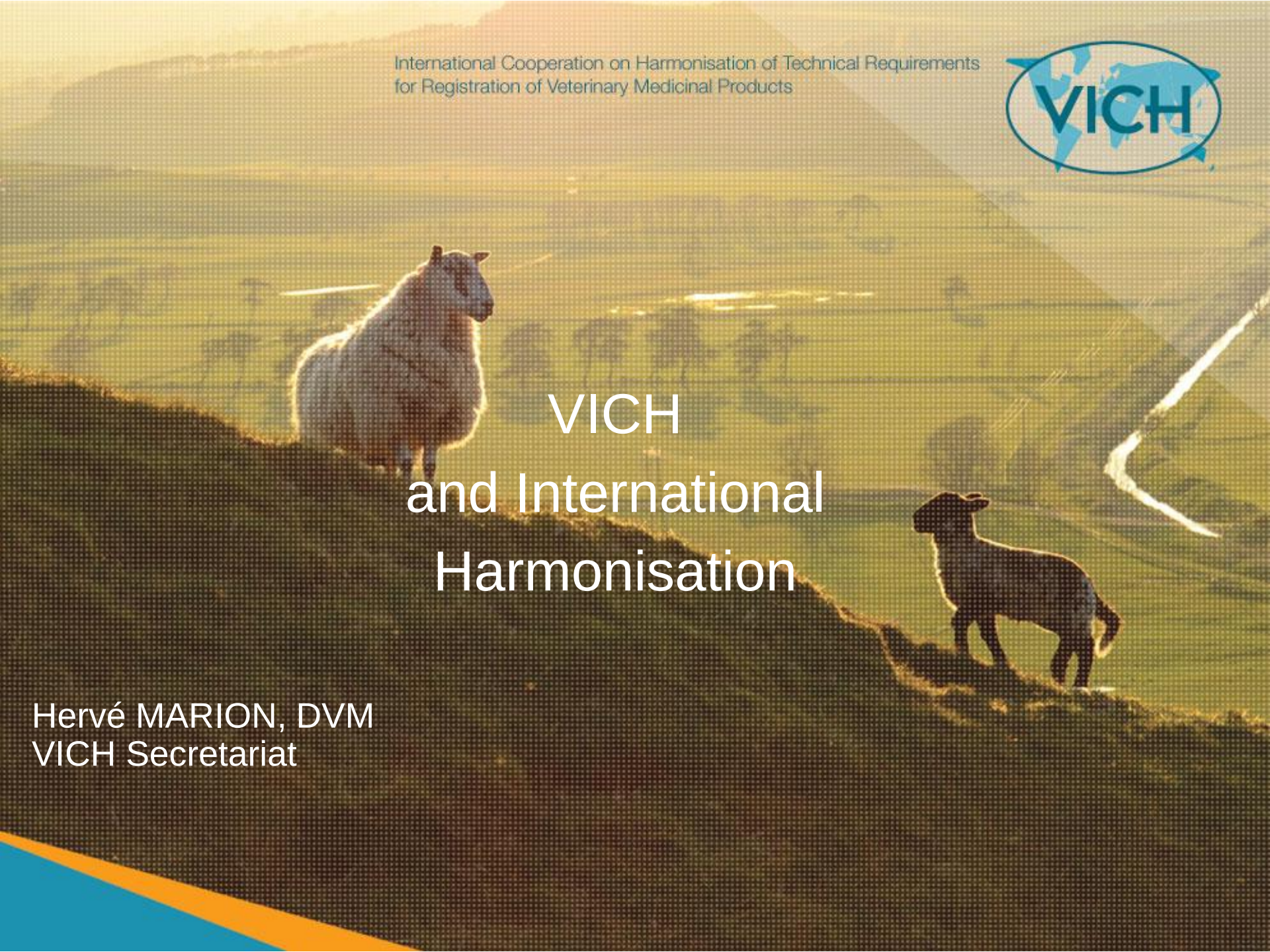

VICH and International Harmonisation

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I. VICH

Background, History and Development

What is VICH?

