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Health

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de Sanidad
Animal

Contents & results of 3 years of VMP FP training

Susanne Münstermann

OIE Scientific and Technical Department

*Regional Seminar for National Focal Points for
Veterinary Products, Maputo, 3 - 5 December 2013*



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Introduction

- Full recognition by OIE of the global importance of Veterinary products* for **animal health, animal production**  **food safety and food security**
- However, in some countries, poor legislation, registration and distribution practices lead to poor quality or counterfeit products, posing a threat to animal and public health
- Global market of Veterinary Products is increasing, with food animals taking 60% of the share

* **Veterinary products= veterinary drugs, biological and diagnostic tests**

Introduction (contd)

- Veterinary Products (VP) are mentioned in the 5th Strategic Plan of OIE:
 - *Strengthen collaboration with International Organisations on legislation, registration, control and monitoring of use of VPs*
 - *Strengthen training efforts for national **Focal Points** to organise, manage and implement legislation pertaining to registration, quality control and final use of VPs*
 - *Strengthen the collaboration with VICH*
- Guidance was also taken from the two Regional Conferences on Veterinary products¹, held in 2008 and 2009 in Middle East and Africa, respectively

“Towards harmonisation and improvement of registration, distribution and quality control”

► The OIE Focal Point approach

- The General Assembly of OIE has established a system of **national Focal Points (FP)**, who are under the authority of the Delegate, in eight areas of OIE's work:

- Animal disease notification
- Animal production food safety
- Animal welfare
- Aquatic animal diseases
- **Veterinary products**
- Wildlife diseases
- Laboratories
- Communication



- FPs are the **link** between OIE and country, should establish a **network** with the relevant authorities and enhance communication to experts, the Delegate and stakeholders, all on their respective specific topic

► Focal points for Veterinary Products

Tasks for the FP:

- Establish a network of experts or communicate with existing networks
- Dialogue with relevant competent authority/ies
- Monitor legislation and control of VP and compare with existing international standards
- Conduct consultation process with recognised experts on draft texts of standards/GLs and recommendations
- Assist the Delegate to comment on OIE draft standards and GLs (e.g. questionnaire on AMR!!)

Receives from OIE:

- Information from VICH*
- Reports from BSC pertaining to VPs
- **TRAINING**



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

The “FP Veterinary Products” training concept

- **Timeline:**

1 st cycle	2010
2 nd cycle	2011 / 12
3 rd cycle	2013/ 14

- **Objective overall:**
 - ▶ provide good VP governance concepts
 - ▶ understanding of OIE
 - ▶ Enable FPs to comment on relevant OIE standards and Guidelines
 - ▶ address global and regional issues

Specific objectives

- **1st cycle:**

- Improve understanding of OIE mandate and activities; specifically of Delegates and FPs
- Overview of existing structures relevant for VPs
- Modalities of production and use of VPs

- **2nd cycle:**

- OIE strategy on VPs: update national legislation; collaboration with international organisations; communication & training
- VICH, its role and importance
- Registration and use of VPs, Pharmacovigilance, counterfeits
- Prudent and responsible use of antimicrobial agents
- Residues and antimicrobial resistance (AMR)

► Specific objectives of current 3rd cycle

- **3rd cycle:**

- Improve understanding on OIE procedures for new FPs as a separate session
- Follow up of the 2013 OIE Conference on AMR
- Improve understanding of validation of diagnostic tests
- Understand newest developments in anti-parasitic drugs
- Address relevant regional topics

Implementation modalities:

By region



1st cycle:

Africa
Asia & Pacific
Americas
Europe
North Africa & Middle East

2nd cycle:

Anglophone Africa (2012)
Francophone Africa (2011)
North Africa & Middle East
Asia & Pacific
Americas
Europe

3rd cycle: (2013)

North Africa & Middle East
Sub-Saharan Africa

► Implementation modalities (contd):

- **Expertise** from Collaborating Centres (CCs)
 - **Agence Nationale du Médicament Vétérinaire (ANMV) of ANSES, France**
 - **Centre of Veterinary Medicine of FDA, USA**
 - **Centre for Veterinary Biologics, USDA APHIS, USA**
 - **National Veterinary Assay laboratory & National Institute of Animal Health, Tokyo, Japan**
- **Coordination** amongst these three Centres to input expertise according to regional needs and language
- **Collaboration with international organisations:** invitation of WHO, FAO, IFAH

continued

- **OIE input** through presentations by staff from Headquarter, Regional and sub-Regional offices
- **Regional input:** last session of each course dedicated to regional issues of specific relevance to VMP, presented by experts from the region
- **Excursions to local pharmaceutical companies:** wherever possible, organise a visit and get a better understanding of the industry in the host country

Conceptual progression

After **1st cycle** (recall objectives!) feedback was used to develop **2nd cycle**

- Better integration of all CCs and key partners (VICH, IFAH, FAO, WHO)
- Interactive Workshops on
 - VICH GLs
 - Residue monitoring Plan
 - AMR monitoring system



Workshop on the establishment of antimicrobial resistance monitoring and quantities of antimicrobials used in animals:

Is there a monitoring of the quantities of antimicrobials used in animals?	
Yes / No	
If Yes:	
permanent	
Punctual	
Isolated studies ?	
Description	

