Dr. Gérard Moulin
Anses/ANMV
OIE Collaborating Centre on Veterinary medicinal products
BP 90203 - 35302 FOUGERES CEDEX, FRANCE
gerard.moulin@anses.fr

Overview of VICH Global outreach initiatives and potential benefits

Workshop for OIE national Focal Points for Veterinary Products
23 – 26 November 2010, Johannesbourg, South Africa

1

Summary

- VICH global outreach:
  a steering committee initiative
- Result of the OIE/ VICH survey (All countries)
- Results of the OIE/ VICH survey for Africa
- Next steps
- VICH guidelines related to biologicals

2

The starting point

- ***First reflexion 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 Secretariat)

3

The 21st Steering Committee initiative

- During its 21st meeting, the SC established a task force 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 co operations existing in some non VICH regions
  - the needs of the countries regarding training and capacity building

4

Proposal for a global outreach strategy

The VICH global outreach as part of the governance of the 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

5

The 22st SC – first outcomes

- **Proposed objectives for the global outreach:**

  International harmonisation,

  Better access to VMPs,

  Mutual recognition,

  Regional approaches

6

The 22nd SC – first outcomes

- **Proposed operational objectives**
  - ***Communication***
  - ***Training***
  - ***Sharing of information***
  - ***Animation of a network***
  - ***Exchange of practical experiences***
  - ***Stengthening interaction between VICH and OIE***

7

The 22nd SC – first outcomes

- Prepare a new discussion paper...
- ...on the basis of the result of a **questionnaire** to OIE Members in agreement with OIE headquarters,
- ... in order to assess the way forward taking into account needs and constraints

...a key milestone for the VICH III Strategy

8

Background VICH 4

- **Fourth public conference on the International Harmonisation of Technical Standards for Veterinary Medicinal Products VICH impact and future expectations**

  Paris, 24- 25 June 2010 at OIE Headquarters

- **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 were devoted to exploring the role of VICH in the global regulatory environment, plans for a VICH Global Outreach Strategy, and the value and future vision of VICH.**

OIE/VICH questionnaire

Main results

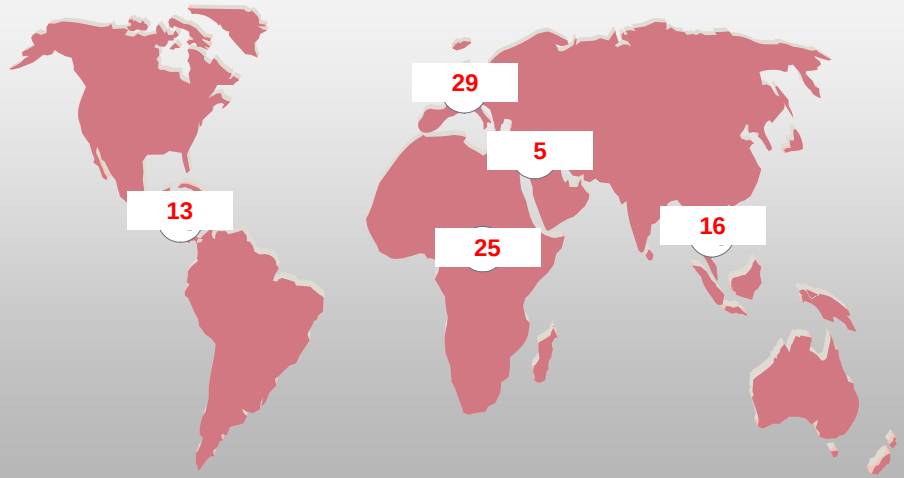
10

Number of answers

- Questionnaire sent in June 2009 to OIE Members
- 2 months consultation
- 91 answers covering 88 Member countries
  - 26 from VICH countries
  - 62 from non VICH countries

11

176 Member Countries (2010)
88 answers



Americas: 13/29 – Africa: 25/52 – Europe: 29/53 – Middle East: 5/20 – Asia: 16/35

12

Needs of developping countries

- **VICH to assist** countries with a minimal infrastructure in place AND to assist OIE in developing further the regulatory framework
- 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)

- Developing countries need of 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

13

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)