VICH = International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products

- International tripartite cooperation programme
- US-JAPAN-EU (+ AUS/NZ + Canada + South Africa as observers)
- Discussion Forum for Regulatory Authorities and Industry – A unique set-up of public and private sector expertise sharing

VICH - the regions

VICH Members

Committed to implement VICH Guidelines

VICH Observers

Voluntarily implement VICH Guidelines

OIE (World Organisation for Animal Health): Associate Member

IFAH (International Federation for Animal Health): Secretariat

VICH – the history

1980 ies	First talks on harmonisation of veterinary medicines registration around the world at the meetings of the International Technical Consultation on Veterinary Drug Registration (ITCVDR)
1990	Meetings on harmonisation of veterinary biologicals (1992: Ploufragan, France, 1994: Arlington, USA, 1995: Singapore)
1991	Creation of ICH with 1st conference
1992	7th ITCVDR conference in Argentina: concept of VICH emerged
1994	OIE ad hoc Group on the Harmonisation of the Regulation of Veterinary Medicines: develops scope, membership and objectives of VICH
April 1996	1st VICH Steering Committee in the OIE headquarters in Paris, France
Nov. 1999	1st VICH Public Conference in Brussels, Belgium
Oct. 2002	2nd VICH Public Conference and 11th Steering Committee meeting in Tokyo, Japan
May 2005	3rd VICH Public Conference and 16th Steering Committee meeting in Washington DC, USA

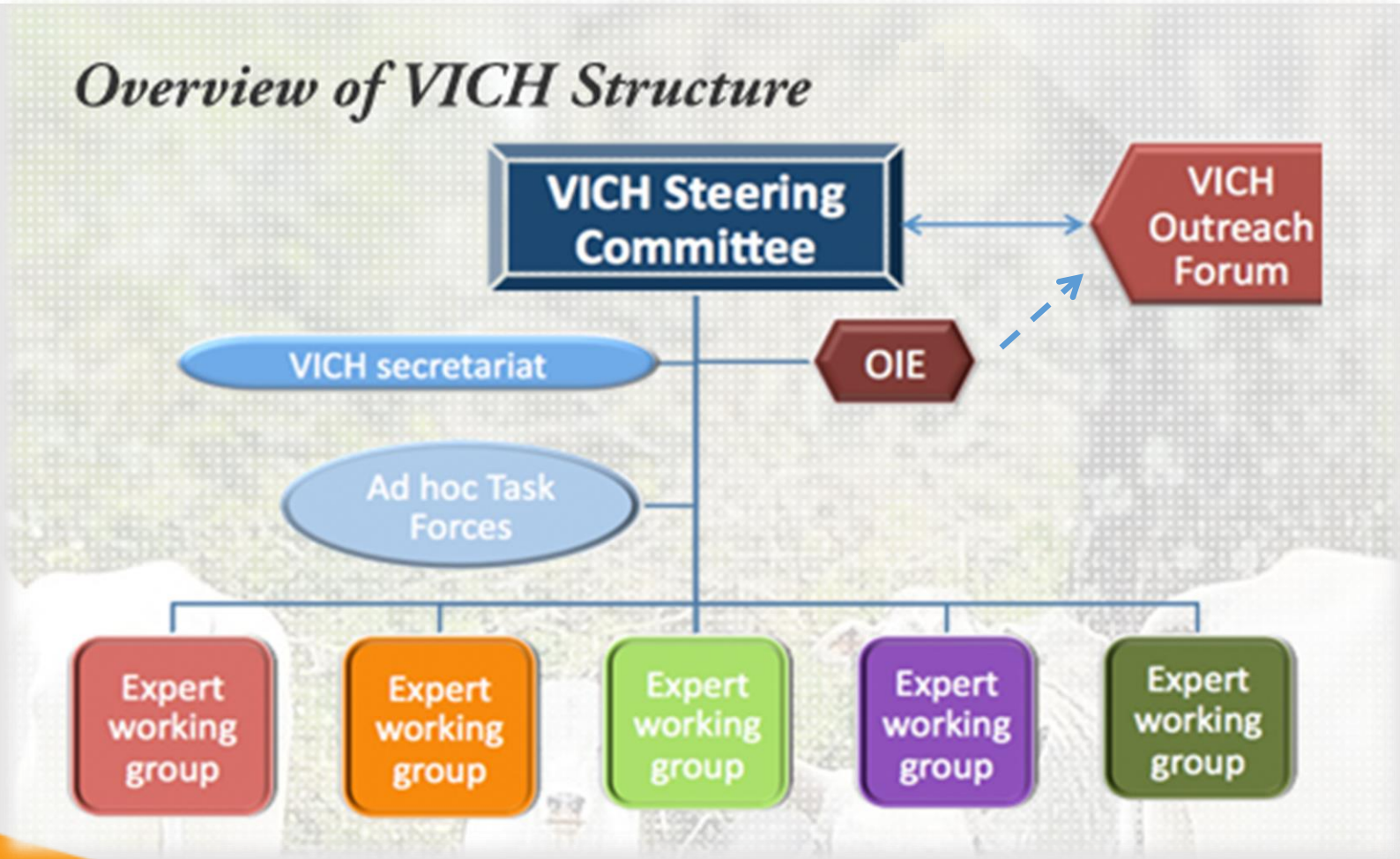
VICH – the history cont'

