OIE Annual Report on Antimicrobial Agents Intended for Use in Animals

BETTER UNDERSTANDING OF THE GLOBAL SITUATION





WORLD ORGANISATION FOR ANIMAL HEALTH
Protecting animals, preserving our future

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Director General's Foreword



Dr Monique Éloit
OIE Director General

The One Health approach is widely recognised as the cornerstone of the strategy to stem the development of antimicrobial resistance (AMR) worldwide. With this in mind, the OIE and its Tripartite partners – the Food and Agriculture Organization of the United Nations (FAO) and the World Health Organization (WHO) – have built on their long-lasting collaborative relationship, and on 20 November 2020, they launched a new One Health Global Leaders Group on Antimicrobial Resistance as part of their shared call for united action to preserve the effectiveness of antimicrobials.

The creation of this group also followed a recommendation of the UN Interagency Coordination Group on AMR, supported by the Secretary-General of the United Nations. Specifically, the General

Assembly of the United Nations through Resolution A/RES/71/3 adopted a political declaration approved at the high-level meeting of the General Assembly on AMR on 21 September 2016, which among other actions, reaffirmed that the blueprint for tackling AMR is the Global Action Plan (GAP) on AMR developed by WHO in collaboration with, and subsequently adopted by, the OIE and FAO.

The responsibility of the OIE to collect data on the use of antimicrobials in animals is reiterated in the GAP on AMR where the OIE is requested to 'build and maintain a global database on the use of antimicrobial medicines in animals'. As a result of the tremendous efforts of its Members, the OIE Annual Report on Antimicrobial Agents Intended for Use in Animals has been published every year since December 2016 and has highlighted steady progress.

The OIE's partners consider data collection on the use of antimicrobials in animals and the progress achieved by the 156 OIE Members, one non-contiguous territory of an OIE Member, and three non-OIE Members that participated in the data collection in the fifth round, to be a major milestone in the global effort to contain AMR. The OIE recognises the efforts of OIE Delegates and the National Focal Points for Veterinary Products in contributing to this extraordinary effort. The OIE also commends the non-contiguous territory and the three non-OIE Members that engaged in the data collection in the fifth round.

Finally, the OIE strongly supports its Members in these efforts through the implementation of its Strategy on Antimicrobial Resistance and the Prudent Use of Antimicrobials, published in November 2016. In 2020, the OIE began the phase in this strategy to build an interactive information technology (IT) system for OIE AMU Data Collection. This system is expected to facilitate OIE Members' instant access to their data which will guide decisions at the national level. To further support Members, and being mindful of the current COVID-19 situation, in 2021, the OIE adapted its Workshops on the OIE Antimicrobial Use Data Collection to a virtual format, being delivered via webinars to all OIE Regions, and by introducing a tool to assist in calculating the amounts of active ingredients and to obtain feedback on needs related to the future IT System for the OIE Data Collection.

I hope that this report will further encourage OIE Members and non-OIE Members alike to continue to participate in this initiative. Your constant support and involvement will increase the accuracy and robustness of our understanding of the global use of antimicrobial agents in animals.



Executive Summary

This fifth *OIE* Annual Report on Antimicrobial Agents Intended for Use in Animals provides details of the global use of antimicrobial agents adjusted for animal biomass for 2017, and interprets the overall findings of the fifth annual data collection on the use of antimicrobial agents in animals, providing a global and regional analysis. Additionally, in this edition of the report, for the first time, a section on trends of antimicrobial agents adjusted for animal biomass is included (here for the period of 2015 – 2017).

Results of the Fifth Round of Data Collection (Section 3)

The OIE template used to collect data was designed to allow all countries to participate, regardless of whether a formalised national data collection system currently existed. In 2019, the fifth round of data collection reports were submitted by 156 Members (156 out of 182; 86%), including data reported by one non-contiguous territory¹ of an OIE Member with its own reporting mechanism and three non-OIE Members. One hundred and thirty-three reports (133 out of 160; 83%) included quantitative data for one or more years between 2017 and 2019, 16% more than the fourth annual report. In previous rounds, most of the countries reported their data through Reporting Option 1. For this fifth round, 51% of the countries reported quantities through Reporting Option 3, which allows for more details in data; this was facilitated through an Excel Calculation Tool that the OIE developed.

In the fifth round of data collection, countries were asked to provide information on the barriers faced in reporting quantities of antimicrobials intended for use in animals. Twenty-three countries reported primarily a lack of regulatory framework, human resource constraints and lack of information technology (IT) tools to collect the data, perform calculations and analyse the antimicrobial quantities. Three of these countries (3 out of 23; 13%) confirmed that actions will be undertaken in the near future to facilitate their reporting of quantities of antimicrobials to the OIE.

For responses on the use of antimicrobial agents as growth promoters, a total of 112 responding countries (112 out of 160; 70%) did not use any antimicrobial agents for growth promotion in animals in their countries as of 2019, regardless of the presence or absence of legislation or regulations. Forty-two countries (42 out of 160; 26%) reported use of antimicrobials for growth promotion; of these, 20 countries (20 out of 42; 48%) had a regulatory framework that either provided a list of antimicrobials that could be used as growth promoters or provided a list of those that should not be used as growth promoters. The six remaining countries (6 out of 160; 4%) indicated that they were unsure whether or not antibiotics were being used as growth promotors in the field.

2017 Analysis of Antimicrobial Quantities (Section 4)

This section covers all 2017 data provided during any of the five rounds of data collection. The analysis of antimicrobial agents adjusted by animal biomass was performed in 102 countries for 2017, 10% more than the fourth annual report. The calculations of animal biomass allowed for an analysis of reported antimicrobial quantities adjusted by a denominator. Animal biomass was calculated as the total weight of live domestic animals in a given population and year, used as a proxy to represent those likely exposed to the quantities of antimicrobial agents reported. Animal biomass was calculated for food-producing species of countries reporting quantitative data for 2017, primarily using data from

For the purpose of the OIE AMU Data Collection, 'non-contiguous territory' means: an insular territory separated from the mainland but affiliated to an OIE Member, with its own AMU monitoring system. For simplicity, the 153 reports received from 152 Members and one non-contiguous territory are referred to through the remainder of this report as 153 countries reporting to the OIE their antimicrobial usage.

the OIE World Animal Health Information System (OIE-WAHIS) and the Food and Agriculture Organization of the United Nations Statistical Database (FAOSTAT). The target year of this fifth round of data collection was 2017.

The global estimate of antimicrobial agents used in animals in 2017 adjusted by animal biomass, as represented by the quantitative data reported to the OIE from 102 countries, was 107.68 mg/kg. An approach for an upper-level estimate of 117.48 mg/kg was made adjusting by country-level estimates of how much data on antimicrobial agents used in animals they had captured in 2017. The 2017 analysis demonstrates a much stronger global participation in the data collection, with an estimated global biomass coverage of 83%, increased from 36% in 2014.

Trends from 2015 to 2017 (Section 6)

This section presents the changes of the mg/kg, antimicrobial classes and animal biomass. Of the 69 countries that provided data for all years between 2015 and 2017, an overall decrease of 34% in the mg/kg was observed at the global level; a decrease was noted across all OIE Regions. Globally, antimicrobial quantities dropped from 174.01 mg/kg in 2015 to 114.84 mg/kg in 2017. A projection for an upper-level estimate, based on country-level evaluations of how much data on antimicrobials were captured, also presented a reduction, from 176.71 mg/kg in 2015 to 116.30 mg/kg in 2017.

As a result of the multiple challenges that countries face as they advance towards quantitative data collection on antimicrobial use in animals, the OIE continues to advise caution in the interpretation and use of the quantitative data presented in this report. The report transparently describes the reasons for uncertainty associated with both the complex and simple estimates presented. The limitations of this analysis include quantitative data source errors, which may lead to overcounting of antimicrobial amounts by some countries new to the process of data collection.

The OIE remains strongly committed to supporting its Members in developing robust and transparent measurement reporting mechanisms for antimicrobial use, but the challenges faced by many of our Members must not be under-estimated. Concurrent to engagement with countries to improve these data, the methodology for calculating animal biomass will continue to be refined. While data collection systems further develop, this annual report will provide an essential global and regional analysis of antibiotic use in animals, and changes over time.

The development of a Phase 2 OIE Global Database seeks to deliver a software scenario where OIE Members are able to complete the data-entry requirements, calculate the antimicrobial quantities, and have their animal biomass estimated through confidential access to a central database. Members will be provided with functional access to the database to review, analyse, present and use their own data, in line with the OIE's responsibility for global and regional data aggregation and analysis.

