Session 1 - 31 March 2020 : The OIE AMU Questionnaire + Calculation of Kilograms of Active Ingredients

1. If a product, e.g. ciprofloxacin, is indicated for use in many species but we don't have provision to collect data from the farm etc, what should we indicate on the submission? Can you please clarify?
   All antimicrobial quantities for several animal species (with no possible distinction between *terrestrial food-producing animals*, *aquatic food-producing animals* and *companion animals*), should be declared in the grey column of the Reporting Options (called "all animal species").

2. Is it possible that we can learn from other countries about techniques for collecting data? For example, how to collect data on the animal species and administration using an online database.
   Yes, at OIE we encourage networking and capacity building. During the AMU Workshop (the face-to-face meeting) we will have interventions from countries sharing their experiences on monitoring antimicrobial quantities.

3. There are times when animal owners and paraprofessionals use antimicrobials but don't report it to the authorities. This may give false information. In my view this is a global issue.
   Obtaining data from animal owners/farmers and paraprofessionals is not easy and it requires collaboration and communication between the Veterinary Services and relevant stakeholders in order to obtain good datasets. Ideally, the source of information should be as close to the point of use as possible; however, at a global level very few countries can provide data at a farm level. Countries that have been monitoring their sales of antimicrobials in animals for more than a decade are now analysing their possibilities to estimate or obtain data from farm-level. In any case, experience has shown that whenever possible, sales data at the package level should be collected, keeping in mind that the data will be measured in kg of antimicrobial agent. Therefore, we would suggest to countries to start by refining their sales, imports or prescription data at a first step, making sure that there are no errors in these datasets and as a second step to explore the possibilities to obtain data at a farm-level by starting depending on farm structures with specific species.

4. Previously OIE headquarters shared the new AMU tool with certain countries, but it's only possible to summarize using Reporting Option 1. Is there a newer version that enables the data to be summarized in Reporting Option 3?
   Yes, the new version of the Excel tool for the calculations allows that the data can be reported through Reporting Option 2 and 3; and also display some basic graphs that could help countries to analyse their data. If you were using the old version of the Excel tool, you will not feel that there are big difference between the tools, because in the past we had already included those fields/cells that were capturing the necessary

data to allow countries to pass to Option 2 (animal species) and Option 3 (routes of administration). We would suggest you copy and paste your datasets in the new version and see if you are able to progress to a higher Reporting Option.

5. Aside from monitoring selective pressure from antimicrobial use to microbes, what are the OIE's short, intermediate, and long-term goals for collecting antimicrobial use in terms of policy perspective? How can the goals answer policy needs at national, regional, and global levels to make policy more coherent?
   Precise AMU data will allow following trends and checking if policy measures or rules have been successfully implemented. They will also show any potential shift from one antimicrobial class to another in case of requested restrictions on the use of specific antimicrobials classes, such as recommended in the OIE List of Veterinary Important Antimicrobial agents for animals . Also, now the OIE has a new Critical Competency (CC) in its Performance of Veterinary Services (PVS), *CCII-9 antimicrobial resistance (AMR) and antimicrobial use (AMU),* this could allow a more specific understanding on AMR and AMU surveillance, One Health governance of AMR, AMR specific drug regulation and veterinary contribution to the National Action Plans on AMR.

6. In order to calculate the active ingredient in base form, which is the active form of antimicrobials, some may be registered with conversion factors different to the OIE list. Do we need to calculate the amount of total antimicrobial in the final product and use the OIE's conversion factors?
   It is difficult to give a precise answer to this question without having a full picture of the case you quoted. If you can give us some examples on how the calculation is performed at your level, we may come back to you with precise answers.
   It would be useful to precisely identify the substance, the national unit used, the national conversion factor, and the calculation made at the national level.
   In any case, for pragmatic reasons the OIE accepts the reporting of antimicrobial agents in amounts of chemical compound as declared on the product label of the veterinary medicinal product.

7. What should we do about some antimicrobials registered without any conversion factors available? Or should we can calculate them using the traditional way based on molecular weight?
   In case you are not able to find specific conversion factors, please contact the Antimicrobial Use Team *(antimicrobialuse@oie.int).*

8. Is it possible to include a minus function in the Excel sheet? Our country calculates the data by using the numbers from import minus export, then minus the stock (i.e. import – export – stock = AMU).
   Yes, negative numbers can be declared in the Excel tool that assists with the calculations. This can allow entry of data from different sources (e.g. exports and imports). If different data sources are reported, we would just remind you to be attentive to avoid overlaps or duplications of the data.