June 2008	First reflection on Global Outreach
June 2010	4th VICH Public Conference , 24th Steering Committee and plenary exchange on Global Outreach Strategy in the OIE headquarters
November 2011	Contact meeting with selected non-VICH country representatives in Tokyo, Japan
June 2012	1st VICH Outreach Forum meeting in Brussels, Belgium
February 2013	2nd VICH Outreach Forum meeting in Auckland, New Zealand
November 2013	3rd VICH Outreach Forum meeting in Washington DC, USA
June 2014	30th Steering Committee and 4th Outreach Forum meetings in Brussels, Belgium
October 2015	5th VICH Public Conference, 6th VICH Outreach Forum meeting and 32nd Steering Committee in Tokyo, Japan

II. VICH

Structure, Role and Objectives

Overview of the VICH structure



What is the role of VICH?

- VICH's role is to harmonise **technical** requirements for data necessary for the marketing authorisation (also called registration) of a veterinary medicinal product
- Development, implementation and maintenance of VICH Guidelines in the VICH regions
  - ✓ Guidelines relating to studies (study design and testing strategy) to support product authorisation
    - ✓ Quality, safety and efficacy (including bioequivalence)
  - ✓ Pharmacovigilance Guidelines (post-marketing safety monitoring)

It is NOT the role of VICH to:

- Provide guidance to establish regulatory systems and regulations for marketing authorisations for Veterinary Medicinal Products
- Decide which studies are necessary to obtain a marketing authorisation
- Assess data or provide guidance on the assessment approach
- Grant marketing authorisations
- Establish safety standards

These are typically the roles of national competent authorities and governments!

How do the roles of VICH, OIE and Codex differ?

- **VICH** develops harmonised data requirements, i.e. standards of the scientific studies on quality, safety and efficacy that are required to obtain a marketing authorisation for a veterinary medicinal product

  ⇨**VICH Guidelines**

- **OIE** sets international standards for animal health and welfare, including laboratory animals, adopted by its 180 Member Countries.
  - Standards on animal health are:
    - Recognised by WTO
    - References for international trades
    - Used by trading countries to:
      - Set up their national animal health policies
      - Protect themselves from the introduction of diseases and pathogens, without setting up unjustified sanitary barriers

  ⇨ **OIE normative documents**

How do the roles of VICH, OIE and Codex differ?

- **OIE** also supports its Member Countries in improving the legal framework and resources capacity of national Veterinary Services and setting standards on animal production food safety

- The **Codex Alimentarius Commission** develops, on international level, food safety standards, guidelines and related texts (recognised by WTO as references for international trade) such as:
  - Codes of practice under the Joint FAO/WHO Food Standards Programme to protect consumers and ensure fair practices in the food trade
  - Maximum residue limits (MRLs) for residues from veterinary drugs in foodstuffs from animal origin under the Joint FAO/WHO Expert Committee of Food Additives (JECFA)

⇨ **Codex food safety standards**

VICH Objectives and Guiding Principles

- ✓ Establish and implement harmonised requirements for veterinary medicines in the VICH regions, which
  - Meet high standards of Quality, Safety & Efficacy to protect public health, animal health & welfare and the environment
  - Minimise the use of test animals and costs of product development
- ✓ Provide a basis for wider international harmonisation of technical requirements
- ✓ Ensure efficient processes for maintaining and monitoring consistent interpretation of data requirements following implementation
- ✓ Provide technical guidance enabling response to significant emerging global issues and science of relevance

