REPORT OF THE MEETING OF THE OIE WORKING GROUP ON ANTIMICROBIAL RESISTANCE

Online meeting, 7–9 April 2020

1 Opening

The OIE Working Group on Antimicrobial Resistance (AMR) (hereafter referred to as ‘the Group’) met from 7th to 9th April 2020 via an on-line application, 13:00 – 15:00 (Central European Time), each of the three days, coordinated by the OIE Headquarters in Paris, France.

Dr Matthew Stone, OIE Deputy Director General, welcomed the Group members. He discussed the decision to transition the OIE ad hoc group on AMR to a Working Group, and the implications of this change, including reporting directly to the World Assembly of Delegates. He referred to the Terms of Reference (ToRs) for the Group, which form a broad strategic oversight of the OIE’s engagement on AMR, covering both engagement through the Tripartite, as well as activities for which OIE has the lead. He noted that the Group can provide technical advice and oversight to drive forward these activities. He thanked the Group members for their participation in the OIE’s Work Programme through this Group.

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 Global AMR initiatives and issues of interest for the Group

Dr Saija Kalenius, as the OIE Liaison Officer within the Tripartite (WHO/FAO/OIE) AMR Joint Secretariat, provided an update on the follow-up of the United Nations’ Secretary-General’s report A/73/869 and the AMR Multi Partner Trust Fund (MPTF).

The OIE has continued to work with FAO and WHO in line with the recommendations of the OIE General Session Resolution 14/87, contributing to the implementation of the IACG recommendations, and the Multi-partner Trust Fund on AMR.

The Tripartite has submitted the draft ToRs of a Global Leader’s Group for UNSG’s consideration. A multi-sectorial advisory group was created to advise the Tripartite on the establishment of Independent Panel for Evidence and has started its work, being expected to submit its proposal for the ToRs to the Tripartite in May 2020. This Panel aims to independently generate and communicate assessments on the science and evidence related to AMR across the One Health Spectrum.
Regarding the AMR MPTF, its Steering Committee in the meeting of 18th March discussed country draft concept notes. Nine countries were invited to submit full proposals. The concept notes for MPTF global program have been submitted to the Tripartite Joint Secretariat by the Tripartite technical teams. Building on the MPTF conceptual framework, Theory of Change, the Tripartite has also assigned the Tripartite Joint Secretariat with the task of starting to prepare a broader Tripartite AMR Strategic Framework.

During the Group’s discussion on this topic, it was clarified that the Tripartite is also working on a framework for mapping collaboration with different organisations and potential division of labour, which will be a priority for the latter half of the year.

Mr Ben Davies provided an update on the Monitoring and Evaluation (M&E) Framework of the Global Action Plan (GAP) on AMR. The Framework, launched in June 2019, is in the process of being piloted in up to six countries (currently interrupted because of COVID-19) with missions to Tajikistan and Zimbabwe concluded, and Indonesia, Kenya, South Sudan and Peru on hold, although desk review pilot approaches are currently being explored. Detailed indicator methodology notes have been published as an annex to the GAP M&E Framework. A concept has been submitted to the MPTF for finance to ensure that the Tripartite agencies are sufficiently resourced to deliver the GAP M&E mandate. The proposal includes support to strengthen AMR National Action Plans (NAP) M&E capability at country level. The Tripartite AMR country self-assessment survey (TrACCSS), now in its fourth round, has been integrated into the overall GAP M&E Framework. Returns for this fourth round are low compared to last year because of the global response to COVID-19 and the deadline for country returns has been extended to the 31st May, after which the county returns will be analysed and trends reported. Data from the third round of TrACCSS was used to inform the UN Secretary General’s Report on AMR to the United Nations General Assembly (UNGA) in September 2019. The quality of data collected has improved with each year, and in some cases including correction to data from previous years. All responses to TrACCSS since 2016 are available in a global open access data base at https://amrcountryprogress.org/.

Dr Tomoko Ishibashi presented on the Codex Alimentarius Task Force for Antimicrobial Resistance (TFAMR). The objectives of the TFAMR are to develop science-based guidance on the management of foodborne AMR taking full account of the GAP on AMR, in particular objectives 3 (reduce the incidence of infection) and 4 (optimise the use of antimicrobials), standards, guidelines and other work of relevant international organisations, such as FAO, OIE and WHO, and the One-Health approach, to ensure that Members have the necessary guidance to enable coherent management of antimicrobial resistance along the food chain. The ToRs of the TFAMR are to review and revise as appropriate the Code of Practice to Minimise and Contain AMR (currently planned for adoption at Step 5), and to consider the development of Guidance on Integrated Surveillance of AMR (currently planned for Step 2/3 for redrafting).