9. For Reporting option 2, do we have to use OIE system of animal grouping? In our country we have Classification of antimicrobials to be used for different animal groups. But our grouping of animals is not as per the requirement of reporting option 2. We have classification of antimicrobials for small animals, small animals and large animals, large animals, poultry and aquatic animals.
   If you already have a classification of animals in your country, you do not need to change this; however, when reporting to OIE, you might need to regroup some of these animals in order to match them with the OIE categories. For example, poultry, large animals and small ruminants will need to be regrouped in order to use Reporting Option 2 or 3. However, for the future of the OIE AMU Data Collection, we are considering obtaining more detailed data (by individual animal species).

10. How do we make the calculation if more than one class of antibiotic is included? Can you give us an example to better understand?
    If you are using the OIE Excel tool, you will only declare the different molecules for the product. If you are using a different system or doing manual calculations, you will need to do the calculations for each of the different molecules of the product as follows:

Product Name: Happy pet
Package size: 100 ml
Active ingredients: Oxytetracycline and Colistin Sulfate
Concentration (Strength): Oxytetracycline 200 mg / 1 ml; Colistin sulfate 2 000 000 UI/ml
Units imported: 1,150 units of 100 ml

Calculations for Oxytetracycline

Step 1: Calculation of the content of antimicrobial agent per package

$$= \frac{Active\ substance\ concentration\ x\ Package\ size}{Concentration\ conten}$$

$$= \frac{200\ mg\ x\ 100\ ml}{1\ ml}$$ = **20 000 mg** of Oxytetracycline in one bottle of 100 ml

Step 2: Multiply the result from Step 1 by the units imported during the year

=20 000 mg x 1 150 units
= **23 000 000 mg** of Oxytetracycline in 1 150 bottles of 100 ml

Step 3: Convert to kg

$$= \frac{23\ 000\ 000\ mg}{1\ 000\ 000}$$ = **23 Kg** to be reported under the **Tetracyclines** class

Calculations for Colistin Sulfate

Step 1: Calculation of the content of antimicrobial agent per package

$$= \frac{Active\ substance\ concentration\ x\ Package\ size}{Concentration\ conten}$$

$$= \frac{2\ 000\ 000\ UI\ x\ 100\ ml}{1\ ml}$$ = **200 000 000 IU** of Colistin sulfate in one bottle of 100 ml

Step 2: Multiply the result from Step 1 by the units imported during the year

=200 000 000 IU x 1 150 units
= **230 000 000 000 IU** of Colistin sulfate in 1 150 bottles of 100 ml

Step 3: Using the conversion factor for IU to mg
=230 000 000 000 IU x 0.000049 (Conversion factor for IU of Colistin Sulfate)
= 11 270 000 mg

Step 4: Convert to kg

$$= \frac{11\ 270\ 000\ mg}{1\ 000\ 000}$$ = **11.27 Kg** to be reported under the **Polypeptides** class

11. When should the conversion factor be used & when is it not needed?
    Conversion factors are needed in the following cases:
    - When the molecules are declared in **International Units (IU).** For example, Colistin sulfate 2 000 000 IU/ml; in this case we would like to convert IU to mg, the conversion factor for Colistin sulfate is 0.00049.
    - When the molecules are **long-acting salts**. For example, benethamine benzylpenicillin, in this case we would like to obtain the kg of active ingredient of benzylpenicillin only, then we use the conversion factor of 0.65.
    - When the molecules are **prodrugs**. For example, penethamate hydroiodide, in this case the conversion factor for penethamate is 0.63.

    The different conversion factors are listed in table 2 and 3 of the Annex for the calculations.

12. Thank you to the OIE for developing the new tool for collecting AMU data. It is user-friendly and we get good cooperation from pharmaceutical companies to complete.
    We have experienced that some countries, after the AMU Workshops, have conducted trainings for the pharmaceutical industry so they are able to use this tool and report to the Veterinary Services. When doing this, we just remind you that you will need to validate their data (sometimes there might be human errors when entering the concentrations of the molecules, for example 40 g/ml instead of 40mg/ml); and also you will have several Excel files that you will need to consolidate into one file. When doing this exercise, we would like to highlight that you will require more time and

effort to collect all the necessary data related to the veterinary products only during the first year; however, **for future rounds of data collection, you do not need to collect all the information again** (routes of administration, animal species, molecules and their concentrations), **but only update the column related to the number of times that product and its package size has been imported, sold or prescribed in your country**.

13. New tool seems user-friendly.
    Many thanks and if possible, we and we would appreciate to receive your feedback to improve our tools.

