

Anthelmintic Efficacy Expert Working Group (AEWG)

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Introduction

The AEWG was formed in April 1997 and finished in January 2001.

The objectives of the VICH AEWG were to establish uniform international standards for anthelmintic effectiveness evaluation that:

- Expedite registration of new anthelmintics;
- Serve as models for regulators;
- Assist investigators in preparing plans to effectively demonstrate the effectiveness of new anthelmintics;
- Reduce the number of studies and experimental animals and;
- Reduce overall study costs.

AEWG Composition (1999)



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1 FEDESA, EU; 2 AHI, USA; 7 AVCARE, Australia;
5 FDA/CVM, USA; 4 JVPA, Japan; 6 JMAFF, Japan.

Guidelines adopted

The first guideline produced was the overall guidance "Efficacy of Anthelmintics: General Requirements (EAGR)".

The EAGR was a significant step towards standardizing and simplifying methods used for evaluating new anthelmintics and generic products for use in domesticated animals.

Individual guidelines were developed for bovine, ovine, caprine, porcine, canine, feline and poultry to support the EAGR. This individual guidelines are to be read and used in conjunction with the EAGR.

The EAGR plus the individual guidelines need to be read in conjunction with the World Association for the Advancement of Veterinary Parasitology (WAAVP) published efficacy guidelines to obtain a comprehensive understanding of what is involved in conducting such studies.

These VICH guidelines have been further published along with the relevant WAAVP guidelines in the scientific journal *Veterinary Parasitology* so to ensure their wider uptake globally.

Key scientific issues

Important aspects from the EAGR:

Product equivalence guidance offered for:

- poorly or nil absorbed anthelmintics.
- systemic anthelmintics that can be measured in blood plasma and the limitations of pharmacokinetics as an indicator of anthelmintic effectiveness.

An acceptable effectiveness standard is set at greater than or equal to 90%.

Guidance offered on statistical analysis plus the arithmetic versus geometric means debate.

A minimum of 6 animals per study group is recommended and justified.

Important aspects of individual species guidelines

Dose determination studies

Generally use adult parasites (laboratory or field strains) and induced infestations incorporating the dose limiting parasite species/stage with a minimum of 4 animal study groups (0, 1/2, 1 and 2 x the anticipated anthelmintic dose).

Dose confirmation studies

A minimum of 2 studies against various helminth strains using animals raised in disparate geographic locations/ climates and husbandry conditions. At least one of these studies conducted in the region where registration is being pursued and both studies to be conducted under conditions representative of where product use will occur.

Persistent effectiveness studies

Multiple daily parasite challenge to host animals (2 studies).

Field effectiveness studies

Study and animal numbers influenced by animal species; geographic location; local/regional situations and dose limiting parasite. Anthelmintic to be tested in the breed/age range/class/production type of animal intended to be treated and indicated on the approved label. Effectiveness claims only to be approved on a species by species basis.

Guidelines (WAAVP) under development

The WAAVP Guidelines Standing Committee - Jozef Vercruyse (chair), Peter Holdsworth & Maggie Fischer - is in the process of expanding the WAAVP guidelines with:

- Guidelines on Bioequivalence for generic parasiticides.
- Efficacy guidelines for gastrointestinal protozoa (ruminants) including *Giardia*, *Cryptosporidium* and *Eimeria*.
- Guidelines on statistics related to efficacy studies; mainly for the faecal egg count reduction test (FECRT), new guidance is needed to improve the reliability in the use of the test and the interpretation of the test results.

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