CODEX ALIMENTARIUS COMMISSION E

Food and Agriculture Organization of the United Nations

World Health Organization

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Agenda Item 5 **CX/RVDF 15/22/5**

April 2015

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON RESIDUES OF VETERINARY DRUGS IN FOODS

Twenty-second Session

San José, Costa Rica, 27 April – 1 May 2015

REPORT OF THE OIE ACTIVITIES, INCLUDING THE HARMONIZATION 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.**
- **Key focus of the OIE's work relevant to CCRVDF since 2013 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 CCRVDF, the Working Group held its 13th and 14th meeting in October 2013 and 2014, respectively. The reports are available on the OIE website at: http://www.oie.int/fileadmin/Home/eng/Food_Safety/docs/pdf/A_APFSWG_2013.pdf, and http://www.oie.int/fileadmin/Home/eng/Food_Safety/docs/pdf/A_APFSWG_October_2014.pdf.

The OIE provided support to the FAO and WHO JECFA secretariats in carrying out pilot surveys on veterinary drugs needed in developing countries, a request from the last CCRVDF meeting.

The OIE was pleased to actively support and participate in the launch of the World Health Day on Food safety held at the Rungis food market on the outskirts of Paris. 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) includes 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), are included in the Strategic Plan as they are considered to be essential tools for any effective animal health and welfare policy. The OIE's Sixth Strategic Plan (2016-2020) will be proposed for adoption at the OIE General Session in May 2015, and builds on the success of the Fifth Strategic Plan.

Since its last report to CCRVDF in 2013, 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**

As part of the OIE global initiative for Good Governance of National Veterinary Services, and at specific request of a Member, the OIE conducts assessments of the quality of Veterinary Services and Aquatic Animal Health Services using the OIE PVS Tool (PVS standing for Performance of Veterinary Services). 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 Terrestrial Code. To date (March 2015) the OIE has received 133 national requests to conduct initial external PVS evaluations and 123 missions have been completed. Relevant information may be found at: http://www.oie.int/en/support-to-oie-members/pvs-pathway/.

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 key 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.

Countries, international organisations and partners are encouraged to make use of all OIE country PVS Evaluation mission reports, OIE country PVS Gap Analysis mission reports, and OIE country PVS Pathway Laboratory mission reports available.

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 in many developing countries the veterinary legislation is inadequate to address the challenges of today and of the future. 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 Members 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 (March 2015) the OIE has received 61 official requests for missions on veterinary legislation and 40 have been completed. Relevant information may be found at: http://www.oie.int/en/support-to-oie-members/veterinary-legislation/.

- **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 for the OIE National Focal Points for the 180 Member Countries in veterinary products is underway worldwide, on a region-by-region basis. To date, three cycles of training workshops for Focal Points for Veterinary Products have been held in Europe, the Americas, Africa and Asia-Pacific, reaching about 450 participants. In line with the 'One Health' concept, the FAO and WHO are regularly invited to participate in these training activities. A key focus of these trainings, in particular of the third training cycle, is good governance of veterinary medicinal products, including antimicrobial resistance.

- **OIE twinnings**

The laboratory twinning programme of the OIE continues to mobilise the expertise of the entire network of the 296 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 69 twinning projects have been approved, and a quarter of laboratories from completed projects have gone on to become OIE Reference Laboratories.

Subsequent to the OIE Global Conference on Veterinary Education and the Role of Veterinary Statutory Bodies on 4-6 December 2013 in Foz de Iguacu, Brazil, twinning of veterinary education establishments has commenced with 5 projects underway, 4 additional twinnings approved and further 4 being reviewed. Expected outputs of such twinning include that veterinary students graduate with the day 1 competencies recommended by the OIE in 2012, to be developed through the recommended core curriculum (May 2013), which include the responsible use of veterinary products including antimicrobial agents to reduce the development of resistance.

3. Antimicrobial resistance

Since 1997, in recognition of the growing importance of antimicrobial resistance 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
- Worldwide data collection on the use of antimicrobial agents in animals – a new OIE activity linked to the international animal health reporting

➢ **International standard setting and guideline development**

The OIE standards are published (online / 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 and Vaccines for Aquatic Animals*. Guidelines on antimicrobial resistance developed since 1997 have progressively been transformed into standards; current standards are listed below.

