



**JOINT FAO/WHO FOOD STANDARDS PROGRAMME**  
**CODEx COMMITTEE ON RESIDUES OF VETERINARY DRUGS IN FOODS**  
**Twenty-fourth Session**

**REPORT ON 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 OIE has a long-standing collaboration and regularly participates in meetings of the Codex Alimentarius Commission (CAC). The OIE also participated in the previous Task Force on Antimicrobial Resistance (AMR) that took place between 2007 and 2011.

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. AMR is of highest interest to the OIE and its 181 Member Countries and is also one of the priority topics for tripartite (FAO, OIE, WHO) collaboration.

3. The OIE's Fifth Strategic Plan (2011–2015) included 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 with Codex and expansion of the programme on International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products (VICH), were included in the 5<sup>th</sup> Strategic Plan as they are considered to be essential tools for any effective animal health and welfare policy.

4. At the OIE General Session in 2015, the OIE's Sixth Strategic Plan (2016–2020) was adopted and sets out three major objectives leading to economic prosperity and social and environmental well-being.

- Objective 1: Securing animal health and welfare by appropriate risk management
- Objective 2: Establishing trust through transparency and communication
- Objective 3: Ensuring the capacity and sustainability of Veterinary Services

The OIE Sixth Strategic Plan is available at the following link:  
[http://www.oie.int/fileadmin/Home/eng/About\\_us/docs/pdf/6thSP\\_ANG.pdf](http://www.oie.int/fileadmin/Home/eng/About_us/docs/pdf/6thSP_ANG.pdf).

5. At the OIE's 84<sup>th</sup> General Session in 2016, the World Assembly unanimously adopted **Resolution No. 36**, which mandates that OIE compile AMR activities into a strategy. In November 2016, the OIE Strategy on Antimicrobial Resistance and the Prudent Use of Antimicrobials was published. Aligned with the Global Action Plan on AMR, the strategy recognises the importance of a "One Health" approach involving human and animal health as well as plant and environmental needs. It outlines the goals and projects the OIE has in place to support Member Countries in their fight against AMR, and to encourage the national ownership and implementation of international Standards. The document is available at the following link.  
[http://www.oie.int/fileadmin/Home/eng/Media\\_Center/docs/pdf/PortailAMR/EN\\_OIE-AMRstrategy.pdf](http://www.oie.int/fileadmin/Home/eng/Media_Center/docs/pdf/PortailAMR/EN_OIE-AMRstrategy.pdf)

## 2. Antimicrobial resistance

### ➤ Standards and guidelines related to AMR

6. The primary mandate of the OIE is to produce 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 181 OIE Member Countries.

7. 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 is supported by the OIE *ad hoc* Group on AMR, which includes representatives from WHO, FAO, and, when relevant, the Codex secretariat. The OIE *ad hoc* Group provides expertise by updating the chapters relevant to AMR in the OIE *Terrestrial Animal Health Code*<sup>1</sup>, *Aquatic Animal Health Code*<sup>2</sup> and *Manual of Diagnostic Tests and Vaccines for Terrestrial Animals*<sup>3</sup>.

8. Code chapters include:

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

Specific recommendations on the use of antimicrobial agents in animals are published in the:

- OIE List of Antimicrobial Agents of Veterinary Importance. This List, developed as a draft list in May 2006 and refined in 2007, was submitted to the 75<sup>th</sup> International Committee and adopted unanimously by Resolution No. XXVIII. during the General Session in May 2007. The List identifies antimicrobial agents used in animals around the world, highlights where no or few alternatives for treatment of animal diseases exists, and provides guidance on use of antimicrobial agents that are of highest critical importance in human medicine. The List that was updated several times since 2007 was reviewed by the *ad hoc* Group in January 2018 to take into account the latest update of the WHO List of Critically Important Antimicrobials, and following the recommendations of the **OIE Resolution No. 38** (85 GS 2017) to define the purpose of ionophores.

The current List is available at:

[http://www.oie.int/fileadmin/Home/eng/Our\\_scientific\\_expertise/docs/pdf/Eng\\_OIE\\_List\\_antimicrobials\\_May2015.pdf](http://www.oie.int/fileadmin/Home/eng/Our_scientific_expertise/docs/pdf/Eng_OIE_List_antimicrobials_May2015.pdf)

9. The OIE standards and guidelines are published (online and 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 for Aquatic Animals* and are available at: [http://www.oie.int/fileadmin/home/eng/Media\\_Center/docs/pdf/PortailAMR/EN-book-AMR.PDF](http://www.oie.int/fileadmin/home/eng/Media_Center/docs/pdf/PortailAMR/EN-book-AMR.PDF)

10. The OIE *ad hoc* Group on AMR continues to work, with the participation of FAO and WHO, in support of the global efforts to prevent and combat AMR through updating Chapter 6.7 of the *Terrestrial Code*, Harmonisation of national antimicrobial resistance surveillance and monitoring programmes. The *ad hoc* Group also proposed definitions of “Therapeutic use” and “Growth promotion” for the Chapter 6.8 of the *Terrestrial Code*, Monitoring of the quantities and usage patterns of antimicrobial agents used in food-producing animals. The Group also supports the worldwide collection of data on the use of antimicrobial agents in animals.

