

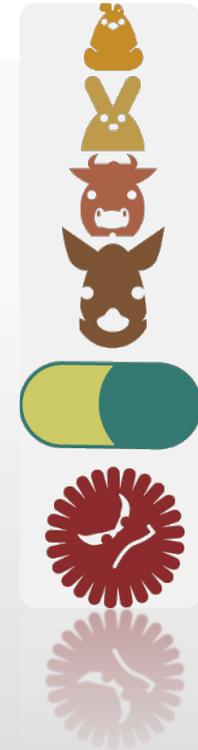
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Acting Head of the Scientific and Technical Department
World Organisation for Animal Health (OIE)

Strategy of the OIE regarding
veterinary products (*vaccines,
diagnostic kits and veterinary drugs*)

Regional Seminar for OIE National Focal Points for
Veterinary Products , Maputo, Mozambique,
3 – 5 December 2013

3rd Cycle





First part:
**Strategy of the OIE regarding
veterinary products**





Background

RESOLUTION No. 25 on Veterinary Products (2009)

- Seven considerations
- Six recommendations to OIE Member Countries
- Seven recommendations to the OIE



RESOLUTION No. 25 on Veterinary Products

- Four considerations including references to:
 - previous recommendations adopted in 1994, 2003, 2006 and 2007);
 - the Regional Conferences on Veterinary Medicinal
- Three considerations on past and ongoing OIE activities:
 - Including VICH, quality of laboratories and vaccines



RESOLUTION No. 25 on Veterinary Products

Six recommendations to OIE Member Countries:

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

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.



RESOLUTION No. 25 on Veterinary Products

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

Seven recommendations to 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.



RESOLUTION No. 25 on Veterinary Products

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.



RESOLUTION No. 25 on Veterinary Products

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.**



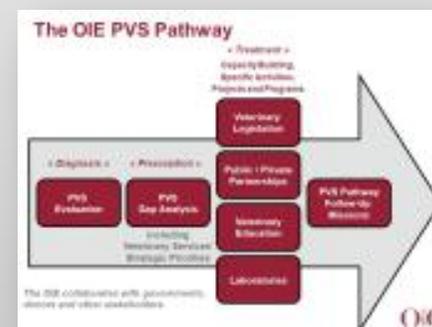
The OIE Strategy regarding veterinary products

Based on complementary approaches:

- ✓ **Development and updating of international standards and guidelines**
- **Support to Veterinary Services and laboratories**
- Modernisation or updating of national legislation
- OIE procedure for the validation of diagnostic assays
- Supporting veterinary education & day one competences
- Collaboration with international organisations
- Communication and capacity building

The OIE Strategy regarding veterinary products

- **Support to Veterinary Services and laboratories**
 - The tool for the evaluation of Veterinary Services compliance with OIE international standards on quality (**OIE PVS Tool**) includes the assessment of the governance of veterinary medicinal products in the Member Countries.
 - The PVS evaluation tool is completed with the Gap Analysis Tool (“prescription tool”) which is a quantitative evaluation of a country’s needs and priorities.



The OIE Strategy regarding veterinary products

Support to Veterinary Services and laboratories

- The OIE laboratory twinning programme launched to mobilise the expertise of the whole network of the 284 OIE Reference Laboratories and Collaborating Centres, assists in developing capacities of key laboratories in developing countries.
- Updated information is available at <http://www.oie.int/en/support-to-oie-members/laboratory-twinning/>

**TWINNING
LABORATORIES**



The OIE Strategy regarding veterinary products

Based on complementary approaches:

- ✓ Development and updating of international standards and guidelines
- ✓ Support to Veterinary Services and laboratories
 - **Modernisation or updating of national legislation**
 - OIE procedure for the validation of diagnostic assays
 - Supporting veterinary education & day one competences
 - Strengthening veterinary statutory bodies and veterinary oversight on use of antimicrobials in animals
 - Collaboration with international organisations
 - Communication and capacity building



The OIE Strategy regarding veterinary products

- **Modernisation or updating of national legislation**
 - First OIE Global Conference on Veterinary Legislation: Djerba (Tunisia), 7-9 December 2010
 - A specific lecture was presented on measures that should be developed to ensure good governance related to veterinary medicinal products to ensure the availability of quality products, non-counterfeits, useful for combating epizootic diseases and to control the health status of the herd.
- Recommendations (http://www.oie.int/fileadmin/Home/eng/Conferences_Events/docs/pdf/recommendations/ANG_Recommendations.pdf)



