CODEX ALIMENTARIUS COMMISSION

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Food and Agriculture Organization of the United Nations

World Health Organization

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Agenda Item 4 **CX/RVDF 21/25/4**

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JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON RESIDUES OF VETERINARY DRUGS IN FOODS

25th Session
(Virtual)
12-16 and 20 July 2021

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

(Prepared by OIE)

1. Introduction

1. In the capacity of an observer organisation, the World Organisation for Animal Health (OIE) has a long-standing collaboration and regularly participates in meetings of the Codex Alimentarius Commission (CAC).

2. The OIE addresses food safety-related issues in its standard-setting activities and works closely with CAC and its Committees, and with other international organisations in promoting safe international trade in animals and their products. The Antimicrobial Resistance (AMR) is of highest interest to the OIE and its 182 Members and is also part of the tripartite (FAO, OIE, WHO) collaboration.

3. The OIE Six Strategic Plan (2016-2020) has been successfully implemented with the following strategic objectives:

   - Ensure the health and well-being of animals and the safety of animal-based food and products, and reduce the transmission of diseases, notably by controlling the risks at the human-animal-environment interface;
   - Establish trust between stakeholders and trading partners in cross-border trade of animals and animal-based products and foods, through transparency and good communication on the incidence of epidemiologically important diseases, and through the OIE standards on the sanitary safety of exchanges;
   - Strengthen the capacity and sustainability of National Veterinary Services.

4. The 7th Strategic Plan is ready for endorsement by the OIE Council and adoption at the next 88th General Session in May 2021. The Antimicrobial Resistance & Veterinary Products Department will continue to contribute to the development of the OIE's 7th Strategic Plan including the quality of veterinary products and the OIE data collection on antimicrobial agents intended for use in animals (OIE AMU Database).

2. Antimicrobial resistance

➢ Standards and guidelines related to AMR

5. The primary mandate of the OIE is to produce standards published in *Codes* and *Manuals* covering terrestrial and aquatic animals, which provide best practices to protect and promote animal health and welfare. Their development involves regular review and formal adoption at the annual General Session by the World Assembly, made up of Delegates designated by the governments of the 182 OIE Members.

6. Since 1997, in recognition of the growing importance of AMR at a global level, the OIE has developed standards and guidelines aimed at supporting responsible and prudent use of antimicrobial agents in animals and monitoring of AMR and use in animals. The OIE standard-setting process ensures that standards are updated, when relevant, in order to accommodate new findings and Member Country comments. This work was supported by the OIE *ad hoc* Group on AMR, which included representatives from WHO, FAO, and, when relevant, the Codex secretariat. The OIE *ad hoc* Group provided expertise by updating the chapters relevant to AMR in the OIE *Terrestrial Animal Health Code*[1], *Aquatic Animal Health Code*[2] and *Manual of Diagnostic Tests and Vaccines for Terrestrial Animals*[3]. Code chapters include:

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1 http://www.oie.int/en/international-standard-setting/terrestrial-code/access-online/
2 http://www.oie.int/en/international-standard-setting/aquatic-code/access-online/
3 http://www.oie.int/en/international-standard-setting/terrestrial-manual/access-online/

- Harmonisation of national AMR surveillance and monitoring programmes,
- Monitoring of the quantities and usage patterns of antimicrobial agents used in food-producing animals,
- Responsible and prudent use of antimicrobial agents in veterinary medicine, and
- Risk analysis for AMR arising from the use of antimicrobial agents in animals.

7. The *Manual of Diagnostic Test and Vaccines for Terrestrial Animals* provides technical specifications for Laboratory methodologies for bacterial antimicrobial susceptibility testing.

8. The 2nd edition of the booklet of OIE standards and guidelines related to AMR has been published and is also available in print and online at:

   http://www.oie.int/fileadmin/home/eng/Media_Center/docs/pdf/PortailAMR/EN-book-AMR.PDF.

