

Mandate for the VICH TF for Efficacy Studies for Combination Products

Objectives

- To elaborate a discussion paper describing a more focused scope for the development of a VICH guideline for efficacy studies for the combination of veterinary drugs
- To address and reflect on various topics of interest expressed in the comments received from VICH SC and VOF members.

Scope

The TF will prioritize the target products for the (one or several) guideline(s), such as:

- antiparasitic combination products,
- antimicrobial combination products,
- antimicrobial / anti-inflammatory combination products
- coccidiostat / antimicrobial combination products,
- etc.

The TF will also explore the possibility of creating a general policy document for combination products.

Actions

As a first step, the TF will develop a catalogue of main groups/classes of approved combination products in VICH and VOF countries/regions in order to ensure a proper knowledge of the existing situation and to perform an efficient needs assessment before developing a VICH guideline.

The TF will further analyse the Concept Paper submitted by China as well as all relevant guidelines for combination products already in place in VICH countries.

The TF will submit the discussion paper to the SC.

Membership and Procedures

The TF will be composed of SC members (1 person per VICH delegation) and VOF members interested in this topic, including China, with a maximum of 3 VOF members participating in the TF.

Scientific experts will be included in the TF as needed.

The TF will be led by JMAFF and will work by electronic procedure only.

Reference documents

1. Concept paper on the Needs to Develop a VICH Guidance for Efficacy Studies for Combination Drug Products (Draft) (VICH/IN/13025)
2. Guidance on Pharmaceutical Fixed Combination Products (EMEA/CVMP/83804/2005)
3. CVM GFI #24 Drug Combinations for Use in Animals (CVM)
4. World Association for the Advancement of Veterinary Parasitology (W.A.A.V.P) Guideline: Anthelmintic combination products targeting nematode infections of ruminants and horses. (Veterinary Parasitology 190, 306-316, 2012)