Regional Seminar for OIE National Focal Points for Veterinary Products
Vienna (Austria), 20 – 22 November 2012

Context and Resolutions
The OIE Fifth Strategic Plan
OIE Strategy regarding veterinary products
Context and Resolutions
The Resolution on Veterinary Products (N° 25) adopted by the OIE Member Countries at the 77th OIE General Session in May 2009 promotes a coherent strategy related to veterinary products and strengthens OIE involvement in this field.

VICH(*) activities were taken into account.

The term “veterinary products” is used to cover:

- veterinary medicinal products (in particular antimicrobial agents)
- vaccines
- diagnostics

(*) International cooperation on harmonisation of technical requirements for Registration of Veterinary Products
RESOLUTION No. 25 on Veterinary Products (1)

• Seven considerations

• Six recommendations to OIE Member Countries

• Seven recommendations to the OIE
RESOLUTION No. 25 on Veterinary Products (2)

- Four considerations including references to:
  - previous recommendations adopted in 1994, 2003, 2006 and 2007);
  - the Regional Conference on Veterinary Medicinal Products organised in Dakar « Towards harmonisation and improvement of registration, distribution, and quality control » (2008).

- Three considerations on past and ongoing OIE activities:
  - Including VICH, quality of laboratories and vaccines
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 (4)

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.
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.
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 (7)

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 (8)

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 Fifth Strategic Plan (2011-2015)
The OIE Fifth Strategic Plan (1)

Mentions explicitly the need to:

- Develop and update standards, guidelines and recommendations on diagnostic tests, vaccines and veterinary drugs including antimicrobials.

- Promote the use of OIE recognised assays and diagnostic kits by both the public and the private sectors.

- Strengthening collaboration with relevant international and regional Organisations on technical and legal issues related to veterinary products including legislation, registration, control and monitoring of use.
Highlights the importance of Focal Points for the OIE:

- The World Assembly of Delegates has established a system of national focal points in six areas of the OIE’s work. **Focal points** are established under the authority of the Delegate of each OIE Member. They assist the OIE Delegate and act as a direct contact point with the OIE in their respective areas.

- While focal points serve primarily as a means of improved communication between Member Countries and the OIE, their functions also include establishing networks and improved communications at the country level often between two or more Competent Authorities.
The fifth strategic plan proposes to strengthen OIE Focal Points including Veterinary Products:

- OIE will continue to strengthen the network of focal points in their respective areas of competence, mainly through training courses and workshops at the Regional and Sub-Regional levels.
OIE Strategy regarding veterinary products
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
- Collaboration with international organisations
- Communication and capacity building
The OIE Strategy regarding veterinary products

- Development and updating of international standards and guidelines: example of antimicrobial resistance


Section – 6: Veterinary Public Health

- Chapter 6.7. Harmonisation of national antimicrobial resistance surveillance and monitoring programmes
- Chapter 6.8. Monitoring of the quantities of antimicrobials used in animal husbandry
- Chapter 6.9. Responsible and prudent use of antimicrobial agents in veterinary medicine
- Chapter 6.10. Risk assessment for antimicrobial resistance arising from the use of antimicrobials in animals
Adopted in May 2012 (80th General Session)

• **Terrestrial Animals Code** Chapters (update)
  - 6.7. Harmonisation of national antimicrobial resistance surveillance and monitoring programmes
  - 6.8. Monitoring of the quantities and usage patterns of antimicrobial agents used in food producing animals

• **Manual of Diagnostic Tests and Vaccines for Terrestrial Animals** 2012 (update)
  - 4.1. Laboratory methodologies for bacterial antimicrobial susceptibility testing (guidelines)
Ad hoc Group on antimicrobial resistance (ongoing)

Third meeting: December 2011

- Addressed first part of Member Countries comments on Chapter 6.9. Responsible and prudent use of antimicrobial agents in veterinary medicine

- Updated Chapter 6.10. Risk assessment for antimicrobial resistance arising from the use of antimicrobials in animals taking into the outcome of the Codex Ad Hoc Intergovernmental Task Force on Antimicrobial Resistance adopted by the Codex Alimentarius Commission in July 2011. In addition to WHO and FAO, the Codex secretariat was invited to participate as an observer in this meeting.
Fourth meeting of the ad hoc Group: July 2012

- Addressed additional Member Country comments on Chapter 6.9. on “Responsible and prudent use of antimicrobial agents in veterinary medicine”
- Started the update of the OIE List of Antimicrobials of Veterinary Importance (http://10.0.0.112/fileadmin/Home/eng/Our_scientific_expertise/docs/pdf/OIE_list_antimicrobials.pdf).