The OIE Strategy regarding veterinary products

Modernisation or updating of national legislation

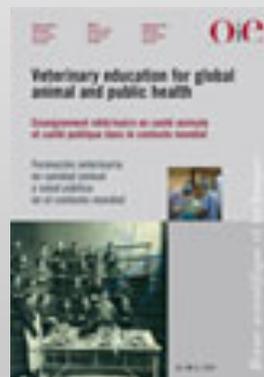
- Veterinary Legislation: new Code chapter adopted in May 2012
 - http://www.oie.int/fileadmin/Home/eng/Support_to_OIE_Members/docs/pdf/A_Update_2012_Chapter_3.4_Vet_legislation.pdf
 - Essential elements to be covered in veterinary legislation
- **Legislation missions**
 - help governments that wish to modernise the national veterinary legislation and help the veterinary services to meet the OIE standards
- OIE website: <http://www.oie.int/en/support-to-oie-members/veterinary-legislation/>

The OIE Strategy regarding veterinary products

■ OIE World Conferences

Global Conference on Veterinary Education and the Role of the Veterinary Statutory Body

■ 4-6 December 2013, Foz de Iguazu (Brazil)





The OIE Strategy regarding veterinary products

Based on complementary approaches:

- ✓ Development and updating of international standards and guidelines
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- ✓ Supporting veterinary education & day one competences
- **Collaboration with international organisations**
- Communication and capacity building



The OIE Strategy regarding veterinary products

- **Collaboration with international organisations**
FAO / OIE / WHO Tripartite Annual Executive & Coordination Meetings: **AMR one of the priority topics:**
- **Speak with one voice and take collective action** through a coordinated approach with shared responsibilities to tackle antimicrobial resistance worldwide
- **Support the joint AMR capacity building** initiatives as agreed by the Tripartite
- **Action: AMR focal points to prepare an action plan** for the Tripartite in view of the development of a joint Tripartite global strategy on the containment of AMR



Tripartite technical focal points for antimicrobial resistance

- Technical Focal Points met three times
- Identified common areas for cooperation
- Developement of a tripartite work plan is ongoing
- Common messages are identified
- Mutual participation in relevant *ad hoc* Groups, meetings and trainings



The OIE Strategy regarding veterinary products

Based on complementary approaches:

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- ✓ Support to Veterinary Services and laboratories
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- ✓ Collaboration with international organisations
- **Communication and capacity building**



The OIE Strategy regarding veterinary products

- **Communication and capacity building**
 - **Focal point trainings**
- **Third cycle of regional workshops for OIE Focal Points for Veterinary Products started with the Inter-Regional Seminar for OIE National Focal Points for Veterinary Products here in Algiers (Algeria)**
- **Next seminar: Maputo (Mozambique), 03-05 December 2013 (3rd Cycle)**

The OIE Strategy regarding veterinary products

Communication

- Fact sheets



Antimicrobial resistance

http://www.oie.int/fileadmin/Home/eng/Media_Center/docs/pdf/Fact_sheets/ANTIBIO_EN.pdf

Second part: Whats next ?

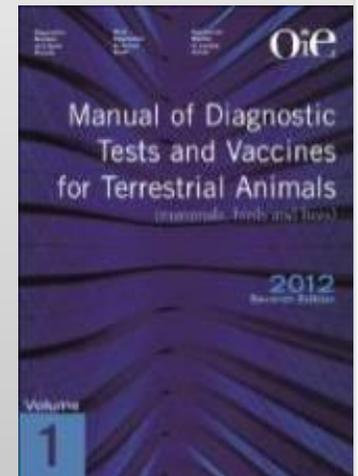


The OIE Strategy regarding veterinary products: Whats next ?

- **Vaccines:**

Chapter 1.1.8. Minimum requirements for vaccine production facilities (under study)

Chapter 1.1.9. Quality control of vaccines (under study)



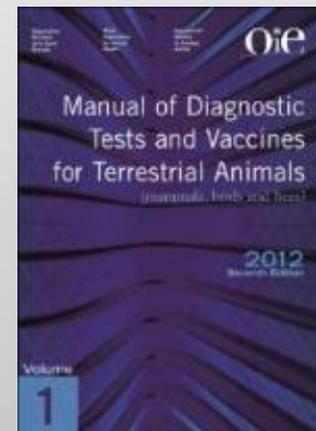
The OIE Strategy regarding veterinary products: Whats next ?

- Diagnostic kits

- Chapter 1.1.5.

[Principles and methods of validation of diagnostic assays for infectious diseases](#)
(NB: Version adopted in May, 2013)

- **Appendices to be published**





The OIE Strategy regarding veterinary products: Whats next ?

- **Veterinary drugs**
- Antimicrobial agents and Antimicrobial resistance : High priority
 - Collection of data on antimicrobial usage
 - Tripartite activities
 - Support actions to implement the OIE standards
- Antiparasitical drugs to be considered



Contacts

- OIE Delegate
- OIE Regional and Subregional Representations Regional interests/contacts
- OIE Collaborating Centers
- OIE Headquarters: Scientific and Technical Department

Thank you for your attention



Last questions ?

World Organisation for Animal Health
Protecting animals, preserving our future