



JOINT FAO/WHO FOOD STANDARDS PROGRAMME
CODEx COMMITTEE ON RESIDUES OF VETERINARY DRUGS IN FOODS
Twenty-third Session

Houston, Texas, United States of America, 17 – 21 October 2016

REPORT ON THE OIE ACTIVITIES, INCLUDING THE HARMONISATION OF TECHNICAL REQUIREMENTS FOR REGISTRATION OF VETERINARY MEDICINAL PRODUCTS (VICH)

Key messages:

- Close cooperation with Codex, the relevant ‘fellow’ standard-setting body recognised by the SPS Agreement of the WTO.
- The key focus of the OIE’s work relevant to CCRVDF since 2015 was on antimicrobial resistance, in close cooperation with FAO and WHO, and in providing support to the VICH initiative.

1. Cooperation between the OIE and the Codex Alimentarius Commission

In the capacity of an observer organisation, the OIE has participated in several meetings of the Codex Alimentarius Commission (CAC) and its subsidiary bodies, and we welcome the participation of Codex staff and experts in OIE meetings, notably, the OIE Working Group on Animal Production Food Safety (APFSWG). The APFSWG coordinates the food safety activities of the OIE to reduce food-borne risks to human health due to food-borne hazards arising at the production phase of the food chain. Members include high level experts from FAO, WHO and Codex, and internationally recognised experts in animal production food safety from around the globe. Since the last report of the OIE to CCRVDF22, the APFSWG held its **15th meeting** at the OIE Headquarters **from 3 to 5 November 2015**. The report is available on the OIE website at:

http://www.oie.int/fileadmin/Home/eng/Food_Safety/docs/pdf/AFFS_reports/A_Report_Nov_2015.pdf

The OIE will continue to address food safety-related issues as a high priority in its standard-setting work and will work closely with CAC and its Committees, and with other international organisations in promoting safe international trade in animal and their products.

2. Capacity building

The capacity building activities, including governance of veterinary medicinal products, are considered by the OIE as a high priority for animal and public health. The OIE’s Fifth Strategic Plan (2011–2015) included actions such as good governance of veterinary services, the reinforcement of veterinary services capacities and infrastructure, including veterinary legislation, and more generally the linkages between animal health, food safety and food security. Veterinary medicinal products, in particular strengthened liaison to Codex and expansion of the programme on International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products (VICH), were included in the 5th Strategic Plan as they are considered to be essential tools for any effective animal health and welfare policy.

At the OIE General Session in 2015, the **OIE’s Sixth Strategic Plan (2016–2020)** which builds on the success achieved in recent years was unanimously adopted by the 180 Member Countries.

The 6th Strategic Plan sets out three major objectives to achieve its global vision: “Protecting animals; preserving our future” leading to economic prosperity and social and environmental well-being.

Objective 1: Securing animal health and welfare by appropriate risk management

Objective 2: Establishing trust through transparency and communication

Objective 3: Ensuring the capacity and sustainability of Veterinary Services

http://www.oie.int/fileadmin/Home/eng/About_us/docs/pdf/6thSP_ANG.pdf

Since its last report to CCRVDF in 2015, the OIE continued to undertake a number of capacity building initiatives around the world, out of which the following are of importance as far as veterinary medicinal products are concerned:

➤ **The OIE PVS Pathway**

The OIE PVS (Performance of Veterinary Services) Pathway is a global programme for the sustainable improvement of a country's compliance with OIE standards on quality of OIE Veterinary Services. The programme is central to the OIE's mission.

As part of the OIE global initiative for Good Governance of National Veterinary Services, and at the specific request of a Member Country, the OIE conducts assessments of the quality of Veterinary Services and Aquatic Animal Health Services using the OIE PVS Tool. Subsequent steps in the PVS Pathway include PVS Gap Analysis, PVS Pathway Laboratory missions, Veterinary Legislation missions and PVS Evaluation Follow-Up missions, to help improve and monitor compliance of the veterinary infrastructure with the OIE quality standards set out in the OIE *Terrestrial Animal Health Code*. To date (August 2016) the OIE has received **136 national requests** to conduct initial external PVS evaluations and **129 missions** have been completed. Relevant information may be found at:

<http://www.oie.int/en/support-to-oie-members/pvs-evaluations/status-of-missions/>

For the animal health sector, the OIE underlines the need to invite countries to undertake OIE PVS Evaluation Follow-Up missions, when relevant. These missions are important to measuring the progress that countries have made during the implementation of the PVS Pathway in sustainably improving their compliance with OIE intergovernmental standards on the quality of Veterinary Services. Further implementing the OIE PVS Evaluation Follow-Up missions provides a mechanism to assess, monitor and accompany progress towards global health security.