At TFAMR7, in December 2019, major points included agreement on a definition of medically important antimicrobials (MIA), and on a definition of food production environment. Discussion resulted in further agreement on the principle on the responsible and prudent use of antimicrobials, and also the principles regarding the use of antimicrobials in specific circumstances (preventive use and use for growth promotion), including consideration of whether the focus of these principles should be MIA, or all antimicrobials. Regarding the Guidance on Integrated Surveillance of AMR, there was no time for substantial discussion, but general agreement was achieved, regarding the use of the terms “monitoring and surveillance program” (rather than “monitoring and surveillance system”), “along the food chain” (rather than “throughout the food chain”), and “continuous improvement” (rather than “progressive approach”).

It was clarified that the OIE Working Group does not have an active role in providing input for the TFAMR, and that the OIE is an observer in the TFAMR. However, it was noted that the Terrestrial and Aquatic Animal Health Codes and the OIE List of the Antimicrobial Agents of Veterinary Importance contain important guidance on the responsible and prudent use of antimicrobials and integrated surveillance of AMR in animals.
Dr Elisabeth Erfacher-Vindel presented the group with information on the 3rd International Symposium on Alternatives to Antibiotics (ATA), organised by the USDA with the support of the OIE and participation of industry, which took place from 16th to 18th December 2019 in Bangkok, Thailand. There was a focus on accelerating registration of new technologies, with a variety of ideas presented. The categories of alternatives which were agreed on included vaccines, microbial-derived products, phytochemicals, immune-related products, innovative drugs/chemicals/enzymes, and regulatory pathways to enable licensing of alternatives to antibiotics. All interventions are available at the following link: https://www.ars.usda.gov/alternativestoantibiotics. The STAR-IDAZ International Research Consortium for Animal Health (STAR-IDAZ IRC), for which the OIE is part of the scientific secretariat, was also participating and organised a workshop back to back with this symposium to ensure initiatives are aligned. A questionnaire was sent to all participants to come up with a research agenda for future coordination of research in this field.

4 Other matters for consideration

Dr Dante Mateo presented the OIE’s current work on aquaculture. He has been working on developing a plan for the OIE to enhance its support to Member Countries to control AMR in aquaculture settings. A review of the current status of available OIE standards, guidelines and activities was conducted, and specific actions have been suggested to overcome the challenges identified and to enhance current tools to minimise and contain AMR in aquaculture. The framework has been shared with relevant OIE Departments and the Aquatic Animal Health Standards Commission for input and comments. Following this consultation period, the framework will be further developed into a full workplan, including additional details and a Theory of Change. The final workplan will describe the identified challenges and ways to address them and will propose activities in line with the objectives of the OIE Strategy on Antimicrobial Resistance and the Prudent Use of Antimicrobials and the OIE Aquatic Animal Health Strategy currently under development. A member of the Group noted that while there should be alignment to the greatest extent possible between the Terrestrial and Aquatic Codes, fundamental differences between terrestrial and aquatic species should be taken into account.

5 Any other business

Dr Rebecca Hibbard provided the group with an update on the OIE’s current work on quality of veterinary products. A project proposal for the quality of veterinary products with a monitoring and evaluation framework has been developed. The work is projected to take place in three phases:

   - Phase 1: Development of a global information and alert system for substandard and falsified veterinary products
   - Phase 2: Development of guidance for surveillance of veterinary product quality and exploration of options for laboratory testing (national or regional) of veterinary product quality.
   - Phase 3: Exploration of options for strengthening field-level surveillance of veterinary product quality.

The project is being presented to the Focal Points for Veterinary Products for feedback during the 6th cycle of Training Seminars and will be submitted to the Fleming Fund.

Dr Mária Szabó presented the group with information about the ongoing 6th cycle of seminars for OIE National Focal Points for Veterinary Products. The first seminar was held in Addis Ababa and Debre Zeit, Ethiopia, (9th to 11th July 2019) for English-speaking African countries. The second seminar was held in Lomé, Togo (9th to 11th October 2019) for French-speaking African countries. The most recent seminar was held in Kuala Lumpur, Malaysia (14th to 16th January 2020) for the Asia-Pacific Region. The next seminar for the Middle East (originally scheduled for 31st March to 2nd April 2020 in Abu Dhabi, United Arab Emirates) was postponed due to COVID-19.
The 6th 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 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, and pharmacovigilance.