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

Terrestrial Animal Health Code (Terrestrial 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 (Terrestrial Manual)

Guideline 3.1.	Laboratory methodologies for bacterial antimicrobial susceptibility testing	Current version adopted in May 2012

Aquatic Animal Health Code (Aquatic 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*	*Proposed for adoption in May 2015*

Additional guidelines:

Furthermore, an *OIE List of Antimicrobial Agents of Veterinary Importance* was developed. 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. Since the last OIE report to CCRVDF, the list was revised in August 2013, and in December 2014 in the light of technical comments received.

- **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,
- and the regulation of veterinary medicines and VICH to ensure quality veterinary medicines.

- **International Collaboration**

Considering that antimicrobial resistance is a global, multidisciplinary issue, the OIE is permanently renewing and strengthening collaboration with WHO and FAO, and Member countries. This close cooperation, which is actively being developed, will help to obtain the benefits of synergies amongst the different organisations.

- Meetings of the OIE/FAO/WHO technical focal points on Collaborative Activities on Antimicrobial Resistance

  Having first met in 2009 with the aim of finding common areas for cooperation and maintaining good communication between FAO, OIE and WHO, the group met twice since the last report to CCRVDF in December 2013 and September 2014 to develop common messages and to coordinate the activities of the three agencies at the technical level, including participation in relevant training seminars organised by the partner organisations.

- The FAO/OIE/WHO Tripartite

  During the 18th FAO/OIE/WHO tripartite annual executive and coordination meeting in February 2012 antimicrobial resistance was identified as a priority topic for the three organizations and recommendations were adopted in order to reinforce the collaboration of the three organizations; it continues to be a priority topic and was discussed at each subsequent annual tripartite meeting.

- Development of the WHO Global Action Plan on Antimicrobial Resistance

  The OIE actively contributed to the WHO-led development of the Global Action Plan on Antimicrobial Resistance that is proposed to the WHO Member Countries for adoption at the World Health Assembly in May 2015.

- Additional cooperation

  The OIE furthermore actively contributes to other relevant international forums that work on antimicrobial resistance, such as the WHO Strategic and Technical Advisory Group (STAG) on antimicrobial resistance that has met several times since its inception in September 2013, and country-led initiatives such as the Global Health Security Agenda led by the USA.

- **Worldwide collection of data on the use of antimicrobial agents in animals**

Based on the recommendations from the OIE Global Conference on responsible and prudent use of antimicrobial agents in animals, in particular recommendation n°7 to the OIE “to collect harmonised quantitative data on the use of antimicrobial agents in animals with a view to establish a global database” and on the results of a questionnaire sent to all Member Countries, the OIE established a new *ad hoc* Group to set up a global database on the use of antimicrobial agents in animals. The group met three times in 2014 (6 to 8 January, 8-9 July 2014, and 10-12 December 2014). The Group develops an overall approach to collect and report standardised quantitative data on antimicrobial agents used in animals supporting implementation of Chapter 6.8 of the Terrestrial Animal Health Code and Chapter 6.4 of the Aquatic Animal Health Code.

4. OIE and VICH activities

Since its formal creation in April 1996, VICH provides a forum for a constructive dialogue between Regulatory Authorities and the Animal Health Industry on the technical requirements for product registration. The EU, Japan and the USA are full members of VICH, Australia, Canada, New Zealand and since 2014 also South Africa, participate in VICH as observers, with one delegate representing governmental Authorities and one representing Industry associations.

The OIE is a founding member of the VICH and supported the Steering Committee in encouraging additional countries to utilize the VICH Guidelines through an outreach programme. After general discussions at the 4th public VICH conference in June 2011 and a 'Contact meeting' with interested countries during the 26th VICH Steering Committee meeting in November 2011, the "Outreach Forum" was officially established and now convenes at every VICH Steering Committee meeting. Considering the key role of good governance of veterinary medicinal products in the OIE's global strategy, the OIE continues to provide support to the VICH process and to actively relay information on VICH to the 180 OIE Member Countries.

Three VICH Steering Committee and linked VICH Outreach Forum meetings took place since the last OIE report to the CCRVDF in August 2013,:

- November 2013, Auckland, New Zealand: 29th Steering Committee and 3rd Outreach Forum meeting
- July 2012, Brussels, Belgium: 30th Steering Committee and 4th Outreach Forum meeting
- February 2013, Washington DC, USA: 31st Steering Committee and 5th Outreach Forum meeting.

