

GUIDANCE FOR COMPLETING THE QUESTIONNAIRE TEMPLATE FOR THE COLLECTION OF DATA ON ANTIMICROBIAL AGENTS INTENDED FOR USE IN ANIMALS



ANIMUSE – 9TH Round



**World Organisation
for Animal Health**
Founded as OIE

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Introduction



WOAH proposes to collect data on [antimicrobial agents](#) intended for use in animals from WOAHH Members implementing Chapter 6.9, 'Monitoring of the quantities and usage patterns of antimicrobial agents used in food-producing animals' of the Terrestrial Animal Health Code and Chapter 6.3 'Monitoring of the quantities and usage patterns of antimicrobial agents used in aquatic animals' of the Aquatic Animal Health Code, and to contribute to the global effort against antimicrobial resistance.

WOAH Members differ in the degree to which they collect, collate and publish data on antimicrobial sales or use in animals and also in the degree to which they can stratify the quantities of antimicrobial agents intended for use in animals or for use in different animal species.

Through this initiative, by means of a specific template (hereafter 'WOAH template'), WOAHH seeks to collect data on antimicrobial agent intended for use in animals from all WOAHH Members in a harmonised way. Using a phased approach, WOAHH will initially focus on sales¹ of antimicrobial agents intended for use in animals as an indicator of actual use. All antimicrobial agents intended for use in animals and listed in WOAHH List of antimicrobial agents of veterinary importance², plus certain antimicrobial agents only used for [growth promotion](#) should be reported. The exceptions are ionophores, which are mostly used for parasite control and therefore need not be reported as antimicrobial agents. WOAHH places highest priority on food-producing animals; however, data on all animals, *including non-food-producing animals*, may be reported. Reporting will occur at antimicrobial class level and, on one occasion, at sub-class level.

For the purpose of reporting data on antimicrobial quantities (amounts sold or imported for use in animals expressed in kilograms (kg) of antimicrobial agent, i.e., [chemical compound](#) as declared on the product label, that is to be calculated from the available information as explained in the Annex to this Guidance document), animals are grouped into 'all animal species', 'non-food-producing animals', 'all food-producing animals', 'terrestrial food-producing animals', and 'aquatic food-producing animals'.

Further refinement of WOAHH collection of data on antimicrobial agent sales or use in animals is anticipated in light of the experience gained with the utilisation of WOAHH template and additional changes might be necessary as countries capabilities of reporting stratified data develop.

Please contact antimicrobialuse@woah.org for any question on WOAHH template.



Required Information and Choices for Reporting

As noted before, WOAHH Members differ in the degree to which data on antimicrobial sales for use in animals is accessible and in the degree to which the quantities of antimicrobial agents used in animals can be further differentiated, for example, by species. Therefore, three different Reporting Options are proposed, using different individual sheets of WOAHH template: 'Baseline Information', 'Reporting Option 1', 'Reporting Option 2', and 'Reporting Option 3'.

¹ 'Sales', in the context of WOAHH data collection on antimicrobial agents used in animals, should be interpreted to include data on import of antimicrobial agents for use in animals.

² <https://www.woah.org/app/uploads/2021/06/a-oie-list-antimicrobials-june2021.pdf>

Baseline Information

This sheet collects administrative information relevant to the data collected with this template. It should be completed by all WOAAH Members.

Based on the answers provided by the countries, the table at the bottom of the sheet is provided to help countries to decide which Reporting Option is the most adapted to their data available.

On this sheet, some fields are formatted in *italics* and grey; these fields are optional, but countries are encouraged to provide information to the greatest extent possible. Subsequently, and in accordance with the level of detail of data on antimicrobial agents used in animals available in the reporting country, either the sheet labelled Reporting Option 1, 2 or 3 should be completed – only one of the three Reporting Options should be selected.



