Legislation requirements for control over veterinary products in South America

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Registration and control

Objectives

- **Quality**
  - Ensure the composition, purity and identity in the products

- **Efficacy**
  - Guarantee that a product will have the desired effect

- **Safety**
  - Assure that the product is not harmful for the animals, the users or the consumers
South American production and market

- **Animal population***
  - Bovine: 317 million
  - Avian: 5842 million
  - Swine: 42 million

- **Animal health products market**
  - 2260 million US dollars
    (8.7 percent growth related to 2005)

Sources: *OIE World Animal Health Information Database. Data for 2008
**International Federation for Animal Health 2008 annual report
The past situation: 25 years ago

- **Official sector**
  - Insufficient regulatory frameworks and resources
  - No communication between regulatory agencies

- **Veterinary products industry**
  - Different product qualities
  - Industry itself did not guarantee the quality
  - Fraudulent market procedures

- **Farmers**
  - Economical losses
  - Lack of demand on quality

- **Human health**
  - Lack of control and avoidance residue systems

- **International commerce**
  - Loss of markets
The challenge

External

- International exigencies
  - Veterinary Services as part of networks
  - Food quality
- Regional Trade Agreements
  - Common regulations and sanitary measures

Internal

- Health
  - Animals - Humans - Environment
Harmonisation initiatives in South and Central America

- Central American Customs Union
  - El Salvador
  - Costa Rica
  - Guatemala
  - Honduras
  - Nicaragua

- Southern Common Market (MERCOSUR)
  - Argentina
  - Brasil
  - Paraguay
  - Uruguay
  - Venezuela

- Andean Community
  - Bolivia
  - Colombia
  - Ecuador
  - Perú
  - Chile (Associated Member)

OIE Member Countries
Harmonisation initiatives...

MERCOSUR (South Common Market)

- Creation of Veterinary Products Commission in 1992
- Production of regulations for registration and control of Veterinary Products from 1992 to 1997

Steps for harmonisation:

1. Legal equivalence – National registration ✔
2. Mutual recognition of registration for products complying on harmonised technical outlines, identified under a common classification system
<table>
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<tr>
<td>29/92</td>
<td>Creation of the Veterinary Products Commission</td>
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<td>3/93</td>
<td>Proposal for the harmonised registration and control system for veterinary products</td>
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<td>11/93</td>
<td>Regulatory Framework for veterinary products</td>
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<td>44/93</td>
<td>Registration formularies</td>
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<td>Veterinary products harmonisation system</td>
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<td>Requisites for registration of antiparasitary products</td>
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<td>Contents of product technical outlines and classification table</td>
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<td>Requisites for registration of antimicrobial products</td>
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<tr>
<td>4/97</td>
<td>Requisites for production and control of vaccines, antigens and diluents for aviculture</td>
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Harmonisation initiatives…

Andean Community

- Approval of Decision 483 in year 2000
  - Covering the aspects related to the registration, manufacture, control, marketing and use of veterinary products

Steps for harmonisation:

1. Legal equivalence ✔
2. National registration ✔
3. Submission and evaluation by Member countries
Central American Customs Union

- Approval of Central American Technical Regulation on veterinary products in 2008
  - Covering the aspects related to the registration, manufacture, control, marketing and use of veterinary products
  - Based on CAMEVET harmonised guidelines

Steps for harmonisation:

1. Legal equivalence ✓
2. Registration on each country under two systems
   - Common Sanitary Registration
   - Simplified Sanitary Registration

   Applied for products included in the Harmonised List of Products (harmonised technical outlines)
CAMEVET
Americas Commitee of Veterinary Medicines

Technical Working Group based on the OIE Regional Representation for the Americas

Composition

Official Members
Veterinary Medicines Focal Points
Representatives of Registration and Control agencies

Associated Members
Representatives of Veterinary Industrial Associations
CAMEVET - Objectives

- **Harmonize**
  Guidelines and procedures for the registration and control of veterinary products

- **Support**
  Official veterinary medicines registration and control agencies

- **Communicate - Share**
  Information for official and industrial sectors

- **Train**
  Members of the official agencies

- **Organize - Participate - Link**
  Meeting and Conferences - International institutions
Audit Guides for Good Manufacturing Practices in pharmacological and biological products |
| IX Seminar (2003) | CAMEVET template for Free Sale Certificates  
CAMEVET template for Exportation Certificates |
| X Seminar (2004) | Registration forms for pharmacological and biological products |
| XII Seminar (2005) | Labelling for veterinary products |
| XIV Seminar (2008) | Efficacy testing in antiparasitary products |
Common requirements for registration and control of veterinary products in South America
Common requirements

- Manufacture of veterinary products
  - Good Manufacture Practices

Different requisites

- No GMP exigencies
- CAMEVET Rules
- WHO Guidelines
- Local regulations
Common requirements

- **Product registration**
  - Similar registration forms
  - Different requisites on stability and efficacy testing
  - Differences in labelling requirements

- **Control activities**
  - Lack of controls
  - Official control on every batch released
  - Reliance on the controls made by the producers and periodic quality audits
Unfinished tasks

Consolidation of Veterinary Medicines Registration and Control areas

Active participation by OIE member countries

Implementation of harmonized guidelines
XVI Seminar on Harmonization of Registration and Control of Veterinary Medicines

Cartagena, Republic of Colombia
September 20 - 25, 2010

Associated events:
• Veterinary Medicines Focal Points Training
• Plenary Meeting of the Veterinary Industry
• Commercial Exhibition
¡Gracias por su atención!

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