



REPORT OF THE MEETING OF THE OIE WORKING GROUP ON ANTIMICROBIAL RESISTANCE
Paris, 1–3 October 2019

1 Opening

The OIE Working Group on Antimicrobial Resistance (AMR) (hereafter referred to as ‘the Group’) met from 1st to 3rd October 2019 at the OIE Headquarters in Paris, France.

Dr Elisabeth Erlacher-Vindel welcomed the members. She provided an introduction to the creation of the OIE AMR Working Group, noting that it was established by the OIE Director General, Dr Monique Eloit, following Resolution No. 14 adopted at the 87th OIE General Session. The Working Group will provide guidance and establish priorities to assist in particular with the implementation of the OIE Strategy on AMR and the Prudent Use of Antimicrobials, and the recommendations of the 2nd OIE Global Conference on AMR and Prudent use of Antimicrobials, as outlined in the Terms of Reference (ToRs). It will also build on the work accomplished by the previous OIE *ad hoc* Group on AMR.

2 Adoption of the agenda and appointment of the rapporteur

The agenda was adopted without additions or revisions. The Group was chaired by Tomoko Ishibashi and Donald Prater acted as rapporteur. The adopted Agenda and List of Participants are presented in Appendices I and II of this report, respectively.

3 OIE introduction

The outcomes and recommendations from the 2nd OIE Global Conference on AMR and Prudent Use of Antimicrobials in Animals were presented. The recommendations¹, mentioned in particular updating standards in the OIE Terrestrial and Aquatic Codes relevant to AMR, working with private sector partners, providing OIE Member Countries with tools and capacity building activities with a greater focus on AMR, including the Performance of Veterinary Services (PVS) pathway, supporting OIE Member Countries in developing communication activities and national action plans relating to AMR, and encouraging research and development for alternatives to antimicrobials.

An update on OIE activities in the different workstreams related to the recommendations and the overall OIE AMR work programme was also provided.

¹ https://www.oie.int/amr2018/wp-content/uploads/2018/11/A_2nd-OIE-Global-Conference_Recommendations_Final_ic.pdf

4 Working Group Terms of Reference and *modus operandi*

The Terms of Reference as approved by the OIE Council were presented and discussed by the Group and are available in [Appendix III](#). The *modus operandi* was discussed and modified with the addition of a new point proposed by the members of the Group (available in [Appendix IV](#))

5 Roundtable from the participants on any new issues of interest for the Group

Information was shared within the Group on antimicrobial use (AMU) and AMR, including an update from members.

Prof. Moritz van Vuuren raised the issue of veterinary oversight of antibiotics, which he noted is a particular issue of importance for the Africa region. He noted that oversight implies that dispensing or prescription of antibiotics should only be done by veterinarians or other authorised animal health workers. This risk management measure is often included in the work of OIE, Food and Agriculture Organisation (FAO), and World Health Organisation (WHO), and was also a topic of importance for the World Veterinary Association (WVA). Compounding of antibiotics, which in the case of production animals may involve combining two or more antibiotics into feed and water, was also mentioned as having potential consequences for AMR. It was noted that compounding pharmacies in some parts of the world are outside of pharmaceutical oversight and do not contribute to the collection of AMU data.

Dr Donald Prater provided an overview of the success on United States Food and Drug Administration (FDA)'s Guidance for Industry (GFI) #213, a voluntary approach to medically important antimicrobials removing production indications (growth promotion) and placing these authorisations under veterinary supervision. Substantial reductions (33%) in the use of medically important antimicrobials in food-producing animals were documented in the first year following implementation. He also shared information about FDA's new GFI #263 Recommendations for Sponsors of Medically Important Antimicrobial Drugs Approved for Use in Animals to Voluntarily Bring Under Veterinary Oversight All Products That Continue to be Available Over-the-Counter.

Dr Gérard Moulin discussed surveillance of AMU in France, including a legislative act obliging all veterinarians, pharmacists, and medicated feed manufacturers to declare their sales to the authorities. A first report was produced in June concerning medicated feed manufacturers, representing data by species. The report compared the results obtained with data from marketing authorisation holders, finding that the data per species was similar. In addition, for some years, French authorities have been working on a platform for declaration of antimicrobial sales by veterinarians. This platform takes place within the context of new European Union (EU) legislation stating that Member States should send data on antimicrobial sales, as well as data on AMU by species (at farm level) to the European Medicines Agency (EMA).

