CODEX ALIMENTARIUS COMMISSION E

Food and Agriculture Organization of the United Nations

World Health Organization

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Agenda Item 4 **CX/RVDF 10/19/4**
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JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON RESIDUES OF VETERINARY DRUGS IN FOODS

Nineteenth Session

Burlington, Vermont, United States of America, 30 August – 3 September 2010

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

1. Cooperation between the OIE and the Codex Alimentarius Commission

The World Organisation for Animal Health (OIE) continues to emphasize the need to reinforce the relationship with the Codex Alimentarius Commission (CAC). In the capacity of an observer organisation, the OIE contributes to the work of several Codex Committees.

In order to strengthen the cooperation between the OIE and the CAC, the OIE Members gave the Director General the mandate, in 2002, to create a specific permanent OIE Animal Production Food Safety Working Group (APFSWG). The Working Group's membership includes internationally recognized experts from the Food and Agriculture Organization of the United Nations (FAO), the World Health Organization (WHO) and the Codex Alimentarius Commission (CAC), and reflects a broad geographical basis.

The APFSWG has drawn up a detailed work programme for the development of standards relevant to animal production food safety, covering hazards that arise on-farm and at slaughter, with a primary focus on measures applicable at the animal production level. The APFSWG recognised that the goals of the OIE can only be achieved by working in collaboration with WHO, FAO and their subsidiary bodies, particularly the CAC. This is essential to avoid contradictory standards, to address gaps between current standards and to ensure the most effective use of available expertise. To this end, the OIE has strengthened formal and informal relationships with relevant international organisations and expert groups. To avoid gaps and duplications between the standards of the OIE and Codex, the Working Group will continue to cross-reference OIE and Codex texts whenever developing standards in the area of animal production food safety.

The Working Group met for the ninth time in November 2009.

During this meeting, the APFSWG's work programme was adopted for 2010. The work programme includes the following topics:

a) Horizontal issues

- Antimicrobial resistance activities:
  - follow up of Codex, FAO, WHO and OIE developments
  - developing new text addressing the issue of antimicrobial resistance for aquatic animals
- Follow any developments in nanotechnology relevant to the work of the APFSWG.
- Consideration of the scientific evidence on the relationship between animal welfare and animal production food safety.
- Animal production food safety in veterinary education following from the recommendations of the OIE Conference ‘Evolving veterinary education for a safer world’ held in October 2009.
- Policy statement on the importance of animal production food safety for food security.

- Food safety issues arising from the ongoing work on the emerging zoonoses at the human animal ecosystem interface (‘One World, One Health’).

b) Disease-specific OIE texts

- Chapters of the OIE Terrestrial Animal Health Code on brucellosis.
- Foodborne zoonoses

c) Continue to strengthen relationship between OIE and Codex by:

- Encourage enhanced OIE input into Codex texts and vice versa.
- Encourage continued close collaboration between the Codex secretariat and the OIE Headquarters.

1.1. 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 strengthening of the actions in this field started with the adoption of Resolution n° 25 on veterinary products at the OIE General Session in May 2009.

During the General Session in May 2010, the Delegates of the 176 OIE Members adopted the OIE's Fifth Strategic Plan (2011-2016). The Plan 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 training of trainers to support OIE national representatives (Delegates) and national Veterinary Services,
- the implementation of a 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 implementation of a network of specific OIE Focal Points for Veterinary Products dealing with veterinary medicines issues
- the continuation of the laboratory twinning programme launched by the OIE in 2006 to mobilise the expertise of the whole network of the 227 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.
- the Second Global Conference of OIE Reference Laboratories and Collaborating Centres , held in OIE Headquarters in June 2010. This conference reaffirmed that scientific excellence was the basis of good governance and the early detection, surveillance and control of animal diseases worldwide.
- regional conferences specifically dedicated to veterinary medicinal products, entitled "Towards the harmonisation and improvement of registration, distribution and quality control" organised in Africa in March 2008 and in the Middle East (Damascus-Syria) in December 2009.
- a new cycle of regional workshops for OIE Focal Points for Veterinary Products starting with its first meeting in July 2010 (Belgrade, Serbia). WHO has been invited to participate in theses future training activities.

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

1.2. 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 four first mentioned and in 2004 for the fifth one. The guidelines are now part of OIE international standards.

A continuous follow-up is ensured by the OIE *ad hoc* Group on antimicrobial resistance enabling whenever needed their update. In particular, Appendix 3.9.4 of the OIE Terrestrial Animal Health Code on guidelines for the responsible and prudent use of antimicrobial agents in veterinary medicine was revised, taking into account the recommendations of the Codex Alimentarius – ALINORM 05/28/31, Appendix VIII 53 Proposed Draft Code of Practice to Minimize and Contain Antimicrobial Resistance. This revised guideline was adopted during the May 2005 OIE General Session.

- Since the last OIE report to CCRVDF, the OIE ad hoc Group on the responsible use of antimicrobials in aquatic animals met in January 2010 in order to draft standards for the responsible production, distribution (including international trade) and use of antimicrobials in aquatic animals for eventual inclusion in the Aquatic Animal Health Code.
- 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.

Since the last OIE report to CCRVDF, two meetings were held in this context:

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

The Group met on 30 September and 1 October 2009 in OIE headquarters in Paris (France) with the aim of finding common areas for cooperation and maintaining good communication between FAO, OIE and WHO in this field. After mapping out the areas where antimicrobial resistance may arise, the ad hoc Group identified five main areas of activities currently addressed by the three organisations:

(1) Guidelines, standards and harmonisation;

(2) Legislation, inspection/control;

(3) Data collection and surveillance;

(4) Capacity building; and

(5) Communication.