The **Baseline Information (Part A and B)** sheet allows participation of **all countries**: and should be completed by all.

| Part A - Contact Information | |
|-----------------------------------|---|
| Title | Salutation (e.g., Dr, Ms, Mr). |
| Name | First or given name, SURNAME or FAMILYNAME. |
| Role with respect to WOAAH | Please choose either 'WOAH Delegate', 'WOAH National Focal Point for Veterinary Products' or 'Other National Authority' to describe your relation to WOAAH. |
| Organisation | Name of the organisation for which you work, administrative subunit, and position. |
| Organisation's Address | Full mailing address of your organisation . |
| Country | Country name. |
| Phone Number | Please provide the telephone number in the format '(country code) phone number'. |
| Email Address | Email address where you can best be reached. |

| Part B - General Information | |
|---|--|
| Questions 1 to 4 are related to the current situation in your country. Responses should not be linked to the year of antimicrobial quantities reported. | |
| 1 | Are data on the amount of antimicrobial agents intended for use in animals available? |
| | Please indicate whether quantitative data (i.e., data on the amount) on antimicrobial agents intended for use in animals are available, by choosing 'Yes' or 'No'. If quantitative data are available for part of your country, choose 'Yes'. |
| 1.1 | <i>Please indicate why the data are not available at this time in your country, if the answer to Question 1 is 'No'</i> |
| | Please indicate the reason why the data are not available in this moment in your country. If the answer to the previous question is 'No'. |
| 2 | Are antimicrobial agents used for growth promotion purposes in animals in your country? |
| | Please indicate if antimicrobial agents as growth promoters are being used in your country, by choosing 'Yes', 'No' or 'Unknown'. |
| 3 | Does your country have legislation/regulations on antimicrobial agents as growth promoters in animals? |
| | Please respond by ticking either 'Legislation/regulation exists - Yes' or 'Legislation/regulation does not exist - No'. |
| 4 | If your country has legislation/regulation on antimicrobial agents as growth promoters in animals, could you please indicate the appropriate case that applies in your country? |
| | Please respond by ticking either 'All antimicrobial agents banned for use as growth promoters', 'Some antimicrobial agents banned for use as growth promoters' or 'One or more antimicrobial growth promoters are authorised'. |
| 4.1 | <i>Please provide a list of antimicrobial agents used or authorised as growth promoters, if any</i> |
| | If any antimicrobial growth promoters are authorised for use in animals, please list the antimicrobial agents (active ingredient name, not product name) authorised for use as growth promoters in animals. |



Part C is reserved to the countries where **data are available**



| Part C - Data information | | |
|---------------------------|--|--|
| 5 | Year for which data apply (Please select only one year per template) | Please provide data for 2022 . If you have data for 2023, please select the year from the list. We do not accept data from other years. If you would like to provide data for the two years, please fill out one template per year of data. If you have found calculation errors in data already submitted to WOAHP for previous years, we ask that you please update your historical data in ANIMUSE . |
| 5.1 | Time period for which data are provided (e.g., 1 January to 31 December 2022) | Please provide further information regarding the reporting year, especially if the data only covers a portion of the calendar year. Follow the format of DD/MM/YYYY. |
| 6 | Data source | <p>Please describe the origin of the antimicrobial quantities intended for use in animals, the preferred data at this stage. The template provides options for data sources, and you are asked to report all data sources that apply. Chapter 6.9 of the Terrestrial Code and Chapter 6.3 of the Aquatic Code provide more detail on potential sources of such information. Possible data sources include:</p> <ul style="list-style-type: none"> • Sales data - complete data on antimicrobials agents sold to / bought from wholesalers. • Purchase data - data based on sampling of a limited number of wholesalers and requiring extrapolation to estimate the full amount of antimicrobials purchased, but should be used with care. • Import data - complete import data from customs. • Veterinary data - complete or representative sample information obtained from veterinarians; if representative sample information is obtained extrapolation to the estimated full use may be possible. • Antimicrobial use data - complete or representative sample information obtained from farm records; if representative sample information is obtained extrapolation to the estimated full use may be possible. • Other data - all other ways of delivering antimicrobial agents to the animals, including distribution through state veterinary services. <p>It is suggested to develop an overview of the drug distribution system in your country. Mapping out the distribution pathways in your country will help you identify the most appropriate source of information on antimicrobial agents for use in animals. Great care is necessary to avoid duplicate or multiple reporting of quantities; mapping out the distribution will also help you devise measures aimed at avoiding multiple reporting. <u>Ideally, the source of information should be as close to the point of use as possible.</u> 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 (please refer to the annex of this document for details on the necessary conversions). Good communication between all parties involved in the data collection is critical to obtain good data sets.</p> |
| 6.1 | <i>Clarification of the data source, if your response to Question 6 is 'Other'</i> | If under Data source the option 'Other' is selected, please explain here which source of information was used. |