As the Chair of the EMA's AntiMicrobial Expert Group (AMEG), he presented the EMA's categorisation of antimicrobials, a task requested by the European Commission. A report has been produced proposing four categories based on WHO and OIE recommendations using a One Health approach. He also mentioned a network meeting of the European Surveillance of Veterinary Antimicrobial Consumption (ESVAC) project organised by the EMA for October 2019, which would be an opportunity to follow up with activities in Europe.

Dr Stephen Page provided a brief presentation of six subjects:

- Antimicrobial stewardship based on the 5R principles of Responsibility, Review, Reduce, Refine and Replace;
- The importance of quality of use in addition to quantity of use as the basis of assessing responsible and prudent use;

- The emerging importance of AMR in companion animals (dogs and cats) as a possible source of resistance of public health significance, and the need for a qualitative risk assessment of the importance of the associated risks;
- Appropriate use of infection control and biosecurity measures (including vaccination) as an important means to reduce use of antimicrobials, reducing the likelihood of pathogens being present to cause disease;
- A current review by the World Small Animal Veterinary Association (WSAVA) Therapeutic Guidelines Group (TCG) which identified a set of 22 common and fundamental principles of responsible use of antimicrobials from among existing guidelines on prudent use. This list is being prepared for later publication, and the results resemble principles identified by a parallel activity in the medical community (<https://www.ncbi.nlm.nih.gov/pubmed/29878216>);
- The use of the WHO List of Critically Important Antimicrobials by a number of international food companies and livestock industries, despite many countries having developed national lists of important antimicrobials, such that it effectively becomes a private standard.

Ms Barbara Freischem mentioned the EMA's ongoing work to provide scientific advice on acts to be issued by the European Commission for the implementation of the new veterinary medicines regulation, Regulation (EU) 2019/6 (published in January 2019). This new regulation required approximately 20 pieces of delegated legislation, for many of which the EMA will be requested to provide scientific advice. The advice on data collection of antimicrobial sales and use by species is finished while the advice on criteria for designating antimicrobials for human use will be finished only in October 2019. Work has started on formal requirements for the data collection and on populating the list of antimicrobials designated for human use only, for which knowledge on off-label use of antimicrobials would be required. A new regulation on medicated feed has also been issued and work is ongoing to ensure aligned requirements in Europe for different methods of oral use (like for example in-feed medication, via drinking water, top dressing or individually administered oral doses), also relevant for antimicrobials.

Dr Liz Tayler commented on the WHO's current transformation regarding the work on AMR, and that the current focus is on country level support. She noted that AMR is a high priority area, citing the recent creation of the position of an Assistant Director General for AMR responsible for two departments.

The FAO observer, Dr Jeffrey Lejeune, provided a brief overview of AMR related activities being conducted at FAO.

6 Tripartite AMR work programme and United Nations driven activities

Dr Saija Kalenius, as the OIE Liaison Officer within the Tripartite Joint Secretariat, briefly summarised the content of the Interagency Coordination Group on AMR (IACG) report², the report of the United Nations Secretary General³, the Tripartite AMR Multi-Partner Trust Fund⁴, the AMR Tripartite Workplan for 2019-2020⁵, and the current status of development of the main activities outlined in these documents. These included the planned future development of the One Health Global Leaders Group on AMR⁶, and the Independent Panel on Evidence for Action against AMR.

² https://www.who.int/antimicrobial-resistance/interagency-coordination-group/IACG_final_report_EN.pdf?ua=1

³ <https://undocs.org/en/A/73/869>

⁴ https://www.oie.int/fileadmin/Home/eng/Media_Center/docs/pdf/PortailAMR/AMR_MPTF_Tripartite_Leaflet_2019.pdf

⁵ <http://web.oie.int/download/WG/AMR/AMR-Tripartite-Workplan-updated-08-April-2019.pdf>

⁶ https://www.who.int/antimicrobial-resistance/interagency-coordination-group/Draft_ToRs_Leaders_Group_AMR_101019.pdf?ua=1

7 OIE List of antimicrobial agents of veterinary importance in animals, subdivision into animal species: Poultry

The OIE List of antimicrobial agents of veterinary importance (hereafter “the List”) was presented, emphasising the effort to subdivide the list by animal species. The proposed subdivision is based on the recommendations of the 2nd OIE Global Conference on AMR and Prudent Use of Antimicrobials, and is a follow up of the preliminary work by the OIE *ad hoc* Group on AMR.

A presentation was made highlighting different options for structuring the List by species (hereafter the “Species Annex”) and presenting a potential methodology for use by the Group. The Group agreed that the overall initial aim would be to develop a pilot methodology to be initially applied for poultry but with the potential for application for other animal species. It was agreed that the Species Annex should not be seen as global treatment guidelines, but rather function as a reference document to inform development of national treatment guidelines, advice on prevention and best practice management, risk management, and risk prioritisation. It was decided that the Group should produce an explanatory text to explain the scope of the Species Annex and emphasise this point, identify other caveats and limitations, and recognise the challenges associated with the project. Furthermore, it was agreed that the narrative text describing patterns of use (e.g. treatment of choice, last resort, useful alternative) should employ a different terminology than the overall classification (veterinary critically important, highly important, important).

