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Background and objectives of the VICH considerations regarding wider international harmonisation

Contact meeting on wider international harmonisation of VICH guidelines

November 15th 2011, Tokyo, Japan

Summary



- OIE views and initiatives
- VICH wider harmonisation:
 - a Steering Committee initiative
 - Results of the OIE/ VICH questionnaire
 - Background of the VICH 4 Conference
 - Organisation of the Tokyo meeting
- Reflections



OIE views and initiatives

General



- One World – One Health concept
- OIE member countries needs:
 - Effective and modern legislation
 - to face new threats
 - to meet the OIE criteria for quality and performance of VS functions
- OIE actions:
 - Guidelines on Veterinary Legislation
 - Evaluation of the Performance of Veterinary Services
- OIE objectives:
 - Help governments in meeting the OIE standards
 - Modernise national veterinary legislation
 - Strengthening the veterinary services



OIE views and initiatives regarding VMP



- Veterinary Medicinal Products (VMPs) :
 - Veterinary tools, contributing to the improvement of animal and public health and food security worldwide
- VMP policy is part of the animal health policy
- Need for **efficacy**, **safety** and **quality** of VMPs
- Need of a strong legislative and regulatory framework implemented through a strong and comprehensive governance linked to national veterinary service



OIE views and initiatives regarding VMP



- Pressure from OIE members to have better access to technical guidelines for authorisation of VMPs
- Need that VICH provide a perspective for collaboration and participation to these countries



OIE views and initiatives regarding VMP



- Fifth OIE Strategic Plan, Point 168 refers to the VICH activities:

“In the area of veterinary drugs, including antimicrobials, will seek to **extend** the coverage of the programme on International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products (VICH) **to all OIE Members** by encouraging the OIE to adopt, if possible, parallel standards proposed by VICH. Delegates to the OIE have nominated a Focal Point for Veterinary Drugs and Vaccines.”



OIE views and initiatives regarding VMP



- Creation of National focal points for veterinary products:
 - To coordinate all matters dealing with VMPs
 - Cycle I of training since July 2010
 - Cycle II started in September 2011 with a special training on VICH Guidelines (organisation of workshops) and participation of VICH members



OIE VIEWS



- The VICH wider harmonisation is part of the governance of VMPs
- Some key drivers for a good governance of VMPs:
 - Part of good veterinary governance
 - Legislative and regulatory framework governing all related activities needed
 - Implementation (stakeholders; competent authorities)
 - Consistent and sustainable approach
 - VICH to be the reference body regarding the technical requirements for registration



Development over time

- First reflection paper in May 2008, recognising the need for wider harmonisation, information and communication
- Constitution of a Working Group
 - (EU, FDA, JMAFF, AHI, IFAH-Europe, JVPA, OIE and the VICH Secretariat)



21st Steering Committee in 2008

- Establishment of a Working Group to enhance the global outreach of VICH
- ... taking into account:
 - The links with OIE and the potential to maximise synergies
 - The resources available
 - The regional harmonisation cooperations existing in some non VICH regions
 - The needs of the countries regarding training and capacity building



22st Steering Committee in 2009

- Proposed objectives for the global outreach:
 - International harmonisation, Better access to VMPs, Mutual recognition, Regional approaches
- Proposed operational objectives:
 - Communication, Training, Sharing of information, Animation of a network, Exchange of practical experiences, strengthening interaction between VICH and OIE
- Preparation of a discussion paper based on the result of a questionnaire to OIE Members in agreement with OIE headquarters in order to assess the way forward