9. Specific recommendations on the use of antimicrobial agents in animals are published in the OIE List of Antimicrobial Agents of Veterinary Importance. The List has been updated several times since 2007, and was reviewed by the OIE *ad hoc* on AMR Group in January 2018 and 2019 to take into account the latest update of the WHO List of Critically Important Antimicrobials. The current List is available at:

   https://www.oie.int/fileadmin/Home/eng/Our_scientific_expertise/docs/pdf/AMR/A_OIE_List_antimicrobials_July2019.pdf

10. Following the adoption of Resolution No. 14 "OIE's engagement in the One Health Global Effort to control Antimicrobial Resistance" by the World Assembly of OIE Delegates in May 2019, a **Working Group on Antimicrobial Resistance** was established (replacing the *ad hoc* Group on AMR) which had its first meeting in October 2019 to support the implementation of the OIE Global Strategy on Antimicrobial Resistance and the Prudent Use of Antimicrobials and the Recommendations of the 2nd OIE Global Conference on AMR. This Working Group has already had three meetings and these meeting reports are available at:

    https://www.oie.int/en/standard-setting/specialists-commissions-working-ad-hoc-groups/working-groups-reports/working-group-on-amr/the-group-reports/#c42477

➢ OIE Collection of data on antimicrobial agents intended for use in animals

11. The OIE started with the annual data collection on the use of antimicrobial agents in animals in the last trimester of 2015. The first report was published in December 2016. Since then, OIE has published an annual report on the use of antimicrobial agents intended for use in animals following an annual round of data collection from OIE Members and non-Members. All OIE AMU annual reports are available at:

    https://www.oie.int/en/scientific-expertise/veterinary-products/antimicrobials/

12. The fifth OIE Annual Report will be published in the second quarter of 2021 and will present the findings of the fifth round of data collection, providing both a global and a regional analysis. The number of Members reporting data has grown from 130 countries for the first report to 160 countries for the fifth report. The fifth report also includes evidence on the barriers that some countries (n=23) experienced in reporting quantitative data on antimicrobial agents intended for use in animals. Additionally, this report provides calculations of animal biomass for food-producing species from 102 Members reporting quantitative data for the year 2017, and an analysis of antimicrobial quantities reported adjusted by a denominator.

13. The sixth data collection round of the OIE Global Database started in September 2020 and is currently taking place.

3. Capacity building

14. Capacity building activities, including good governance of national veterinary services and veterinary products, are key elements for animal and public health.

    National Focal Points

15. The OIE encourages all Members to nominate National Focal Points, under the authority of the OIE Delegate, for eight strategic issues, including for veterinary products.

16. The 5th cycle of training seminars for National Focal Points for Veterinary Products has been completed in Africa, the Asia-Pacific, the Middle East and Europe. In line with the 'One Health' concept, the FAO and WHO are regularly invited to participate in these seminar activities. The 6**th** cycle of seminars **for OIE National Focal Points for Veterinary Products** are ongoing. The first seminar was held in Addis Ababa and Debre Zeit, Ethiopia, (9-11 July 2019) for English-speaking African countries: *Angola, Botswana, Eritrea, Ethiopia, Gambia, Ghana, Kenya, Lesotho, Liberia, Malawi, Mauritius, Mozambique, Namibia, Nigeria, Seychelles, Sierra Leone, Somalia, South Africa, South Sudan, Sudan, Swaziland, Tanzania, Uganda, Zambia and Zimbabwe*. The second seminar was held in Lomé, Togo (9-11 October 2019) for French-speaking African countries: *Algeria, Benin, Burkina Faso, Burundi, Cape Verde, Cameroon, Central African Republic, Chad, Comoros, Cote d'Ivoire, Democratic Republic of the Congo, Djibouti, Equatorial Guinea, Gabon, Guinea, Guinea-Bissau, Madagascar, Mali, Mauritania, Morocco, Niger, Republic of the Congo, Rwanda, São Tomé and Príncipe, Senegal, Togo and Tunisia*.The most recent in person seminar was held in Kuala Lumpur, Malaysia (14-16 January 2020) for the Asia-Pacific Region with the following countries: *Australia, Bangladesh, Bhutan, China (People's Rep. Of) Chinese Taipei, Fiji, India, Iran, Japan, Korea (Rep.of), Lao PDR, Maldives, Malysia, Micronesia (Fed. States of), Mongolia, Myanmar, Nepal, New Caledonia, New Zealand, Pakistan, Papua New Guinea, Philippines, Singapore, Sri Lanka, Thailand, Vanuatu and Vietnam.* To replace the planned trainings, webinars have been held for the Middle East Region (7-9 December 2020) and the Europe Region (17-19 February 2021) to address priority topics from the 6th cycle such as pharmacovigilance, antiparasitic resistance, and substandard and falsified veterinary products.

