CODEX ALIMENTARIUS COMMISSION E

Food and Agriculture Organization of the United Nations

World Health Organization

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Agenda Item 4 **CX/RVDF 12/20/4**

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JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON RESIDUES OF VETERINARY DRUGS IN FOODS

Twentieth Session

San Juan, Puerto Rico, 7-11 May 2012

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

Cooperation between the OIE and the Codex *Alimentarius* Commission

1. The World Organisation for Animal Health (OIE) continues to emphasize the need to reinforce the relationship with the Codex *Alimentarius* Commission (CAC). Collaboration between Codex and OIE is essential given current understanding of the contribution of animal health at the production level to the sanitary safety of the food chain 'from farm to fork'. 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.

2. In 2002, the OIE established a Working Group on Animal Production Food Safety (APFSWG) with the view to improving the coordination and harmonisation of standard setting activities of OIE and CAC. The working group met twice since the last report to CCRVDF (November 2011 and November 2012). Important topics are considered in the 2012 work programme as the antimicrobial resistance, animal production food safety in veterinary education and veterinary legislation, food safety issues arising from the on-going work on the emerging zoonoses at the human animal ecosystem interface ("One health").

3. 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.

Capacity building

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

5. 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.

6. 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 implementation of the tool for the evaluation of Veterinary Services compliance with OIE international standards on quality (OIE PVS Tool). This includes the assessment of the governance of veterinary medicinal products in the Member Countries. The number of PVS Evaluation missions is increasing. By November 2011, there were 108 missions completed and 78 reports available.
- The PVS evaluation tool is now completed with the Gap Analysis Tool ("prescription tool") which is a quantitative evaluation of a country's needs and priorities (50 missions completed by November 2011) .

- Implementation of legislation missions to help governments that wish to modernise the national veterinary legislation and thereby help the veterinary services to meet the OIE standards (23 missions completed in November 2011).
- The continuation of the laboratory twinning programme launched to mobilise the expertise of the whole network of the 265 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. An OIE Laboratory twinning feedback workshop was held in OIE Headquarters in March 2011 in order to share experiences and improve effectiveness, efficiency and impact of the twinning programme.
- The establishment of a network of specific OIE Focal Points for Veterinary Products dealing with veterinary medicines issues.
- Regional conferences specifically dedicated to veterinary medicinal products, entitled "Towards the harmonisation and improvement of registration, distribution and quality control" were organised in Africa in March 2008 and in the Middle East (Damascus-Syria) in December 2009.
- A first cycle of regional training workshops for OIE Focal Points for Veterinary Products started in July 2010 (Belgrade, Serbia) continued in September 2010 (Cartagena, Republic of Colombia), in November 2010 (Johannesburg, South Africa) to finish in June 2011 (Siem Reap, Cambodia).
- The second cycle of regional workshops for OIE Focal Points for Veterinary Products started in September 2011(Dakar Senegal), in December 2011(Casablanca, Morocco), in March 2012 (Mombasa, Republic of Kenya) and specific topics covered are VICH and Antimicrobial Resistance.
- The First Global Conference on Veterinary Legislation held in Djerba (Tunisia) in December 2010. This conference addressed several challenges posed by the improvement of national animal health and welfare systems worldwide. 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.

7. These events are aiming at improving the governance related to veterinary medicinal products covering all steps, production, registration, distribution and use.

Antimicrobial resistance

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

9. 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

10. 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. In particular, the chapter on "Responsible and prudent use of antimicrobial agents in veterinary medicine" was revised. This revised chapter was adopted during the May 2005 OIE General Session.

11. Since the last OIE report to CCRVDF, three meetings were held in November 2010, June 2011 and September 2011 to update all existing OIE standards on antimicrobial resistance. The main task of the September meeting was 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. In addition to WHO and FAO, the Codex secretariat was invited to participate as an observer in this meeting.

12. OIE has also established a list of veterinary important antimicrobials that is published on the OIE Website and that will be updated in 2012.

- The OIE *ad hoc* Group on the responsible use of antimicrobials in aquatic animals met in October 2010, September 2011 and in February 2012 in order to draft standards related to the use of antimicrobials in aquatic animals for eventual inclusion in the *Aquatic Animal Health Code*. An introductory chapter to the recommendations for controlling antimicrobial resistance and a standard on the Principles for responsible and prudent use of antimicrobial agents in aquatic animals has been approved in the May 2011 General Session.

13. 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

14. This Group met for the first time in 2009 in OIE Headquarters in Paris (France) and a second session was organised 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.

(1) Guidelines, standards and harmonisation;

(2) Legislation, inspection/control;

(3) Data collection and surveillance;

(4) Capacity building; and

(5) Communication.

- 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.

OIE and VICH activities

15. 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.

16. VICH was established under the auspices of the OIE.

17. Australia, New Zealand and Canada participate in VICH as observers, with one delegate representing governmental Authorities and one representing Industry associations.