VICH Guiding Principles

- ✓ The decision making process in VICH should be through consensus
- ✓ Procedures should ensure the smooth and consistent functioning of the process for preparation, consultation and adoption of guidelines
- ✓ New topics for development of guidelines are agreed following evaluation of importance and feasibility of project; requires acceptance of all full VICH members
- ✓ Harmonised requirements should replace corresponding regional requirements
- ✓ Transparent and cost-effective procedures, open for public comments
  - Consultation by all regulatory authorities in VICH
  - Consultation procedure by dissemination to OIE Member Countries through OIE
  - VICH public website

VICH Members

- **European Union**
  - European Commission (EC) - European Medicines Agency (EMA)
  - International Federation for Animal Health – Europe (IFAH-Europe)
- **United States**
  - Food and Drug Administration/Center for Veterinary Medicine (FDA-CVM)
  - US Department of Agriculture/Animal Plant Health Inspection Service - Center for Veterinary Biologics (USDA – CVB)
  - Animal Health Institute (AHI)
- **Japan**
  - Japanese Ministry of Agriculture, Forestry and Fisheries (JMAFF)
  - Japan Veterinary Products Association (JVPA)

VICH Observers

- **Australia/New Zealand** –
  - —Australian Pesticides and Veterinary Medicines Authority (APVMA)/New Zealand Ministry for Primary Industries
  - —Animal Medicines Australia Ltd (AMA)/AGCARM/Agricultural Chemicals & Animal Remedies Manufacturers' Association of New Zealand
- **Canada**
  - —Health Canada (HC) - Veterinary Drugs Directorate (VDD) and Canadian Centre for Veterinary Biologics Section (CCVB)
  - —CAHI - Canadian Animal Health Institute
- **Republic of South Africa**
  - Department of Agriculture, Forestry and Fisheries (DAFF) and Department of Health (DH)
  - South African Animal Health Association (SAAHA)

Also participating in VICH
Associate Member/Interested Party

- **Associate Member**
  - — World Organisation for Animal Health (OIE)

- **Interested Party**
  - — AVBC: Association of Veterinary Biologics Companies (USA)

The VICH Steering Committee

- Regulatory Representatives from:
  - EU ➔ EMA + EC
  - JAPAN ➔ JMAFF
  - USA ➔ FDA-CVM + USDA-CVB
  - ANZ ➔APVMA + NZMPI
  - Canada ➔HC-VDD + CCVB
  - South Africa ➔ DAFF + DH
- Representatives from Industry Associations:
  - AHI, JVPA, IFAH-Europe, AMA, AGCARM, CAHI, SAAHA
- OIE - Associate Member
- Secretariat: IFAH Global

The VICH Steering Committee

- ✓Is the decision making body of VICH and drives the process
- ✓Is composed of senior representatives of the member and observer organisations (2 delegates and 1 coordinator for each organisation)
- ✓Meets every 8 to 9 months alternatively in the 3 member regions
- ✓Determines the priority items based on concept papers prepared by its members

The VICH Steering Committee

- ✓Sets up the appropriate Expert Working Groups (EWGs) and appoints topic leaders and EWG chairpersons;
- ✓Considers and resolves issues raised by the EWGs
- ✓Approves the draft Guidelines issued by EWGs before release for public consultation
- ✓Is responsible for a programme of monitoring maintenance and review of guidelines
- ✓Approves (ONLY the regulatory authorities from the EU, Japan and the USA) the final Guidelines for implementation in the member regions

The VICH Expert Working Groups

The VICH Expert Working Groups

- Membership decided by the Steering Committee (SC)
- Composed of a limited number of members
- Each SC member and observer has the right to appoint one expert
- If necessary, and unless otherwise specified by the SC, each expert may be accompanied by one advisor
- Additional experts from non-VICH regions can be appointed by the SC

III. VICH

Members and participants Requirements and Benefits

Rights and obligations of VICH Members

- Members have pledged to implement all finalised 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 sign-off of guidelines (in final steps regulators only)
- Members chair Steering Committee meetings and Expert Working Group meetings