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The OIE would also like to thank all OIE Members, Delegates, National Focal Points for Veterinary Products and other governmental officials who contributed to the fifth annual collection of data on antimicrobial agents used in animals, without which the knowledge and insight presented in this report could not be gained on the global use of antimicrobial agents in animals.

Finally, the OIE would like to thank the OIE Working Group on Antimicrobial Resistance for its guidance in the development of the global database and methodology for the calculation of animal biomass for the fifth round of the OIE data collection on antimicrobial agents intended for use in animals.

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Acronyms and Abbreviations

AMR Antimicrobial resistance

AMU Antimicrobial use

CIPARS Canadian Integrated Program for Antimicrobial Resistance Surveillance

ESVAC European Surveillance of Veterinary Antimicrobial Consumption

FAO Food and Agriculture Organization of the United Nations

FDA United States Food and Drug Administration

JVARM Japanese Veterinary Antimicrobial Resistance Monitoring System

LSU Livestock Unit

NAP National Action Plan

OIE World Organisation for Animal Health

OIE-WAHIS World Animal Health Information System

PVS Performance of Veterinary Services

WHO World Health Organization

OIE Glossary²

Antimicrobial agent: 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.

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.

Monitoring: means the intermittent performance and analysis of routine measurements and observations, aimed at detecting changes in the environment or health status of a population.

Surveillance: means the systematic ongoing collection, collation, and analysis of information related to animal health and the timely dissemination of information so that action can be taken.

Veterinary Authority: means the Governmental Authority of a Member Country, comprising veterinarians, other professionals and paraprofessionals, having the responsibility and competence for ensuring or supervising the implementation of animal health and welfare measures, international veterinary certification and other standards and recommendations in the Terrestrial Code in the whole territory.

Veterinary legislation: means laws, regulations and all associated legal instruments that pertain to the veterinary domain.

Veterinary medicinal product: means any product with approved claims to having a prophylactic, therapeutic or diagnostic effect or to alter physiological functions when administered or applied to an animal.

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 Services: means the governmental and non-governmental organisations that implement animal health and welfare measures and other standards and recommendations in the OIE *Terrestrial Code* and the OIE *Aquatic Animal Health Code* in the territory. The Veterinary Services are under the overall control and direction of the Veterinary Authority. Private sector organisations, veterinarians, veterinary paraprofessionals or aquatic animal health professionals are normally accredited or approved by the Veterinary Authority to deliver the delegated functions.

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² For the purpose of the OIE Terrestrial Code [1]

1. Introduction

1.1. Background

For two decades, the World Organisation for Animal Health (OIE) has engaged in combating antimicrobial resistance through a One Health approach. On the global level, the mitigation of antimicrobial resistance is crucial for the protection of human, animal, plant and environmental health.

In May 2015, during the 83rd General Session of the World Assembly of OIE Delegates, OIE Members officially committed to combatting AMR and promoting the prudent use of antimicrobials in animals, and stated their full support for the Global Action Plan on AMR, developed by the World Health Organization (WHO) in close collaboration with the OIE and the Food and Agriculture Organization of the United Nations (FAO) [9]. One year later, during the 84th General Session, the World Assembly of Delegates directed the OIE to compile and consolidate all the actions to combat AMR [3], and the resultant OIE Strategy on AMR and the Prudent Use of Antimicrobials was published in November 2016 [4].

The structure of this OIE Strategy supports the objectives established in the Global Action Plan, and reflects the mandate of the OIE as described in its Basic Texts and Strategic Plans through four main objectives:

- (1) Improve awareness and understanding.
- (2) Strengthen knowledge through surveillance and research.
- (3) Support good governance and capacity building.
- (4) Encourage implementation of international standards.

With the aim of achieving these objectives, the OIE, through National Focal Points for Veterinary Products, engages with OIE Members. During the 76th General Session in May 2008, OIE Delegates were asked to nominate National Focal Points for Veterinary Products, who would provide technical assistance on improving and harmonising national policies for the control of veterinary products in their countries. The OIE, through its Regions, organises regular seminars for these Focal Points to support good governance and capacity building, and harmonised implementation of OIE standards on responsible and prudent use of antimicrobials.

Of the 136 OIE Members assessed through an initial OIE Performance of Veterinary Services (PVS) Evaluation³ from 2007 to December 2020, almost three-quarters could not regulate veterinary medicinal products (assessed as 'Level 1'⁴] for the Critical Competency [CC] II-8 'Veterinary medicines and biologicals'), or had only some capability of exercising regulatory and administrative control over the import, manufacture and market authorisation (registration) of these products, which would to ensure their safety and quality. Thus these countries were unable to ensure the responsible and prudent use of such products in the field ('Level 2' of the CC II-8). The absence or low level of control

The 'initial' PVS Evaluation mission provides a careful evaluation of the current performance of the national Veterinary Services, and the capacity to undertake ongoing monitoring of performance over time using consistent methods. After some years, countries may request a PVS Evaluation Follow-Up mission, which serves to update the assessment and documents the progress made by countries.

In the OIE PVS Tool, to establish the level of performance, Critical Competencies (CC) with five possible levels of advancement are identified within each of the four Fundamental Components. A higher level of advancement assumes that the VS are complying with the preceding levels (e.g. Level 3 assumes compliance with Level 2 criteria). CCII-8 refers to Veterinary Medicines and Biologicals from 7th Edition of the OIE PVS Tool (2019); for previous OIE PVS Tool editions, the relevant Critical Competency was CCII-9.

of veterinary medicinal products leads to limited control of veterinary products containing antimicrobial agents. These antimicrobial agents can potentially circulate freely in the market and like ordinary goods, they may be falsified or substandard, and/or may be provided without clinical or laboratory diagnosis. This variable quality and unrestricted use of antimicrobial products creates a high-risk conditions for the development and spread of resistance.

In 2019, the 7th edition of the OIE PVS Tool included a new Critical Competency (CC): CCII-9 Antimicrobial resistance (AMR) and antimicrobial use (AMU). This CC allows for a more specific understanding on AMR and AMU surveillance, One Health governance of AMR, AMR-specific drug regulation and the veterinary contribution to National Action Plans (NAPs) on AMR. Between August 2018 and December 2020, 19 countries were assessed through PVS Evaluations based on this new edition of the PVS Tool. It is worth highlighting that for all but one of these countries, this CCII-9 was assessed as:

- 'Level 1' ('The Veterinary Services cannot regulate or control AMR and AMU, and have not developed or contributed to a NAP on AMR covering the veterinary domain'); or
- 'Level 2' ('The Veterinary Services are contributing or have contributed to a NAP on AMR. The NAP has initiated some activities to collect AMU/AMR data or control AMR e.g. awareness campaigns targeting veterinarians or farmers on the prudent use of antimicrobials. The use of antimicrobials for growth promotion is discouraged').

This new edition of the OIE PVS Tool is expected to provide key information related to the ability of Members to control AMU/AMR in the veterinary domain. The status of Members in this regard can be explored more deeply through the OIE Veterinary Legislation Support Programme and its new specific focus on AMR currently being developed and tested in collaboration with the OIE's Tripartite partners (FAO and WHO).

Currently, very little information is available worldwide on resistance patterns in animal pathogens or in animal commensal bacteria. Surveillance of antimicrobial resistance in animal microorganisms is important to assess the level and evolution of antimicrobial resistance in animals, and later to provide a better understanding of the AMU-AMR epidemiology.

The OIE publishes international standards on AMR and AMU. In its *Terrestrial Animal Health Code* (*Terrestrial Code*), Chapter 6.8. 'Harmonisation of national antimicrobial resistance surveillance and monitoring programmes' includes examples of target animal species and animal bacterial pathogens that may be included in resistance surveillance and monitoring programmes [5]. Its *Aquatic Animal Health Code* (Aquatic Code) provides a corresponding Chapter 6.4. 'Development and harmonisation of national antimicrobial resistance surveillance and monitoring programmes for aquatic animals' [6]. The OIE's *Manual of Diagnostic Test and Vaccines for Terrestrial Animals*, Chapter 2.1.1. 'Laboratory methodologies for bacterial antimicrobial susceptibility testing' provides the laboratory methods supporting surveillance and monitoring [7]. During the 87th General Session in May 2019, Members adopted the updates of Chapter 2.1.1., which included guidance on the harmonisation of microbial susceptibility testing in veterinary laboratories.