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

Systems designed to detect substandard or falsified veterinary products also concern products that don’t meet the expected quality, however, these relate to products that could be of legal or illegal origin. In practical terms, at field level, when faced with a veterinary product that does not show the expected effects, it may not always be possible to distinguish between an issue of pharmacovigilance or a problem of quality.

The OIE approach recognises that in low-resource countries, where systems for either pharmacovigilance or veterinary product quality surveillance may not currently exist, there may be limited capacity to set up two separate systems. Consequently, it may be preferable to have one structure dealing with both, pharmacovigilance and veterinary product quality.

There was a question on the apparent OIE approach (from the presentations given to the Group) to include the subject of veterinary product quality seemingly under an overarching definition of pharmacovigilance, as quality and safety surveillance are usually considered to be different topics. It was clarified that the work on pharmacovigilance is indeed a separate project, recognising that it is a joint effort conducted by the National Competent Authority, and the marketing authorisation holders (industry) regarding unwanted or unexpected adverse events associated with registered veterinary products. The OIE is working with HealthforAnimals on a document entitled “How to set up a pharmacovigilance system for veterinary medicinal products” presented to OIE Focal Points for Veterinary Products for their input during the Focal Point Training Seminars.

Dr Szabó also drew the attention to the next VICH (International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products) Outreach Forum meeting that will have a dedicated session on antimicrobials, focusing on two aspects: combination of antimicrobials and environmental risk assessment.

6 OIE List of antimicrobial agents of veterinary importance in animals: refining classification of molecules

The Group discussed the classification of Sulfacetamide on the OIE List of antimicrobial agents of veterinary importance in animals (hereafter “the List”), and advised that it should be added to the Spanish version of the List, correcting this way a previous oversight, as this molecule was included in the English and French versions of the OIE List.

It was acknowledged that there may be further changes to be made to the OIE List in the future, for example, to include considerations of companion animals, and other types of antimicrobial products starting with antiparasitic agents. This will be taken into the Group Work Program, and potentially included in the agenda of a future meeting of the Group.

7 OIE List of antimicrobial agents of veterinary importance in animals: Subdivision of the OIE List into animal species

The Group was provided with an update of the work of the poultry ad hoc Group (Ms Barbara Freischem, Dr Gérard Moulin, Dr Stephen Page, and Professor Moritz van Vuuren), on the development of a species-specific poultry reference document. This will take the form of a chart or table, complementing the current List. The Poultry ad hoc Group has prepared a draft zero of this poultry reference document, an introductory text, an explanation of the methodology used to prepare the reference document, a shortlist of external experts to provide further advice, and a draft invitation letter for these experts.
The Group discussed the draft invitation letter for the proposed experts, and prepared a final version by consensus. It was agreed that the invitation letter needs to specify that the poultry reference document would provide additional information without serving as a treatment guideline. It can contribute to the development and update of national treatment guidelines, advice on prevention and best practice management, risk management, and risk prioritisation. It was proposed that external experts should be given four weeks to contribute their expertise. The poultry ad hoc Group intends to hold an initial videoconference with the experts, once their involvement is confirmed, to clarify the information that is being requested and the intended purpose of the poultry reference document. Once the experts have provided their input, the Group agreed to have an electronic meeting on 26th June 2020 with all Working Group members to discuss the experts’ advice.

The Group indicated their support for the methodology used by the poultry ad hoc Group to prepare the poultry reference document. It was agreed that the proposed experts should be invited to provide additional information for other poultry species, not included in draft zero, where relevant.

Dr Elisabeth Erlacher-Vindel provided considerations relating to subdividing the List for other species, reminding the Group that the development of the poultry reference document could be used as a template for developing equivalent documents for other animal species in the future. Given the development of the OIE’s current work on aquaculture, it was suggested that this might be an appropriate choice for the next species group to be targeted. The Group discussed the possibility that future work on various species groups could be carried out in parallel.

8 OIE Antimicrobial Use (AMU) database: current stage, future development, and Technical Reference Group

Dr Delfy Góchez provided an update on the current stage of the AMU database, and presented the AMU calculations template that has been introduced to OIE Members during dedicated AMU Workshops. The calculation template is an optional document to assist Members in reporting AMU data, and is designed to accompany, not replace, the AMU annual questionnaire. The preliminary results of the fifth round of data collection were presented. As of March 26th, the OIE had received 151 submissions: 148 from OIE Member Countries (out of 182 countries; 81%), two non-OIE Member Countries and one non-Contiguous Territory. Most countries who have responded have provided quantitative data.