11. Based on the recommendations of the 2013 OIE Global Conference on the Responsible and Prudent Use of Antimicrobial Agents and the Tripartite (FAO,OIE,WHO), the OIE has taken the initiative, in line with the Global Action Plan, to build a global database on antimicrobial agents intended for use in animals.

<sup>1</sup> <http://www.oie.int/en/international-standard-setting/terrestrial-code/access-online/>

<sup>2</sup> <http://www.oie.int/en/international-standard-setting/aquatic-code/access-online/>

<sup>3</sup> <http://www.oie.int/en/international-standard-setting/terrestrial-manual/access-online/>

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

12. The first OIE Annual Report on antimicrobial agents intended for use in animals, which described the results of the first phase of data collection, was published in December 2016. Since then, Member Country participation increased for the second phase of data collection. From October 2016 to May 2017, 146 Countries submitted completed questionnaires to the OIE Headquarters: 143 from OIE Member Countries and 3 non-Member Countries. Simultaneously, calculations of animal biomass to use as a denominator in the analysis of quantitative data on antimicrobials intended for use in animals was undertaken.

13. The OIE publishes annually a report on the worldwide distribution of antimicrobial agents intended for use in animals. The second report on the data collection included for the first time an analysis of antimicrobial quantities reported by OIE Region in the context of animal biomass and was published on the OIE website in December 2017.

[http://www.oie.int/fileadmin/Home/eng/Our\\_scientific\\_expertise/docs/pdf/AMR/Annual\\_Report\\_AMR\\_2.pdf](http://www.oie.int/fileadmin/Home/eng/Our_scientific_expertise/docs/pdf/AMR/Annual_Report_AMR_2.pdf)

14. Meanwhile, the OIE launched the third phase of data collection on 30 September 2017.

15. During the 85<sup>th</sup> General Session (May 2017), the World Assembly of Delegates was updated on the progress and future prospects of global action in combatting AMR under the Technical Item 1, and adopted **Resolution No. 38** “Global action to alleviate the threat of antimicrobial resistance: progress and opportunities for future activities under the ‘One Health’ initiative” whereby the continued collection of global data on antimicrobial agents intended for use in animals was affirmed as a key effort in this goal.

16. The report of Technical Item 1 of the 2017 General Session can be found at: [http://www.oie.int/fileadmin/home/eng/Media\\_Center/docs/pdf/85SG/TT1\\_AMR/A\\_85SG\\_9.pdf](http://www.oie.int/fileadmin/home/eng/Media_Center/docs/pdf/85SG/TT1_AMR/A_85SG_9.pdf)

### 3. Capacity building

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

➤ National Focal Points

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

19. The 4<sup>th</sup> cycle of specific training seminars for Focal Points for Veterinary Products has been completed in the, Africa, Asia-Pacific, and Europe and in the Middle East. In line with the ‘One Health’ concept, the FAO and WHO are regularly invited to participate in these seminar activities. The 5<sup>th</sup> cycle of seminars *entitled Regional Workshop for OIE National Focal Points for Veterinary Products (5<sup>th</sup> Cycle)*, are ongoing. So far the first was held in Ezulwini, Swaziland (6–8 December 2017) 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 Abidjan, Côte d’Ivoire (16–18 Janvier 2018) for *French-speaking African countries: Algeria, Benin, Burkina Faso, Burundi, Cabo 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, Sao Tome and Principe, Senegal, Togo and Tunisia*. The third seminar will be held in March 2018 in Thailand for the Asia-Pacific Region and the fourth seminar will be held in April 2018 in Mexico for the Americas Region within the framework of the 5<sup>th</sup> Cycle.

20. The 5<sup>th</sup> cycle of seminars for the Focal Points for Veterinary Products aims to deepen understanding of key issues such as:

- 1) Tripartite activities related to AMR;
- 2) The quality and traceability of veterinary medicinal products (VMPs), including the issue of falsified and substandard veterinary medicines, the harmonisation/convergence of regional registration/authorisation systems for VMPs, and the implementation of VICH guidelines;
- 3) Resistance to antiparasitic drugs and challenges relating to their use.

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

➤ OIE and the VICH activities

22. The OIE continues to be active in assisting 181 Member Countries to build and implement effective legislation to assure the quality, safety and efficacy of veterinary medicinal products, particularly antimicrobial agents. The OIE, as associate Member of the 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 medicines is a necessity for animal health, public health and the facilitation of international trade, and that VICH is one of the necessary tools to achieving these aims. In order to provide OIE Member Countries with the information about efforts to harmonise requirements, the OIE provides a brief summary after each VICH Outreach Forum (VOF) meeting via the Delegate and Focal Points of Veterinary Products and encourages their participation in the VOF meetings.