In the face of increasing global trade, climate change and the emergence and re-emergence of diseases that can rapidly spread across international borders, Veterinary Services need an effective legislative framework to fulfil their key functions.

The OIE is aware that the veterinary legislation in many developing countries does not adequately address either current or future challenges. To address this gap, the OIE World Assembly of Delegates adopted a new chapter in the *Terrestrial Code*, Chapter 3.4. 'Veterinary legislation' in 2012, that was amended in 2013; the chapter also addresses governance of veterinary medicines:

http://www.oie.int/index.php?id=169&L=0&htmfile=chapitre_vet_legislation.htm

OIE Member Countries that have received an OIE PVS Evaluation may benefit from a follow-up mission to provide advice and assistance in modernising the national veterinary legislation. To date (August 2016) the OIE has received **66 official requests** for missions on veterinary legislation and **53** have been completed. Relevant information may be found at:

<http://www.oie.int/en/support-to-oie-members/veterinary-legislation/status-of-missions/>

➤ **National Focal Points**

The OIE encourages all Member Countries to nominate National Focal Points, under the authority of the OIE Delegate, for eight strategic issues, including veterinary products. The aim is to improve communication between the OIE, its Members and agencies responsible for food safety, veterinary products at the national level.

Specific training seminars for the OIE National Focal Points for Veterinary Products for the 180 Member Countries is on-going worldwide on a region-by-region basis. To date (August 2016), the **4th cycle seminars** for Focal Points for Veterinary Products have been held in the Americas, Africa, and Asia-Pacific, and will be held in Europe in October of this year, reaching about 450 participants. In line with the 'One Health' concept, the FAO and WHO are regularly invited to participate in these seminar activities. The 4th cycle seminars for the Focal Points for Veterinary Products aimed to deepen understanding of key issues such as: 1) antimicrobial resistance (AMR), including the Global Action Plan developed by WHO with the support of the OIE and FAO and other Tripartite activities, the OIE database on the use of antimicrobial agents in terrestrial animals, and the aquatic sector; 2) the quality of veterinary medicinal products (VMPs), including the issue of counterfeit medicines, the registration/authorisation system in the region, and implementation of VICH guidelines; and 3) antiparasitic drugs and challenges.

Furthermore, substantial time was provided for updates on good governance of veterinary products, the VICH, and its VICH Outreach Forum, and a discussion about possible support at the technical level from the OIE and OIE Collaborating Centres. The seminars also allocated time for experience-sharing and for discussion among countries in the region.

➤ OIE laboratory twinings

The laboratory twinning programme of the OIE continues to mobilise the expertise of the entire network of the OIE Reference Laboratories and Collaborating Centres and assist in developing capacities of key laboratories in developing countries, thereby helping to extend further the OIE's network of scientific and diagnostic excellence. Since 2007, a total of **35 projects** have been completed, **29 projects** on-going and **six of the candidate laboratories** from completed projects have gone on to become OIE Reference Laboratories.

3. Antimicrobial resistance

Since 1997, in recognition of the growing importance of AMR at a world-wide level, the OIE has developed standards and guidelines aimed at supporting responsible and prudent use of antimicrobial agents in animals.

Key activities include:

- International standard setting and guideline development – an OIE core activity
- International solidarity – an OIE supporting action aimed at supporting OIE Member Countries in the implementation of the OIE standards and guidelines
- International collaboration – FAO, OIE and WHO tripartite coordination
- World Antibiotic Awareness Week (held from 16 to 22 November 2015)

Worldwide data collection on the use of antimicrobial agents in animals – the first phase of this new OIE activity in line with the Global Action Plan has been completed. From **mid-December 2015 to mid-May 2016**, 72% (130/180) of OIE Member Countries submitted the completed template to the OIE Headquarters.