The Group discussed the creation of an issue specific subgroup of designated members and additional experts (hereafter the “Poultry *ad hoc* Group”) for the development of an initial pilot exercise to develop relevant information (in the form of a chart or table) to guide decisions on responsible and prudent use of antimicrobial agents in poultry, complementing the current OIE List of Antimicrobial Agents of Veterinary Importance that aggregates information on all species. The Group drafted a proposal of Terms of References (ToRs) for the Poultry *ad hoc* Group (available in Appendix V), which could be updated over time.

Dr Gérard Moulin, Prof. Moritz van Vuuren, Ms Barbara Freischem, and Dr Stephen Page expressed interest in participating in the Poultry *ad hoc* Group. Other potential members of the Poultry *ad hoc* Group could include the International Poultry Council (IPC), the WVA (given their previous work with OIE in developing a depository of guidelines), and HealthforAnimals. Members of the Group were invited to propose names of additional experts, with the aim to achieve geographical balance, to join the Poultry *ad hoc* Group by mid October 2019, for final decision by the OIE.

A draft timeline for the Poultry *ad hoc* Group was proposed. It was suggested that 12-18 months would be a reasonable timeframe for development of the pilot poultry Species Annex. It was determined that meetings should be whenever possible electronic, with additional physical *ad hoc* meetings as necessary.

It was determined that by the end of 2019:

- The OIE would inform relevant partners (such as IPC) on the current progress of the work, and to invite them to contribute relevant information
- The designated Group members together with identified partner organisations, would further refine the necessary tasks or activities for the Poultry *ad hoc* Group to progress the work

It was agreed that by March 2020 (before the next meeting of the Working Group) the Poultry *ad hoc* Group would produce an early draft of the OIE Poultry Annex. This updated version would be presented to the Group at the next meeting for follow-up discussion.

8 OIE Antimicrobial Use (AMU) database: current stage and future development

Dr Delfy Gochez presented the OIE data collection on antimicrobial agents intended for use in animals, including:

- a) The history of the OIE AMU Data Collection: The project and the related OIE questionnaire was based on Chapter 6.9 of the *Terrestrial Animal Health Code* and Chapter 6.3 of the *Aquatic Animal Health Code*
- b) The data-validation procedure: 80% of the results provided by OIE Member Countries are modified after clarifications with the OIE Antimicrobial Use Team
- c) Future steps: The creation of a software tool/database suitable for OIE Member Countries to submit data is ongoing. The three phases of transition from a spreadsheet to database were outlined:
 - Phase 1: Transition from spreadsheet to database (planned for completion in September 2021).
 - Phase 2: Integration of the database with the OIE's World Animal Health Information System (WAHIS).
 - Phase 3: Division of data by species

The Group discussed the importance of the data collection and acknowledged the OIE work in developing and refining the animal biomass denominator.

The Group supported the creation of a technical reference Group among their members to assist the OIE regarding the database development and its transition phase from a spreadsheet. This group would include a person nominated by Ms Barbara Freischem, Dr Donald Prater, Dr Gérard Moulin, an expert to be nominated by Dr Tomoko Ishibashi from the OIE Collaborating Centre in Japan, Dr Jeffrey Lejeune (FAO), Dr Arno Muller (WHO), and other experts as appropriate.

The Group was informed of the Tripartite Integrated Surveillance System project on AMR/AMU (TISSA), which aims to consolidate human, animal, plants and environmental AMR and AMU data and will be kept informed as the system develops.

9 Other matters for consideration

a) The use of antibiotics in semen

The Group was informed that Chapter 4.7 Collection and Processing of Bovine, Small Ruminant and Porcine Semen of the OIE *Terrestrial Animal Health Code* is to be thoroughly reviewed, and that the Terrestrial Animal Health Standards Commission will be seeking the Group's advice regarding the addition of antibiotics to porcine semen when handling semen samples as described in Article 4.7.7 of Chapter 4.7.

The Group agreed that they would be ready to address any question relating to this topic to the agenda when requested.

b) Comments received on Chapter 6.10 "Responsible and prudent use of antimicrobial agents in veterinary medicine" of the *Terrestrial Animal Health Code*

The Group was informed that a request had been received to amend some articles in Chapter 6.10, and that the Group may be requested to address specific comments in the future. The Group agreed that they would be ready to answer any technical questions relating to this topic and will add this to its work programme when requested.

