



New VICH Guideline – In Progress: Combination Products

U.S. Food and Drug Administration
Center for Veterinary Medicine



Outline

- History
- Process
- Next Steps



Timeline of a Guideline

2013 – Proposal for a guideline and initial Concept Paper leads to a Task Force

2016 – Discussion Document converted to final Concept Paper for a new guideline

2018-2019 – Expert Working Group drafts new guideline

2014-2015 Task Force Develops Discussion Document

2017 – Expert Working Group established

History: From suggestion to Task Force

- A VICH Outreach Forum Member, China, suggested a guideline on combination products at the 2nd Outreach Forum (February 2013).
- FDA worked with China to develop the initial Concept Paper for the Steering Committee.
- The draft Concept Paper was presented at the 3rd Outreach Forum and the 29th Steering Committee (November 2013).
- The Steering Committee agreed to set up a Task Force, chaired by JMAFF, including VOF participants to further develop the topic through development of a Discussion Document.

History: Developing the topic

- JMAFF led the Task Force in surveying the scope of combination products approved in countries and regions and developing the areas a guideline may be able to address.
- JMAFF provided reports on the activities of the Task Force to the 30th Steering Committee (June 2014), 31st Steering Committee (February 2015), and presented a final Discussion Document to the 32nd Steering Committee (October 2015).
- The 32nd Steering Committee agreed that the focus should be on a general combination product guideline and requested a detailed concept paper with more information on the necessary expertise required.



History: A new Expert Working Group

- At the 33rd Steering Committee (June 2016), the draft concept paper was reviewed. The SC agreed that the focus should be on efficacy for combination products and, in particular, justification of the combination.
- The 34th Steering Committee (February 2017) adopted the Concept Paper and created a new Expert Working Group for combination products. The SC nominated Dr. Xu from China to serve as Chair and Dr. Crystal Groesbeck from FDA to serve as topic leader.

The Expert Working Group



- CVDA
- FDA
- AHI (Merial/BIVI)
- Argentina (Zoetis)
- EU (VMD)
- AnimalHealthEurope (Elanco)
- AnimalHealthEurope (Virbac)
- JMAFF
- JVPA
- NZ (MSD AH)

EWG: Process of Developing a VICH Guideline

- 2017
 - A first draft was created by merging existing FDA and EU guidelines
 - The first draft was circulated with discussion questions to the EWG for comments
- 2018
 - Comments from the expert working group were incorporated into the draft
 - The second draft was circulated for additional comments and discussion in March
 - A third draft was developed based on feedback and circulated in September
- 2019
 - The fourth draft was circulated for discussion with a proposal for a teleconference to discuss outstanding issues

Next Steps

- The Expert Working Group will continue to work through the draft guideline through email and teleconference discussions.
- Once there is agreement, the draft guideline will be presented to the Steering Committee with Expert Working Group Members sign off at Step 2.
- The Steering Committee will sign off on the draft at Step 3 to be presented for public consultations by each VICH member and through OIE.
- Comments received through the public consultation will be reviewed and incorporated as needed before the new final guideline is made available and implemented by VICH members.

Opportunity to contribute

- Review and submit comments on the guideline when it is circulated at Step 4
 - Each Regulatory Member – JMAFF, EU, and CVM – will release the draft guideline for formal public consultation.
 - The draft guideline will be posted to the VICH website for public comment.
 - The OIE will circulate notice of the draft guideline's availability.