Since the 22nd Session of the CCRVDF, the World Assembly of Delegates of the OIE has adopted two Resolutions relating to AMR, one at the 83rd General Session (May 2015) and the second at the 84th General Session (May 2016).

Resolution of 2015: **Resolution No. 26: Combating antimicrobial resistance and promoting the prudent use of antimicrobial agents in animals**

http://www.oie.int/fileadmin/Home/eng/Our_scientific_expertise/docs/pdf/AMR/A_RESO_AMR_2015.pdf Resolution of 2016

Resolution No. 36 Combating **Antimicrobial Resistance through a 'One Health' Approach: Actions and OIE Strategy**

International standard setting and guideline development

http://www.oie.int/fileadmin/Home/eng/Our_scientific_expertise/docs/pdf/AMR/A_RESO_AMR_2016.pdf

The OIE standards are published (online and in print) in the *Terrestrial Animal Health Code*, the *Manual of Diagnostic Tests and Vaccines for Terrestrial Animals*, the *Aquatic Animal Health Code* and the *Manual of Diagnostic Tests for Aquatic Animals*.

At the 84th General Session, the OIE Assembly adopted three new chapters of recommendations on the manufacture of vaccines for inclusion in the *Terrestrial Manual*. The new chapters are published on the OIE website at: <http://www.oie.int/en/international-standard-setting/terrestrial-manual/access-online/>

The chapters are:

Chapter 3.7.1.

[Minimum requirements for the organisation and management of a vaccine manufacturing facility](#)

Chapter 3.7.2.

[Minimum requirements for the production and quality control of vaccines](#)

Chapter 3.7.3.

Minimum requirements for aseptic production in vaccine manufacture

The OIE standard-setting process ensures that standards are updated, when relevant, in order to accommodate new findings and Member Country comments. This work is undertaken by the OIE *ad hoc* Group on AMR, which includes representatives from WHO, FAO, and, when relevant, the Codex secretariat.

Terrestrial Animal Health Code

Chapter 6.6.	Introduction to the recommendations for controlling antimicrobial resistance	First adopted in 2003, revision adopted in 2012
Chapter 6.7.	Harmonisation of national antimicrobial resistance surveillance and monitoring programmes	First adopted in 2003, revision adopted in 2012
Chapter 6.8.	Monitoring of the quantities and usage patterns of antimicrobial agents used in food producing animals	First adopted in 2003, revision adopted in 2012
Chapter 6.9.	Responsible and prudent use of antimicrobial agents in veterinary medicine	First adopted in 2003, revision adopted in 2012
Chapter 6.10.	Risk analysis for antimicrobial resistance arising from the use of antimicrobials in animals	First adopted in 2004, revision adopted in 2014

Manual of Diagnostic Tests and Vaccines for Terrestrial Animals

Chapter 3.1.	Laboratory methodologies for bacterial antimicrobial susceptibility testing	Current version adopted in May 2012
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Aquatic Animal Health Code

Chapter 6.1.	Introduction to the recommendations for controlling antimicrobial resistance	First adopted in 2011
Chapter 6.2.	Principles for responsible and prudent use of antimicrobial agents in aquatic animals	First adopted in 2011
Chapter 6.3.	Monitoring of the quantities and usage patterns of antimicrobial agents used in aquatic animals	First adopted in 2012
Chapter 6.4.	Development and harmonisation of national antimicrobial resistance surveillance and monitoring programmes for aquatic animals	First adopted in 2012
Chapter 6.5.	Risk analysis for antimicrobial resistance arising from the use of antimicrobial agents in aquatic animals	First adopted in 2015

For easier reference the OIE has published a new a booklet in April 2016: **OIE Standards, Guidelines and Resolution on antimicrobial resistance and use of antimicrobial agents**. This publication has been prepared to support Global Action Plan on AMR that the WHO developed in collaboration with the FAO and the OIE.