17. The 6**th** cycle of seminars for the Focal Points for Veterinary Products aims to deepen understanding of key issues such as:

- An overview of ongoing activities related to AMR.
- Follow up on the recommendations from the 2nd OIE Global Conference on Antimicrobial Resistance and Prudent Use of Antimicrobial Agents in Animals: Putting Standards into Practice.
- Introduction of new topics such as improving the quality of veterinary products covering substandard and falsified veterinary products, pharmacovigilance, and antiparasitic resistance.

18. The seminars also allocate time for sharing of experiences and lessons learnt between participants from the OIE Regions.

19. A manual on pharmacovigilance with practical guidance on how to set up a pharmacovigilance system for veterinary medicinal products has been prepared in collaboration with HealthforAnimals, in the framework of a public private partnership. It includes relevant references to the VICH guidelines. It will be finalised in 2021 by incorporating the views of the Focal Points for Veterinary Products from all regions within the frame of the 6th cycle training seminars.

➢ <u>OIE and the VICH activities</u>

20. The OIE continues to be active in assisting 182 Members to build and implement effective legislation to assure the quality, safety and efficacy of veterinary medicinal products, particularly antimicrobial agents. ***VICH* (International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products)** is a trilateral (EU-Japan-USA) programme aimed at harmonising technical requirements for veterinary product registration. The OIE, as associate Member of 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 medicinal products is a necessity for animal health, public health, protection of the environment and the facilitation of international trade, and that VICH is one of the necessary tools to achieve these aims. The ***VICH Outreach Forum (VOF)*** is a VICH/OIE initiative with the main objective of providing a basis for wider international harmonization of technical requirements for the marketing authorisation of veterinary medicinal products. The OIE co-chairs the VOF in collaboration with the chair of the VICH Steering Committee (SC). In order to provide OIE Members with information about efforts to harmonise requirements, the OIE provides a brief summary after each VOF meeting via the Delegate and Focal Points for Veterinary Products. The OIE also circulates VICH guidelines and other relevant VICH documents (i.e. adopted concept papers) to OIE Members. When relevant, the OIE Biological Standards Commission is informed about relevant subjects in order to achieve harmonisation as much as possible.

21. The VICH Outreach Forum (VOF) meets regularly alongside the VICH Steering Committee (SC) meeting. Recent meetings are listed below.

- The 10th VOF and 36th SC meetings were held from 25 to 28 June 2018 in Brussels, Belgium.
- The 11th VOF and 37th SC meetings were held in Cape Town, South Africa from 23 February to 1 March 2019 with the 6th VICH Public Conference (27-28 February 2019). The Conference, titled "Unlocking Africa's Potential", welcomed participants from 28 countries. Presentations were delivered by regulators from Africa and abroad, the OIE, industry organizations, the World Bank and the Bill and Melinda Gates Foundation. Speakers shared their experiences of implementing the VICH guidelines, discussed the benefits of adoption, and brainstormed ways to advance efforts towards regulatory convergence.
- The 12th VOF and 38th SC meetings were held from 18 November to 21 November 2019 in Tokyo, Japan. A summary report with the different VICH guidelines and concept papers were disseminated to all Delegates and Focal Points in 2020. The Biological Standards Commission was informed about the relevant guidelines and concept papers.
- The 13th VICH Outreach Forum and 39th VICH Steering Committee and meeting were held electronically (17 November and 16-20 November 2020, respectively). Significant OIE comments were provided to the VICH Steering Committee on the next 5-year VICH Strategy document, adopted during this meeting. (VICH PRIORITIES Phase 5: 2021-2025).
- The 14th VICH Outreach Forum and 40th Steering Committee Meeting is planned for November 2021 in the offices of the EMA (Amsterdam, the Netherlands).