18. Since the last OIE reporting to the CCRVDF in September 2010, three VICH meetings were held:

- One meeting of the VICH ad hoc sub group on Global outreach in December 2010, in OIE Headquarters (Paris, France).
- Two VICH Steering Committee meetings: the 25th meeting in February 2011 in Washington DC (USA) and the 26th meeting in November 2011 in Tokyo (Japan).

19. The VICH ad hoc sub group on Global outreach had as objective to encourage a wider harmonisation of registration requirements and efficient use of resources in regions/countries that are not member of VICH. The Subgroup received the mandate to concentrate on short term actions in communication and training, as well as to develop medium and a longer term strategic vision to include governance and input from non member countries/regions.

- At the **25th meeting** of the VICH Steering Committee held meeting in February 2011 in Washington DC (USA), the Steering Committee further discussed ways forward to achieve wider international

harmonisation of technical requirements for the registration of veterinary medicinal products and agreed to further develop proposals on how to address the needs and expectations of non-VICH countries. The short term objectives were the improvement of information, communication and awareness on VICH and an increase of contributions of non-VICH countries in the consultation process of developing VICH guidelines and potential involvement in guideline development in the future.

20. It was decided as a next step to organise a meeting with certain non-VICH countries/regions in the context of the next Steering Committee meeting in Tokyo.

21. The Steering Committee released for implementation in the regions the following VICH final Metabolism and Residue Kinetics Guidelines:

- VICH Guideline 46 (MRK – Studies to evaluate the Metabolism and Residue Kinetics of Veterinary Drugs in Food-producing Animals: Metabolism Study to determine the Quantity and Identify the Nature of Residues),
- VICH Guideline 47 (MRK – Studies to evaluate the Metabolism and Residue Kinetics of Veterinary Drugs in Food-producing Animals: Laboratory Animal Comparative Metabolism Studies),
- VICH Guideline 48 (MRK – Studies to evaluate the Metabolism and Residue Kinetics of Veterinary Drugs in Food-producing Animals: Marker Residue Depletion Studies to establish Product Withdrawal Periods)
- VICH Guideline 49 (MRK – Studies to evaluate the Metabolism and Residue Kinetics of Veterinary Drugs in Food-producing Animals: Validation of Analytical Methods used in Residue Depletion Studies).

22. The Steering Committee also released for public consultation the draft revised VICH Safety Guideline 36 (Safety – Studies to evaluate the safety of residues of veterinary drugs in human food: general approach to establish a microbiological ADI).

23. The Steering Committee reviewed and acknowledged the progress of the Expert Working Groups on Pharmacovigilance – Electronic Standards Implementation, Quality, Biologicals Quality Monitoring, Safety and Bioequivalence.

24. At its **26th meeting** in November 2011 in Tokyo (Japan), a milestone was reached with the formation of the VICH Outreach Forum, in partnership with OIE.

25. VICH has been listening closely to the requests and needs of countries around the world and agreed to hold a one day contact meeting, supported by OIE, during their 26th Steering Committee. Delegates from 11 countries and 3 regional organisations (UEMOA, ASEAN and Camevet) discussed with the VICH Steering Committee the possibilities of extending VICH activities and Guidelines to other countries and regions. The Steering Committee consequently agreed to create the Outreach Forum. This new VICH Outreach Forum will complement the work of OIE by raising awareness on the options available for the use of existing and future VICH Guidelines. This Forum will enable selected countries to participate in VICH activities and obtain in the future substantial benefits of wider harmonisation.

26. The Forum will be held in conjunction with future VICH Steering Committee meetings and offer opportunities for wider international harmonisation of regulatory requirements, improve information exchange and raise awareness of VICH Guidelines in other countries and regions.

27. The Steering Committee released for public consultation the draft VICH Biologicals GL 50 (Biologicals: TABST - Harmonization of criteria to waive target animal batch safety testing (TABST) for inactivated vaccines for veterinary use) and draft VICH Quality GL 51 (Quality: Statistical evaluation of stability data) for a 6 months consultation period.

28. The draft VICH Biologicals GL 34 (Biologicals: Mycoplasma - Test for the detection of Mycoplasma contamination) was released for a second shorter public consultation period of 3 months.

29. The Steering Committee noted further that the revision of VICH GL 36 (Safety – microbiological ADI: Studies to Evaluate the Safety of Residues of Veterinary Drugs in Human Food: General Approach to Establish a Microbiological ADI) is near to finalisation and will be published for implementation in the regions in the near future.

30. The Steering Committee initiated the development of a VICH GL on Metabolism and Residue Kinetics in fish.

31. The Steering Committee reviewed and acknowledged the progress of the Expert Working Groups on Pharmacovigilance – Electronic Standards Implementation, Biologicals Quality Monitoring, Quality, Safety and Bioequivalence.

32. 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.

OIE Collaborating Centres and Reference Laboratories

33. 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)
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