Additional guidelines

An OIE *List of Antimicrobial Agents of Veterinary Importance* was developed as a draft list in May 2006. The refined list was submitted to the 75th International Committee during the General Session in May 2007 and adopted unanimously by Resolution No. XXVIII. This list identifies antimicrobial agents used in animals around the world, highlights where no or few alternatives for therapy of animal diseases exists, and provides guidance on use of antimicrobial agents that are also of importance (including critical importance) in human medicine. The list was revised in December 2014 in the light of technical comments received, and proposed for adoption in 2015. In May 2015, the updated version of the list was adopted by the World Assembly, and included recommendations on the use of **Fluoroquinolones** and third and **fourth generation Cephalosporins**. This List is available at:

http://www.oie.int/fileadmin/Home/eng/Our_scientific_expertise/docs/pdf/Eng_OIE_List_antimicrobials_May2015.pdf

➤ **International solidarity**

The OIE capacity building initiatives for veterinary products provide support for the implementation of the standards related to antimicrobial use and monitoring of resistance. Of particular importance are:

- the OIE network of National Focal Points for Veterinary Products;
- the OIE initiatives on veterinary legislation and the veterinary legislation support programme Veterinary Statutory Bodies for which a standard is being developed on the design and functioning of national and regional Veterinary Statutory Bodies empowered by the law and by State delegation of the necessary powers to oversee qualifications, ethical standards and professional excellence, as well as to expel anyone whose conduct is improper;
- day 1 competencies of graduating veterinarians and the veterinary core curriculum;
- the regulation of veterinary medicines and the VICH to ensure quality, safety and efficacy of veterinary medicines.

➤ International Collaboration

The OIE continues to collaborate with WHO and FAO on AMR in particular through the development of common documents and through the participation of representatives of these two organisations on the OIE *ad hoc* Group on AMR. The OIE also closely collaborated with WHO and FAO on the development of the Global Action Plan on AMR and the Manual for implementation of National Action Plans. OIE Member Countries are encouraged to follow the guidance of the WHO Global Action Plan, which was developed with the support of the OIE in the spirit of the 'One Health' approach.

Collaboration is also growing at the level of the Directors General, and the three organisations hosted a High Level Dialogue on AMR in April at the United Nations in New York to raise awareness on AMR with the aim of raising the topic at the United Nations General Assembly in September 2016.

➤ Worldwide collection of data on the use of antimicrobial agents in animals

Taking forward Resolution No. 26 *Combating Antimicrobial Resistance and Promoting the Prudent Use of Antimicrobial Agents in Animals*, adopted by the World Assembly in May 2015 during the 83th General Session, the OIE launched, in the last trimester of 2015, an annual collection of data on the use of antimicrobial agents in animals in OIE Member Countries. The template and guidance documents to complete this template were developed by the OIE *ad hoc* Group on AMR, endorsed by the Scientific Commission for Animal Diseases and tested by the Member Countries through the training seminars for OIE National Focal Points for Veterinary Products, as well as through a regional survey. The ultimate aim is to publish annually a report on the worldwide distribution and use of antimicrobial agents in animals. The report and analysis of this first year of data collection will be presented by end in October 2016.

The OIE *ad hoc* Group continues to work in support of the global efforts to prevent and combat AMR, in particular on the OIE collection of data on the use of antimicrobial agents in animals worldwide and on updating Chapter 6.7 *Harmonisation of national antimicrobial resistance surveillance and monitoring programmes* of the *Terrestrial Code*. The aim of the revision is to define criteria for selection of animal pathogens for AMR surveillance and also to have a table providing examples of target animal species and animal bacterial pathogens that may be included in resistance surveillance and monitoring programmes. The *ad hoc* Group met several times from 2015 to 2016 and the next meeting will be held from 23 to 26 January 2017.

4. OIE and the VICH activities

The OIE continues to be active in assisting Member Countries to build and implement effective legislation to assure the quality, safety and efficacy of veterinary medicinal products, particularly antimicrobial agents. The OIE, as associate Member of the VICH provides support and encourages its Member Countries to take the VICH guidelines into consideration. The OIE considers that the international harmonisation of technical requirements for the pre- and post-marketing authorisation of veterinary medicines is a necessity for animal health, public health and the facilitation of international trade, and that VICH is one of the necessary tools to achieving these aims. In order to provide OIE Member Countries with full information about efforts to harmonise requirements, the OIE circulates VICH draft guidelines and other relevant VICH documents to Member Countries for consultation.

