

*Session IV:
Future legislation and international affairs*

VICH / Outreach

Brigitte Boenisch, Merial France – IFAH-Europe
European Medicines Agency/IFAH-Europe Info Day, 7-8 March 2013



Areas to be covered

- What is VICH?
- And what does “Outreach” stand for?
- Highlights from the first two VICH Outreach Forums



What is VICH?

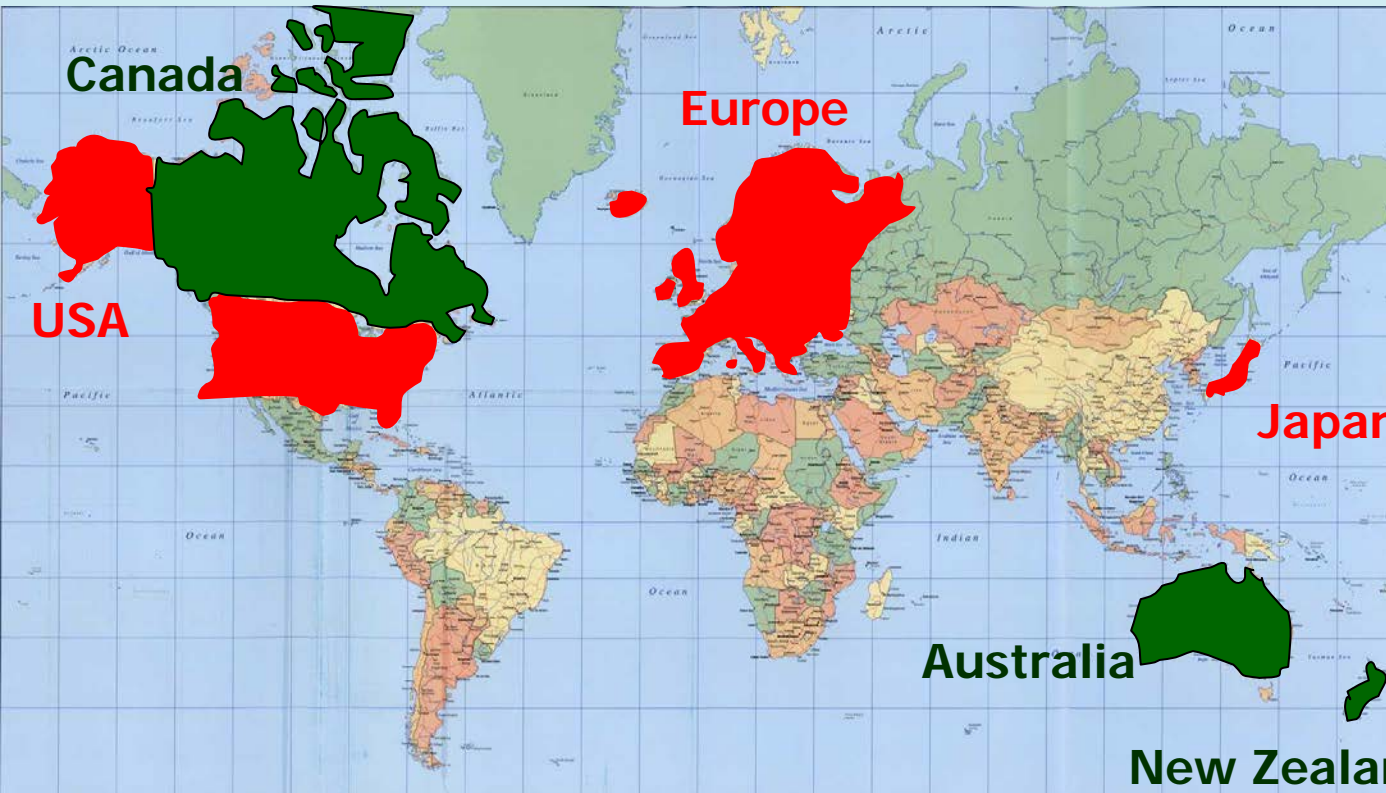


VICH = International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products


