CODEX ALIMENTARIUS COMMISSION E

Food and Agriculture Organization of the United Nations

World Health Organization

Viale delle Terme di Caracalla, 00153 Rome, Italy - Tel: (+39) 06 57051 - Fax: (+39) 06 5705 4593 - E-mail: codex@fao.org - www.codexalimentarius.org

**Agenda Item 4** **CX/RVDF 13/21/4**
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**JOINT FAO/WHO FOOD STANDARDS PROGRAMME**

**CODEX COMMITTEE ON RESIDUES OF VETERINARY DRUGS IN FOODS**

**Twenty-first Session**

***Minneapolis, Minnesota, United States of America, 26 – 30 August 2013***

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

**(OIE Contribution to the 21st Session of the CCRVDF)**

## 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 Codex Commission 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 APFS working group APFS Working Group functions as a steering committee for the OIE's work programme on standards to protect consumers from food-borne hazards arising at the production phase of the food chain. Current and former high level officials of the FAO, WHO and Codex are members of the Working Group. The Working Group held its 12th meeting in November 2012. (APFS) Working Group functions as a steering committee for the OIE's work programme on standards to protect consumers from food-borne hazards arising at the production phase of the food chain. Current and former high level officials of the FAO, WHO and Codex are members of the Working Group. The Working Group held its 11th meeting in November 2011. The report of this meeting is available on the OIE website at:

http://www.oie.int/fileadmin/Home/eng/Food_Safety/docs/pdf/A_APFSWG_Nov__2012.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 bodies in promoting safe international trade in animal and their products.

## 2. Capacity building

The activities including the governance related to veterinary medicinal products are considered by the OIE as a priority regarding animal health and public health.

The OIE's Fifth Strategic Plan (2011-2016) includes new fields of actions in particular 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 are part of the Plan as they are considered as indispensable tools for any effective animal health and welfare policy.

Since its last report to CCRVDF, the OIE continued to undertake a number of initiatives to support Veterinary Services all over 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 Member's request, 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, Veterinary Legislation missions and PVS follow up missions, to help improve compliance of the veterinary infrastructure with the OIE quality standards set out in the Terrestrial Code. To date the OIE has received 119 national requests and 111 missions have been completed. Relevant information may be found at: http://www.oie.int/support-to-oie-members/pvs-pathway/

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'.

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 the OIE has received 39 official requests for missions and 28 have been completed.

**National focal points**

The OIE encourages all Member countries to nominate National Focal Points, under the authority of the OIE Delegate, for seven strategic issues, including veterinary products. The creation of these OIE National Focal Points aims to improve communication between the OIE, its Members and agencies responsible for food safety, veterinary products and SPS at the national level on these important topics.

Specific training for OIE National Focal Points for 178 Member Countries in veterinary products is underway worldwide, on a region by region basis. To date, two cycles of training workshops for Focal Points on veterinary products have been held in Europe, in the Americas, in Africa and in the Asia-Pacific. In line with the 'One Health' concept, the WHO has been invited to participate in these training activities. A third one is currently on progress and will begin in October in North Africa.

**OIE twinnings**

The continuation of the laboratory twinning programme launched to mobilise the expertise of the whole network of the 277 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 excellence. A regional Seminar on the OIE Laboratory Twinning Programme was held in Johannesburg in October 2012 in order to provide feedback on OIE Laboratory Twinning Projects in the Africa region and to take advantage of the established feedback process of the OIE to ensure project success, further development of expertise and sustainability.

## 3. Antimicrobial resistance

Since 1997, due to the growing importance of antimicrobial resistance at a world-wide level, the OIE implemented an action plan in this field.