14. Due to the sheer size of file with a lot of complex Excel functions, I am looking forward to using the online database system, which is promising and practical for users.
    For the future of the OIE Data Collection, we would like to use the logical of this Excel and the experiences from countries to develop something that is suitable and user-friendly for them. Therefore, we would like to encourage countries to test this tool and to provide feedback to OIE as this will allow us to deliver a better tool in the future. We remind you that the Excel functions are restricted to the Antimicrobial Use Team and countries are not asked to modified them; the aim of these formulas are the heart and mind of the tool to enable calculations of kg of active ingredients for the countries and then to report them using the OIE Reporting Options.

Session 2 - 01 April 2020 : The OIE Animal Biomass Denominator

1. Please confirm regarding animal weight at slaughter - whole dead animal or "dressed" weight (with head/feet/hide/internal organs removed)? Can we use animals' live weight at farm prior to slaughter process for biomass calculation?
   The OIE Animal Biomass Methodology is based on live weight. The live weight of the animal before slaughter was seen as globally the most easily accessible and representative of average weights for calculation of animal biomass. Also, these live weights could be extrapolated from production/slaughter data using species-specific carcass conversion coefficients[1].

2. Are regional standard weights valid for a region as diverse as ours?
   Countries were grouped by sub-region as defined by livestock unit classifications[2]. A sub-regional mean live weight was then determined by calculating the average live weight of a species for countries within the sub-regional grouping from their production data. In future we will try to further refine the data using information that will be provided to WAHIS.

3. In our country, we have different subtypes of poultry (such as breeders, layers, and pullet) from those described in OIE methodology, should we include them?
   The current WAHIS annual report of live animal populations already includes detailed sub-categories for poultry (broilers, layers, turkeys, other birds, backyard poultry); we encourage our Members to report these animal population reports with the best accuracy possible.

4. How do we account for animals not slaughtered? For example, a country that exports a large number of animals live or has a large standing herd of cattle.
   For animals living for more than 1 year, it was considered that census data (number of animals present at one time) can be a good basis to evaluate the number of animals present in the country during the year, rather than using slaughter data.
   Imported and exported animals are commonly subtracted and added, respectively, from animal populations when calculating animal biomass, so that only animals raised in the country, the time during which they would have been potentially treated with antimicrobials, are considered. In the latest 4th report, this was currently included only for bovine species due to limited reliability of the global datasets.

5. Will the production statistics and AMU data have matching years?
   Yes, the overall objective of the methodology is to obtain the biomass of animals present during the year of analysis in a specific country using internationally available data for that given year.

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[1] Góchez D., Raicek M., Pinto Ferreira J., Jeannin M., Moulin G. & Erlacher-Vindel E. (2019). – OIE Annual Report on Antimicrobial Agents Intended for Use in Animals: Methods Used. Front. Vet. Sci., 6. doi:10.3389/fvets.2019.00317

[2] FAO. Food and Agriculture Organization of the United Nations. Guidelines for the Preparation of Livestock Sector Reviews. (2011). Available online at: http://www.fao.org/3/i2294e/i2294e00.pdf

6. Can we see the grouping of countries?
   Countries were grouped by sub-region as defined by livestock unit classifications[1]. Country specificities will be addressed during the planned future workshop dedicated to the database on antimicrobial agents intended for use in animals for the Asia, Far East and Oceania region.

7. What is the “cycle factor”?
   For animals of production groups which are slaughtered and repopulated a certain number of times within 1 year a multiplication factor may be used, this is referred to as the “cycle factor”.

8. Which National Focal Point provides current population data to the OIE on WAHIS?
   The animal population data is reported to WAHIS through the annual reports provided by National Authorities. This is country dependent, but experience has shown that often the National Focal Point for Notifications has access to the WAHIS reporting.

9. Does animal biomass includes aquatic farm animals?
   In the current calculation we consider farmed fish for aquaculture, but again this will evolve with the new OIE-WAHIS where we will have sub-categories for molluscs and crustaceans. The integration of aquaculture also relies on countries reporting aquaculture data to the WAHIS annual report.

Session 3 - 02 April 2020 : The Future Software of the OIE AMU Database

1. In case I want to cite data from OIE AMU database for publication, do I need a permission from the data owner or the OIE?
   In order to comply with data protection regulations, in the future AMU system we are considering that countries must specify the confidentially of their data (once validated by the country and the AMU Team) as follows:
   - All data only available for the OIE AMU Team;
   - All data available for the OIE AMU Team and certain data available for partners and donors; or
   - All data available for the AMU Team and certain data made publicly available.