| | |
|---|---|
| 7 Estimated coverage of accessible data on total amount (in %) | Please provide an estimate of the extent to which the quantitative data you report are representative of the overall antimicrobial agents intended for use in animals. |
| 7.1 <i>Explanation of estimated coverage</i> | <p>Please explain in this field which data were not captured on the antimicrobial agents used in animals reported for your country in WOA template.</p> <p>Data coverage may vary by geographical aspects; examples include but are not limited to situations that use may be well known for urban but not rural areas, or that use in certain representative regions is well known but not actually measured throughout the whole country. Incomplete data coverage may include situations where importation is not covered, or partial statistical sampling of relevant establishments (farms, veterinary practices, etc.) is carried out. Another source of incomplete data may lie in market segment coverage, where incomplete data is available from certain market segments (e.g., some production systems are not covered, such as extensive versus intensive farming systems or certain wholesalers who do not report their data).</p> |
| 8 Is the information extrapolated from representative samples? | Please indicate whether the data provided in your report have been extrapolated from representative samples. |
| 8.1 <i>Explanation of extrapolations carried out, if your response to Question 8 is 'Yes'</i> | Please explain in this field the nature of any extrapolations that were carried out in order to provide the data recorded in WOA template. |
| 9 Can data be differentiated by animal group? | <p>Please respond by ticking 'Yes' or 'No'.</p> <p>For the purposes of the database, animal group means: 'Terrestrial food-producing animals', 'Aquatic food-producing animals' or 'Non-food-producing animals'. If your data is differentiated by any of these groups, please select 'Yes'.</p> |
| 10 <u>Animal groups covered by the data</u> | <p>Please indicate here which animal groups are covered by the data provided, by selecting the appropriate category or categories from the list. The choices are: 'Data with no differentiation (all animals combined)', 'Data with no differentiation between terrestrial and aquatic animals excluding non-food-producing animals', 'Data for terrestrial food-producing animals and non-food-producing animals (combined)', 'Data for terrestrial food-producing species', 'Aquatic food-producing animals', 'Data for aquatic food-producing animals' and 'Data for non-food-producing animals'. Multiple selections are possible.</p> |



| | |
|---|--|
| <p>11 Food-producing animal species covered by the information on antimicrobial quantities</p> | <p>Animal species considered to be food-producing animals vary between countries. WOAAH needs to gain an understanding of how this difference impacts the antimicrobial quantities reported to WOAAH and future reporting of summary quantities by WOAAH. Please indicate which animals are considered to be food-producing animals covered by the quantities. Multiple selections are possible.</p> |
| <p>11.1 <i>Clarification of other species considered to be food-producing, if your response to Question 11 is 'Other commercial poultry' or 'Other'</i></p> | <p>Please provide any explanations you may feel necessary to explain which animal species covered by the data are raised for the purpose of providing food for humans.</p> |
| <p>11.2 Non-food-producing animal species covered by the information on antimicrobial quantities</p> | <p>WOAH needs to gain an understanding of how this difference could impacts the antimicrobial quantities reported to WOAAH and future reporting of summary quantities by WOAAH. Please indicate which animals are considered to be non-food-producing animals covered by the quantities. Multiple selections are possible.</p> |
| <p>11.3 <i>Clarification of other species considered to be non-food-producing animals, if your response to Question 11.2 is 'Other'</i></p> | <p>Please provide any explanations you may feel necessary to explain which animal species covered by the data are considered non-food-producing animals (e.g. rabbits).</p> |
| <p>12 Can data be differentiated per route of administration?</p> | <p>Please respond by ticking either 'Yes' or 'No'.</p> |
| <p>13 National report(s) on sales/use of antimicrobial agents in animals available on the web?</p> | <p>Please respond by ticking either 'Yes' or 'No'.</p> |
| <p>13.1 <i>Please provide the link to the report, if your response to Question 13 is 'Yes'</i></p> | <p>If answer is 'Yes' to Question 13, please insert the link to the site where the report is available on the internet.</p> |