OIE/VICH questionnaire

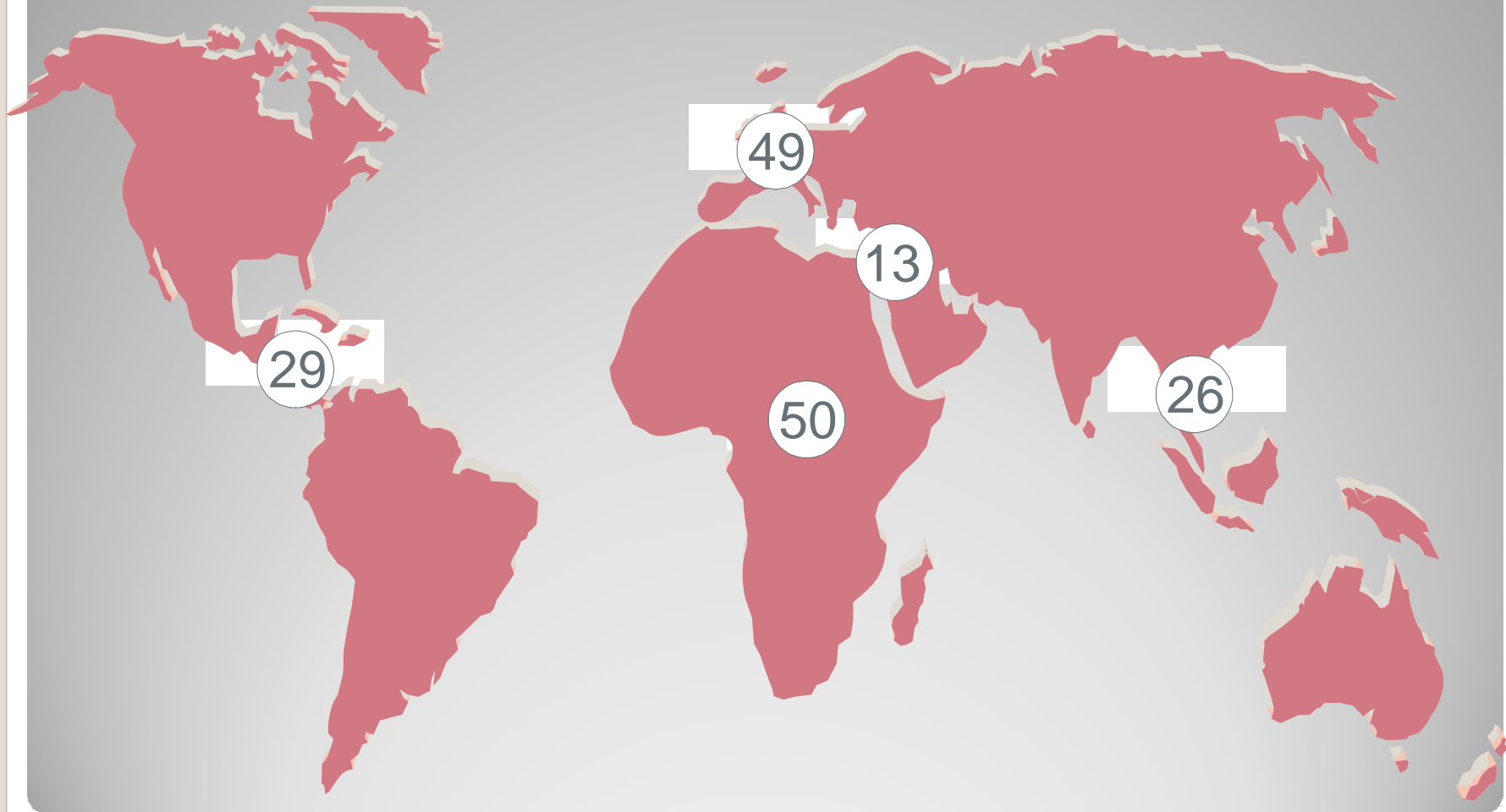
Main results

QUESTIONNAIRE

Very often	<input type="checkbox"/>
Often	<input type="checkbox"/>
Sometimes	<input checked="" type="checkbox"/>
Rarely	<input type="checkbox"/>



176 Member Countries (2010): **89** answers



Americas: 13/29 – Africa: 25/52 – Europe: 28/53 – Middle East: 6/20 – Asia: 16/35

