VICH Guidelines: A Foundation for Regulatory Cooperation

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Outline

• Foundation
• Regulatory Cooperation Council
• Accomplishments
• Summary
Foundation for Regulatory Cooperation

• Relationships between authorities

• Confidentiality agreements

• Similar requirements and guidelines
VICH Guidelines

• Provide harmonized technical requirements for development of data to demonstrate safety, efficacy, and quality of a veterinary medicinal product in order to seek an approval or marketing authorization.

• VICH Members agree to implement harmonized guidance as their own and to accept studies conducted following VICH guidelines.
Regulatory Cooperation Council

- Regulatory Cooperation Council (RCC) Agreement was established in 2011 between the United States and Canada

- Goal: Make it easier for American and Canadian firms to do business on both sides of the border through greater regulatory alignment

- Work would not compromise health, safety, environmental protection, sovereignty or privacy rights in either country
RCC Joint Action Plan

• The Joint Action Plan established 29 specific initiatives for greater regulatory alignment

• Each initiative represented an opportunity to resolve existing issues while setting precedent for future solutions – lasting regulatory cooperation mechanisms to ensure ongoing alignment

• One initiative focused on veterinary drugs
Veterinary Drug Joint Action Plan

- Building on the high degree of harmonization and cooperation already in place between Health Canada – Veterinary Drugs Directorate (VDD) and the U.S. Food & Drug Administration (FDA) - Center for Veterinary Medicine (CVM)

- Addressing producers concerns about the disparity and the availability of veterinary drugs

- Ensuring similar focus on safety, effectiveness and quality of approved veterinary drugs; however, different regulatory frameworks
Veterinary Drug Joint Action Plan

• Goal: To facilitate simultaneous new animal drug submissions in both countries with a view to promote the simultaneous availability of drugs to end users, as well as to further align MRLs whenever possible.

• Initiatives:
  – Complete simultaneous review pilot project for drug submissions made simultaneously in both countries.
  – Continue to build on scientific collaboration in the establishment of comparable human food safety standards, including the further alignment of MRLs/tolerances whenever possible.
RCC Joint Forward Plan

• In August 2014, the Joint Forward Plan was approved and announce as a continuation of the Regulatory Cooperation Council Agreement

• The Joint Forward Plan identified veterinary drugs as one of the 24 areas of continuing collaboration between the U.S. and Canada

• Established a new veterinary drugs work plan between Health Canada – VDD and U.S. FDA – CVM for continued work.
Veterinary Drug Joint Forward Plan

- Three new initiatives included in the new veterinary drugs work plan:
  - Build on the work accomplished under the initial Joint Action Plan by expanding simultaneous reviews
  - Determine criteria for the selection of veterinary drugs for simultaneous review
  - Explore the expanded use of electronic means for submissions to help streamline the preparation of simultaneous applications
Stakeholder involvement

• Continuing outreach to industry stakeholders in the U.S. and Canada
  – Sharing information on workplans and updates
  – Feedback on specific simultaneous review projects

• Simultaneous review is only possible through the commitment of Sponsors to work with both Agencies
Accomplishments

• 10 simultaneous approvals of veterinary drugs
  – Species
    • 6 approvals in companion animals
    • 4 approvals in food animals
  – Type of approvals
    • 8 original approvals
    • 2 supplemental approvals (addition of new claims)

• As of today, 18 ongoing simultaneous reviews of veterinary drugs submissions/applications
Summary

• Foundation was in place
  – Confidentiality Agreement established in 2003
  – Frequent communication and established relationship
  – Similar regulatory requirements, although not identical
  – Implemented VICH Guidelines

• CVM and VDD have continued to build our regulatory cooperation as we have gained experience in working together