Rights and obligations of 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

Benefits of VICH to participants

- Acceptance of multilaterally agreed guidelines for studies undertaken to ensure product quality, safety and efficacy as well as to protect public health, animal health and welfare and the environment
- Use of harmonised technical guidelines for veterinary medicines in the countries/regions participating in VICH
- Minimisation of the use of test animals and costs of product development

Benefits of VICH to participants - cont'

- Facilitation and acceleration the authorisation of Veterinary Medicinal Products in the countries/regions participating in VICH
- Provision a basis for future international harmonisation of registration guidelines
- Participation in a forum dealing with new, emerging global issues and relevant science

Benefits of VICH to participants - cont'

- Sharing information with others through public conferences (VICH Public Conferences I-IV)
- Reduction of costs and time for developing new product and bringing them on the market*

  * For example, cost/benefit study showing savings from implementing VICH stability testing guidelines
- Provides all participants with a better understanding of the content and implementation of guidelines and regulations

Benefits of VICH to participants - cont’

- Participation in a global product development approach
- Increase of pooling and leveraging of regulatory resources
- Assurance of more regulatory certainty in that results from studies carried out in accordance with VICH guidelines are recognised
- Reduction of impediments to trade in veterinary medicines and food

Potential Benefits of VICH to Other Countries or Regions

- Countries and regions currently not part of VICH can profit of many of the benefits as experienced by current VICH participants
- Those benefits will depend greatly on the nature of the veterinary medicines regulatory system that exists in each country or region

The VICH Outreach Forum

- Composed of participants from 14 countries and 3 regional organisations that have expressed an interest in the work of VICH
- Countries: Argentina, Brazil, China, India, Korea, Morocco, Malaysia, Mexico, South Africa*, Thailand, Taiwan, Philippines, Russia & Ukraine
- Regional organisations:
  ASEAN, CAMEVET & UEMOA

* Has become a VICH Observer in 2013

The VICH Outreach Forum

- First met in June 2012
- Meets every 9 – 10 months (in the frame of SC meetings), chaired by VICH in collaboration with OIE
- Objectives are:
  - ✓ To provide a basis for wider international harmonisation of registration requirements,
  - ✓ To improve information exchange and
  - ✓ To raise awareness of VICH and VICH guidelines with non-VICH countries/regions

IV. VICH

The Guidelines and their development process

The VICH Process

- Thorough selection of topics by SC based on assessment of benefits and feasibility for harmonisation and resources requirements
- Work mandated by the SC to Expert Working Groups
- Elaboration and adoption of guidelines in a 9-step procedure
- Taking particular note of ICH guidelines taking account of veterinary specific needs
- Consequent need for maintaining and updating existing guidelines on a regular basis

The VICH Process

- Programme runs in cost-effective and transparent way
- Expert Working Groups work through emails, teleconferences and face-to-face meetings to progress their work
- Steering Committee
  - ✓ Monitors progress of Expert Working Groups and provides support and direction
  - ✓ Monitors implementation of Guidelines in the VICH regions

Development of a VICH Guideline: The 9 step procedure

Step 1	▪ Concept paper to propose issue ▪ Review by SC ▪ Appointment of Topic Leader/Chairman
Step 2	EWG to produce draft Guideline
Step 3	SC to approve draft Guideline for consultation
Step 4	Public consultation in the regions
Step 5	EWG to review comments and finalise Guideline
Step 6	SC to adopt final Guideline
Step 7-8	Implementation of Guideline
Step 9	Recommendation for review
→	9 step procedure

Development of a VICH Guideline

Step 1

- Concept paper to propose issue
- Review by SC
- Appointment of Topic Leader/Chairman

- The SC defines a priority item from a **detailed concept paper** sponsored by one of its members

- The SC establishes an appropriate EWG, if needed, and designates a chairperson. A topic leader in charge of drafting a guideline is appointed and given a clear mandate to do the expected work

Development of a VICH Guideline

Step 1

- Concept paper to propose issue
- Review by SC
- Appointment of Topic Leader/Chairman