In addition to surveillance of antimicrobial resistance, monitoring of antimicrobial use is critical to understanding possible areas of risk for the development of resistance. In 2012, the OIE developed a questionnaire with the following objectives: (1) to enhance the OIE's engagement in the initiative to prevent antimicrobial resistance; (2) to conduct a survey of the implementation by OIE Members of OIE *Terrestrial Code* chapter on 'Monitoring of the quantities and usage patterns of antimicrobial agents used in food producing animals'; (3) to improve awareness of antimicrobial use in animals by OIE Members; and (4) to determine what actions are needed to help the OIE to develop its strategy in this field. A total of 152 of 178 (85%) OIE Members completed the questionnaire. The answers received

showed that, in 2012, 27% of responding Members had an official system in place for collecting quantitative data on antimicrobial agents used in animals.

The results were presented at the first OIE Global Conference on the Responsible and Prudent Use of Antimicrobial Agents for Animals held in March 2013 in Paris, France. The recommendations to OIE Members resulting from the conference included calls:

- To establish an official harmonised national system for collecting data on the monitoring of antimicrobial resistance in relevant animal pathogens and quantities of antimicrobial agents used in food-producing animals at the national level based on the OIE standards.
- To contribute to the OIE initiative to collect data on the antimicrobial agents used in foodproducing animals (including through medicated feed) with the ultimate aim of creating a global database hosted by the OIE.

Following these recommendations, in 2015, the OIE World Assembly unanimously adopted Resolution No. 26 during the 83rd General Session, officially mandating the OIE to gather data on the use of antimicrobial agents in animals worldwide [2]. As a result, this global database was created in compliance with chapters of the *Terrestrial Code* ('Monitoring of the quantities and usage patterns of antimicrobial agents used in food-producing animals') [8] and of the *Aquatic Code* ('Monitoring of the quantities and usage patterns of antimicrobial agents used in aquatic animals') [6].

In the framework of the Global Action Plan on Antimicrobial Resistance [9], the OIE leads the building and maintenance of the global database on antimicrobial agents intended for use in animals, supported by FAO and WHO within the Tripartite collaboration.

In 2015, the OIE launched its first annual data collection on antimicrobial agents intended for use in animals. The OIE template and guidance documents were developed by the previous OIE *ad hoc* Group on Antimicrobial Resistance, endorsed by the Scientific Commission for Animal Diseases, and tested by Members through regional training seminars for OIE National Focal Points for Veterinary Products.

During this first round of data collection on antimicrobial agents used in animals, 130 Members (n = 180; 72%) participated. The report resulting from this impressive participation in the first annual data collection, the *OIE Annual Report on Antimicrobial Agents Intended for Use in Animals: Better Understanding of Global Situation* [10], was published in December 2016. In this fifth round of data collection, 160 countries submitted their reports, an increase of 23% since the first round of data collection in 2015.

As part of the fifth round, the OIE requested quantitative data on antimicrobials used in animals for the 2017 calendar year, but also accepted data from 2018 and 2019. The wider timespan of quantitative data collected allows for countries, which are at various stages of development of their antimicrobial use monitoring systems, to contribute to the OIE data collection. However, this request presents a challenge for data analysis. As the timespan of quantitative data collected from the fifth round of data collection is broad, it was decided that this fifth report, analysis of antimicrobial quantities would focus on 2017. This single year extended analysis will enable a greater level of comparison of data as well as favouring assessments of trends for future rounds of data collection. Comparison of quantitative data also requires a denominator with which to interpret the antimicrobial quantities reported.

To address these challenges, this report provides an examination of quantitative data in the context of relevant animal populations and includes an analysis of antimicrobial quantities adjusted for animal biomass on a global and regional level by year. The focus year of this additional analysis is 2017, using quantitative data reported to the OIE by 102 countries during all rounds of data collection.

For the sixth round of data collection currently under way, the OIE has requested quantitative data for 2018, but will also accept data for 2019 and 2020. Accepting some repeated years of quantitative data from previous rounds provides an opportunity for countries to correct and enrich the quality of these data sets where relevant. Over time, and once the reporting of data has become more routine, the OIE will request data for one specific calendar year. This way, OIE reporting will progress in parallel with the development of data collection systems from its Members, as global monitoring on the use of antimicrobial agents becomes more systematic and reliable.

1.2. Scope

This report presents the results of the fifth round of the annual collection of data on antimicrobial agents intended for use in animals. The data collection highlights the current situation of governance of veterinary antimicrobials in responding OIE Members and participating non-contiguous territories, and includes submissions of quantitative data where countries are able to provide them for inclusion in the global database on the use of antimicrobial agents in animals. The report also highlights the barriers countries face that impede data collection, analysis and reporting.

In addition to the descriptive analysis of the fifth round of data collection, the report includes a global and regional analysis of quantitative data on antimicrobial agents intended for use in animals adjusted by animal biomass. The focus year of this quantitative analysis is 2017; additionally, 2014, 2015 and 2016 data sets are updated in this report based on Members historical updates.

Currently, countries report data mainly from sales or imports of antimicrobial agents from the *OIE List* of Antimicrobial Agents of Veterinary Importance, which prioritises antimicrobials crucial to maintaining the health and welfare of animals worldwide. The data collection template and resulting report were prepared, taking into account the differences between OIE Members in their governance and surveillance of veterinary antimicrobials.

For countries reporting quantitative data, the amounts of antimicrobial agents intended for use in animals that were sold, purchased or imported were provided to the OIE in kilograms (kg) of antimicrobial agent (chemical compound as declared on the product label). These reported figures were calculated according to the guidance provided in Annex 8.

The country information was provided to the OIE in confidence for the purpose of better understanding the global and regional situation related to the use of antimicrobial agents in animals, and therefore does not present any data on an individual country level. Nevertheless, Members are encouraged by the OIE to publish national reports on the use of antimicrobial agents in animals whenever possible and are requested to indicate in the OIE template if such data are available online. The list of countries with national reports on veterinary antimicrobial usage that can be accessed publicly can be found in Section 11 of this report, together with relevant links.

2. Materials and Methods

Every September the OIE invites its Members to participate in its annual data collection on antimicrobial agents intended for use in animals. In order to analyse the antimicrobial quantities reported, OIE Headquarters developed a formula to calculate animal biomass. The materials and methods for report antimicrobial quantities and estimating animal biomass are summarised in Section 2.1 and 2.2 of this report. More information can be found in the 'OIE Annual Report on Antimicrobial Agents Intended for Use in Animals: Methods Used' article published in *Frontiers in Veterinary Science* in September 2019 [11].

2.1. Antimicrobial Quantities Reported

Resolution No. 26 of the 83rd General Session in 2015, 'Combating Antimicrobial Resistance and Promoting the Prudent Use of Antimicrobial Agents in Animals', included recommendations that:

- 'The OIE develop a procedure and standards for data quality for collecting data annually from
 OIE Member Countries on the use of antimicrobial agents in food-producing animals with the
 aim of creating an OIE global database to be managed in parallel with the World Animal Health
 Information System (WAHIS).
- OIE Member Countries set up an official harmonised national system, based on OIE standards, for the surveillance of antimicrobial resistance and the collection of data on the use of antimicrobial agents in food-producing animals, and actively participate in the development of the OIE global database'.

In response to these recommendations, the previous OIE *ad hoc* Group on Antimicrobial Resistance developed a template for harmonised data collection, as well as guidance for its completion. This OIE template was translated into the three OIE official languages (i.e. English, French and Spanish) and further refined in the sixth round.

An annex to the guidance was also provided giving more detailed instructions on mathematical calculations to obtain quantities of active ingredients from veterinary medicinal products containing antimicrobial agents sold. All antimicrobial agents destined for use in animals and contained in the OIE List of Antimicrobial Agents of Veterinary Importance [12], in addition to certain antimicrobial agents used only for growth promotion, were reportable.

The updated OIE template (Annex 6) and accompanying guidance documents (Annexes 7 and 8) were sent to all 182 OIE Members, four non-contiguous territories and five non-OIE Members by e-mail in September 2019. The deadline for submission was 2 December 2019, but responses were accepted on a conditional basis until mid-May 2020.

As with previous rounds of data collection, countries responded to the questionnaire through an Excel spreadsheet using predefined conditional formulas and analysis tools. This spreadsheet, referred to as the 'OIE template' contains four worksheets labelled 'Baseline Information', 'Reporting Option 1', 'Reporting Option 2', and 'Reporting Option 3'.

