Health Canada Santé Canada

Canada

Perspectives of a VICH observer country

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YOUR HEALTH AND SAFETY... OUR PRIORITY.

Purpose

- Share Health Canada's experience as an observer regulator at VICH

- Provide concrete examples of international regulatory cooperation enabled by participation in VICH

Canada's History at VICH

- Canada was granted observer status at VICH in 2002 and takes part in the following:
  - Steering Committee
  - Discussion on concept papers
  - Review of guidelines before implementation and after implementation
  - Participation in expert working groups and task forces
  - VICH Outreach Forum

- Health Canada's Veterinary Drugs Directorate (VDD) is Canada's regulatory representative on the Steering Committee. VDD also represents the Canadian Food Inspection Agency (CFIA) – Canadian Centre for Veterinary Biologics
- The Canadian Animal Health Institute is the industry representative for Canada at VICH – Steering Committee meetings and expert working groups

VICH: Benefits for Canada

- Being an observer country has allowed Canada to:
  - Contribute to the international harmonization of data requirements
  - Improve its understanding of other regulatory approaches and implement international best practices
  - Enable participation by scientists, both VDD (drugs) and CFIA (biologics), in VICH expert working groups
  - Develop strong partnerships via Steering Committee, expert working groups, and provides opportunities for face to face discussions with other regulators

- To date, Canada has adopted and implemented 44 Guidelines. A small number have not been adopted or implemented with modifications because of domestic regulatory constraints or operational differences

International Regulatory Cooperation (1)

- Regulatory cooperation is becoming increasingly important considering:
  - Increasing volume and complexity of veterinary drug and vaccine applications
  - Rapid development of new technologies
  - Resources can be a challenge for regulators
- International forums including VICH have built an important foundation for further cooperation
  - In the area of veterinary drugs, regulators and industry have for many years worked on harmonising technical requirements and food safety standards through a number of international forums such as VICH and CODEX.

International Regulatory Cooperation (2)

Two international regulatory cooperation models have been developed and implemented, with concrete benefits:

1. Simultaneous scientific collaboration between the U.S. FDA Center for Veterinary Medicine and Health Canada's Veterinary Drugs Directorate (2012 to present)

- Canada-US Regulatory Cooperation Council - Simultaneous market access in the US and Canada for veterinary drugs
- A drug company files a submission to both regulators at the same time and the regulators conduct the review in parallel and independently. Discussion and collaboration occurs with the scientific evaluators throughout the review. Regulators make their own independent decision.
- Canada and the US have simultaneously approved 11 veterinary drugs and 17 are ongoing
- Next steps: improving processes internally and for sponsor applications, as well as considering other types of submissions as being eligible

International Regulatory Cooperation (3)

2. Joint Reviews between Health Canada's Veterinary Drugs Directorate, Australian Pesticides and Veterinary Medicines Authority and the New Zealand Ministry for Primary Industries

- A company files a regulatory submission with all countries simultaneously
- The regulatory evaluation of the veterinary drug submission is shared. The primary review of each technical section is led by one regulator e.g., efficacy, target animal safety, human food safety and project management
- Primary reviews, concerns, risk assessments etc. are shared between regulators and secondary reviews are undertaken by the others
- Assessments are used by regulators as the basis for independent regulatory decision-making

International Regulatory Cooperation (4)

Benefits:

- Increases the effectiveness and the robustness of regulatory decisions, creates a community of global regulatory scientists that can share knowledge and expertise

- Regulatory predictability, concurrent regulatory decisions and multiple market access

- Facilitates timely access to new drugs for producers, veterinarians and companion animal owners to better manage the health of their animals

- Benefits smaller animal health markets like Canada

Lessons Learned

Challenges and Opportunities

- Finding a willing sponsor to participate, particularly for joint reviews
- Coordinating submission review timing, ensuring similar data packages and project management
- Submission management and regulatory differences (e.g. timelines, dossier format)
- Lack of common submission platform and common electronic gateway represents a future opportunity for enhanced collaboration
- Maintaining transparency with companies and communications

How did VICH enable regulatory cooperation?

- Harmonised technical data requirements for regulatory submissions enable cooperation while submissions are under regulatory review

- Steering Committee meetings have enabled relationship building, senior level discussions and broader understanding of global regulatory environment

- Participation of scientists in expert working groups supports knowledge transfer and exchange, collaboration and building a global regulatory scientific community

Next steps

- Continued participation at VICH
- Expanding scope of existing international partnerships – pre-market, post market, innovation, emerging issues
- Expanding regulatory cooperation with “like minded” regulators
- The future is regulatory cooperation, and the future is now

Thank you / Merci