Fifth meeting: 4 - 6 December 2012

- To address Member Country comments on Risk Assessment
- To finalise the update of the OIE List of Antimicrobials of Veterinary Importance
A similar approach was taken for aquatic animals:

- An OIE ad hoc Group on the responsible use of antimicrobials in aquatic animals met three times.
- **Adopted in May 2011** by the 178 OIE Member Countries for inclusion in the *Aquatic Code*.
  - Chapter 6.2. Introduction to the recommendations for controlling antimicrobial resistance and
  - Chapter 6.3. Principles for responsible and prudent use of antimicrobial agents in aquatic animals were
The OIE Strategy regarding veterinary products

Adopted in May 2012 (80th General Session)

Two new chapters in the *Aquatic Code*

- Monitoring of the quantities and usage patterns of antimicrobial agents used in aquatic animals (new Chapter 6.4.)
- Development and harmonisation of national antimicrobial resistance surveillance and monitoring programmes for aquatic animals (new Chapter 6.5.)

- Chapter on risk assessment is under development
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• 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.
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Support to Veterinary Services and laboratories

• The OIE laboratory twinning programme launched to mobilise the expertise of the whole network of the 277 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/
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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

(https://www.oie.int/fileadmin/Home/eng/Conferences_Events/docs/pdf/recommendations/ANG_Recommendations.pdf)
Modernisation or updating of national legislation

- Veterinary Legislation: new Code chapter adopted in May 2012
  - 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

- Updated information is available at the OIE website
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- Collaboration with international organisations
  - In the capacity of an observer organisation, the OIE participated in several meetings of the Codex Commission and its subsidiary bodies
  - OIE participated as an observer at the
    - Codex ad hoc Intergovernmental Task Force on Antimicrobial Resistance:
Collaboration with international organisations

- Cooperation with WHO and FAO.
  - OIE/FAO/WHO Contact points meeting on Collaborative Activities on Antimicrobial Resistance (AMR)
  - This Group met for the first time in 2009 at OIE Headquarters in Paris (France) and a second time in Geneva in 2011 with the aim of finding common areas for cooperation and maintaining good communication between FAO, OIE and WHO in this field.
  - Third took place at the FAO Headquarters in August 2012
  - Mutual participation in relevant meetings and trainings are on-going.
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• Collaboration with international organisations
  18th FAO / OIE / WHO Tripartite Annual Executive & Coordination Meeting, Paris, 1 - 2 February 2012, OIE Headquarters:

• Tripartite Strategy: AMR one of the priority topics

• R13- Headquarters to nominate focal points for rabies and AMR in the three organisations to define and implement the immediate next steps for collaboration.

• R14- Scale up AMR to address all sectors. Focus should include legislation and capacity building.
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- Communication and capacity building
  - Focal point trainings
    - the second cycle of regional workshops for OIE Focal Points for Veterinary Products were organised in September 2011 (Dakar, Senegal), in December 2011 (Casablanca, Morocco), in March 2012 (Mombasa, Republic of Kenya), in July 2012 (Bangkok, Thailand). Planned: October 2012 (Brazil, Americas), November 2012 (Europe)
    - Major topics include VICH and Antimicrobial Resistance
Communication and capacity building: OIE Questionnaire

- In order to enhance the OIE’s engagement in the initiative to prevent antimicrobial resistance and taking into account the experience gained from the second cycle of training workshops organised for the OIE National Focal Points for Veterinary Products, the OIE has developed a questionnaire to gather information, at the global level, on the current practices employed by OIE Member Countries to monitor the quantities of antimicrobial agents used in animals.

- Sent to the 178 OIE Delegates and Focal Points on Veterinary Products (June 2012): 148 answers (October)
The purpose of this questionnaire survey is to collect information on the quantities of antimicrobial agents used in animals by OIE Member Countries and their monitoring strategies. The responses to the questionnaire will be compiled and analysed at the OIE Headquarters with the aim of providing an overview of the situation at the OIE Global Conference on the Prudent Use of Antimicrobial Agents for Animals, which will be held in Paris, (France) from 13 to 15 March 2013.
OIE GLOBAL CONFERENCE ON THE RESPONSIBLE AND PRUDENT USE OF ANTIMICROBIAL AGENTS FOR ANIMALS

International Solidarity to Fight against Antimicrobial Resistance

Paris (France), 13–15 March 2013
The OIE Strategy regarding veterinary products

Communication and capacity building
Conferences

- OIE Delegates and Focal Points will be invited
- Recommendations will be adopted and
- Further guidance will be provided
- [http://www.oie.int/eng/A_AMR2013/introduction.htm](http://www.oie.int/eng/A_AMR2013/introduction.htm)
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Communication and capacity building: Conferences

The OIE hosted a Symposium on Alternatives to Antibiotics in Animal Health: Challenges and Solutions

http://www.alternativestoantibiotics.org/

The outcome will be presented at the OIE Global Conference in March 2012
The focus of this Review is to address the various factors that must be taken into account when trying to understand the antimicrobial resistance problem, with a particular focus on the use of antimicrobials in animals.
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Communication and capacity building

All information is available at the OIE website: www.oie.int

- ANTIMICROBIAL RESISTANCE (AMR):
  - http://www.oie.int/fileadmin/Home/eng/Conferences_Events/docs/pdf/A_Announce_AMR_Conference.pdf
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

Any questions?