After the Baseline Information sheet is completed, remember that only one of the three Reporting Options should be selected.



Overall amount sold for use / used in animals by antimicrobial class, with the possibility to separate by type of use.

Reporting Option 1

The sheet Reporting Option 1 is designed for the reporting of data on amount or type of antimicrobial agents used in all animals. Data may be reported overall for all animal species, but can be separated by antimicrobial class and possibly by type of use (veterinary medical including prevention of clinical signs, or growth promotion; see definitions in the Glossary section of this document).

For this Reporting Option 1, complete the columns 'Veterinary Medical' (including prevention of clinical signs) and 'Growth Promotion'. The sum of sales for 'Veterinary Medical' and 'Growth Promotion' should equal the amount entered in the column 'Overall Amount (Veterinary Medical Use + Growth Promotion)' for each class.

WOAH template for the collection of data on antimicrobial agents intended for use in animals
Reporting option 1 - Overall amount sold for/used in animals by antimicrobial class, with the possibility to separate by type of use

| Antimicrobial Class | Overall Amount: Veterinary Medical Use + Growth Promotion | Amount: Veterinary Medical Use (including prevention of clinical signs) | Amount: Growth Promotion |
|---|---|---|--------------------------|
| | All animal species (kg) | All animal species (kg) | All animal species (kg) |
| Aminoglycosides | 0 | 0 | 0 |
| Amphenicols | 0 | 0 | 0 |
| Artemisins | 0 | 0 | 0 |
| Cephalosporins (all generations) | 0 | 0 | 0 |
| 1-2 gen. cephalosporins | 0 | 0 | 0 |
| 3-4 gen. cephalosporins | 0 | 0 | 0 |
| Cyclic polypeptides | 0 | 0 | 0 |
| Fluoroquinolones | 0 | 0 | 0 |
| Glycopeptides | 0 | 0 | 0 |
| Glycylglycylglycyls | 0 | 0 | 0 |
| Lincosamides | 0 | 0 | 0 |
| Macrolides | 0 | 0 | 0 |
| Nitrofurans | 0 | 0 | 0 |
| Oribacteriins | 0 | 0 | 0 |
| Other quinolones | 0 | 0 | 0 |
| Penicillins | 0 | 0 | 0 |
| Polysporins | 0 | 0 | 0 |
| Polymyxins | 0 | 0 | 0 |
| Quinolones | 0 | 0 | 0 |
| Streptogramins | 0 | 0 | 0 |
| Sulfonamides (including trimethoprim) | 0 | 0 | 0 |
| Tetracyclines | 0 | 0 | 0 |
| Others | 0 | 0 | 0 |
| Aggregated class data (combined classes only) | 0 | 0 | 0 |
| Total kg | 0 | 0 | 0 |

Overall amount sold for use / used in animals by antimicrobial class, with the possibility to separate by type of use and animal groups.

Reporting Option 2

If the data can be differentiated by use in all food-producing animals, non-food-producing animals and / or by use in terrestrial and aquatic food-producing animals, Reporting Option 2 is the appropriate choice. Further differentiation by antimicrobial class, Veterinary Medical, including prevention of clinical signs, or growth promotion is possible.