Part A (Contact Person for Antimicrobial Agents Use Data Collection) and Part B (General Information) of the 'Baseline Information' sheet can be completed by any country, and collects information on the current situation of governance of veterinary antimicrobials, including the Competent Authority for regulation of antimicrobial use in animals, use of growth promoters, and barriers to reporting quantitative data on antimicrobial agents used in animals, if any. For countries able to provide quantitative data on antimicrobial agents intended for use in animals, the 'Baseline Information' sheet also contains questions relevant to data collection in Part C (Data Collection of Antimicrobial Agents

Intended for Use in Animals), including year covered, data sources and food-producing species included. Countries providing multiple years of quantitative data are asked to provide a single template for every year of data, with Part C modified, if necessary, to reflect the reported quantitative data.

Following completion of the Baseline Information, the template either directs countries to submit the questionnaire if no quantitative data were available, or to complete one of the three 'Reporting Options' if quantitative data were available. The three reporting options represent increasing levels of detail of quantitative data on antimicrobial classes used in animals, with the possibility of separating amounts reported by type of use (Veterinary medical use, which includes use to treat, control or prevent disease; and Non-veterinary medical use, which includes use for growth promotion), animal groups (Terrestrial, Aquatic or Companion) and routes of administration.

All responses submitted by the designated contact person for a Member were validated by the country's Delegate. Member responses were compiled and analysed at OIE Headquarters.

Whenever necessary, staff from OIE Headquarters engaged with respondents to clarify and validate responses. These questions were addressed to the contact person listed, who was usually the OIE National Focal Points for Veterinary Products.

2.2. Animal Biomass Estimation Methodology

Background

To compare quantitative data reported on antimicrobial agents intended for use in animals between regions and over time, a rate is necessary to evaluate these data in the context of associated animal populations, which vary in size and composition. To this end, and in conjunction with the development of the antimicrobial use database, the previous OIE *ad hoc* Group on Antimicrobial Resistance agreed to analyse the antimicrobial quantities reported using animal biomass as a denominator.

Animal biomass is calculated as the total weight of the live domestic animals in a given population and year, used as a proxy to represent those likely exposed to the quantities of antimicrobial agents reported. As data on antimicrobial agents are reported by country, animal biomass for the purpose of this report is the total weight of that country's production animals. Currently, due to insufficient data, it was not possible to incorporate companion animals in the total biomass.

Animal biomass is currently employed as a denominator in analysis of quantitative antimicrobial use data by other national and regional antimicrobial use surveillance groups, such as the European Surveillance of Veterinary Antimicrobial Consumption (ESVAC), the US Food and Drug Administration (FDA), the Canadian Integrated Program for Antimicrobial Resistance Surveillance (CIPARS), and the Japanese Veterinary Antimicrobial Resistance Monitoring System (JVARM).

Data Sources and Methodology Development

While several methodologies have been developed for the calculation of animal biomass by other surveillance groups, none could be directly used for the OIE global database. Particularly, these methodologies utilise available data on animal populations detailed by production class, estimates of live animal weights, import/export data, and total annual populations of production groups living for less than one year (i.e. poultry, veal calves, fattening pigs, lambs and kids). On a global level, such detailed data are not yet available for many countries.

Data collected by global animal surveillance databases (OIE-WAHIS, FAOSTAT) are point-in-time species-level census data⁵ with little-to-no detail relating to production class. Such data are difficult to interpret given that production classes within a species can have very different average weights, such as beef cattle and veal calves. Additionally, given that census data are collected at a specific time of the year, the total annual population is not known for production groups which are slaughtered and repopulated a certain number of times within one year (this multiplication factor is hereafter referred to as the 'cycle factor').

The development of the methodology for the calculation of an annual animal biomass utilised globally available census data from the OIE-WAHIS interface. OIE-WAHIS data are reported by national Veterinary Services through the OIE Delegate, with the active support of OIE Focal Points for Animal Disease Notification, and the figures are subsequently validated by OIE staff. When an animal population figure is not reported to WAHIS, the data point is left blank.

FAOSTAT animal population data were used as a complementary dataset. FAOSTAT data are similarly primarily obtained from national governments, but sources expand beyond national Veterinary Services to national statistics offices and other relevant agencies. When a national government does not report a figure to FAOSTAT, FAO uses local expert resources to estimate a figure, or their statistical team to imputate⁶ a data point. The two datasets are therefore similar but can display variation.

Where census data were used, the OIE-WAHIS and FAOSTAT figures were first cross-referenced with each other, and then with national reports or literature when necessary. FAOSTAT data were utilised when an OIE-WAHIS data point was not available or was outside of expected variation without explanation.

In addition to census data, FAOSTAT also reports numbers and tonnes of production animal species slaughtered by country each year, similarly undifferentiated by production class. As OIE-WAHIS does not collect this information, FAOSTAT slaughter data was used exclusively when these data were needed. For species living less than one year, it was necessary to use data on a number of animals slaughtered to represent an annual population, as this information cannot be extrapolated from point-in-time census data without a cycle factor.

The formulas for calculating biomass by species were developed with these considerations in mind using the two globally available datasets, OIE-WAHIS and FAOSTAT, and the results compared to references from countries where more detailed animal population data by production class were available. These references include animal biomass figures either directly supplied by Members, or calculated from animal population data in Eurostat, the statistical office of the European Union.

The formulas chosen for the calculation of the OIE denominator reflect the best-fit estimations using the more general global animal population data (OIE-WAHIS, FAOSTAT) when compared to these available reference figures. The derived formulas were then applied to all countries providing quantitative data for the target year.

The methodology for calculation of animal biomass was developed with the support and validation of the previous OIE *ad hoc* Group on Antimicrobial Resistance, shared with Members in the report of the OIE Scientific Commission for Animal Diseases meeting of September 2017 and published in *Frontiers in Veterinary Science* in September 2019 under the title 'OIE Annual Report on Antimicrobial Agents Intended for Use in Animals: Methods Used' [11]. The potential for inaccuracies in the estimation of animal biomass, in particular from extrapolating data available for one region of the world to other regions, is further discussed in Section 7.3 of the report.

⁶ According to the *OECD Glossary of Statistical Terms* imputation is the process used to determine and assign replacement values for missing, invalid or inconsistent data that have failed edits' (https://stats.oecd.org/glossary/detail.asp?ID=3462)

⁵ Point in time census data represents the number of living animals in a country at the time of survey.

Year of Analysis

The target year of the fifth round of data collection, 2017, is the focus of the additional analysis of antimicrobial quantities adjusted for the animal biomass denominator. Countries providing quantitative data on antimicrobial agents intended for use in animals for 2017 during all rounds of data collection were included in this additional analysis.

Calculations of Live Weights for All Species

Live weights of animals were calculated using FAOSTAT slaughter data, where available, using the following two formulas:

carcass weight
$$(kg) = \frac{\text{weight of species slaughtered } (kg)}{\text{number of species slaughtered (heads)}}$$

Carcass weights were converted to live weights from the animal at time of slaughter using conversion coefficients (k) as defined by Eurostat [13]. Conversion coefficients represent the difference between a processed carcass weight and the expected live weight of that animal species before slaughter, expressed as a fraction.

live weight
$$(kg) = \frac{carcass\ weight\ (kg)}{conversion\ coefficient\ (k)}$$

For the purposes of this report, 'live weight' refers to the calculated weight (in kg) of an animal before slaughter, unless otherwise specified.

Countries were grouped by sub-region as defined by OIE Regions and Sub-Regions and also taking into account livestock unit (LSU) classifications. Sub-regional mean live weights were then determined by calculating the average live weight of a given species for countries within the sub-regional grouping.

Methodology for Calculating Species Biomass by Country

As animal population data are collected on the country level, animal biomass was calculated for each of the following species for each country that reported quantitative data to the OIE for 2017.

All weights and biomass figures are measured in kilograms.

Bovine (including cattle and domestic buffalo) biomass was calculated according to the following principles:

- 1. From the calculated sub-regional mean live weight, the weights of the different bovine production categories [adults, young (between 1 and 2 years of age), calves (<1 year of age)] were determined by applying relevant weight proportions standards, originating from livestock unit ratios as defined by Eurostat [15].
- 2. Consecutively, the weight of each bovine production category was then multiplied by a predicted population ratio resulting in a representative weight for bovines for the sub-region. The applied population ratios were calculated in the reference Eurostat database and consider an anticipated renewal rate of 30%.

⁷ Livestock units (LSU) [14], used for aggregating the numbers of different categories of livestock, are usually derived in terms of relative feed requirements. Conversion ratios are generally based on metabolisable energy requirements, with one unit being considered as the needs for maintenance and production of a typical dairy cow and calf.