The first milestone was to issue five guidelines:

- Guidelines for the harmonisation of antimicrobial resistance surveillance and monitoring programmes
- Guidelines for the monitoring of the quantities of antimicrobials used in animal husbandry
- Guidelines for the responsible and prudent use of antimicrobial agents in veterinary medicine
- Laboratory methodologies for bacterial antimicrobial susceptibility testing
- Risk assessment for antimicrobial resistance arising from the use of antimicrobials in animals

These guidelines were adopted respectively by the OIE general session of OIE in May 2003 for the first four and in 2004 for the fifth one. The guidelines are now part of OIE international standards and published in the OIE *Terrestrial Animal Health Code* and the *Manual of Diagnostic Tests and Vaccines for Terrestrial Animals.*

- A continuous follow-up is ensured by the OIE *ad hoc* Group on antimicrobial resistance enabling their update whenever required. Since the last OIE report to CCRVDF three guidelines were revised and adopted in the 80$^{th}$ general session in May 2012 (harmonisation of antimicrobial resistance surveillance and monitoring programmes, monitoring of the quantities and usage patterns of antimicrobial agents used in food producing animals, Laboratory methodologies for bacterial antimicrobial susceptibility testing.
- A similar approach has started in view to developing similar guidelines for aquatic animals. The ad'hoc group on the responsible use of antimicrobials in aquatic animals developed a first guideline on principles for responsible and prudent use of antimicrobial agents in aquatic animals that was adopted in 2011. Two additional guidelines were adopted in May 2012 (Monitoring of the quantities and usage patterns of antimicrobial agents used in aquatic animals and Development and harmonisation of national antimicrobial resistance surveillance and monitoring programmes for aquatic animals).

- Since the last OIE report to CCRVDF, two meetings of the OIE ad'hoc group on antimicrobial resistance were held in July 2012 and December 2012 to revise the OIE list of antimicrobial agents of veterinary importance and to update the chapter on 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. WHO and FAO, the Codex secretariat was invited to participate as an observer in this meeting.

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.

- The OIE/FAO/WHO Consultative *ad hoc* Group on Collaborative Activities on Antimicrobial Resistance

This Group met for the first time in 2009 in Geneva in 2011 and a third meeting was organised in August 2012 with the aim of finding common areas for cooperation and maintaining good communication between FAO, OIE and WHO in this field.

As a concrete outcome, WHO and FAO experts have been invited to OIE *ad hoc* Group meetings on antimicrobial resistance. WHO was also invited in OIE Focal points trainings organised in the different regions.

During the 18th FAO/OIE/WHO tripartite annual executive and coordination meeting held in February 2012 in OIE headquarters, Antimicrobial resistance was identified as a priority topic for the three organizations and recommendations were adopted in order to reinforce the collaboration between the three organizations.

A number of other actions have been implemented by OIE on antimicrobial resistance:

- AMR was part of the second cycle of OIE focal point training
- OIE hosted a symposium on alternatives to antibiotics in animal health in September 2012 and organized in March 2013 a global conference on the responsible and prudent use of antimicrobials agents for animals.
- A survey of the implementation of the guideline on monitoring of the quantities and usage patterns of antimicrobial agents used in food producing animals was launch and the analysis of the answer of the 152 OIE Member countries were presented in the OIE global Conference in March 2013.
- A special issue of the Scientific and technical review on Antimicrobial resistance in animal and public health was published in April 2012.

## 4. OIE and VICH activities

Since its formal creation in April 1996, the VICH provides a forum for a constructive dialogue between Regulatory Authorities and the Animal Health Industry on the technical requirements for product registration in the EU, Japan and the USA.

Australia, New Zealand and Canada 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 has since 2008 proposed to its Steering Committee to encourage also other countries to utilize the VICH Guidelines through an Outreach programme.

Two contact meetings with non-VICH countries were held at the 25th SC meeting in Washington DC (USA) in February 2011 and at the 26th SC meeting in Tokyo in November 2011. After this Contact meeting, the "Outreach Forum" was officially established.

Since the last OIE reporting to the CCRVDF in May 2012, three VICH meetings were held:

- Two VICH Outreach Forum meetings: the 1st in July 2012 in Brussels (Belgium) and the 2nd meeting in February 2013 in Washington DC (USA).
- Two VICH Steering Committee meetings: the 27th meeting in July 2012 in Brussels (Belgium) and the 28th meeting in February 2013 in Washington DC (USA).

