Pharmaceutical Combination Products Expert Working Group

Chairperson: Daniel Laucks (US FDA)

Introduction

The Pharmaceutical Combination Products Expert Working Group (EWG) represents the first VICH EWG formed in response to a proposal by a VICH Forum partner. At the 3rd VICH Outreach Forum meeting in November 2013, CVDA (China) presented a draft concept paper that outlined the need for a harmonized guideline for fixed combination investigational veterinary products (FC-IVPPs). In response, the VICH Steering Committee formed a task force to create a discussion paper on the scope of the guidelines. Chaired by JMAFF (Japan), the task force finalized its' work in March 2017 and the Steering Committed approved the formation of the EWG later that year. The first Chair of the EWG was Dr. Shinxin Xu from CVDA (China), who served in that position until he handed over the Chair to Dr. Daniel Laucks in 2022. He remained a part of the EWG as an expert until his recent retirement.

While the development of FC-IVPPs shares many principles with that of single active compound products, FC-IVPPs also represent unique challenges and opportunities in their development not applicable to single active compound products.

Guidelines under development

The EWG is tasked with creating a general guideline that brings together the common principles important to the development of FC-IVPPs. The general guideline is intended to cover concepts common to all types of FC-IVPPs. While some classes of drugs (antiparacitics, antibiotics) may have additional considerations when included in FC-IVPPs, those will not be specifically addressed in the general guideline.

New topics

While the EWG's primary charge is the development of a harmonized guideline, the EWG and the Steering Committee recognize that the original concept paper brough forward by China, a VICH Forum partner, highlighted the need for a guideline to serve as a resource for jurisdictions working to develop their regulatory approach to FC-IVPPs. As such, the EWG is exploring how VICH can best provide such a resource and is considering types of documents beyond a harmonized guidance to help achieve this objective.

Key scientific issues resolved

The EWG recognizes that substantive differences in the regulatory approach to the approval/authorization of FC-IVPP exist across jurisdictions. However, many common scientific principles underly these different approaches. The EWG seeks to highlight these common principles and how they may be used to support the development of FC-IVPPs.

Key benefits of the harmonized guidelines

The Pharmaceutical Combination Products EWG endeavors to create a harmonized guideline that will not only support the efficient development of scientifically sound combination products across VICH member jurisdictions, but that can also serve as a resource for other jurisdictions as they develop their own regulatory pathways for the development and authorization of combination products.

EWG Composition

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