If sales of antimicrobial agents for use in animals can be differentiated into sales for medical purposes, for growth promotion and additionally by animal group, please complete under the heading 'Veterinary Medical (including prevention of clinical signs)' the columns for 'All animal species', 'Non-food-producing animals', 'All food-producing animals (terrestrial and aquatic)', 'Terrestrial food-producing animals', and 'Aquatic food-producing animals'. These animal groups include all age groups and life stages of the relevant group. The first column of the table 'Overall Amount (Growth Promotion + Veterinary Medical)' allows reporting of the total amount for all uses and animal categories per antimicrobial class. The last column labelled 'Growth Promotion' captures the amounts sold for growth promotion purposes in terrestrial and aquatic food-producing animals.

For Reporting Option 2, 'Growth Promotion' can be reported jointly for terrestrial and aquatic food-producing animals.

WOAH template for the collection of data on antimicrobial agents intended for use in animals
Reporting option 2 - Overall amount sold for/used in animals by antimicrobial class, with the possibility to separate by type of use and species group

| Antimicrobial Class | Overall Amount: Veterinary Medical Use + Growth Promotion | Amount: Veterinary Medical Use (including prevention of clinical signs) | | | | | Amount: Growth Promotion |
|---|---|---|---------------------------------|---|---|-------------------------------------|---|
| | All animal species (kg) | All animal species (kg) | Non-food-producing animals (kg) | All food-producing animals (terrestrial & aquatic) (kg) | Terrestrial food-producing animals (kg) | Aquatic food-producing animals (kg) | All food-producing animals (terrestrial & aquatic) (kg) |
| Aminoglycosides | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Amphenicols | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Artemisins | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Cephalosporins (all generations) | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 1-2 gen. cephalosporins | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 3-4 gen. cephalosporins | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Cyclic polypeptides | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Fluoroquinolones | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Glycopeptides | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Glycylglycylglycyls | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Lincosamides | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Macrolides | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Nitrofurans | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Oribacteriins | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Other quinolones | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Penicillins | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Polysporins | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Polymyxins | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Quinolones | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Streptogramins | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Sulfonamides (including trimethoprim) | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Tetracyclines | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Others | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Aggregated class data (combined classes only) | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Total kg | 0 | 0 | 0 | 0 | 0 | 0 | 0 |

Classes of Antimicrobial Agents for Reporting

All antimicrobial classes used in animals (for [veterinary medical](#) including prevention of clinical signs, as well as growth promotion, whether classified as veterinary medicines or not, *with the exception of ionophores*) should be included in the table by the reporting WOA Member.