23. The VICH Outreach Forum meets regularly following each VICH Steering Committee (SC) meeting.

24. The 8<sup>th</sup> Outreach Forum and 34<sup>th</sup> SC meetings were held from 28 February to 2 March 2017 in Buenos Aires, Argentina.

25. The 9<sup>th</sup> Outreach Forum and 35<sup>th</sup> SC meetings were held in Tokyo, Japan from 13 to 16 November 2017.

26. The press releases are available on the website: <http://www.vichsec.org/activities/press-releases.html>

27. The VICH Outreach Forum is growing. A first contact meeting with 11 non-VICH countries and three non-VICH regional organisations was held under the chairmanship of OIE. Currently 16 countries and four Regional organisations are Members of the VICH Outreach Forum.

28. Nigeria, Uganda and Saudi Arabia joined in 2016, and Zimbabwe has recently joined the VICH Outreach Forum in 2017.

Upcoming VICH meetings:

29. 10<sup>th</sup> meeting of the VICH Outreach Forum will take place from 26 to 27 June 2018 in Burges (Belgium).

30. In 2019, there will be an opportunity for countries to learn more about the work of VICH, the role of its guidelines and the VICH Outreach Forum at the public 6<sup>th</sup> VICH Public Conference, which will be held in February 2019 in Cape Town, South Africa. This public conference will focus on VICH global outreach activities, as well as the current work achieved by the VICH Expert Working Groups.

<http://www.vichsec.org/activities/dates-of-next-meetings/next-vich-conference.html>

➤ The OIE PVS Pathway

31. 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 what the PVS Pathway is can be found on the OIE website at <http://www.oie.int/support-to-oie-members/pvs-pathway/>.

32. The programme has proven an unmitigated success over the last decade. To date (March 2018) 139 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/> .

33. In April 2017 the OIE organised a PVS Pathway Think Tank Forum as a platform to review, consult and plan for the evolution of the PVS Pathway, including AMR specific management relevant to Veterinary Services capacity, particularly in assessing the prudent and responsible use of antimicrobials in animal populations. This methodology is currently being finalised and the aim is to pilot it in candidate countries in 2018. The result should be that PVS mission findings and recommendations relevant to AMR are developed and presented in a more readily accessible and usable form for the country or its international partners to guide further AMR legislation, policies and/or activities to target the risks. The methodology will also be closely aligned with FAO-OIE-WHO Tripartite AMR initiatives, including the AMR national action plan self-assessment questionnaire, and the inclusion of AMR in IHR MEF<sup>4</sup> Joint External Evaluations.

➤ Veterinary Education

34. The OIE Recommendations on the competencies of graduating veterinarians ('Day 1 graduates') 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 Member Countries. 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](http://www.oie.int/fileadmin/Home/eng/Support_to_OIE_Members/Vet_Edu_AHG/DAY_1/DAYONE-B-ang-vC.pdf). Similar work on the education of veterinary paraprofessionals is ongoing.

#### 4. International Collaboration

➤ Global Action Plan on AMR

35. The OIE closely collaborated with WHO and FAO (the Tripartite) on the Global Action Plan on AMR, which was developed based on the 'One Health' approach. OIE Member Countries are encouraged to follow the guidance of the Global Action Plan and the Tripartite developed a Manual for implementation of National Action Plans. An annual survey on the implementation of National Action Plans has also been developed and the questionnaire for the second survey was sent in autumn 2017.

36. The OIE continues to collaborate with WHO and FAO on AMR, in particular through the development of tripartite frameworks on stewardship and on monitoring and evaluation of activities related to AMR.

➤ Interagency Coordination Group on Antimicrobial Resistance

37. Collaboration is also increasing at the highest political level and the three organisations hosted a High Level Dialogue on AMR in April 2016 at the United Nations in New York to raise awareness on AMR. On 21 September 2016, during the 71<sup>st</sup> Session of the United Nations General Assembly, Member States adopted the Political Declaration of the High-level Meeting on AMR contained in Resolution A/RES/71/3 and in March 2017 an *ad hoc* Interagency Coordination Group on AMR was established. The second meeting of this UN Interagency Coordination Group on AMR took place at the OIE Headquarters in mid-October. The objective of the Group is to provide practical guidance for approaches needed to ensure sustained effective global action to address AMR, including options to improve coordination, taking into account the Global Action Plan on AMR. It will produce a report to the Secretary-General for the 73<sup>rd</sup> session of the UN General Assembly.

➤ OIE Reference Centres

38. The OIE's scientific work is supported by its worldwide network. In 2017, the OIE has a global network of 267 Reference Laboratories covering 118 diseases or topics in 38 countries, and 55 Collaborating Centres covering 49 topics in 29 countries. The complete list of Reference Centers is available at the following link:

<http://www.oie.int/en/our-scientific-expertise/collaborating-centres/list-of-centres/>

Reference Centres with particular focus on AMR are

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<sup>4</sup> IHR MEF: International Health Regulations monitoring and evaluation framework

**Veterinary Medicinal Products**

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**Antimicrobial resistance**

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Administration (FDA), Department of Health and  
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