



Requirements and Consequences of the Implementation of VICH Guidelines

Merton V. Smith, Ph.D., J.D.
Director, International Programs
Center for Veterinary Medicine, FDA



The Veterinary Medicine Industry in 1996 and Today

- In 1996 VICH participating countries/region = 90% of the veterinary medicine global market
- In 2011 VICH participating countries/region = 70% of the veterinary medicine global market
- Increase in international movement of animals, people, and foods derived from animals



The Veterinary Medicine Industry in 1996 and Today (continued)

- Increase in demand for foods derived from animals especially from developing countries
- Increase in new product development in non-VICH participating countries/regions
- Increase in need to share review and registration information and pool or leverage limited regulatory resources



Categories of Current VICH Participants

- European Union, United States, and Japan = Members
- Canada, Australia, and New Zealand = Observers
- World Organization for Animal Health = Associate Member
- Association of Veterinary Biologics Companies = Interested Party



Requirements for VICH Members

- Members have pledged to implement all finalized VICH Guidelines*
- Members participate in Steering Committee meetings and in Expert Working Group meetings
- Members consult with stakeholders concerning draft and final VICH guidelines
- Members are permitted to participate in voting
- Members chair Steering Committee meetings and Expert Working Group meetings

* Guidelines are not regulations in the United States



Requirements for VICH Observers

- Observers have made no pledges regarding the implementation of VICH Guidelines but they are encouraged to use them
- Observers participate in Steering Committee meetings and in Expert Working Group meetings
- Observers consult with stakeholders concerning draft and final VICH guidelines
- Observers do not take part in voting



Requirements for the VICH Associate

- Associate has made no pledge regarding the implementation of VICH Guidelines
- Associate participates in Steering Committee meetings but not in Expert Working Group meetings
- Associate does not take part in voting
- Associate chairs the Global Outreach Initiative and shares VICH information with OIE members



Requirements for the VICH Interested Party

- Interested Party has made no pledge regarding the implementation of VICH Guidelines but is encouraged to use them
- Interested Party attends Steering Committee meetings (but does not participate in the discussions) and does not attend Expert Working Group meetings
- Interested Party does not take part in voting



Consequences for Current VICH Participants: Benefits

- Reaches multilateral agreement on guidelines for the studies that are undertaken to ensure high standards of product quality, safety and efficacy to protect public health, animal health and welfare and the environment
- Implements these harmonized regulatory guidelines for veterinary medicines in the countries/regions participating in VICH
- Minimizes the use of test animals and costs of product development



Benefits to Current VICH Participants

(Continued)

- Facilitates and accelerates the authorization of Veterinary Medicinal Products in the countries/regions participating in VICH
- Provides a basis for future international harmonization of registration guidelines
- Provides a forum for dealing with new, emerging global issues and relevant science



Benefits to Current VICH Participants (Continued)

- Replaces national/regional requirements with corresponding harmonized guidelines
- Utilizes a process that is transparent, cost-effective, and open for public comments
- Shares information with others through public conferences (VICH Public Conferences I-IV)
- Reduces costs and time for all stakeholders*

* For example, cost/benefit study showing savings from implementing VICH stability testing guidelines



Benefits to Current VICH Participants (Continued)

- Provides a unique opportunity for industry to work with regulators in a collaborative manner serving their common interests
- Provides a discussion forum for highly experienced and qualified scientific experts
- Provides all participants with a better understanding of the content and implementation of guidelines and regulations



Benefits to Current VICH Participants

(Continued)

- Encourages a global product development approach
- Encourages pooling and leveraging of regulatory resources
- Provides more regulatory certainty
- Reduces impediments to trade in veterinary medicines and food



Potential Benefits to Other Countries or Regions

- Future VICH participants could see all or many of the same benefits as experienced by current VICH participants
- Those benefits will depend greatly on the nature of the veterinary medicine regulatory program that exists in each country or region



Need for Oversight of Veterinary Medicine Registration and Use

- Authorization of veterinary medicines around the world almost universally follows a similar model requiring premarket that is based in veterinary legislation and regulation
- Stems from a country's sovereign need for government oversight of nation's health and consumer safety
- But implementation of this regulatory model by each country is often inconsistent or spotty



Worldwide Diversity of Approaches to Regulating Veterinary Medicines

- Authorities that review all (or some) safety, efficacy, and quality data before products can be registered or licensed
- Authorities that pool their regulatory resources to review and monitor products
- Authorities that want to know the basis for approvals in other countries*

* All authorities should want to know the basis for approvals in other countries for medicines that are used (or will be used) in their own countries where that information is relevant



Need for Veterinary Medicine Regulatory Infrastructures

- But some countries have no significant regulatory programs for controlling veterinary medicines
- Some countries have diffuse, non-harmonized controls at state or local levels
- Some countries have a critical need to identify a government focal point and build information sharing networks: OIE veterinary medicines focal points initiative



Need for Veterinary Medicine Regulatory Infrastructures

- All regulatory programs need a core set of scientific competencies to be in place, and standards and procedures need to be available and implemented to undertake data assessments and/or understand the assessments conducted by others
- Special considerations for some countries or regions: for example, need to deal with lack of products for minor uses or minor species or special local or regional conditions of use



Potential Benefits to Countries or Regions not now Participating in VICH

- By understanding VICH and the work products of VICH, benefits would accrue to countries or regions that review testing data that support product safety, quality, and efficacy
- Benefits would also accrue to countries and regions that utilize and/or rely on data and assessments of other regulatory authorities



Critical Need to More Effectively Share Product Information

- Sharing data in real time by utilizing available information technologies: premarket product reviews and regulatory standards, adverse drug events, GMP/GLP/GCP inspection results, recalls, and others*
- Sharing information to synergize efforts and best utilize limited resources
- Examples of sharing information: United States with others, UEMOA, CAMEVET, European Union

* For example, CVM's Freedom of Information Summaries and other publicly available information



Further Discussion

Questions?



Final Remarks

Thank you!