The Group observed that a larger range of antimicrobial agents are reported to the AMU database than are currently included on the OIE List, an issue that the Group is considering addressing in a future meeting. The possibility of collecting data on the quality or appropriateness of antimicrobial use was discussed by the Group. However, it was noted that the AMU database as it currently stands is a neutral way to collect information on AMU, and it is based on the related Codes of the OIE and resolutions adopted by the World Assembly, which provide the legal mandate for the AMU data collection. Furthermore, the definition of appropriate AMU may be challenging for a global system, where differences in the diseases present in a given country may mean antimicrobial agent availability and use may vary across different countries.

Mr Mduduzi Magongo updated the group on the IT project for the AMU database. He indicated that the procurement and selection process for the IT supplier to develop the AMU database system has been concluded. Contract negotiations are now ongoing with the identified supplier and the project start date is scheduled for June 2020. The first phase of the AMU interactive system is expected to be ready for use by Member Countries for the 7th round of AMU data collection (2022).

Draft ToRs for the OIE AMU Database Technical Reference Group (TRG) whose creation was proposed at the last Group meeting in October 2019, were presented. The Group discussed the ToRs, making several modifications, presented in Appendix III.

Dr Elisabeth Erlacher-Vindel presented the Group with considerations on AMU data collection at field level, as part of the response to the recommendations of the 2nd OIE Global Conference on AMR and Prudent Use of Antimicrobials. A number of countries have recently asked the OIE for guidance on collecting AMU data at field level for projects at a national level, and for this reason, it is proposed to advance discussion of this topic. The OIE could provide guidance to assist Members regarding the minimum information that needs to be collected at field level in order to calculate AMU data, and to facilitate harmonisation between approaches used by different countries. This could potentially include updating relevant chapters in the Terrestrial Animal Health Code. It was agreed to add this topic to the agenda of the next meeting and the work programme of the Group.
9 **Review of the work programme**

The work programme was reviewed by the Group and updated. It is available in Appendix IV.

10 **Date of next meeting**

The proposed date of the next meeting is 26th June 2020, by remote connection. The proposed date of the next face-to-face meeting, to be confirmed upon evolution of the COVID-19 pandemic, is 13th to 15th October 2020 in Paris.

11 **Adoption of report (online)**

The Group adopted the draft report via online consensus.

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…/Appendices
MEETING OF THE OIE WORKING GROUP ON ANTIMICROBIAL RESISTANCE

Zoom online meeting, 7–9 April 2020, 13:00 – 15:00 (CET)

Provisional Agenda

Day 1 (April 7)

1. Opening

2. Adoption of the agenda and appointment of rapporteur

3. Global AMR initiatives and issues of interest for the group
   - Update on Tripartite global initiatives

4. Other matters for consideration

5. Any other business

Day 2 (April 8)

6. OIE List of antimicrobial agents of veterinary importance in animals: refining classification of molecules

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

Day 3 (April 9)

8. OIE Antimicrobial Use (AMU) database: current stage, future development and Technical Reference Group

9. Review of the work programme

10. Date of next meeting

11. Adoption of report
Appendix II

MEETING OF THE OIE WORKING GROUP ON ANTIMICROBIAL RESISTANCE
Paris (via Zoom), 7-9 April 2020

List of Participants

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TERMS OF REFERENCE

Purpose

To supplement direct feedback received at country level, the purpose of the OIE Antimicrobial Use (AMU) database Technical Reference Group (TRG) is to:

Support the OIE Antimicrobial Resistance and Veterinary Products (AMR & VP) and Digital Transformation and Information Systems Departments in the development of an Antimicrobial Use database, by:

a) Contributing to an efficient transition from the collection of AMU data via an Excel template into a database system, providing advice, inputs and sharing previous related experiences

b) Considering the above-mentioned transition to suggest refinements of the preparation of the “OIE Annual report on antimicrobial agents intended for use in animals”

c) Sharing experience on collection of AMU data on species and field levels

Background

Following Resolution No. 26: Combating Antimicrobial Resistance and Promoting the Prudent Use of Antimicrobial Agents in Animals, adopted by the OIE World Assembly during the 83rd General Session in May 2015, the OIE launched an annual collection of data on antimicrobial agents intended for use in animals. This OIE activity is also in line with the Global Action Plan on AMR, and with the OIE Strategy on Antimicrobial Resistance and the Prudent Use of Antimicrobials. Since the first launch of the OIE AMU Data Collection, the OIE has produced three annual reports on antimicrobial agents intended for use in animals which were published in December 2016, 2017 and February 2019, respectively.