Bovine biomass was calculated by multiplying the representative weight determined for each subregion by the census population of bovines for each country within the sub-region, according to the following formula:

```
 \begin{array}{l} \textit{census population} \times [(\textit{sub} - \textit{regional mean live weight} \times \textit{LSU}_{\textit{calves}} \times \textit{P.pop}_{\textit{calves}}) \\ + \big(\textit{sub} - \textit{regional mean live weight} \times \textit{LSU}_{\textit{young 1-2yrs}} \times \textit{P.pop}_{\textit{young 1-2yrs}}\big) \\ + \big(\textit{sub} - \textit{regional mean live weight} \times \textit{LSU}_{\textit{adults}} \times \textit{P.pop}_{\textit{adults}}\big) \, \big] \end{array}
```

Whereby,

P.pop_{calves}, *P.pop_{young 1-2yrs}*, and *P.pop_{adults}* represents the proportion (P.pop) of calves (less than 1 year), young (between 1 to 2 years of age) and adults (over 2 years of age) in the total living cattle population, respectively, as calculated using Eurostat animal population data and considering an anticipated renewal rate of 30%.

LSU_{calves}, LSU _{young 1-2yrs}, and LSU _{adults} represents the livestock unit ratios for calves, young and adults, respectively, as defined by Eurostat [15].

And, *sub-regional mean live weight* represents the calculated mean live weight for adult cattle at the sub-regional level.

Swine biomass was calculated according to the following formula:

```
(live weight \times number slaughtered) + (census population \times sow weight \times 0.09)
```

Whereby,

live weight \times number slaughtered represents the expected biomass of fattening pigs slaughtered in a country in one year,

And $census\ population \times sow\ weight \times 0.09$ represents the expected biomass of pigs retained for breeding purposes, calculated with the following considerations:

- Sow weight: the standard weight of a sow in Europe is 240 kg [16]. This weight was adapted by region using livestock unit ratios (Americas = 240 kg, Asia, Far East and Oceania = 240 kg, Africa = 192 kg);
- o 0.09 is the expected percentage of sows in a given swine population, as calculated using Eurostat animal population data.

Poultry biomass was calculated according to the following formula:

```
(live weight chicken \times number of chicken slaughtered)
```

- + (live weight turkey × number of turkey slaughtered)
- + (live weight ducks \times number of ducks slaughtered)
- + (live weight geese × number of geese slaughtered)

Equidae biomass was calculated according to the following formula:

```
(live weight horse \times horse census population)
```

- + (live weight donkey \times donkey census population)
- + (live weight mules \times mule census population)

The live weight of horses, donkeys, and mules was calculated for sub-regions where equine slaughter is common and data were available. For sub-regions where equine slaughter is not practiced and/or where data were unavailable, regional average live weights were applied.

Sheep and goat biomass were calculated according to the following formula:

$$(live\ weight\ \times\ number\ slaughtered)\\ + \left(census\ population-\frac{number\ slaughtered}{1.5}\right)\times\ standard\ adult\ weight$$

Whereby,

(live weight \times number slaughtered) represents the expected biomass of sheep and goats slaughtered in a country in one year,

And $\left(census\ population - \frac{number\ slaughtered}{1.5}\right) \times standard\ adult\ weight\ represents the\ expected\ biomass\ of\ animals\ retained\ for\ breeding\ purposes,\ calculated\ with\ the\ following\ considerations:$

- 1.5 is the average number of breeding cycles per year;
- The standard weight of a breeding sheep in Europe is 75 kg [16]. This weight was used globally based on livestock unit ratios.
- The standard weight of breeding goats was adapted regionally according to bibliographical reviews [17].

Rabbit biomass was calculated according to the following formula:

(live weight
$$\times$$
 number slaughtered) + $\left(\text{census population} - \frac{\text{number slaughtered}}{5}\right) \times 4.5 \text{ kg}$

Whereby,

(live weight \times number slaughtered) represents the expected biomass of rabbits slaughtered in a country in one year,

And $\left(census\ population - \frac{number\ slaughtered}{5}\right) \times 4.5\ kg$ represents the expected biomass of animals retained for breeding purposes, calculated with the following considerations:

- o 5 is the average number of breeding cycles per year;
- o The standard weight of a breeding doe is 4.5 kg [18].

Camelid and cervid biomass were calculated according to the following formula:

 $standard\ weight\ imes\ census\ population$

According to the following considerations [19]:

- o Standard weight cervid: 80 kg
- Standard weight camel: 450 kg
- Standard weight llama/alpaca: 100 kg

Aquaculture biomass was only included in the total biomass for countries that included aquaculture in their reported data on intended antimicrobials use in animals. Aquaculture data are collected in OIE-WAHIS and FAO as tonnes of farmed aquatic food-producing animals produced annually.

The aquaculture biomass for aquatic food-producing animals is essentially composed of farmed fish but this annual report also includes data on farmed crustaceans, molluscs and amphibians.

Cats and dogs were not included in the calculation of animal biomass at this time due to inconsistency in reporting of their populations, and lack of information on average weights. For the countries where companion animal data were available, their contribution to overall animal biomass was found to be relatively minor (<1%). In the future, an analysis of companion animal data will hopefully become feasible.

Changes in the Methodology for the Calculation of Animal Biomass

The results for animal biomass from previous years analysis (2014, 2015 and 2016) shown in this report may differ from the results of published previous reports as they have been recalculated using the latest updated datasets to support comparison. More information on the impact of the updated animal biomass analysis is provided in Section 5 Updates of Historical Data.

2.3. Antimicrobial Quantities Adjusted for Animal Biomass

Quantitative data reported on antimicrobial agents intended for use in animals was adjusted for animal biomass according to the following calculation:

 $\frac{antimic robial\ agents\ reported\ (mg)}{animal\ biomass\ (kg)}$

For regional and global analyses, country data for both the numerator and denominator for each OIE Region, were summed before the rate was calculated.

3. Results of the Fifth Round of Data Collection

3.1. General Information

The OIE maintains Regional offices throughout the world covering Africa, the Americas, Asia, Far East and Oceania, Europe and the Middle East. The data collection template was sent to all OIE Members in all OIE Regions. In addition, it was sent to four non-contiguous territories and five non-OIE Members that asked to be part of the survey. (The list of all OIE Members is provided in Annex 9.)

In this fifth round of data collection, from September 2019 to May 2020, 160 countries submitted completed reports to OIE Headquarters: 156 from OIE Members (n = 182; 86%), one non-contiguous territory of an OIE Member and three non-OIE Members. The proportion of responses received from the different OIE Regions varied from 58% to 100% (Table 1). The responses from the non-contiguous territory and non-OIE Members were included in the analysis of the Americas for geographical reasons.

For simplicity when reporting results, this section refers to the 156 OIE Member, one non-contiguous territory and three non-OIE Members as the 160 countries that responded to the questionnaire during the fifth round of data collection.

For specific information on the OIE Regions, refer to the Annex for each region (Annexes 1-5).

Table 1. Number of Countries that Responded to the OIE Survey in the Fifth Round of Data Collection, by OIE Region

OIE Region	Number of Countries that Submitted Reports by OIE Region	Number of OIE Members*	Proportion of response (%)
Africa	39	54	72%
Americas**			
OIE Members	29	31	100%
Non-contiguous territories	1	n/a	n/a
Non-OIE Members	3	n/a	n/a
Asia, Far East and Oceania	31	32	97%
Europe	48	53	91%
Middle East	7	12	58%

^{*} Distribution of countries by OIE Region is in accordance with the OIE Note de Service 2010/22 (Annex 9).

^{**} Due to geographical distribution, non-contiguous territories were included in the Americas.

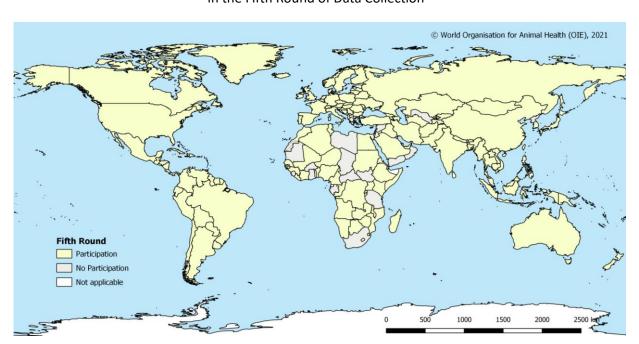


Figure 1. Geographical Distribution of OIE Members that Responded to the OIE Survey in the Fifth Round of Data Collection

Profile of the Contact Person

Each Member designates a Delegate to the OIE, and this person most commonly selected usually leads the country's official Veterinary Services. At the 76th General Session, held in May 2008, the World Assembly of Delegates to the OIE determined that OIE Delegates should also nominate National Focal Points to assist them in their work on specific topics. Of these, the designated National Focal Points for Veterinary Products are responsible for any information relating to veterinary medical products in the country. Since 2008, the OIE has been training and supporting the Focal Points for Veterinary Products through regional or sub-regional seminars.