The Group, noting the similarity between the text under discussion in Codex Alimentarius Task Force on Antimicrobial Resistance (TFAMR) (Code of Practice) and Chapter 6.10, suggested that it would be preferable to consider any possible amendments to Chapter 6.10 following completion of discussions in TFAMR. This would ensure alignment on key concepts in the respective standards of the Codex and the OIE.

10 Development of a Work Programme

The Group discussed and agreed a Work Programme which is presented in Appendix VI of this report. The Group agreed that the Work Programme would contain important issues for the next 1-2 years, with consideration that additional issues could be added over time, based on the recommendations of the OIE 2nd Global Conference on AMR and Prudent Use of Antimicrobial Agents and other issues referred to the Group. The Group expressed the desire to be informed about the development and implementation of capacity building activities undertaken by OIE, for example, the PVS pathway, OIE Focal Point Trainings and e-learning, and other activities mentioned in the Group ToRs. The Group would also like to be informed on key Tripartite activities as related to the Group ToRs, so that they can be taken into account as the Work Programme is further elaborated.

11 Any other business

None.

12 Date of next meeting

The proposed date of the next meeting is 7-9 April 2020.

13 Adoption of report

The Group adopted the draft report.

.../Appendices

MEETING OF THE OIE WORKING GROUP ON ANTIMICROBIAL RESISTANCE

Paris, 1–3 October 2019

Agenda

1. Opening
2. Adoption of the agenda and appointment of rapporteur
3. OIE introduction
4. Working Group Terms of Reference (ToRs) and modus operandi
5. Roundtable from the participants on new issues of interest for the Group
6. Tripartite AMR work programme and United Nations driven activities
7. OIE List of antimicrobial agents of veterinary importance in animals, subdivision into animal species: Poultry
8. OIE Antimicrobial Use (AMU) database: current stage and future development
9. Other matters for consideration
 - Use of antimicrobials in semen
 - Comments received on OIE Terrestrial Animal Health Code Chapter 6.10 Responsible and prudent use of antimicrobial agents in veterinary medicine
10. Development of a work programme
11. Any other business
12. Date of next meeting
13. Adoption of agenda

MEETING OF THE OIE WORKING GROUP ON ANTIMICROBIAL RESISTANCE

Paris, 1–3 October 2019

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OIE WORKING GROUP ON ANTIMICROBIAL RESISTANCE

Paris, 1–3 October 2019

Terms of Reference

The OIE Working Group on Antimicrobial Resistance will:

1. Report to the OIE Director General, who will transmit the report, or relevant parts of it, to the appropriate OIE Specialist Commissions and the OIE World Assembly of Delegates.
2. Maintain a global perspective and foresight on antimicrobial resistance regarding animal health and the interface with human health, food production and the environment.
3. Assist the OIE Director General and OIE Specialist Commissions to identify risks and risk management options associated with antimicrobial resistance through development and maintenance of OIE International Standards (*Terrestrial Animal Health Code*, *Aquatic Animal Health Code*, *Manual of Diagnostic Tests and Vaccines for Terrestrial Animals* and *Manual of Diagnostic Tests for Aquatic Animals*.)
4. Identify and assist the OIE Director General in the development of additional guidance related to antimicrobial resistance to assist the interpretation and implementation of OIE International Standards.
5. Assist the OIE Director General, as requested, in the implementation of other aspects of the OIE Strategy on Antimicrobial Resistance and the Prudent use of Antimicrobials, in particular:
 - a) the maintenance of the OIE collection of data intended for use of antimicrobial agents and its connection to the World Animal Health Information System and the Tripartite Integrated Surveillance System on AMR;
 - b) the maintenance and further refinement of the OIE List of Antimicrobial Agents of Veterinary Importance and the follow up of its recommendations;
 - c) the development and implementation of capacity development activities in OIE Member Countries related to antimicrobial resistance, including through the PVS Pathway, OIE Focal Point training, and e-learning platforms;
 - d) the design and implementation of communication activities to raise awareness, improve understanding and create behavioural change;
 - e) the conceptualisation, prioritisation, implementation and interpretation of research on antimicrobial resistance and alternatives to antimicrobials and its impacts on animal health, animal welfare and veterinary public health.
 - f) the establishment of an information system on falsified and substandard drugs, and the development of work programme activities to manage associated risks;
 - g) the support of the OIE and Member Countries in the development, implementation, interpretation and response to monitoring and evaluation activities.

