OIE Strategy for Veterinary Products and Terms of Reference for the OIE National Focal Points

Dr Elisabeth Erlacher-Vindel,
Deputy Head of the Scientific and Technical Department
OIE Strategy for Veterinary Products

Based on complementary approaches:

- Development and updating of international standards
- Support to Veterinary Services and laboratories
- Modernisation or updating of national legislation
- Communication and training programmes
Development and updating of international standards

**OIE develops and publishes international**

- Health standards for the prevention and control of animal diseases as well as for the safe trade in animals and animal products
  => *Codes*
- Biological standards for diagnostic tests and vaccines
  => *Manuals*

**Adopted by OIE Member Countries and Territories during the General Session each May by consensus**

Developed using a science-based approach
Terrestrial Code (Two volumes)

Volume I: General Provisions (Horizontal issues)
- User’s guide - Glossary
- Section 1: Animal disease diagnosis, surveillance and notification
  Prescribed and alternative diagnostic tests for OIE-listed diseases
- Section 2: Risk analysis
- Section 3: Quality of Veterinary Services
- Section 4: General recommendations: disease prevention and control
- Section 5: Trade measures, import/export procedures and veterinary certification
- Section 6: Veterinary Public Health
  Antimicrobial resistance surveillance; monitoring; prudent use; risk assessment
- Section 7: Animal welfare

Volume II: Recommendations applicable to OIE-listed diseases
OIE Manual of Diagnostic Tests and Vaccines for Terrestrial Animals (two volumes)

- Describes internationally agreed laboratory methods for disease diagnosis
  - To enable the requirements for health certification in connection with trade to be met
  - To avoid differences in interpretation of results

- Covers the production and control of biological products
Part 1 – General Information - Section 1

**Introductory chapters:**

- Validation of diagnostic assays
- Methodologies for bacterial antimicrobial susceptibility testing
- Biotechnology in diagnosis and vaccine development
- Veterinary vaccine production
- Tests for sterility of biological materials
- International standards for vaccine banks
- International regulation of veterinary biologicals
Part 2 – OIE-Listed Diseases and Other Diseases of Importance to International Trade

Volume I & II:
The general structure of the disease-specific chapters is as follows:

Summary
A. Introduction
B. Diagnostic techniques
C. Requirements for vaccines

Key references

http://www.oie.int/eng/normes/mmanual/A_summary.htm
OIE Code and Manual for Aquatic Animals

- Chapters on antimicrobial resistance under development
- Principles and methods of validation of diagnostic assays for infectious diseases
- Recommendations applicable to specific diseases

http://www.oie.int/eng/normes/fmanual/A_summary.htm
Development and updating of international standards

issue/problem identified by Delegates, OIE Specialist Commissions, industry, scientists, individuals

- New scientific information, e.g. from research or from a disease outbreak
- New diseases – emerging diseases
- New approach to control, e.g. vaccination

addressed by appropriate Specialist Commission as a new or revised standard

- Using Working Groups and ad hoc Groups for specialist tasks, e.g. vaccines related to new and emerging technologies, validation of diagnostic assays, antimicrobial resistance, etc.
Developing / updating international standards

Assembly: Delegates of 175 Members

COMMISSIONS, DELEGATES, SCIENTISTS

PROBLEM

Specialist Commissions

Review

Advice of experts or other Specialist Commissions

Draft text

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DELEGATES

ASSEMBLY

Comments

OIE INTERNATIONAL STANDARD

Adoption
Support to Veterinary Services and Laboratories

**OIE-PVS tool : Evaluation of the Performance of Veterinary Services**
- Takes into account public and private components and interactions with stakeholders
  - Takes into account Veterinary Laboratory capabilities

**Gap Analysis of PVS outcomes: Evaluation of Needs and Priorities**
- To identify specific activities, tasks and resources required to address ‘gaps’
- Preparation of investment programmes (if needed, commitment from donors)
Support to Veterinary Services and Laboratories

187 OIE Reference Laboratories and 35 Collaborating Centres
- Collaborating Centre for Veterinary Medicinal Products
  AFSSA Fougères,
  Agence nationale du médicament vétérinaire, France

OIE- Laboratory twinning programme
- Link between OIE Reference Laboratory or Collaborating Centre (Parent) and national laboratory (Candidate)
- Aims to improve expertise and diagnostic capacity with eventual aim of reaching OIE standards
Modernisation or update of national legislation

- OIE Guidelines for Veterinary Legislation
  - essential elements to be covered in veterinary legislation

- First OIE Global Conference on Veterinary Legislation: « Modernising veterinary Legislation » to be held in Djerba (Tunisia), 6–8 December 2010

www.oie.int
Communication and Training Programmes

OIE Conference on Veterinary Medicinal Products in Africa
Dakar (Senegal), 25–27 March 2008

OIE Conference on Veterinary Medicinal Products in the Middle East
Damascus (Syria), 2–4 December 2009
Communication and Training Programmes

**OIE-Training of OIE Focal Points**
- Training Workshops in all five Regions on:
  - animal disease notification
  - Wildlife
  - aquatic animals diseases
  - veterinary products
  - animal production food safety
  - animal welfare

**Regional Workshops for OIE National Focal Points for Veterinary Products**
- First workshop in Europe: 26–28 July 2010, Belgrade, Serbia
National Focal Points for Veterinary Products

During the 76th General Session in May 2008 the importance of the focal point for information on animal diseases was re-iterated.