For the fifth round of antimicrobial use data collection, the OIE template was most frequently completed by the Member's National Focal Point for Veterinary Products (98 out of 156 Members). The OIE recognises the efforts of National Focal Points for Veterinary Products, as in most countries, the National Focal Point for Veterinary Products was responsible for the completion of the OIE template (Figure 2). However, in Europe the Focal Points were less often responsible for responding to the survey, with another national Competent Authority supplying the data. This result may be linked to differing levels of progress in the development of data collection systems, where a specific institution may already be mandated to undertake this responsibility (Figure 3).

Figure 2. Contact Person Profile of 156 Members that Submitted an OIE Report in 2019

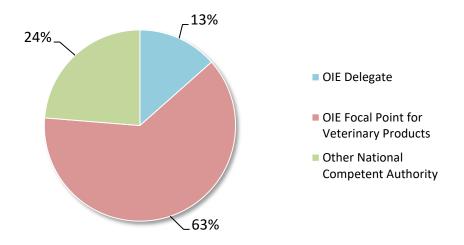
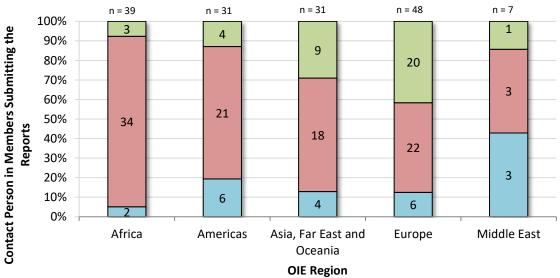


Figure 3. Regional Proportion of Contact Persons of 156 Members that Submitted a Response to the OIE Survey in the Fifth Round of Data Collection



□ OIE Delegate □ OIE Focal Point for Veterinary Products □ Other National Competent Authority

3.2. Reporting Options

The OIE template was designed to allow all countries to participate in the annual data collection even if the quantitative data on antimicrobial agents intended for use in animals were not nationally available. Even if no quantitative data collection system existed in the country, the template section titled 'Baseline Information' can still be completed. This section contains three parts (A, B and C), as described in Table 2.

Quantitative data collection (Part C) is further broken down into three sections: 'Reporting Options' 1, 2 and 3, where the actual quantities of antimicrobial agents for use in animals are reported with increasing specificity.

Table 2. OIE Template Sections and How Countries Respond Based on Available Data

	Countries <u>not</u> able to provide antimicrobial quantities	Countries able to provide antimicrobial quantities		
OIE Template Sections		By antimicrobial class only	By antimicrobial class and animal groups	By antimicrobial class, animal groups and route of administration
Baseline Information				
Part A. Contact Person for Antimicrobial Agents Use Data Collection	✓	✓	✓	✓
Part B. General Information	✓	✓	✓	✓
Part C. Data Collection on the Use of Antimicrobial Agents in Animals		✓	✓	✓
Reporting Option 1		✓		
Reporting Option 2			✓	
Reporting Option 3				✓

To see the full OIE template for data collection, see Annex 6.

Corrections Made to Data Reported in the Previous Rounds of Data Collection

Data from previous rounds have been updated based on new information and corrections reported by the Members in the fifth round, and therefore may differ from the results of the previous reports.

Some countries, where critical errors in the data were identified, were retrospectively removed from previous rounds. As a result, the antimicrobial quantities of some countries have been removed, but their responses related to growth promoters and barriers to the collection of data were retained. The OIE supports these countries in identifying possible data points and provides tools to calculate the amounts of active ingredients of antimicrobial veterinary products.

Results of the Fifth Round

In the fifth round of data collection, Baseline Information (parts A and B) were completed by 160 countries (156 Members, one non-contiguous territory and three non-OIE Members). Of these, seven countries submitted data for the first time, and 13 countries, that missed the fourth-round reporting, renewed their participation in this fifth round. One hundred and four countries have achieved consistent participation since the launch of the first round in 2015.

The ability of a country to provide quantitative information reflects its capacity to collect detailed data on antimicrobial agents intended for use in animals. For the first round of data collection, 86 OIE Members reported quantities of antimicrobial agents intended for use in animals (n = 130; 66%). In this fifth round, 133 countries (n = 160; 83%) reported quantitative data, demonstrating growing commitment to the development of monitoring systems for veterinary antimicrobial agents (Figure 4).

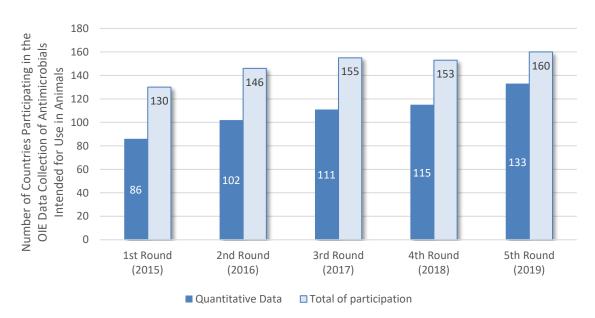
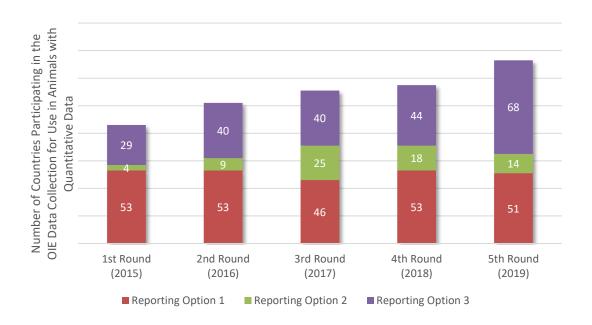


Figure 4. Number of Countries Participating in All Rounds of the Data Collection

Reporting Option 3 allows countries to distinguish antimicrobial quantities by type of use and route of administration (distinguishing by group of animals is optional) and this option was the one chosen most frequently by respondents (68 out of 133 countries). The fifth round was the first time that this highest level reporting option became the predominant one, facilitated through an Excel Calculation Tool that the OIE developed and presented to the following OIE Regions: Africa; the Americas; and Asia, Far East and Oceania regions. Twenty-five percent of the countries providing antimicrobial quantities during the fifth round used the OIE Tool. Reporting Option 1 allows countries to distinguish antimicrobial quantities by antimicrobial class and provides with the possibility of separating by type of use (veterinary medical use or growth promotion [8]) was chosen by 51 countries. Finally, Reporting Option 2 which allows countries to distinguish quantities of antimicrobial agents by type of use and animal group (food-producing terrestrial and aquatic species and companion animals) was chosen by 14 countries. (Figure 5).

When differentiated by OIE Region, more Members from Europe provided quantitative data (98%) than other OIE Regions. Most countries in the European Union already have a detailed system in place for data collection on antimicrobial agents intended for use in animals. These data are reported to the European Surveillance of Veterinary Antimicrobial Consumption (ESVAC) project that was launched by the European Medicines Agency a decade ago, in September 2009. (OIE Regional analysis can be found in Annexes 1-5.)

Figure 5. Number of Countries Participating with Quantitative Data (Reporting Options) in All Rounds of the Data Collection



3.3. Years of Quantitative Data Reported

Table 3. Breakdown of Country Response Types in the Fifth Round of Data Collection

Number of countries that <u>responded</u> to the OIE questionnaire	
Number of countries that <u>provided quantities</u> of antimicrobial agents	133
 Number of countries that provided quantitative data for <u>only one year</u> between 2017 and 2019 	125
 Number of countries that provided quantitative data for <u>more than one year</u> between 2017 and 2019 	8

Most countries providing antimicrobial quantities submitted data for only one year between 2017 and 2019 (125 out of 133 countries; 94%). Eight countries submitted quantitative data for more than one year within this timeframe. Given these multiple submissions, 144 responses were provided by 133 countries (Table 3) in the fifth round of data collection.

Fifty-four responses (n = 144; 36%) provided data for 2019 during the fifth round of data collection and 53 responses to the target year which was 2017 (Figure 6). These findings reinforce what was presented in previous OIE Reports that most Members outside European Union have only recently begun to collect this information and therefore only have access to current information rather than historical information (Figure 7).