| Antimicrobial class | Guidance |
|---|---|
| Aminoglycosides | Includes aminocyclitols (e.g., streptomycin, dihydrostreptomycin and spectinomycin) and all other aminoglycosides (e.g., gentamicin, kanamycin, neomycin, apramycin). |
| Amphenicols | Includes florfenicol and thiamphenicol. |
| Arsenicals | Includes nitarsonsone, roxarsone and others. |
| Cephalosporins | May be reported as Cephalosporins (all generations) or in relevant category groupings (1-2 generation cephalosporins and 3-4 generation cephalosporins). |
| Cyclic polypeptides | Includes bacitracin, enramycin and gramicidin. |
| Fluoroquinolones | Includes danofloxacin, difloxacin, enrofloxacin, marbofloxacin and other fluoroquinolones, but not other quinolones (e.g., flumequine, oxolinic acid, nalidixic acid), which are reported separately. |
| Glycopeptides | Includes avoparcin and others. |
| Glycophospholipids | Includes bambarmycin (i.e., flavomycin). |
| Lincosamides | Includes lincomycin, pirlimycin and others. |
| Macrolides | Includes substances with all macrolide structures, such as erythromycin, spiramycin, tylosin, tylvalosin, gamithromycin, tildipirosin, tulathromycin and others. |
| Nitrofurans | Includes furazolidone, nitrofurantoin, nitrofurazone and others. |
| Orthosomycins | Includes avilamycin and others. |
| Other quinolones | Includes flumequine, nalidixic acid, oxolinic acid and others. |
| Penicillins | Includes all penicillins (e.g., natural penicillins, aminopenicillins and others), but excludes other beta lactam antimicrobials like cephalosporins. |
| Pleuromutilins | Includes tiamulin, valnemulin and others. |
| Polymyxins | Includes colistin and polymyxin. |
| Quinoxalines | Includes carbadox, olaquinox and others. |
| Streptogramins | Includes virginiamycin, pristinamycin, and others. |
| Sulfonamides (including trimethoprim) | Includes all sulfonamides, as well as trimethoprim and similar compounds. |
| Tetracyclines | Includes chlortetracycline, doxycycline, tetracycline, and oxytetracycline. |
| Others | All others not covered, including coumarin antimicrobials, e.g., novobiocin, fusidic acid, kirromycins, phosphonic acids like fosfomycin, rifamycins, thiostrepton. |
| Aggregated class data (confidential purposes only) | It may not be possible to individually report sales by class name for one or more antimicrobial classes for animal use (e.g., to protect <u>confidential</u> (proprietary) information or as required by legislation). Such amounts may be reported in this line. Report here the individual or cumulative amounts of antimicrobial classes used in animals that cannot be reported independently for confidentiality / proprietary reasons. If more than one data aggregation exists in your country, please sum them up for WOA template. |

Explanatory notes on the fields below the tables Reporting Options 1, 2 and 3 are provided.

| | |
|--|--|
| If 'Others' are reported under 'Antimicrobial class', please list the classes reported | Please indicate the antimicrobial molecules under the class 'Others' <input type="checkbox"/> Bicazamycin <input type="checkbox"/> Fosfomycin <input type="checkbox"/> Fusidic acid <input type="checkbox"/> Nisihexide <input type="checkbox"/> Novoblokin <input type="checkbox"/> Rifampicin <input type="checkbox"/> Rifaximin <input type="checkbox"/> Others (needs to be listed below) |
| | If you selected 'Others', please provide the names of the molecules separated by ';' (e.g. dimetridazole; halquinol; metronidazole; mapticin). <free text field> |
| If 'Aggregated class data' are reported, please list the classes combined | Please indicate the antimicrobial classes that need to remain confidential : <input type="checkbox"/> Aminoglycosides <input type="checkbox"/> Amphenicols <input type="checkbox"/> Arsenicals <input type="checkbox"/> 1-2 gen. cephalosporins <input type="checkbox"/> 3-4 gen. cephalosporins <input type="checkbox"/> Fluoroquinolones <input type="checkbox"/> Glycopeptides <input type="checkbox"/> Glycophospholipids <input type="checkbox"/> Lincosamides <input type="checkbox"/> Macrolides <input type="checkbox"/> Nitrofurans <input type="checkbox"/> Orthosomycins <input type="checkbox"/> Other quinolones <input type="checkbox"/> Penicillins <input type="checkbox"/> Pleuromutins <input type="checkbox"/> Cyclic polypeptides <input type="checkbox"/> Quinolones <input type="checkbox"/> Streptogramins <input type="checkbox"/> Sulfonamides (incl. trimetoprim) <input type="checkbox"/> Tetracyclines <input type="checkbox"/> Polymyxins |
| | Please report any additional calculations applied <free text field> |



| Field name | Information to be provided |
|---|--|
| If 'Others' are reported under 'Antimicrobial class', list the classes reported | Please indicate the substance or substances reported as 'Others' by ticking the ones listed in this field. If the substance is not listed by WOA, please indicate the name of the substances separated by ';' in the free text field by using whenever possible the terminology of the WOAH List of antimicrobial agents of veterinary importance . |
| If 'Aggregated class data' are reported, please list the classes combined | If in your country there are data for one antimicrobial class that need to remain <u>confidential</u> , then the data can be reported in this category. If for your country there are Aggregated class data, please indicate here which antimicrobial classes cannot be reported individually by ticking the classes of antimicrobial agents. Multiple selections are possible. |
| Please report any additional calculations applied | Please describe calculations carried out in addition to the ones recommended by WOA in Sections 1 and 2 of the Annex to the Guidance for completing WOA template. |