2. Will the OIE be collecting information on route of administration?
   The OIE is currently collecting information on routes of administration through Reporting Option 3. The future OIE AMU IT System will also allow you to report this information during Phase 1 of the IT project. As a reminder, the OIE routes of administration are: “oral”, “injection” and “others”.

3. Can you analyse production data associated to AMU?
   If the question refers to antimicrobial production (manufacture of veterinary products): currently, there are countries collecting and reporting these types of data. In the future AMU IT System, this data source will also be reported and analysed. When reporting veterinary products that have been manufactured in your country, you will need to declare if they have been used only in your country or if part of the production has been allocated for exports.
   If the question refers to animal production: Yes, this will be possible via the Business Intelligence tool which will be integrated in the AMU System. In Phase 1, production data will be manually imported from the existing public data sets (WAHIS and FAOSTATS). However, in phase 2, AMU will be linked to OIE-WAHIS and this process will be automated.

4. How can we get the AMU data collected & analysed by the OIE to advocate for control [of AMU]?
   Before the release of the future AMU IT System, the Delegate of your country can contact the Antimicrobial Use Team (*antimicrobialuse@oie.int*) and request all historical data that have been reported to OIE. The AMU Team will share the reports and available graphs. During the current round of data collection, we are actively sharing graphs with the Focal Points for Veterinary Products and the Delegates. In the future AMU IT System, the country will have access (at any time) to all their data that have been reported to OIE.

5. Who is the data in the online system collected from? Farmers, veterinarians, feed mills, sales, purchase, importers and exporters?
   The AMU system will be capable of collecting data from various sources; however, these data must be validated by the OIE Delegate or OIE Focal Point. Data sources vary

between countries, and it depends on the data that are available to the Veterinary Services.

6. Can some countries share their experiences on how to get sales data from markets?
   Yes, at OIE we encourage networking and capacity building. During the AMU Workshop (the face-to-face meeting) we will have interventions from countries sharing their experiences on monitoring antimicrobial quantities.

7. What is the data validation process? Is it done by Member countries or the OIE?
   The AMU system will automate most of the standard validation processes. However, the AMU Team will still retain some validation process of the data. During this second process the AMU Team will (as is currently done) contact the country and clarify specific country situations and datasets; in this process the country will need to validate the reported data and exchanges with the AMU Team.

8. Who has administrator rights within the country? How many can the system support?
   The system will be able to synchronize for the OIE Delegates of each country and OIE Focal Points for Veterinary Products (or equivalent as agreed by the Delegate). The system will support different roles for authenticated users (such as administrators and contributors). Depending on the role, User Interface (UI) items will be hidden or disabled. The exact roles will be clarified and agreed in the conception stage of the project; however, the AMU Team will have overall administrator rights.

9. Morgan's explanation sounds like Microsoft Power BI using AI (Azure). Is this the case?
   Yes, we are indeed considering Microsoft Power BI using AI (Azure) as the underlying technology for the AMU System.

10. Is there a history log to monitor data changes made by system users in the country?
    Yes, a full audit trail will be available to track all changes related to the whole AMU system.

11. Are there any longer-term plans to develop some kind of bench-marking system that attempts to define what constitutes reasonable anti-microbial use for a given production system?
    The AMU database will replace over time the excel file system to collect data (even if Excel files will still be accepted), but all other purposes linked to standards and guidelines will be followed in the usual way of standard setting or establishment of recommendations.

12. Will we see a difference between data submitted using the Excel sheet and that directly typed into the future online database?
    There will be no difference between the submitted data. Those countries using the Excel sheet will have the same data analysis and access to graphs and historical data.

13. The lists of antimicrobials from OIE and WHO classifications are different. E.g. colistin, which can be both polypeptides in OIE and polymyxins in WHO. Would it be better if you provided us an Excel file for mapping by ATC vet code? It would be much easier and more convenient when we need to report to many organizations.
    In the future for data at a farm-level, we might consider the indications of the different products.
    ATCvet codes are not used in the current OIE AMU Data collection as many countries are not able to declare the purpose/indication for the use of the molecules. For example, you might have the following different ATCvet codes for Colistin:
    QA07AA10: ANTIDIARRHEALS, INTESTINAL ANTI-INFLAMMATORY/ANTIINFECTIVE AGENTS
    QJ01XB01: ANTIBACTERIALS FOR SYSTEMIC USE
    QJ51XB01: OTHER ANTIBACTERIALS FOR INTRAMAMMARY USE
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