22. The press releases are available on the website: https://www.vichsec.org/en/library/press-releases.html.

- The OIE will strengthen support to the OIE VOF Member Countries more actively and keep the OIE Focal Points of Veterinary Products informed on matters related to VICH activities.

23. The 36th SC meeting adopted the final VICH Guideline 56 "MRK: Residues in Honey - Studies to evaluate the Metabolism and Residue Kinetics of Veterinary Drugs in Food-producing Species: Study Design Recommendations for Residue Studies in Honey for establishing MRLs and Withdrawal Periods."

24. The 37th SC adopted VICH GL57 on "MRK: Residues in Fish: - Studies to evaluate the Metabolism and Residue Kinetics of veterinary drugs in food-producing species: marker residue depletion studies to establish product withdrawal periods in aquatic species."

25. The 38th SC adopted VICH GL58 "(Quality GL) on Stability Testing of New Veterinary Drug Substances and Medicinal Products in Climatic Zones III and IV" for implementation by the VICH Members by November 2020.

26. The VICH SC has developed training materials on VICH guidelines. These materials aim to make understandable how the guidelines should be used. The primary audience for these training materials are VICH Outreach Forum Member Countries. At the moment, there are seven modules available including ten VICH Quality Guidelines (GL). New training tools which are of relevance for this committee include the Metabolism and Residue Kinetics Guidelines. The training materials are posted on the VICH website (https://vichsec.org/en/training.html).

➢ The OIE PVS Pathway

27. The **OIE PVS (Performance of Veterinary Services) Pathway** is a global programme for the sustainable improvement of a country's Veterinary Services in compliance with OIE's internationally agreed standards on the quality of Veterinary Services. As a flagship programme of the OIE, it is central to the OIE's core mission of improving animal health and welfare around the world. At the specific request of a Member Country, the OIE conducts an independent and staged process of assessments and planning on the quality of Veterinary Services and Aquatic Animal Health Services including veterinary medicines and biologicals 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* or *Aquatic Animal Health Code*. Further background on the PVS Pathway can be found on the OIE website at:

http://www.oie.int/en/support-to-oie-members/pvs-pathway/.

28. The programme has proven an unmitigated success over the last decade. To date (February 2020) 141 Member Countries have been actively engaged via national requests to conduct initial OIE PVS Evaluation missions. Relevant information may be found at:

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

29. The **PVS Tool** assesses a Critical Competency 'Veterinary Medicinal Products (VMPs)': This way, the results of the PVS Evaluations revealed that nearly three-quarters of the assessed countries cannot regulate VMPs (24% of assessed countries) or have only some capability to exercise regulatory control over VMPs (47% of assessed countries).

30. Following the 2017 PVS Pathway Think Tank Forum (which aimed at reviewing, consulting and planning for the evolution of the PVS Pathway), the 2019 Edition of the PVS Tool included a Critical Competency dedicated to AMU/AMR. This new edition is available at:

https://www.oie.int/fileadmin/Home/eng/Support_to_OIE_Members/docs/pdf/2019_PVS_Tool_FINAL.pdf.

31. A cross-analysis which was conducted over reports of the OIE PVS Pathway Veterinary Legislation Support Programme (VLSP) showed that most recurrent weaknesses of AMR-relevant legislation seem to be the following: 1) gaps in the legislation on VMPs; 2) issues related to withdrawal times and maximum residue limits; 3) issues related to the Competent Authority for VMPs. There also seems often be a need to improve the legislation governing the veterinary profession (veterinarians and VPPs).

