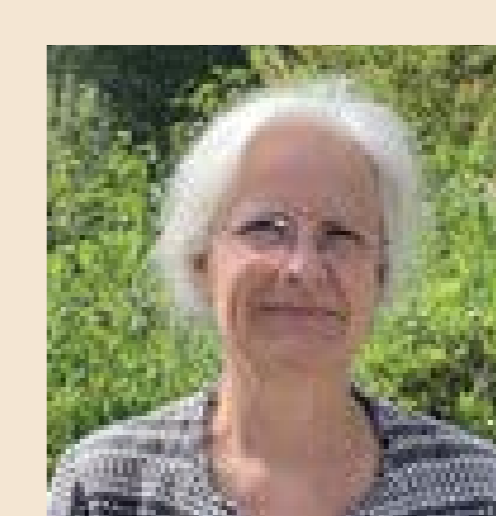
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Photo taken during the 2017 in-person meeting: L to R: Yoko Aoki (Japan, translator), Terry Settje (US, AHI, advisor), Yumi Kondo (Japan, JVPA, advisor), Virginia Recta (US, FDA, advisor), Tomoe Ogino (Japan, JMAFF, EWG member), Tadato Komatsu (Japan, JPVA, EWG member), Aimee Phillippi-Taylor (US, FDA, EWG Chair), Emily Smith (US, FDA, EWG member), Andrew DeRosa (US, AHI, EWG member), Thomas Geurden (EU, AHE, EWG member), Michelle Wooster (Australia, APVMA, past EWG member), Heather Aitken (Canada VDD, EWG member), Steffen Rehbein (EU, AHE, EWG member), and Masako Ishika Coxall (Japan, translator).

Not pictured: R. Koike (Japan, JMAFF, advisor), Yuko Endo (Japan, JMAFF, past EWG member)



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