A draft work plan was agreed by the *ad hoc* Group for common and joint activities between the organisations in the short, medium and long term.

Codex Task Force

The 3rd Codex Ad Hoc Intergovernmental Task Force on Antimicrobial resistance was held in Jeju (Republic of Korea) in October 2009 with the participation of OIE. Keeping in mind that protection of human health and the prudent and responsible use of antimicrobials in animals or plant protection is the ultimate objective in antimicrobial resistance risk management, the OIE has continuously supported the work of this Task Force. In developing Guidance on methodology and processes for risk analysis for antimicrobials, this Task Force will contribute to minimize the risk of antimicrobial resistance and will also help avoiding the duplication of existing guidelines. The OIE is looking forward the finalisation of the risk analysis guidance and will follow closely the outcome.

1.3. 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.

VICH was established under the auspices of the OIE.

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

Since the last OIE reporting to the CCRVDF in May 2009, four VICH meetings were held:

- One meeting of a task force on VICH Global Outreach in October 2009, in Washington DC (USA).
- Two VICH Steering Committee meetings: the 23rd meeting in November 2009 in Kobe (Japan) and the 24th meeting in June 2010 in the OIE Headquarters in Paris (France). Good progress was achieved on a number of areas.
- The 4th VICH Conference in June 2010, at the OIE Headquarters, in Paris (France).

The task force on VICH Global Outreach has for objective to encourage a wider harmonisation of registration requirements and efficient use of resources in regions/countries that are not member of VICH. The task force, chaired by the OIE, met in October 2009 in Washington (USA) in order to suggest actions to put in place, taking into account the VICH objectives and non VICH countries needs.

At the 23rd meeting of the VICH Steering Committee held in November 2009 in Kobe (Japan), the program of the VICH IV Public Conference was finalised. The Steering Committee reviewed the proposal for a future strategy on global outreach towards non-VICH countries, in collaboration with OIE. It was intended that this strategy might be finalised after receiving input from non-VICH countries during the VICH Conference.

The Steering Committee adopted the following draft Metabolism and Residue Kinetics Guidelines for release for public consultation at step 4: VICH GL 46 (Nature of Residues), VICH GL 47 (Comparative Metabolism Studies), VICH GL 48 (Marker Residue Depletion Studies) and VICH GL 49 (Analytical Methods used in Residue Depletion Studies).

The Steering Committee agreed to initiate work on developing a guideline on requirements to establish bioequivalence of veterinary medicinal products and a guideline on statistical evaluation of stability data.

The Steering Committee reviewed the progress of the Expert Working Groups on Pharmacovigilance, Quality, Biologicals Quality Monitoring, Microbiological ADI and Safety.

The Fourth Public Conference on the International Harmonisation of Technical Standards for Veterinary Medicinal Products "VICH impact and future expectations"(VICH 4) took place from 24 to 25 June 2010 at the World Organisation for Animal Health (OIE) Headquarters in Paris. More than 160 delegates from 30 countries attended the event.

The Conference provided direct access via 6 workshops to members of the expert working groups responsible for drafting the VICH guidelines. Three workshops were devoted to exploring the role of VICH in the global regulatory environment, plans for a VICH Global Outreach Strategy, and the value and future vision of VICH.

At its 24th meeting held in the OIE Headquarters in Paris from 23 to 26 June 2010, the VICH Steering Committee laid the foundation for the VICH strategy for the years 2011 to 2015. The priority area that was identified for attention is its global outreach strategy.

Building on the Conference's outcome, the Steering Committee discussed the proposal for a future strategy on extending the appreciation of VICH activities towards non-VICH countries and regions, "the global outreach strategy". Working closely with OIE, the strategy is directed at wider understanding of VICH standards as part of capacity building in the area of veterinary medicines regulation.

The Steering Committee adopted the draft VICH pharmacovigilance Guideline 35 (Pharmacovigilance: ESTD - Electronic Standards for Transfer of Data). The public consultation period will be 6 months.

The Steering Committee also adopted at step 6 and released at step 7 for implementation in the regions the following VICH final Guidelines: VICH GL 30 (Pharmacovigilance of Veterinary Medicinal Products: controlled list of terms.) and VICH GL 42 (Pharmacovigilance: Data Elements for Submission of Adverse Events Reports).

These three new Guidelines complete the package of Guidelines on pharmacovigilance requirements in the VICH regions, and mark the finalisation of the development of the pharmacovigilance Guidelines.

The Steering Committee reviewed the progress of the Expert Working Groups on Quality, Biologicals Quality Monitoring, Metabolism and Residue Kinetics, Microbiological ADI and Safety.

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 176 OIE Members.

1.4. OIE Collaborating Centres and Reference Laboratories

The OIE's scientific work is supported by its worldwide network of more than 220 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

- AFSSA Fougères
  Agence nationale du médicament vétérinaire
  B.P. 203
  35302 Fougères Cedex
  FRANCE
  Tel: (33[0]2) 99.94.78.78/78.71 Fax: (33[0]2) 99.94.78.99

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 Fax: (+81-42) 325-5122

Antimicrobial resistance

- Dr Chris Teale
  VLA Weybridge
  New Haw, Addlestone, Surrey KT15 3NB
  UNITED KINGDOM
  Tel: (44-1743) 46.76.21 Fax: (44-1743) 44.10.60