- Created in 1996
- International tripartite cooperation programme
- Brings together Regulatory Authorities and Industry in a constructive, science-based dialogue



The VICH regions



 =
VICH member,

 =
VICH observer

OIE (World
Organisation for
Animal Health) =
associate member

IFAH = Secretariat

The VICH process

- **The VICH Steering Committee (SC)**
 - topics, draft guidelines, final guidelines for implementation
- **VICH Expert Working Groups**
 - specific expertise for guideline development
- **Transparent guideline development**
 - VICH 9-step process, public website, conferences
- **Commitment**
 - VICH members have committed to implement VICH guidelines in their veterinary product regulatory processes
 - VICH observers voluntarily do so

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



VICH

WHAT IS VICH ?

VICH is a trilateral (EU, USA, Japan) agreement for harmonising technical requirements for registration. Its full title is **Cooperation on Harmonisation of Requirements for Registration of Medicinal Products**. VICH was officially established in April 1996.

VICH AND ITS ROLE FOR MEDICINAL PRODUCTS
[Spanish-Arabic & Chinese](#)

THE VICH/OIE WIDER COOPERATION MEETING ON GUIDELINES FOR THE REGISTRATION OF VETERINARY MEDICINALS (TOKYO, JAPAN, 15 NOVEMBER 2011)

VICH STRUCTURE
• Overview of VICH processes

VICH PROCESS
• The Process - The Steering Committee

VICH TOPICS
• Quality

VICH GUIDELINES
• Summary table of VICH guidelines



And what does “Outreach” stand for?

- Results from one of the VICH objectives:
Provide a basis for widening international harmonisation of registration requirements

Reaching out to non-VICH countries and regions

- Included in VICH Strategy and in Fifth OIE Strategic Plan

“Outreach” as a strategy

- Extend information and communication about VICH work and guidelines to non-VICH countries
- Encourage reference to those harmonised quality, safety and efficacy standards
- Avoid development of new standards which differ from those already established by VICH - *regulatory predictability, no duplication*
- Co-operation on a more global level
- Close collaboration with OIE as a pre-requisite to successful implementation of VICH wider international harmonisation objective

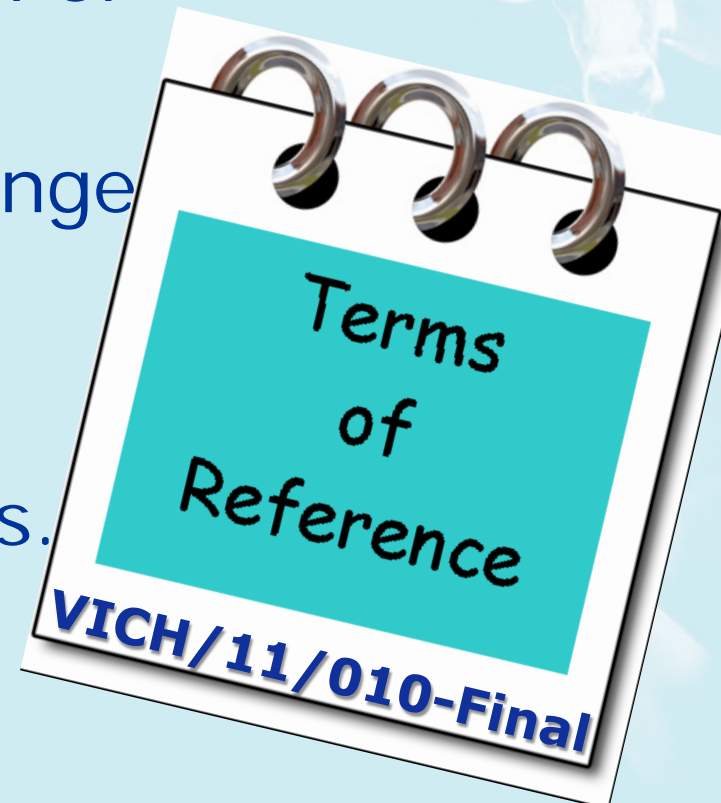
Creating opportunity for dialogue and exchange