The amount of the antimicrobial agents intended for use in animals in kilograms (kg) should be reported. Where data are available in the form of

- number of packages of a given pharmaceutical preparation sold;
- international units; or
- % weight per volume (% w/v),

a mathematical conversion will be necessary, which is explained in the Annex to this document. In cases where the amount sold for the listed class is part of a data aggregation reported under 'Aggregated class data (confidential purposes only)', please select the class under this category on the explanatory notes below the tables Reporting Options 1, 2 and 3.

Ideally, WOA is interested in the amount of [active ingredient](#) (moiety), that is, the substance as listed in *WOAH List of antimicrobial agents of veterinary importance* (e.g., benzylpenicillin), not the total weight of the actual chemical compound (salt, ester or other, for example: sodium or potassium benzylpenicillin) contained in a veterinary medicinal product or traded as bulk material. At this stage of the project, the precision gained by the refined reporting of amounts of active ingredient, achieved by mathematical conversion of amounts of chemical compound as declared on the product label, is not justified. Therefore, WOA template will accept the amounts of chemical compound as declared on the product label. Data on amounts of active ingredients will also be accepted, but the additional calculations carried out should be described in the corresponding free-text field on the Reporting Option 1, 2 or 3 sheets in WOA template.

For data sourced from customs, import or other bulk trading, information will likely come as tons of chemical compound. Please convert into kg for reporting in WOA template; the Annex provides conversion factors from different weight units to kg.

For veterinary medicinal products, the content of the antimicrobial agent(s) may be stated in one of several ways, including strength in

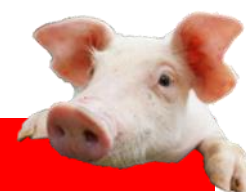
- milligram (mg) or gram (g) of the active ingredient per volume or weight or other unit, for example millilitre (ml), or kilogram (kg) or tablet,
- International Units (IU) per weight, volume or other unit, or
- in percentage (%) weight per weight (w/w) or weight per volume (w/v).

The [Annex](#) provides details on the necessary conversions.

For veterinary medicinal products containing more than one antimicrobial agent, the amounts of each should be added to the respective class columns.

If there are no quantities to report for a class or route of administration, please enter a zero (0) in the corresponding field of the table.

Please refer to the Annex of this document for detailed examples and the calculations necessary to report kg of antimicrobial agents intended for use in animals. As explained above, in most cases the amount of the chemical compound as declared on the product label can be reported, though WOAHA Members wishing to provide more refined data on amounts of active ingredients are welcome to do so, on the condition that they describe the calculations used.



Glossary of Terms

For the purpose of this database, a number of terms require clarification, in order to ensure a harmonised approach to data collection.

• Active ingredient

Antimicrobial agents are chemical compounds that can come in various forms. In order to render an antimicrobial agent suitable for use in a veterinary medicine, or to achieve desirable pharmacokinetic or organoleptic properties, antimicrobial agents can exist as different salts or esters or other chemical compounds. The active ingredient is the part of the chemical compound responsible for the antimicrobial action. The name used to refer to an antimicrobial agent listed on WOAHA *List of antimicrobial agents of veterinary importance* is generally identical to the active ingredient of that agent.