- At the **27th meeting** of the VICH Steering Committee held meeting in July 2012 in Brussels (Belgium) :

The *1st Outreach Forum* meeting was attended by SC, OIE, 6 non-VICH countries and 1 regional organization. The Forum participants shared their experiences with the use of VICH Guidelines and took the opportunity to discuss the challenges for their wider uptake. The participants considered ways to raise

awareness of VICH Guidelines in other parts of the world and to progress international harmonization of technical requirements for the registration of veterinary medicinal products.

The Steering Committee, OIE and participants to the Forum collaborated to develop a series of actions intended to facilitate the broader understanding of VICH activities and how they can be integrated into regulatory systems of Forum members:

- Translation and training: there was general agreement on the necessity to make existing translated GLs widely available. It was decided to organize a survey amongst forum members to define their needs for technical training on specific GLs and finding out which GLs are most important for translation ;
- Clarification of terminology: the general paper on VICH shall be reviewed.

The *Steering Committee* released for implementation in the regions the revision of VICH Guideline 36 : Safety – microbiological ADI: Studies to Evaluate the Safety of Residues of Veterinary Drugs in Human Food: General Approach to Establish a Microbiological ADI).

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.

At its **28th meeting** in February 2013 in Washington DC (USA),

The *2nd meeting of the VICH Outreach Forum* took place in conjunction with the 28th VICH Steering Committee meeting held in Washington DC from 19 to 21 February 2013. It was attended by 9 countries and 2 regional organizations.

The outcome of the "VICH needs assessment" survey which was carried out during the period between the 27th and 28th SC meeting by OIE was presented: GLs that need to be translated with priority; GLs that countries wish to have training in and topics for discussion.

The Steering Committee, OIE and the Forum participants discussed ways to improve the understanding of VICH Guidelines in other regions in particular through translations and training opportunities.

South Africa had submitted an application to become an Observer to the VICH SC.

The VICH *Steering Committee* adopted the following 4 new Guidelines:

- VICH GL 34 (Biologicals: Test for the detection of Mycoplasma contamination)
- VICH GL 35 (Pharmacovigilance: Electronic Standards for Transfer of Data)
- VICH GL 50 (Biologicals: Harmonization of criteria to waive target animal batch safety testing (TABST) for inactivated vaccines for veterinary use)
- VICH GL 51 (Quality: Statistical evaluation of stability data).

These new Guidelines have been published for implementation in the regions and are available on the VICH website (www.vichsec.org).

The Steering Committee reviewed and acknowledged the progress of the work of the Expert Working Groups on Pharmacovigilance – Electronic Standards Implementation; Quality; Safety; Biologicals Quality Monitoring; Metabolism and Residue Kinetics; and Bioequivalence.

The Steering Committee initiated work by the Biologicals Quality Monitoring Expert Working Group on harmonizing criteria to waive target animal batch safety testing for live vaccines for veterinary use.

The Steering Committee further initiated the development by the Metabolism and Residue Kinetics Expert Working Group of a Guideline on residue studies in honey.

The Steering Committee created a new Expert Working Group with the mandate to develop a Guideline on Electronic File Formats.

Considering the key role of good governance on veterinary medicinal products within the OIE's global strategy, the OIE will continue to provide its support to the VICH process and will continue to actively relay information on VICH to the 178 OIE Members.

**5. OIE Collaborating Centres and Reference Laboratories**

The OIE's scientific work is supported by its worldwide network of currently 265 OIE Collaborating Centres and Reference Laboratories. 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, HFV-1, Room 177
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
SÉNÉGAL
Tel: +221 33 865 10 08

***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
Tel: +1-515 337.72.66 - Tel2: +1-515 337.61.00

Center for Veterinary Biologics
USDA, APHIS, Veterinary Services
P.O. Box 844
Ames, Iowa 50010
UNITED STATES OF AMERICA
Tel: +1 515 337.72.66

***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
Tel: (+81-42) 321-1441

***Antimicrobial resistance***

VLA Weybridge
New Haw, Addlestone, Surrey KT15 3NB
UNITED KINGDOM
Tel: (44-1743) 46.76.21