Is there a plan to monitor antimicrobial resistance?	
Yes / No	
If Yes:	
<input type="checkbox"/> permanent	
<input type="checkbox"/> punctual	
<input type="checkbox"/> Isolated studies ?	
Monitoring of AMR in:	
<input type="checkbox"/> In live animals	
<input type="checkbox"/> At the abattoir	
<input type="checkbox"/> In food from animal origin	
Monitoring of :	
<input type="checkbox"/> Commensals	
<input type="checkbox"/> Zoonotic bacteria	
<input type="checkbox"/> Indicator bacteria	

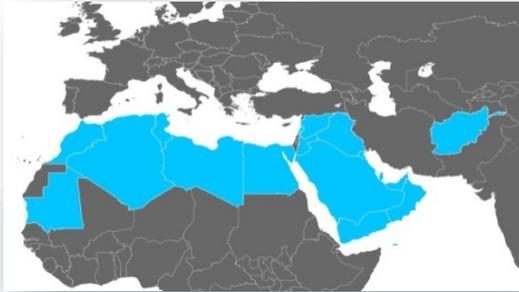
Example of WS during 2nd cycle training

In the discussion we highlight the need for harmonisation of methods!

continues

- After **2nd cycle** (recall objectives!) feedback was used to develop **3rd cycle**
 - Key topics were retained (e.g. AMR, VICH, good governance of VMPs) new topics were added, namely:
 - Validation of diagnostic test kits
 - Anti – parasitic drugs
-  including interactive workshops

Summary of participation in OIE FP VP trainings



North Africa & Middle East



Central & East Europe



Anglophone
Africa

fi				
fi				
	298	54		

Feedback from participants

- Appreciate continuity of training programme and evolution of content
- Use training event to network and build intra-regional contacts
- Have a better understanding of OIE and FP's possibilities to give input
- Facilitates FP's participation in other OIE activities (e.g. VICH Outreach Forum, intra-regional meetings)



**FP VP Training
Bangkok, 2012**



Conclusions

- OIE has established a functioning network of Focal points for Veterinary Products
- Training should be continuous to deepen knowledge and interaction between OIE and Focal points
- “cycle” approach was appreciated as it offers continuity, repetition of the basic principles, combined with new, specific aspects
- AMR as an important topics is continued in the 3rd cycle and new topics have been added
- Collaboration with FAO and WHO has been strengthened

Where to find relevant information?

http://www.oie.int/en/our-scientific-expertise/vete... This page can't be displayed Veterinary products: OIE - ...

Suggested Sites Amazon eBay Toshiba Places Web Slice Gallery Web Slice Gallery Suggested Sites

Oie World Organisation for Animal Health Font size: - AAA+ Language: | Français English Español

Keywords Search + Advanced search

Home About us **Our scientific expertise** Support to OIE members Animal health in the World International Standard Setting Animal welfare One Health Publications and documentation

Home > Our scientific expertise > **Veterinary products**

Our scientific expertise

- > Overview
- > Collaborating Centres
- > Reference Laboratories
- > Biological threat reduction
- > OFFLU, the animal influenza network
- > CMC-AH, The Crisis Management Centre-Animal Health
- > Registration of diagnostic kits
- > **Veterinary products**
- > VICH Outreach Forum
 - Antimicrobials
 - Diagnostic tests
 - Reference reagents
- > Specific information and recommendations

Veterinary products

Veterinary products are important tools in the prevention and control of animal diseases. The definition of veterinary products may vary from one country to another; for OIE purposes, they include vaccines, veterinary medicines, such as antimicrobial agents, and diagnostic kits. To ensure effective and sustainable animal disease control while minimising risks to humans and animals, governments are expected to provide appropriate regulations on the authorisation, manufacturing, distribution and use of veterinary products through their veterinary legislation.

In this context, the OIE develops for its Member Countries international standards, guidelines and recommendations for veterinary products. These reference documents can be found in the five following publications: *Terrestrial Animal Health Code, Aquatic Animal Health Code, Manual of Diagnostic Tests and Vaccines for Terrestrial Animals, Manual of Diagnostic Tests for Aquatic Animals* and *OIE Quality Standard and Guidelines for Veterinary Laboratories: Infectious Diseases*.

The OIE also actively promotes activities related to harmonisation of veterinary legislation. As an associated member, the OIE supports the initiative for an *International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products (VICH)*. Some specific collaborative activities and translated VICH Guidelines can be joined under VICH Outreach Forum.

In parallel and in synergy with the development of international standards, guidelines and recommendations, the OIE provides a permanent support to Veterinary Services and laboratories to enable OIE Member Countries to implement them.

The work of the OIE in the field of veterinary products is supported by three Collaborating Centres, which are world-leading institutes, and a Reference Laboratory on Antimicrobial Resistance.

Actions taken by OIE Member Countries are coordinated by the OIE National Focal Points for veterinary products, who provide technical assistance to national Delegates in improving and harmonising national policies for veterinary products.

In May 2009, the World Assembly of Delegates adopted during the 77th OIE General Session *Resolution No. 25 on Veterinary products*, which clearly recommends the OIE to strengthen its actions and to further develop a coherent strategy in this field. This position has since then been reflected in the *Fifth Strategic Plan (2011-2015)* of the OIE, which was adopted at the 78th OIE General Session in May 2010 by this same Assembly.

Additional information available: Link to the *OIE Bulletin 2010 No. 1 "Veterinary Medicinal Products"*.

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de la Santé Animale

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de Sanidad Animal

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