The VICH Outreach Forum meets regularly, back to back with each VICH Steering Committee (SC) meeting. The last meeting was held from 20 to 23 June 2016 in Brussels, Belgium (33th SC and 7th Outreach Forum meeting).

In 2015 there was an opportunity for countries to learn more about the work of VICH, the role of its guidelines in the regulation of veterinary medicines and the VICH Outreach Forum at the public **VICH 5 Conference**, which took place in Tokyo from 27 to 29 October. The theme of the 5th VICH Conference was '**Reaching Out to the World**'. During the Conference, the debate focused on the benefits of VICH Guidelines for non-VICH countries, their needs and priorities regarding the technical requirements for the registration of veterinary medicinal products, and the contribution of the VICH to the global 'One Health' approach. The conference documents from the **5th Public VICH Conference** are available on the VICH public website <http://www.vichsec.org/conference-documents.html>

During the 6th VICH Outreach Forum meeting (Tokyo) a decision was taken to conduct a joint survey by the OIE and HealthforAnimals among the VICH-Outreach Forum Countries. The goal was to obtain a general view of the current situation in the region. The OIE conducted separately the VICH Survey in order to evaluate the level of knowledge of the VICH activities, the level of acceptance and implementation of the VICH Guidelines and their priorities for the training. The joint result was presented in the last 7th VICH Outreach Forum meeting in Brussels, Belgium.

Upcoming VICH meetings:

Argentina will be hosting the 34th VICH SC and the 8th VOF meetings in Buenos Aires from 27 February– to 2 March 2017 with the support of the FDA and the Animal Health Industry.

5. OIE Collaborating Centres and Reference Laboratories

The OIE's scientific work is supported by its worldwide network of currently **311** OIE Collaborating Centres and Reference Laboratories.

In 2016, the OIE has a global network of **260** Reference Laboratories covering 119 diseases or topics in 39 countries, and **51** Collaborating Centres covering 46 topics in 26 countries. ”

In the area of veterinary medicinal products, the following institutions/experts work closely with the OIE Headquarters:

Veterinary Medicinal Products

ANSES Fougères - Agence nationale du médicament vétérinaire (ANMV), B.P. 203
35302 Fougères Cedex
FRANCE

Veterinary Drug Regulatory Programmes

Center for Veterinary Medicine, Food and Drug Administration (FDA), Department of Health and Human Services, 7519 Standish Place, HFV-1, Room 177, Rockville, Maryland 20855,
UNITED STATES OF AMERICA

Control of Veterinary Medicinal Products in Sub-Saharan Africa

Ecole Inter-Etats des Sciences et Médecine Vétérinaires (EISMV), Chargé de Recherche au Laboratoire de Contrôle des médicaments (LACOMEV)
B.P. 5077 Dakar
SÉNÉGAL

Diagnosis of Animal Diseases and Vaccine Evaluation in the Americas

National Veterinary Services Laboratories
USDA, APHIS, Veterinary Services
P.O. Box 844, Ames, Iowa 50010
UNITED STATES OF AMERICA
and

Center for Veterinary Biologics
USDA, APHIS, Veterinary Services
P.O. Box 844, Ames, Iowa 50010
UNITED STATES OF AMERICA

Diagnosis and Control of Animal Diseases and Related Veterinary Product Assessment in Asia

National Institute of Animal Health (NIAH)
3-1-5, Kannondai, Tsukuba, Ibaraki, 305-0856
and

National Veterinary Assay Laboratory (NVAL)
1-15-1, Tokura, Kokubunji, Tokyo, 185-8511
JAPAN

Diagnosis of Animal Diseases and Vaccine Evaluation in the Americas

Institute for International Cooperation in Animal Biologics

College of Veterinary Medicine
Iowa State University
Ames, Iowa 50011
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USDA, APHIS, Veterinary Services
P.O. Box 844
Ames, Iowa 50010
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