Delegates were also requested to nominate additional focal points for wildlife, veterinary products, animal production, food safety, animal welfare and aquatic diseases.
Official nomination
- by Delegates transmitted to the Scientific and Technical Department of the OIE Headquarters (f.diaz@oie.int)

Responsibilities of focal points are under the authority of the OIE Delegate

Will enable the OIE Delegate to more efficiently manage his/her OIE Member obligations
Terms of Reference of National Focal Points

Terms of Reference (ToRs) for focal points
- established by OIE Headquarters for all focal points

Specific ToRs on Veterinary Products
- Developed in consultation with the OIE Collaborating Centre for Veterinary Medicinal Products, AFSSA Fougères, France
- Sent to all Delegates in March 2009
Terms of Reference for OIE National Focal Points on Veterinary Products

- Establish a network of veterinary product experts within his/her country or communicate with existing network;

- Establish a dialogue, cooperation and communication with Competent Authority for veterinary products and relevant authorities;

- Monitor legislation on and control of veterinary products to ensure that these are in support of OIE international standards, guidelines and recommendations;
Terms of Reference for OIE National Focal Points on Veterinary Products

- Act as a contact point with the OIE on matters related to veterinary products;

- Receive reports of the VICH activities and copies of the reports of the Biological Standards Commission and other relevant reports and conduct an in-country consultation process;

- Prepare comments for the Delegate on relevant meeting reports, including comments on the proposals for new or revised OIE standards related to Veterinary Products.
RESOLUTION No. 25 on Veterinary Products

Adopted at the 77th OIE General Session in May 2009

The committee recommends that the OIE Members

1. Promote and enhance in their respective countries good veterinary governance, which includes the compliance of Veterinary Services with OIE international standards, as an instrumental and essential prerequisite to the establishment and effective implementation of adequate and appropriate legislation covering all aspects of products for veterinary use, including registration, quality control, distribution and final use.

2. Develop and improve international and regional cooperation in the establishment and enforcement of legislation to harmonise the regulatory framework between Members so as to assist countries in need to effectively institute and maintain such mechanisms.
RESOLUTION No. 25 on Veterinary Products

The committee recommends that the OIE Members

3. Allocate appropriate human and financial resources to Veterinary Services and laboratories to correctly implement the OIE standards and guidelines related to veterinary products and their control.

4. Nominate a national focal point for OIE on matters related to veterinary products according to the suggested Terms of Reference and encourage his/her participation in training sessions and appropriate international gatherings and meetings.
The committee recommends that the OIE Members

5. Promote the responsible and prudent use of veterinary medicinal products, in particular of antimicrobials used in veterinary medicine, and the monitoring of the potential existence or development of antimicrobial resistance.

6. Actively encourage the recognition and application of the international recommendations, guidelines and tools developed by the OIE and adopted by the International Committee on veterinary products.
RESOLUTION No. 25 on Veterinary Products

That the OIE

1. Continue to develop and update standards, guidelines and recommendations on diagnostic tests, vaccines and veterinary drugs, including antimicrobials.

2. Continue to work on the use of biotechnologies to improve vaccines and diagnostic tests, as well as on the innocuity of recombinant vaccines with regard to food safety.

3. Continue to strengthen capacity building activities including training particularly directed at Delegates and focal points, to enable OIE Members to organise, manage and implement appropriate legislation for veterinary products including registration, quality control, distribution and final use of veterinary products preferably using a regional or sub-regional basis.
4. Provide and promote communication on OIE standards, guidelines, and recommendations related to veterinary products, particularly on veterinary drugs and vaccines.

5. Continue to actively participate in and support VICH activities and to share outcomes with OIE Members with a view to promoting VICH guidelines at global level.

6. Develop and improve collaboration with relevant international and regional organisations on issues related to veterinary products and, whenever appropriate, in support of the mandate of the OIE.

7. Include and strengthen all above-mentioned matters within the Fifth Strategic Plan of the OIE.
Key elements:

- International standards
- National legislation
- Functional Veterinary Services
- Existence of technically and scientifically recognised laboratories
- Training and communication
Thank you for your attention

Organisation mondiale
de la santé animale

World Organisation
for Animal Health

Organización Mundial
de Sanidad Animal

www.oie.int – oie@oie.int

12 rue de Prony, 75017 Paris, France