Figure 6. Years of Quantitative Data Reported in the Fifth Round of Data Collection, from 144 Responses Provided by 133 Countries

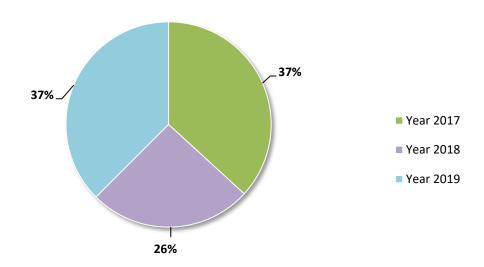
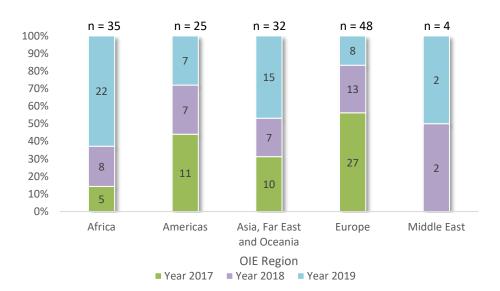


Figure 7. Years of Quantitative Data Reported in the Fifth Round of Data Collection, from 144 Responses Provided by 133 Countries by OIE Region



3.4. National Reports Available Online

In the OIE template, countries were asked if a national report on the antimicrobial agents used in animals was available online. In the fifth round of data collection, 95 countries (n = 133; 71%) did not publish online national reports, Europe is the only region where more than 50% of countries' national reports are available online (Figure 8).

The OIE encourages all Members to publish their own national reports on the sales or use of antimicrobial agents in animals, to ensure transparency and to assess trends.

The list of countries with public national reports for the antimicrobial agents intended for use in animals can be found in Section 11 of this report, along with the relevant links.

140 133 Number of Countries Reporting Antimicrobial 115 120 111 102 100 86 Quantities 80 60 38 38 37 37 40 32 20 0 1st Round 2nd Round 3rd Round 4th Round 5th Round (2015)(2016)(2017)(2018)(2019)**OIE Rounds** ■ Total of countries providing antimicrobial quantities National reports available online European National Reports available online

Figure 8. Number of Countries Participating in All Rounds of the OIE Data Collection with National Reports Available online

3.5. Country Barriers to Providing Quantities of Antimicrobial Agents in Animals

In the fifth round, 35 countries that had previously reported barriers during the fourth round were observed to have made progress. Fourteen of these countries progressed from reporting Baseline Information to reporting antimicrobial quantities. Of these 14 countries, seven had previously indicated that a lack of IT tools impeded their progress to report antimicrobial quantities. During the fifth round, all seven countries used the OIE Calculation Tool to report their quantities mainly using Reporting Option 3.

Of the countries responding to the fifth round, 27 (n = 160; 17%) provided only Baseline Information with no antimicrobial quantities. Of these, 23 countries (n = 27; 85%) outlined their barriers to reporting antimicrobial quantities. The barriers have been grouped into five categories (Figure 9). Countries tended to report one main barrier, but five countries reported two. The relative importance of these categories may change when analysing the results on a regional level (Annexes 1-5).

For a description of the barrier grouping categories, see the following explanatory section for each category.

12 Number of Countries Reporting Barriers to 10 10 10 Submitting Quantitative Data 8 6 5 4 2 2 1 0 Lack of regulatory Lack of Lack of IT tools, funds and Insufficient regulatory Circumstances that prevent framework coordination/cooperation human resources monitoring antimicrobial enforcement between national agents authorities and with the

Figure 9. Country Barriers to Reporting Quantitative Data on Antimicrobial Agents Intended for Use in Animals in 23 Countries during the Fifth Round of Data Collection

Lack of regulatory framework

Seven countries indicated regulatory framework limitations or absence for the manufacture, registration, distribution, commercialisation and pharmacovigilance of veterinary products. One of these countries reported that actions were being taken to address the absence of legislation and that the country was working to provide data. Another country mentioned that no regulatory framework existed for its animal sector, including veterinary medicinal products.

Barrier Categories

Three countries' legislation did not provide a legal basis for collecting data on antimicrobial agents intended for use in animals or indicated that a mechanism for data collection did not exist.

Lack of coordination/cooperation between national authorities and with the private sector

Within this category, four countries reported that the relevant data were held by a national authority outside of the Veterinary Authority. For these countries, the OIE requested further information on which agencies were involved in the data collection. Two countries indicated the quantities of antimicrobial agents intended for use in animals were under the legal authority of the Ministry of Health explaining that the Ministry of Health had the legal competency for the authorisation and importation of veterinary medicinal products, while the Veterinary Authority was in charge of their responsible use.

One country reported a lack of collaboration or coordination with relevant stakeholders, such as the pharmaceutical companies and veterinarians.

Lack of IT tools, funds and human resources

Eight countries described their main problem in data collection to be that records (mainly imports of veterinary products and the information related to their authorisation) were not yet digitised. For these countries, the time burden would be too great to calculate the amounts of active ingredients for veterinary products. In five of these countries, the import customs system does not record the package size/presentation of the veterinary products, but does record the weight of the shipment (in tonnes or kilograms); this created confusion in these countries as they were intending to report the shipment

weights to the OIE rather than the calculated weights of active ingredients. The OIE shared the OIE Calculation Tool with them and expects that they will contribute with data in the future rounds.

The absence of funds to address the resources needed to engage in AMU data collection was raised by one country. This country also fell under the classification of a lack of regulatory framework.

Two countries were unable to report antimicrobial quantities due to lack a of dedicated staff within the Veterinary Authority for the collection and analysis of the data. It was noted that other technical staff were potentially available to assist the OIE Focal Point for Veterinary Products for this task; however, in one country, the list of approved veterinary products was extensive and needed to be cross-checked with import permits available in hard copy only. The OIE assisted in transferring the list of approved veterinary products to the OIE Calculation Tool and it is expected that the country will report data in the sixth round.

Insufficient regulatory enforcement

One country considered the situation of illegal veterinary products on the market to be an impediment to the collection of antimicrobial quantities intended for use in animals. The country also mentioned its lack of a regulatory framework.

Circumstances that prevent monitoring antimicrobial agents

One country reported insecurity and economic crisis as the main reasons that prevented it from reporting antimicrobial quantities in animals. Another country that cited a lack of technical capacity also reported that COVID-19 had worsened its situation.

Summary on barriers

Most respondents who communicated barriers to the OIE, faced compliance and structural barriers with the application of OIE Standards and weak enforcement of regulatory frameworks for veterinary products. The development of a robust regulatory framework for importation, manufacture, registration, distribution, commercialisation and use of veterinary products — and the capability for effective enforcement — within these countries should be prioritised to facilitate the monitoring of the use of antimicrobial agents in animals. The work of the OIE through the PVS Pathway provides essential support in helping countries to identify their policy, regulatory and resourcing gaps. The Antimicrobial Use Team compared the responses from the countries with available mission reports (18 reports available for 23 countries) from the OIE PVS Pathway ⁸. In most of the cases, the mission reports had identified the same country barriers for legislation that were reported to the Antimicrobial Use Team.

Chronologically in the OIE PVS Pathway Cycle (https://www.oie.int/fr/solidarite/processus-pvs/), following a PVS Evaluation, countries can request different kinds of options, including a PVS Gap Analysis, and/or a Veterinary Legislation Identification mission:

The 'initial' PVS Evaluation mission provides a careful evaluation of the current performance of the national Veterinary Services, and the capacity to undertake ongoing monitoring of performance over time using consistent methods. After some years, countries may request a PVS Evaluation Follow-Up mission, which serves to update the assessment and progress made by countries.

⁻ The PVS Gap Analysis supports countries by providing detailed planning based on their PVS Evaluation results, i.e. by determining their priority goals, as well as the strategies, activities and investments required to achieve these objectives (https://www.oie.int/en/solidarity/pvs-pathway/planning-gap-analysis/).

⁻ The Veterinary Legislation Identification Mission aims to obtain a detailed picture of the current state of a country's national veterinary legislation and to identify gaps and weakness in that legislation. If the experts involved in this mission find that the country has sufficient political will and the human and financial resources to successfully undertake it, the mission can be followed by a Veterinary Legislation Agreement, aimed at supporting the country in correcting its deficiencies in veterinary legislation (https://www.oie.int/en/solidarity/options-for-targeted-support/veterinary-legislation-support/).

