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REPORT OF THE MEETING OF THE OIE *AD HOC* GROUP ON TECHNICAL REFERENCES FOR AQUATIC ANIMALS Paris (via Zoom), 4-5 May 2021

1 Opening

The OIE *ad hoc* Group on Technical References for Aquatic Animals (hereafter referred to as 'the Group') met from 4^{th} to 5^{th} May 2021 via an on-line application, 13:00 - 16:00 (Central European Time), coordinated by the OIE Headquarters in Paris, France.

Dr Elisabeth Erlacher-Vindel, Head of the OIE Antimicrobial Resistance and Veterinary Products (AMR & VP) Department, welcomed the Group members and thanked them for their participation in the Group. She informed them that the OIE is scaling up its work on antimicrobial resistance (AMR) in aquaculture, and has several future projects in this area, including the development of a *Technical Reference Document Listing Antimicrobial Agents of Veterinary Importance for Aquatic Species* which will be the output of the Group's work and the main topic of this meeting. She clarified that the work of the Group is hosted under the OIE's permanent Working Group on AMR and will be linked to the OIE's Aquatic Animal Health Standards Commission (AAHSC).

2 Short self-introduction by participants

The Group members each made a short self-introduction.

3 Adoption of the agenda and appointment of the rapporteur

The agenda was adopted without additions or revisions. The Group was chaired by Dr Donald Prater and Dr Siow Foong Chang acted as rapporteur. The adopted Agenda and List of Participants are presented in <u>Appendices I and II</u> of this report, respectively.

4 Brief description of the OIE

4.1 Antimicrobial Resistance and Veterinary Products (AMR&VP) Department

Dr Elisabeth Erlacher-Vindel presented the Group with information on the AMR &VP Department, which hosts AMR related issues, and collaborates with colleagues in other OIE Departments, the OIE Regional Representations, and the AAHSC on topics related to AMR in Aquaculture. An internal OIE AMR in Aquaculture Network has been formed to ensure the flow of regular information on related topics between these entities.

4.2 OIE List of Antimicrobial Agents of Veterinary Importance

Dr Jorge Pinto Ferreira presented the current *OIE List of Antimicrobial Agents of Veterinary Importance* (hereafter the *OIE List*), available here: https://www.oie.int/app/uploads/2021/06/a-oie-list-antimicrobials-june2021.pdf

He also presented the *Technical Reference Document Listing Antimicrobial Agents of Veterinary Importance for Poultry* (hereafter referred to as the *Poultry Technical Reference Document*), which was the first species specific Technical Reference Document to be completed. The *Poultry Technical Reference Document* is currently published as an Appendix to the October 2020 report of the Working Group on AMR here:

https://www.oie.int/fileadmin/Home/eng/Internationa_Standard_Setting/docs/pdf/WGAMR/A_WG_AM <u>R_Oct2020.pdf</u>

A Subgroup of the Working Group on AMR has now commenced work to develop a *Technical Reference Document Listing Antimicrobial Agents of Veterinary Importance for Swine*, which will be undertaken in parallel with the work of this Group to develop a *Technical Reference Document Listing Antimicrobial Agents of Veterinary Importance for Aquatic Animals* (hereafter referred to as the *Aquatic Technical Reference Document*). Each of these Technical Reference Documents will in the future be an annex to the *OIE List*.

5 Overview of Terms of Reference – deliverables

5.1 Technical Reference Document Listing Antimicrobial Agents of Veterinary Importance for Aquatic Animals

The Group reviewed their Terms of Reference (ToRs), available in <u>Appendix III.</u> Dr Dante Mateo highlighted the three deliverables of the Group:

- Main table, an updated version of the OIE List of Antimicrobial Agents of Veterinary Importance, targeting PIS (Pisces) species (fish, and crustaceans only)
 - Annex 1: List of major pathogens and diseases affecting the main aquatic animal species (fish and crustaceans only)
 - Annex 2: Antimicrobial classes used to treat aquatic animal infections (based on Annex 1)

Dr Dante Mateo also presented the template documents for commencing work on the Aquatic Technical Reference Document. The Group agreed to use the same methodology to develop the Aquatic Technical Reference Document as that used for the Poultry Technical Reference Document, adapting this as needed and making note of any necessary changes to the methodology in the meeting reports for transparency.

The Group discussed several considerations for the scope of the Aquatic Technical Reference Document, which are listed below.