Needs of developing countries

- VICH to assist countries with a minimal infrastructure in place AND to assist OIE in developing further the regulatory framework for VMPs
- The first priority is to assist these countries in implementing the existing "basic" GLs.
- Priority 1 = Q;S; E /Priority 2 = PV /Priority 3 = Ecotox
(countries will require guidance for implementation)
- Countries need resources and understanding
- Most of the new topics suggested are not in the scope of VICH activities.
- However, many of these are covered by other international organisations



Needs of transitional countries

- All have already established a regulatory framework
- Need for more information and clarification
- How could the major transitional countries (China, Brazil, India...) or regions (South America - Camevet, Asia - ASEAN) participate or contribute actively to:
 - VICH SC activities as Interested Parties/Observers
 - Expert Working Groups, in particular for the revision process of GLs.
 - Translation (French, Spanish, Arabic, Chinese).
 - Development of information documents
- Need for training
- Interest in the development of new topics (residue depletion, bioequivalence, minor use - minor species, disinfectants, diagnostics)



First expectations of the responding countries

- OIE to help countries to put in place:
 - Infrastructure, Legislation
 - To organise trainings
- VICH
 - To elaborate technical requirements for registration
 - To participate to information and training
 - To reflect on enlargement



VICH 4 in 2010 in Paris



4th public conference on VICH impact and future

- More than 160 delegates from 30 countries attended
- This conference had two main objectives:
 - To publicly review the achievements of the VICH initiative since its inception in 1996
 - To learn directly from non VICH member countries what their needs and expectations from VICH are
- 3 workshops to explore the role of VICH in the global regulatory environment, plans for a VICH Global Outreach Strategy, and the value and future vision of VICH.



Outcomes of the VICH 4 Conference

- Needs of non VICH countries both in the scope of VICH activities and of OIE
- Needs better information and communication, a lot of confusion about what structure can do
- Many countries want to adopt the VICH GLs
- Require more training on VICH GLs
- Needs for specific GLs



24th Steering Committee in 2010

- Discussion about the VICH strategy for the years 2011 to 2015
- Priority area identified for attention: the VICH global outreach strategy
- A working group chaired by OIE was established in order to propose an action plan



25th Steering Committee in 2011

- Further discussion about ways forward to achieve wider international harmonisation of technical requirements for the registration of veterinary medicinal products
- Agreement to further develop proposals on how to address the needs and expectations of non-VICH countries



25th Steering Committee in 2011

- Short term objectives identified:
 - to improve information, communication and awareness on VICH
 - to increase contributions of non-VICH countries in the consultation process of developing VICH guidelines and potential involvement in guideline development in the future
- Organisation of a meeting with certain non-VICH countries/regions before the 26th Steering Committee meeting in Tokyo



25th Steering Committee in 2011

- Defined objectives of the Tokyo meeting on 15th November 2011:
 - To provide an opportunity to meet each other
 - To provide more information on VICH activities and reflections concerning wider harmonisation
 - To obtain views on the best way forward to get involved in such actions



Reflection



- Objectives of the wider harmonisation:
- A science-based initiative with clear harmonisation objectives
- It is not a regulatory initiative



Reflection



- Target of the outreach:
 - as a first step, areas where VICH can have most impact:
- Countries with a solid regulatory framework established
- Regional organisations with specific initiatives regarding VMPs (UEMOA, ASEAN, CAMEVET, SADC...)



Reflection

- The objective is that the same technical standards are accepted in all countries
- Needs a forum where non VICH countries could discuss
- Necessary to define:
 - The conditions of membership
 - The role and responsibilities of all parties



Conclusion

- The VICH wider international harmonisation project is one of the responses to the OIE Strategy to improve availability of quality, safe and effective VMPs by a:
 - Reduction of administrative burden
 - Increased quality of requirements through mutual learning
 - Removal of trade barriers as a response to globalisation
 - Reduction of animal testing



Thank you for your attention



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