14

First expectations of the responding countries

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

15

OIE/VICH questionnaire

Africa

Main results

16

Analysis of the questionnaire for Africa

- **25 respondants**
  - Algeria
  - Botwana
  - Cameroun
  - Chad
  - Dem. Rep. Congo
  - Egypt
  - Guinea
  - Gabon
  - Guinea-Bissau
  - Ivory Coast
  - Mali
  - Marocco
  - Mauritania
  - Nigeria
  - Mozambique
  - Namibia
  - Niger
  - Senegal
  - Togo
  - Tunisia
  - Uganda
  - Zambia
  - Ethiopia
  - South Africa
  - Tanzania

17

OIE part - Legislation in Place

- **20 of the 25 countries has some legislation in place**
- **5 of the 25 countries have no legislation in place**

	Yes	No
Definition of MRLs (Maximum Residue Levels)	3	17
Authorisation of Veterinary medicinal products	17	3
Manufacturing	14	6
Importation	20	0
Distribution	18	2
Usage	17	3
Control	16	4
Pharmacovigilance	11	9
Inspection	14	6

18

OIE Part - New legislation planned?

- **18 of the 25 countries plan to put in place a new legislation**

	Yes
Definition of MRLs (Maximum Residue Levels)	8
Authorisation of Veterinary medicinal products	10
Manufacturing	3
Importation	3
Distribution	4
Usage	5
Control	7
Pharmacovigilance	9
Inspection	6

19

OIE part - Need for support to elaborate/ improve legislation?

- 22 countries need some support for legislation:
  - Main request for support:
    - Autorisation of Veterinary Medicinal Products: 3
    - Control: 5
    - Pharmacovigilance: 4
    - Legislation: 6
    - Inspection: 4
    - LMR: 3

20

OIE part - Infrastructure in place

- Do you have active laboratories in place for:

	Yes	No
The control of pharmaceuticals	11	14
The control of immunologicals	8	17
The control of residues	9	16
The control of antimicrobial resistance	4	20
The control of antimicrobial sales	5	18
Pharmacovigilance		6
Inspection		7
Legislation		4
Marketing authorisation		5

All countries need support

21

VICH part

- 16 countries know VICH, 10 are aware of VICH guidelines
- 22 countries think that VICH guideline are of interest for their countries
- 18 think that they can be implemented, 2 not, the main reason for difficulties in implementation in that VICH guidelines are considered as high level standards

22

VICH Part

- Interest in development of new guidelines:
  - Vaccines
  - Minor species
  - Residue depletion…
- Need for training on VICH guideline
  - 23 countries would like to have trainings on guidelines
- Need for more information on VICH
  - 21 countries would like more information on VICH

23

Next steps

24

24th VICH Steering committee 26 June 2010

- During the 24th meeting of the VICH Steering Committee the VICH strategy for the years 2011 to 2015 was discussed
- The priority area that was identified for attention is its global outreach strategy
- A working group chaired by OIE was establish in order to propose an action plan

25

VICH guidelines related to biologicals

26

VICH GL related to immunologicals

3 topics explored:

- **Biologicals quality monitoring**
- **Target Animal Safety**
- **Stability**

27

Biologicals quality monitoring

- Testing of residual formaldehyde
  VICH GL25 (Biologicals: Formaldehyde)
  EWG consensus signed in 2000
  Implemented in May 2003
- Testing of residual moisture
  VICH GL26 (Biologicals: Moisture) EWG consensus signed in 2000
  Implemented in May 2003

28

Biologicals quality monitoring (Cnt)

- Testing for the detection of Mycoplasma contamination

  VICH Draft GL34 (Biologicals: Mycoplasma) April 2002 - For a 12-month public consultation at step 3 - Draft 1

GL 34 should be soon be finalised

29

Target Animal Safety

- Target Animal Safety - Examination of Live Veterinary Vaccines in Target Animals for Absence of Reversion to Virulence
  VICH GL41 draft 1 – EWG consensus signed in 2004 - Recommended for adoption at step 3 in May 2006

- Target Animal Safety for Veterinary Live and Inactivated Vaccines
  VICH GL44 (TAS Biologicals) - July 2008 - For implementation in July 2009

30

Stability

- Stability testing of new biotechnological/biological veterinary medicinal products

VICH GL17 (Stability: biotechnologicals/biologicals)

EWG consensus signed in 1999
Implemented in July 2001

31

Thank you for your attention

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de la santé animale

World Organisation
for Animal Health

Organización Mundial
de Sanidad Animal

12 rue de Prony, 75017 Paris, France - www.oie.int – oie@oie.int

32