32. In the context of the OIE/FAO/WHO Tripartite collaboration on mitigation of AMR, OIE (via the VLSP), contributed to the development of tools by FAO for assessing national legal frameworks for mitigation of AMR, participated in FAO Regional Workshops on legislation relevant to AMR (Burkina Faso, Nigeria, Thailand), and organized a pilot joint OIE/FAO Veterinary Legislation Identification mission with specific content on AMR legislation which was conducted in the Philippines in June 2019. It is expected that additional pilot combined missions will be conducted in 2020.

➢ Veterinary Education

33. The OIE Recommendations on the competencies of graduating veterinarians ('Day 1 graduates', 2012) prepare the Day 1 veterinary graduate to promote global veterinary public health and provide a basis for advanced training and education for veterinarians in all OIE Members. The OIE Guidelines on Veterinary Education Core Curriculum (2013) are a companion to the previous document and are to assure the quality of education required for the public and private components of National Veterinary Services. Further information is available at the following link:

http://www.oie.int/fileadmin/Home/eng/Support_to_OIE_Members/Vet_Edu_AHG/DAY_1/DAYONE-B-ang-vC.pdf.

34. The OIE has also produced OIE Competency Guidelines for Veterinary Paraprofessionals (2018) and OIE Curricula Guidelines for Veterinary Paraprofessionals (2019):

https://www.oie.int/en/solidarity/options-for-targeted-support/veterinary-and-veterinary-paraprofessional-education/.

The documents for veterinary paraprofessionals include references to antimicrobial resistance and recognise the need to train veterinary paraprofessionals on the proper use of antibiotics.

4. International Collaboration

➢ Global Action Plan on AMR

35. The OIE has continued its close Tripartite collaboration with WHO and FAO (the Tripartite) on the delivery of the Global Action Plan on AMR. OIE Members are encouraged to follow the guidance of the Global Action Plan, and develop National Action Plans to address AMR at national level. Together with FAO and WHO, the OIE has developed a comprehensive Monitoring and Evaluation Framework for the Global Action Plan, which was published in June 2019 and is currently being piloted in seven countries. A component of the Global Action Plan Monitoring and Evaluation Framework includes the existing Tripartite Annual Survey on the implementation of National Action Plans. Now in its fourth year, this annual survey has been renamed as the Tripartite Country Self-Assessment Survey (TrACSS) and the OIE facilitates the participation of its Members in this process where necessary.

36. The OIE has been strengthening its collaboration with FAO and WHO in AMR, notably through the establishment of the Tripartite Joint Secretariat on AMR, and the Multi-Partner Trust Fund on AMR in 2019.

➢ AMR in connection to the United Nations General Assembly

37. The OIE has been actively participating in strengthening the global One Health AMR response. The OIE participated in the work of an ad hoc Interagency Coordination Group (IACG) on AMR, established in 2017, as a member and by providing resources to support its function. The group published its report in April 2019. The Tripartite prepared the Secretary-General's report for the 73rd session of the UN General Assembly on the implementation of the political declaration A/RES/71/3 of the high-level meeting of the General Assembly on antimicrobial resistance, and on recommendations emanating from the IACG. The OIE is currently working together with FAO and WHO to follow up on the recommendations and observations of the two reports.

➢ OIE Reference Centres

38. The OIE's scientific work is supported by its worldwide network. In 2019, the OIE had a global network of 254 Reference Laboratories covering 106 diseases or topics in 37 countries, and 58 Collaborating Centres covering 50 topics in 28 countries. The complete lists of Collaborating Centres and Reference Laboratories are available at the following links:

https://www.oie.int/en/scientific-expertise/collaborating-centres/list-of-centres/

https://www.oie.int/en/scientific-expertise/reference-laboratories/list-of-laboratories/

39. Collaborating Centres or Reference Laboratories with a particular focus on VMPs or AMR include:

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

Antimicrobial resistance (reference laboratory)

Animal and Plant Health Agency
New Haw, Addlestone,
Surrey KT15 3NB
UNITED KINGDOM

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

National Veterinary Assay Laboratory (NVAL)
1-15-1, Tokura, Kokubunji, Tokyo, 185-8511
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Training of official veterinarians, diagnosis of infectious animal diseases and zoonoses, and control of veterinary drugs in West and Central Africa

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