A key success of VICH during this time period is the sustained success of the VICH Outreach Forum, with regular participation of countries and regional organisations from 6 continents. Discussions, with time for debate in small groups, provide for input into the work of the VICH Steering Committee, training on topics requested by the Forum participants, and sharing of experience by the Forum participants on issues such as participation in the work of VICH, utilisation of VICH guidelines in their country's system for the registration of veterinary medicines, or updates on regional initiatives. One VICH Outreach Forum participant contributes to the development of a concept paper as the basis of guideline development, another participates in an Expert Working Group. Training topics range from the role of VICH guidelines in regulatory systems for veterinary medicine, generics – definitions and related terms, on technical aspects of bioequivalence, on the waiving of target animal batch safety testing, and on how to comment on VICH guidelines under development, pharmacovigilance, bioequivalence and waiving of target animal batch safety testing to GLP/GCP guidance.

Hand-in-hand with the progress of the Outreach Forum, the Steering Committee developed a training and communication strategy outlining training on VICH guidelines in two levels: level 1 covering general understanding of VICH and the guidelines, level 2 considering training modules on specific guidelines. The first level training material will be placed on the VICH website. The Steering Committee continues to work on the challenges posed by implementation of the second level. The Steering Committee also revised and modernised the VICH procedural texts, and initiated the development of the Phase IV strategy for the years 2016-2020, to be finalised in October 2015.

Since the last report in August 2013, the VICH Steering Committee mandated the Quality Expert Working Group to develop guidance on stability testing in the climatic zones III and IV, based on the need for such guidance identified by OIE Member Countries through an OIE survey. The Steering Committee reviewed the discussion papers prepared by the Task Forces on combination products and on the revision of the VICH anthelmintic guidelines, and will drive these topics forward at the next Steering Committee meeting in October 2015.

VICH Guidelines: The following VICH Guidelines were released for implementation in the regions: VICH GL 24 Pharmacovigilance of veterinary medicinal products: management of Adverse Event Reports (AERs), VICH GL 30 Pharmacovigilance of Veterinary Medicinal Products: controlled list of terms, VICH GL 35 Pharmacovigilance: Electronic Standards for Transfer of Data, VICH GL 42 Pharmacovigilance: Data Elements for Submission of Adverse Event Reports, VICH GL 53 Electronic File Format - Electronic Exchange of Documents: File Format Requirements.

Two guidelines were released for consultation: VICH GL 52 Bioequivalence: Blood level – Blood Level Bioequivalence Study, and VICH GL 54 Safety: Acute Reference Dose (ARfD): Studies to Evaluate the Safety of Residues of Veterinary Drugs in Human Food: General Approach to Establish an Acute Reference Dose (ARfD).

All VICH draft and final guidelines are available on the VICH website (www.vichsec.org).

The Steering Committee reviewed and acknowledged the progress in the drafting of VICH concept papers and new VICH guidelines by the Expert Working Groups on Pharmacovigilance – Electronic Standards Implementation, Biologicals Quality Monitoring, Quality, Safety, Metabolism and Residue Kinetics and Bioequivalence.

The 5th VICH public conference aimed at introducing the VICH achievements and current activities to a wider audience and scheduled to take place in Tokyo, Japan on 27 (evening) to 29 October 2015 under the theme 'Reaching out to the world'. The programme was finalised and key topics include: the contribution of VICH to the global One Health approach, the contribution of VICH to animal welfare in tests for veterinary medicinal products and the benefits of the VICH Outreach Forum to all countries. All information on the 5th VICH public conference is available at http://vich5.com/.

- **Upcoming VICH meetings**:

25-27 and 30 October 2015: 32nd VICH Steering Committee and 6th Outreach Forum meeting, Tokyo, Japan

27 (evening)-29 October 2015: 5th VICH Public Conference, 27-29 October, Tokyo, Japan (http://vich5.com/)

5. OIE Collaborating Centres and Reference Laboratories

The OIE's scientific work is supported by its worldwide network of currently 296 OIE Collaborating Centres and Reference Laboratories. On 14-16 October 2014, the third conference of the OIE Collaborating Centres and Reference Laboratories took place in Incheon, Republic of Korea, under the theme "Challenges and expectations for the future".

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
Tel: (+33[0]2) 99.94.78.78/78.71

Veterinary Drug Regulatory Programmes

Center for Veterinary Medicine
Food and Drug Administration (FDA)
Department of Health and Human Services
7519 Standish Place,
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Rockville, Maryland 20855
UNITED STATES OF AMERICA
Tel: +1-240 276.90.25

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
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Diagnosis of Animal Diseases and Vaccine Evaluation in the Americas

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USDA, APHIS, Veterinary Services
P.O. Box 844
Ames, Iowa 50010
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and

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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

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