- The aquatic species to be included within the scope of the Aquatic Technical Reference Document

Food-producing aquatic animals: The *OIE List* includes only antimicrobial agents for use in foodproducing animals. The Group agreed that as an annex to this list, the *Aquatic Technical Reference Document* should also limit its scope to food-producing animals. Consequently, the Group decided that ornamental fish would not be included in the *Aquatic Technical Reference Document* at this stage. However, the Group acknowledged the importance of antimicrobial use in ornamental fish and proposed that if the *OIE List* is updated in the future to include companion animals or other non-food-producing species, ornamental fish could also be included. The Group was informed that this would be consistent with the approach in other AMR workstreams, noting that ornamental fish will be included in the coming update to the OIE Template for the OIE AMU Data Collection within the category of companion animals. The Group agreed to add a sentence to its ToRs indicating that the *Aquatic Animal Reference Document* will be limited to food-producing aquatic species. The Group also agreed to add text to the "Scope" of the *Aquatic Technical Reference Document* explaining the limitation to food-producing aquatic species, while acknowledging the importance of ornamental fish and other non-food producing aquatic species that will not be included. **Subcategorisation of aquatic species:** The Group also discussed the possibility of using subcategories of fish and crustaceans. Dr Dante Mateo presented the subcategories for fish and crustaceans that will be included in the most recent update of the OIE Template for the AMU data collection: "cyprinids (carps)", "cichlids (tilapia)", "siluriforms (catfishes)", "salmonids (salmon/trout)", "other (freshwater/diadromous) fish", and "marine fish", and "penaeids (marine shrimp/prawns)". The Group agreed to consider use of subcategorisation once more information had been collected on the molecules that may be included in the *Aquatic Technical Reference Document*, noting that use of a molecule in a particular species or subcategory could be indicated in the comments.

The Group suggested adding text to the "Scope" of the *Aquatic Technical Reference Document* to indicate that it is not intended to be an exhaustive list of all food-producing species of fish and crustaceans. Furthermore, as products may be registered for a range of aquatic species, it was proposed that comments in the table of molecules could also be used to indicate where a molecule is of importance for a particular species.

- The criteria for inclusion of antimicrobial molecules on the Aquatic Technical Reference Document

The Group identified several issues of antimicrobial use that may need to be given special consideration when determining the criteria for including an antimicrobial molecule on the *Aquatic Technical Reference Document* – off-label use of antimicrobial agents, use of combination antimicrobial agents, use of compounded antimicrobial agents, and use of antimicrobial agents other than antibacterials.

Authorised antimicrobial agents: The Group was informed that the *Poultry Technical Reference Document* only included antimicrobial molecules which were authorised for use in at least one country. However, it was acknowledged that a different approach may need to be used in the context of aquatic animal species, as there are comparatively fewer veterinary antimicrobials authorised for use in these species, and off-label use of veterinary products may be more common. It was proposed to include these products with the notification "used but not authorised" in the comments section for the molecules in question, and to decide on the basis of all inputs whether these are included.

Combinations of antimicrobial agents: The Group also raised the issue of use of combinations of antimicrobials in aquatic species. It was noted that although the OIE List and the *Poultry Technical Reference Document* contain some instances of combinations of antimicrobials, this is only in rare cases where use of these combinations is well recognised. The Group agreed to have further discussion on how to determine when combinations of antimicrobials can be considered to be "well-recognised" in aquatic animals.

Compounded antimicrobial agents: The Group also discussed the use of compounded antimicrobials in aquatic species and considered whether further input might be needed.

Antimicrobial agents other than antibacterial agents: The Group also considered that these other antimicrobial agents (e.g. antiprotozoal agents) may need to be included on the *Aquatic Technical Reference Document*, as was the case for the *Poultry Technical Reference Document*.

- Inclusion of recommendations on the Aquatic Technical Reference Document

The Group reiterated that the *Aquatic Technical Reference Document* is not intended to function as a treatment guideline, although it may be used as a tool to assist countries in the development of their own national treatment guidelines. Where appropriate, some general recommendations for certain molecules could be included in the comments section (as was done for the *Poultry Technical Reference Document*).

- Data sources for the Aquatic Technical Reference Document

The Group was informed that the data sources used for the *Poultry Technical Reference Document* included consultation with external experts, and information extracted from the OIE AMU Database, and considered that the same approach could be used for the *Aquatic Technical Reference Document* where necessary. External expertise could be helpful to address any specific areas identified by the Group.

The Group discussed the ways of working for the next eighteen months. The Group agreed to start by working on the Excel Spreadsheet template. Dr Gérard Moulin agreed to start providing input to the Excel Spreadsheet template before this is circulated to the rest of the Group for continued input.

The Group agreed to seek information from a variety of sources, including the initial report used to establish the OIE List, marketing authorisations and publicly available databases of authorised veterinary products in different countries, and proposed that Group members should share any potentially useful resources that they are aware of to the OIE, to then be shared with the Group.

It was agreed to use taxonomically validated pathogen names for Annexes 1 and 2 of the *Aquatic Technical Reference Document* when these are completed.

6 External expert group

It was agreed to postpone discussion on consulting external experts until the need for additional expertise has been better identified by the Group.

7 Date of next meeting

The proposed date of the next meeting is September $21^{st} - 22^{nd} 2021$.