- Contact Meeting on Wider International Harmonisation, Tokyo, 15th November 2011
 - ✓ 11 countries (Argentina, Brazil, China, Indonesia, Korea, Malaysia, Morocco, South Africa, Taiwan, Thailand, Ukraine)
 - ✓ 3 regional organisations (CAMEVET, ASEAN, UEMOA)
 - ✓ VICH Steering Committee
- 26th VICH SC Meeting took into account the input and discussions at the Contact Meeting
- Decision to create **VICH Outreach Forum**

Highlights from the first two VICH Outreach Forums

Objectives

- To provide a basis for wider international harmonisation of registration requirements,
- improve information exchange
- raise awareness of VICH and VICH guidelines with non-VICH countries/regions.



VICH Outreach Forum

1st Meeting, Brussels, 26/27 June 2012



- Collaborating and sharing of translations of guidelines
- Feedback on acceptance of existing guidelines
- Collating comments on concept papers and draft guidelines
- Ideas for new topics
- Training needs

- Updates by countries
- Confusion between roles of OIE and VICH (and other international bodies, e.g. CODEX):

Legal/regulatory framework vs. technical data requirements for product marketing authorisation



VICH Outreach Forum

2nd Meeting, Washington, 19/20 February 2013



Participation from:

- 9 countries (Brazil, China, India, Korea, Russia, South Africa, Taiwan, Thailand, Ukraine)
- 2 regional organisations (CAMEVET, UEMOA)
- VICH Steering Committee

Chaired by:

- VICH (Dr. Bernadette Durham) & OIE (Dr. Jean-Pierre Orand)



2nd VICH Outreach Forum

Report from VICH Steering Committee

Report from SC:

- Explanatory document updated to provide further clarity
- Collating comments on draft guidelines (publication)
- Link to available translations from OIE website



- Enabling Forum members to input ideas for new topics
- Collaboration between OIE and VICH regarding training
- VICH homepage to be re-vamped

2nd VICH Outreach Forum

Topics covered (1)

- VICH Needs assessment survey conducted by OIE following the 1st VICH Outreach Forum
 - Training needs: 1) Quality GLs
2) Pharmacovigilance
3) GCP, metabolism & residue kinetics
 - Needs for translations: Forum members will start to translate the GLs identified as top priority (French, Spanish, Russian, Chinese), some OIE support
 - Topics of interest: clarified which are out of scope and how they can be addressed (definitions, legal, regulatory, enforcement, political)



2nd VICH Outreach Forum

Topics covered (2)

- Clarification of questions:
 - Definitions (new VMPs vs. generics, CODEX vs. VICH vs. OIE)
 - Role of VICH GLs vs. OIE standards
 - Topics being worked on (e.g. BE)
 - How to actively participate? (topics, concept papers, EWGs – e.g. residues in fish, honey)
- Experience with VICH (GLs) in countries
- Role of VICH and VICH GLs in marketing authorisations
- Overview and explanation of VICH Stability GLs
- Overview of public consultation process for GLs in the different VICH regions



2nd VICH Outreach Forum

Conclusions from meeting



- Very good dialogue & fruitful exchanges
 - ⇒ interest in more active participation to GL development
- « Lost in translation »
 - language a real issue
 - ⇒ adapt format accordingly
- Interest and degree of involvement varies with level of background information
 - ⇒ Fully exploit available communication tools (new VICH website, Q&As on subjects already discussed, training presentations)
- Potential for new topics arising
 - ⇒ e.g. stability requirements climatic zones III and IV, efficacy of combined products

Summary

- Outreach is part of VICH mandate & objectives
 - recently added as a key strategic focus (2011-2015)
- Decision to establish a **VICH Outreach Forum** (Nov. 2011) following 1st VICH Contact Meeting
- **VICH Outreach Forum**
 - 1st meeting in Brussels in June 2012
 - 2nd meeting in Washington in February 2013
- Forum provides excellent **opportunity** to:
 - exchange,
 - learn about each other's needs and expectations,
 - work towards addressing them with the appropriate partners

**THANK YOU FOR YOUR
ATTENTION !**

