



# VICH Guidelines: A Foundation for Regulatory Cooperation

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# Outline

- Foundation
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- 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 announced 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