- The SC ensures that each expert is properly briefed and has a clear mandate enabling him/her to meet the expected outcome in the timeframe defined by the SC, in accordance with established VICH procedural guidance
- The SC ensures that each topic leader has the required competence and interpersonal skills to lead an EWG and achieve its objectives
- Internal VICH Guidance documents – work procedures

Development of a VICH Guideline - cont'

Step 2 EWG to produce draft Guideline

- The appropriate EWG elaborates a draft guideline, and submits it to the Secretariat with the signatures of all experts

Development of a VICH Guideline - cont'

Step 3 SC to review and approve draft Guideline

- The draft guideline is submitted to the SC for approving its release for consultation

Development of a VICH Guideline - cont'

Step 4 Public consultation in the regions

- Following approval by the SC, the draft guideline is circulated to all interested parties for consultation, applying an appropriate consultation period (normally 6 months).
- **World wide public consultation** through OIE members and VICH website
- EVERYBODY can comment

Development of a VICH Guideline - cont'

Step 5 EWG to review comments and finalise guideline

- The EWG reviews the comments and **provides feedback** on the use of the comments (VICH Website)
- At this step, the topic leader must be a representative of a regulatory authority
- The EWG prepares a revised draft and submits it to the Secretariat with the signatures of all experts.

Development of a VICH Guideline - cont'

Step 6 SC to adopt final Guideline

- The revised draft guideline is submitted to the SC for approval

- Only the representatives from the regulatory authorities sign off the final VICH guideline

Development of a VICH Guideline - cont'

Step 7-8 Implementation of Guideline

- Once approved by the SC, the final guideline and a proposed date for its implementation (usually 1 year) are circulated to the regulatory authorities represented in the SC

- The VICH Guideline is **available for all** on the VICH public website

Development of a VICH Guideline - cont'

Step 9 Recommendation for review

- Science is not cast in stone…
- Regular maintenance and review of VICH final guidelines
- In principle after 3 years
- **Discussion Document** considered by the SC
- Formal Concept Paper if need to review

⇨ VICH 9 step procedure

Existing VICH Guidelines - Summary

Pre-approval				
	General			GL9, GL53
	Biologicals			GL50
		Quality		GLs 34, 25 & 26
		Safety		
			TAS	GLs 41 & 44
	Pharmaceuticals	Quality		GLs 1, 2, 3, 4, 5, 8, 10, 11, 17, 18 (R), 39, 40, 45, 51
		Efficacy		GL52
			Anthelmintics	GLs 7, 12, 13, 14, 15, 16, 19, 20 & 21
		Safety		
			Environmental Safety	GLs 6 & 38
			Metabolism and Residue	GLs 46, 47, 48, 49
			Toxicology	GLs 22, 23, 28, 31, 32, 33 & 37
			Target Animal Safety	GL 43
			Antimicrobial Safety	GLs 27 & 36
Post-approval				
	Pharmacovigilance			GLs 24, 29, 30, 35 & 42


Final and draft Guidelines available on:
www.vichsec.org

V. VICH

The Achievements

Achievements

- **Confidence building and close collaboration between the participants since 1996!**
  - Considerable improvements of harmonization of data requirements between regions, thus
    - ✓ Reduction of animal testing
    - ✓ Reduction of costs
  - Better understanding of regulations and concerns in the other regions
  - Unique discussion forum between acknowledged worldwide scientific experts from both the Regulatory agencies and the Animal Health companies

Achievements

- All decisions in the SC and the EWGs are made **by consensus**
- Unique opportunity for regulators and industry to discuss topics openly enabling a pooling of expertise to jointly draft guidelines on regulatory data requirements
- Opportunity to update regional standards
- Acceleration of Veterinary Medicinal product development for Livestock & Companion Animals
- Increase availability of Veterinary Medicines

Achievements

- Increased uniformity of regulatory process and technical requirements for VICH members and observers, and OIE Members
- Global product development approach
- Increased Product Safety and Consumer Safety
- Contribute to the Global One Health approach

Achievements

- Reduction of animal-based tests – commitment to the "3 R" (Reduce – Refine – Replace)
- Reduction in number of animals used (Safety)
- Regulatory Agencies implement in the 5 regions ➔ Official publication – change of regulatory requirements/legislation
- Availability of the best global scientific expertise

The VICH public website (http://www.vichsec.org)