• Antimicrobial agent

As defined in the glossaries of the Terrestrial Code and the Aquatic Code, this means a naturally occurring, semi-synthetic or synthetic substance that exhibits antimicrobial activity (kill or inhibit the growth of micro-organisms) at concentrations attainable *in vivo*. Anthelmintics and substances classed as disinfectants or antiseptics are excluded from this definition. In the context of WOAHA template, this term is being used as a general reference to substances with antimicrobial activity.

• Antimicrobial classes for use in animals

Any antimicrobial agent belonging to the antimicrobial classes listed on WOAHA *List of antimicrobial agents of veterinary importance* is included. In addition, antimicrobial agents used exclusively for growth promotion are also included. With the exception of ionophores, which are mostly used for parasite control, all uses of these substances should be reported, whether the antimicrobial agents are categorised as veterinary medicines or not.

- **Chemical compound as declared on the product label**

As explained for active ingredient, an antimicrobial agent may exist in the form of various chemical compounds. For example, benzylpenicillin (the active ingredient) the sodium, potassium, procaine, benzathine or benethamine salts, and the prodrug penethamine hydroiodide are used in veterinary medicine. In consequence they may be traded as bulk products or be included in veterinary medicinal products containing antimicrobial agents (see explanation below). The term chemical compound as declared on the product label refers to the substance as it is reported on the label of a veterinary medicinal product or a bulk container or in the information provided to customs. This may be either the active ingredient (e.g. benzylpenicillin) or the complete chemical compound (e.g. sodium benzylpenicillin).

- **Extrapolation**

An approach by which the total amount of antimicrobial agents used in animals was derived from a limited, but representative dataset. Details on the approach should be provided. Caution should be exercised in situations where the data sources are not representative of the whole. For example, extrapolation from a limited number of wholesalers may not adequately represent the entire antimicrobial sales market.

- **Food-producing species**

The animal species that are managed by people for the purpose of producing food for humans. The relevant species may differ between countries.

- **Growth promotion, growth promoters**

means the administration of antimicrobial agents to animals only to increase the rate of weight gain or the efficiency of feed utilisation.

- **Quantitative data**

The term 'quantitative' refers to a type of information based in quantities or else quantifiable data (objective properties) — as opposed to 'qualitative' information which deals with apparent qualities (subjective properties). Quantitative data may also refer to mass, time, or productivity. In the context of this template, quantitative data means that the amount of antimicrobial agents used in animals can be determined, for example through information on amount of antimicrobials imported, or number of packages of specific antimicrobial products used in animals, and is reportable in the metric 'kg antimicrobial agent'.

- **Sales of antimicrobial agent(s) used in animals versus use data**

For the purpose of data collection through WOA template, sales data, also referred to as 'amount of antimicrobial agent(s) used in animals' relates to the amounts of antimicrobial agents imported and/or sold within a country for use in animals. Sales data are used as an approximation of actual use. Use data refers to the amount of antimicrobial agents actually administered to animals. Such data are difficult to collect in most environments, as the data sources would be at the level of individual farmers or veterinarians.

• **Veterinary Medical use**

Means the administration of an antimicrobial agent to an individual or a group of animals to treat, control or prevent disease:

- to treat means to administer an antimicrobial agent to an individual or a group of animals showing clinical signs of an infectious disease;
- to control means to administer an antimicrobial agent to a group of animals containing sick animals and healthy animals (presumed to be infected), to minimise or resolve clinical signs and to prevent further spread of the disease;
- to prevent means to administer an antimicrobial agent to an individual or a group of animals at risk of acquiring a specific infection or in a specific situation where infectious disease is likely to occur if the drug is not administered.

• **Veterinary medicinal product containing antimicrobial agent(s)**

As defined in the glossaries of the Terrestrial Code and the Aquatic Code, the term veterinary medicinal product means any product with approved claim(s) to having a prophylactic, therapeutic or diagnostic effect or to alter physiological functions when administered or applied to an animal. A veterinary medicinal product containing antimicrobial agent(s) refers to veterinary medicinal products used for their antimicrobial effect due to one or more antimicrobial agents they contain.

