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The VICH Blood Level BE Guideline:
Summary of TF Perspectives

Firstly, I wish to express my appreciation to the VICH SC for providing me with the opportunity to chair this TF. It has been an absolute pleasure to work with this international team of distinguished scientists.

Despite our inability to reach consensus on all points, consensus was reached on the fundamental need for a harmonized veterinary blood level BE Guideline. There was also consensus on the public health, animal health, and animal welfare impact of such a VICH blood level BE Guideline.

Differences in opinion focused on the breadth of the proposed Guideline. IFAH and Canada emphasized the need to integrate the issue of biowaivers into the proposed Guideline because such considerations will ultimately determine conditions under which a blood level BE study is needed. While the AHI, IFAH, Canada, JVPA and US FDA expressed a desire to see the potential for future BE topics considered within the framework of the proposed EWG, the CVMP and JMAFF expressed strong discomfort with any suggestion of an intention to develop BE Guidelines on other, more complex areas. Specifically, the CVMP stated that they consider it "premature to agree to commit to further work without having identified the precise areas, whether there is a need for harmonization, and the resource demands of such work". The CVMP suggested that once the basic BE Guideline is completed, the SC may at that time request that the EWG review whether a list of complex BE issues should be developed and if any of those challenges should be addressed within the constructs of future VICH BE Guidelines. Similarly, JMAFF considered it more appropriate for a new CP to be commissioned for the purpose of developing a list of other issues and/or additional Guidelines.

In an effort to address these opposing perspectives, the most current (3rd) version of the CP was written so that the introduction would define the general conditions under which the contents of the VICH veterinary blood level BE Guideline would apply. Within that summary, the complex issues not covered by the proposed blood level BE Guideline would be delineated. Once the blood level BE Guideline would be completed (Step 6), the EWG would have the opportunity to provide the SC with a recommendation for considering the development of additional Guidelines based upon the list provided in the introduction. The intent of this proposal was that the EWG would not be committing to any additional Guideline development, but would have the opportunity to provide the SC with recommendations on strategies for future harmonization. Both the JMAFF and CVMP expressed strong discomfort with this proposal and recommended that this point of disagreement be resolved by the SC prior to convening a VICH blood level BE Guideline EWG.

As indicated by the FDA, our primary objective, the development of a blood level BE Guideline, should not be derailed by this point of disagreement. Therefore, the TF looks forward to the wisdom of the SC to resolve this challenge so that we progress forward with the convening of an EWG that will develop this very important Guideline.