8 Any other business

None.

9 Adoption of report (online)

The Group adopted the draft report via online consensus.

.../Appendices

MEETING OF THE OIE AD HOC GROUP ON TECHNICAL REFERENCES FOR AQUATIC ANIMALS

Paris (via Zoom), 4-5 May 2021

Day 1 (May 4)

- 1. Opening
- 2. Short self-introduction by participants
- 3. Adoption of the agenda and appointment of rapporteur
- 4. Brief description of the OIE
 - 4.1. AMR & VP Department
 - 4.2. OIE List of antimicrobial agents of veterinary importance
- 5. Overview of Terms of Reference deliverables
 - 5.1. Technical Reference Document Listing Antimicrobial Agents of Veterinary Importance for Aquatic Animals
 - Representative fish and crustacean species
 - Major pathogens and diseases affecting fish and crustaceans
 - Antimicrobial classes used in veterinary medicine for fish and crustacean infections

Day 2 (May 5)

- 6. External expert group
- 7. Date of next meeting
- 8. Any other business
- 9. Adoption of report (online)

MEETING OF THE OIE AD HOC GROUP ON TECHNICAL REFERENCES FOR AQUATIC ANIMALS Paris (via Zoom), 4-5 May 2021

List of Participants

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OIE AD HOC GROUP ON TECHNICAL REFERENCES FOR AQUATIC ANIMALS TERMS OF REFERENCE

Purpose

The purpose of the OIE *ad hoc* Group on Technical References for Aquatic Animals is to develop a complementary appendix/annex to the OIE List of Antimicrobial Agents of Veterinary Importance based on up-to-date information on the current use of authorised antibiotics for aquatic animals.

Background

The first OIE List of Antimicrobial Agents of Veterinary Importance was adopted by the OIE World Assembly of OIE Delegates in May 2007. The List was further updated and adopted in May 2013, May 2015, May 2018 and May 2019 by the World Assembly. The List was discussed at the 2nd OIE Global Conference on Antimicrobial Resistance and Prudent Use of Antimicrobial Agents. Among the recommendations to the OIE arisen from the participants was to continue the development of the List, including its sub-division in the different animal species.

The task of sub-dividing the List was delegated to the Working Group on Antimicrobial Resistance. It has been recommended that the sub-division of the List by animal species will constitute "Annexes" of the main List. This sub-division is undertaken by Technical Reference *ad hoc* Groups. A first exercise has been recently done for the antimicrobial agents used in poultry including the development of a methodology that could apply to other species. The second group to be addressed are the species under the category of "aquatic animals".

Objectives

The document will provide relevant information, without serving as a treatment guideline, complementing the current OIE List of Antimicrobial Agents of Veterinary Importance. This document is expected to be achieved by further testing of the methodology used to establish the "Technical Reference Document Listing Antimicrobial Agents of Veterinary Importance for Poultry".

By identifying antimicrobial agents used in aquatic animals, it can contribute to the development and update of national treatment guidelines, advice on prevention and best practice management, risk management, and risk prioritisation to minimise and contain AMR.

The document to be produced will be focused on fish and crustaceans, taking into account the information available in the existing the OIE List of Antimicrobial Agents of Veterinary Importance.

It is acknowledged that the situation of antimicrobial agents in aquaculture is very diverse in different regions for licensing, availability, off-label use and the general information provided in the document will need to be interpreted in light of the local context.

Aquatic species-related recommendations stated in the OIE Standards and Guidelines (namely on the OIE List of Antimicrobial Agents of Veterinary Importance) will be considered alongside the document to be produced.

Deliverables

The output is expected to be a table or a chart and annexes that complements the OIE List of Antimicrobial Agents of Veterinary Importance and should include classes of antimicrobials, use patterns and relevant pathogens/diseases in the main species, as follows:

- Main table, an updated version of the OIE List of Antimicrobial Agents of Veterinary Importance, targeting PIS species (fish and crustaceans only)
- Annex 1: List of major pathogens and diseases affecting the main aquatic animal species (fish and crustaceans only)

Annex 2: Antimicrobial classes used to treat aquatic animal infections (based on Annex 1)

The Technical Reference *ad hoc* 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 aquatic animal populations and diseases with respect to the need for different antimicrobial classes;
- production, systems, environments and management practices;
- access to different antimicrobial classes, vaccines and other tools.

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

Prerequisites

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The Group members should:

- Sign the OIE Undertaking on Confidentiality of information;
- Complete the Declaration of Interest Form;
- Understand that the membership of the Group may be retained between its meetings to ensure continuity of the work.

Timelines

18 months to complete the work

Recommended working plan

Electronic meetings with additional physical meetings if necessary and feasible.

Sources of information

- OIE List of Antimicrobial Agents of Veterinary Importance
- Existing treatment guidelines
- Literature search
- Existing marketing authorisations for the species
- Expert advice

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