Appendix III (contd)

6. Support the OIE in its Tripartite activities following the Global Action Plan and its role within the future secretariat in relation to the global governance mechanism that is to be established.
 7. Address specific issues referred to the Working Group by the OIE Director General, which may include matters recommended by Specialist Commissions, Member Countries or the OIE itself.
 8. Support the activities of OIE Collaborating Centres related to veterinary medicinal products and antimicrobial resistance and encourage the establishment and implementation of an effective network of expertise in support of the OIE and its Member Countries.
 9. Support and advise the OIE in its interactions and collaborations with the broad network of animal and veterinary public health sector partners and stakeholders to achieve strong coordination on antimicrobial resistance within this community of interest.
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OIE WORKING GROUP ON ANTIMICROBIAL RESISTANCE
Paris, 1–3 October 2019

Modus operandi

1. The Working Group will hold a face-to-face meeting at least on a yearly basis in Paris, preferably twice a year.
 2. The Working Group will organise additional teleconferences when appropriate.
 3. The Working Group Chair will maintain additional regular communication with the OIE Antimicrobial Resistance and Veterinary Products Department and other Departments as appropriate.
 4. The Working Group will provide a written report of its meetings and teleconferences to the OIE Director General.
 5. The Working Group may request the Director General to co-opt additional experts on specific topics.
 6. Issue-specific designated subgroup members and additional experts can be tasked to advance specific points of the Working Group's work by electronic consultation in between meetings.
 7. The Director General may request individual Working Group members to participate in AMR related *ad hoc* Groups or represent the OIE in relevant meetings or conferences.
 8. The Working Group will develop a work programme and subsequently update it at each meeting based on priorities identified by the OIE Director General.
 9. The operating language of the Working Group will be English.
 10. A representative of WHO and FAO will be invited to participate as active observers in the OIE Working Group on Antimicrobial Resistance.
 11. Representatives from relevant private sector organisations that have a cooperation agreement with the OIE may also be invited to participate as active observers depending on the agenda, at their own cost.
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OIE POULTRY AD HOC GROUP

Terms of Reference

Purpose: To initiate a pilot project to provide relevant information with the aim of guiding decisions on responsible and prudent antimicrobial use in poultry. This project will inform national treatment guidelines, risk prioritisation and risk management with respect to national action plans, complementing the current OIE List of Antimicrobials of Veterinary Importance. The exercise should focus on chickens (including major production categories, such as layers and broilers), and potentially consider other avian species as feasible. The work should take into account regional differences and practices. The information could also serve as a resource detailing indications and/or usage.

Deliverable: The work product is expected to be a table or a chart that complements the OIE List of Antimicrobials of Veterinary Importance and should include classes of antimicrobials, use patterns and relevant diseases. The expert group should draft explanatory text to support the table or chart also recognising challenges such as variations among countries in:

- the availability of data;
- the distribution of animal populations and diseases with respect to the need for different antimicrobial classes;
- production and management practices;
- access to different antimicrobial classes, vaccines and other tools.

It should be noted that the chart is not intended to be used as a treatment guideline.

Timelines: 12 to 18 months to complete the work

Milestones:

- By the end of 2019: selected members of the OIE Working Group on Antimicrobial Resistance will produce a revised and updated version of the zero-draft OIE Poultry List.
- By March 2020 (before the next meeting of the OIE Working Group on Antimicrobial Resistance): a version 1 draft of the OIE Poultry List completed.

Recommended working plan: Electronic meetings with additional physical meetings if necessary.

Sources of information:

- OIE List
 - Existing treatment guidelines
 - Literature search
 - Existing marketing authorisations for the species
 - OIE work on vaccines that can reduce the use of antimicrobials
 - Expert advice
-

Work Programme for the OIE Working Group on Antimicrobial Resistance

Subject	Issue/Action	Status	Timeline
OIE List of Antimicrobial Agents of Veterinary Importance, subdivision by species	- poultry subdivision pilot exercise	In progress	12-18 months
	- evaluation of the methodology	Future	April 2020
	- consideration of other species	Future work	April 2020
	- addition of companion animals		
OIE Global AMU database	- transition of data collection from spreadsheet to database system, expert advice	In progress	February 2020
	- refinement of the numerator, denominator (biomass), and reporting	Ongoing	
Terrestrial and Aquatic OIE Codes chapters related to AMR	- update and maintenance of the Chapters	On request	
Alternatives to Antimicrobials (ATA)	- information on categorisation of products	In progress	April 2020
	- review of existing information in the OIE Manual for related issues	Future work	
Substandard and falsified products	- to be informed of existing and ongoing work by OIE directly or indirectly linked (including PVS) and by other international bodies	In progress	April 2020

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