The development of an AMU database project was started as a way to alleviate the time-consuming workload of both OIE Members and the OIE AMU team. Currently, an OIE staff member reviews the Excel Spreadsheet data submitted by each Member to check for errors, and then manually enters the data into a separate Excel spreadsheet for data analysis purposes. The OIE staff then conducts basic analysis to review the data entered by the country to check for errors. If errors occur, the OIE staff will communicate with the country to better understand the issues and try to correct them. The work done through an Excel spreadsheet poses risks (e.g. transcription errors) and does not allow the possibility to fully explore the data, especially by the OIE Members who could gain more from deeper insights into their own data.

Therefore, a need has risen for the automation of the AMU Data Collection and analysis process in order to alleviate the time-consuming workload and to ensure data collected is complete and correct. The goal is to make the OIE AMU database a software tool that is suitable for all OIE Members to submit their data and encourage them to use it to inform their national actions plans on AMU.

Specific issues to be addressed

The transition from an AMU data collection system based on an Excel template into a database system has multiple challenges along with risks and potential benefits (ex. data entry mistakes or visualization/usability of the database). It is therefore important to learn from other countries and organisations that already have experience with a database format, to identify such challenges, risks and benefits, and how to address them.
Actions

- Provide suggestions, requests and recommendations regarding the transition from the collection of AMU data via an Excel template, into a database system
- Participate in reviewing and testing the new database to be developed
- Provide expertise on the future AMU database such as interoperability with other databases and ensuring data protection
- Provide feedback on the database for future different development phases
- Report back to the OIE AMR Working Group

Consideration

Members of the OIE AMU database Technical Reference Group, are expected to consider the:

- OIE AMU data collection procedures
- Structure of the related OIE Codes and Manuals chapters, and the use of OIE Glossary definitions
- Resolutions, recommendations and other published reports relevant to the database project

Expectations

AMU database Technical Reference Group members should:

- Sign off the OIE Undertaking on Confidentiality of information (if not done already)
- Complete the declaration of Interest Form
- Read and study in detail all dossiers provided by the OIE prior to a meeting
- Agree on the appointment of the chair and rapporteur of each meeting
- Contribute to discussions

Deliverables

Suggestions and advice that should facilitate the transition from an AMU data collection based on an Excel template into a database system, and future development of the AMU data collection making the process as suitable as possible and ensuring an efficient content management.

Reporting / timeline

The OIE secretariat will draft a short report of each meeting, to be validated by the AMU database Technical Reference Group within 3 week(s) after the completion of that meeting to be submitted to the OIE AMR Working Group, for information and discussion as appropriate.

Membership

The selected panel represents a substantial level of experience, knowledge and international expertise in the development of AMU databases.

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<tbody>
<tr>
<td>Members:</td>
<td>Arno Muller (WHO)</td>
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<td>Carolee Carson (Canada)</td>
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<td>Donald Prater (USA)</td>
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<td>Gérard Moulin (France)</td>
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<td>Kristine Ignate (EMA)</td>
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<td>Mari Matsuda (Japan)</td>
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<td>Reporting:</td>
<td>OIE secretariat</td>
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<td>Invited participants:</td>
<td>Invited as required based on specific items</td>
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### Updated Work Programme for the OIE Working Group on Antimicrobial Resistance

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<thead>
<tr>
<th>Subject</th>
<th>Issue/Action</th>
<th>Status</th>
<th>Timeline</th>
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<tr>
<td>OIE List of Antimicrobial Agents of Veterinary Importance, subdivision by species</td>
<td>- poultry subdivision pilot exercise</td>
<td>In progress</td>
<td>12-18 months (from October 2019)</td>
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<td>- evaluation of the methodology</td>
<td>Future</td>
<td>April 2020</td>
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<td>- consideration of other species</td>
<td>Future work</td>
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<td>- addition of companion animals</td>
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<td>OIE Global AMU database</td>
<td>- transition of data collection from spreadsheet to database system, expert advice</td>
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<td>- refinement of the numerator, denominator (biomass), and reporting</td>
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<td>Field level data</td>
<td>- reflection on obtaining field level data</td>
<td>Ongoing</td>
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<td>Terrestrial and Aquatic OIE Codes chapters related to AMR</td>
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<td>Alternatives to Antimicrobials (ATA)</td>
<td>- information on categorisation of products</td>
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<td>April 2020</td>
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<td>- review of existing information in the OIE Manual for related issues</td>
<td>Future work</td>
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<td>Substandard and falsified products</td>
<td>- to be informed of existing and ongoing work by OIE directly or indirectly linked (including PVS) and by other international bodies</td>
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<td>April 2020</td>
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