A significant barrier was the lack of IT tools that facilitate the collection and analysis of data. In some countries the records (mainly on imports of veterinary products and information related to their authorisation) did not have all the necessary information to calculate the amounts of active ingredients. During the fifth round, the OIE delivered workshops related to AMU data collection in Africa; the Americas; and Asia, Far East and Oceania. The OIE Calculation Tool was presented and assisted countries in these regions in reporting antimicrobial quantities for the first time. It is expected that the tool will continue to overcome the IT tools barrier. Also, this future software will assist participating countries in guiding them through the OIE questionnaire and in performing the calculations to obtain the amounts of active ingredients.

Finally, it is interesting to highlight that several barriers to providing quantities of antimicrobial agents in animals are similar to the weaknesses identified in a cross-analysis of legislation for AMR and veterinary products, conducted in 2018 by the OIE on all existing OIE Veterinary Legislation Identification Mission reports i.e. an incomplete legal framework, weaknesses related to the Competent Authority/Authorities, and inadequate resources to ensure compliance and enforcement. In addition, the OIE highlighted the need for coordination amongst the different national authorities that are part of the monitoring of antimicrobial agents.

3.6. Antimicrobial Agents Used for Growth Promotion

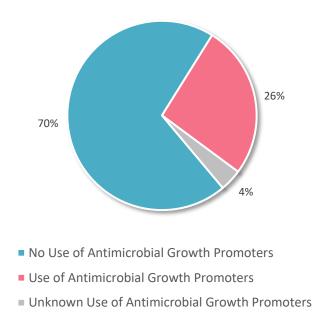
During the 2016 OIE General Session, OIE Members adopted Resolution No. 36, 'Combating Antimicrobial Resistance through a One Health Approach: Actions and OIE Strategy' agreeing to the recommendation that:

'OIE Member Countries fulfil their commitment under the Global Action Plan to implement policies on the use of antimicrobials in terrestrial and aquatic animals, respecting OIE intergovernmental standards and guidelines on the use of critically important antimicrobial agents, and the phasing out of the use of antibiotics for growth promotion in the absence of risk analysis'. [3]

The Baseline Information section of the OIE template includes a question for countries to report any antimicrobial agent authorised or used in animals as growth promoters. Ionophores were excluded from reporting as they are mostly used for parasite control and have different regulatory classifications in different countries; however, 17 countries reported the use of these molecules as growth promoters; and salinomycin and monensin (two specific ionophores) were mentioned by 13 and 11 countries, respectively. According to the WHO list of critically important antimicrobials, ionophores are currently not used in humans.

In this fifth round of data collection, a total of 112 (n = 160; 70%) responding countries did not use any antimicrobial agents for growth promotion in animals, either with or without legislation or regulations. Forty-two countries (n = 160; 26%) reported use of antimicrobials for growth promotion. The six remaining countries indicated that they were unsure if antibiotics were being used in the field or not, four countries did not have legislation related to growth promoters and two countries explained that they had a regulatory framework partially or completely banning this type of use.





During the second round of data collection, where a country's response to the question on the authorisation of antimicrobials as growth promoters had changed from the previous year without explanation, further clarification was requested. This follow-up indicated that the question as phrased in the OIE questionnaire was being interpreted differently by different responding countries, and from year to year. To improve understanding, from the third round of data collection, this question was reworded to obtain clearer results on both legislation and the use of antimicrobial agents as growth promoters.

From 2017 to 2019, among the 129 countries that have systematically provided data to OIE, the number of countries using antimicrobial growth promoters has decrease by 14%. This demonstrates a commitment to the Global Action Plan on AMR through the phasing out of growth promoters.

When differentiated by OIE Region, the Americas and Asia, Far East and Oceania have the highest proportions of countries using antimicrobial growth promoters (Figure 11). Europe has been working on this issue for many years and this is reflected in the responses provided, with Europe being one of the regions with the lowest percentage of use and authorisation of antimicrobial growth promoters.

n = 39n = 7n = 35n = 31n = 4850 Number of Countries Responding on the Use of Antimicrobial Agents as Growth Promoters in 45 40 35 30 14 45 25 30 Animals 17 20 15 20 10 12 5 8 Asia, Far East and Africa Middle East **Americas** Europe Oceania **OIE Region** ■ Unknown Use of Antimicrobial Growth Promoters ■ Use of Antimicrobial Growth Promoters No Use of Antimicrobial Growth Promoters

Figure 11. Number of Countries Using Antimicrobial Agents for Growth Promotion in Animals in 2019, of 160 Responding Countries, by OIE Region

Regulatory framework for antimicrobial agents used as growth promoters

In the OIE template and guidance sent for the fifth round, all countries, regardless of their response to the question relating to the use or otherwise of antimicrobial growth promoters, were asked to respond to the following question: Does your country have legislation/regulations on the use of antimicrobial growth promoters in animals?

All 96 countries that answered 'Yes' to this question were then asked to indicate which type of legislation/regulations existed in the country. In most of the cases, when legislation/regulations exist in a country, the regulatory framework bans the use of antimicrobials as growth promoters (Figure 12).

As presented in Figure 12, 38 countries stated no use of antimicrobials as growth promoters even though no regulatory framework exists. In some cases (n = 3), the countries stated that these molecules were banned without a regulatory framework; therefore, the OIE asked these countries to provide further information on how antimicrobial growth promoters were banned in the absence of legislation or regulations. The following situations were mentioned:

- The country's legislation is being amended to ban growth promoters. Meanwhile, the following
 approaches are being taken to guarantee that these products are not available on the market:
 to not allow their import; to monitor the manufacturing companies to ensure that they only
 produce antibiotics for veterinary medical use and; to not allow their registration.
- Awareness campaigns were created to target poultry farmers.

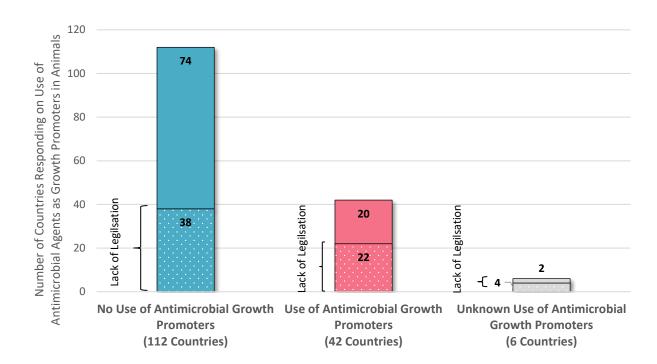


Figure 12. Use of Antimicrobial Growth Promoters by Legislation, in 160 Countries in 2019

Half of the countries reporting the use of antimicrobials as growth promoters do not have a regulatory framework (22 out of 42 countries; 52%).

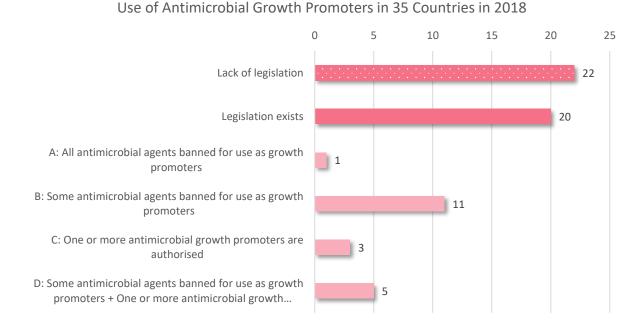
For those 20 countries using antimicrobials as growth promoters within a regulatory framework (n = 20; 48%), the legislation either provides a list of molecules that should not be used as growth promoters (n = 11) or provides a list of antimicrobials that can be used as growth promoters (n = 3), while in other cases, both types of lists have been established (n = 6). It was found that one country with legislation that bans growth promoters reported the use of these molecules in the field (Figure 13), indicating that enforcement of the legislation is needed with feed manufacturers continuing to illegally produce these types of products.

Among the 20 countries using growth promoters within a regulatory framework, some stated that they had partially or completely banned all growth promoters for certain animals.

For those 22 countries using growth promoters without a regulatory framework, most were located in the Americas (12 out of 20; 60%); followed by Africa (6 out of 8; 75%) and Asia, Far East and Oceania (3 out of 12; 25%). In the Americas, two of these eleven countries mentioned their cooperative work with pharmaceutical companies for the voluntary removal of growth promotion claims from the labels of all products that are considered to be Medically Important Antimicrobials in human medicine. Both countries mentioned their success in this collaborative approach with the private sector. Based on these results, and compared to the previous round of data collection, the situation in the Americas and Asia, Far East and Oceania is improving in relation to countries' regulatory frameworks on antimicrobial growth promoters.

For specific information on the OIE Regions, refer to the Annex for each region (Annexes 1-5).

Figure 13. Type of Legislation for Growth Promotion in 42 Countries that Reported the Use of Growth Promoters in 2019



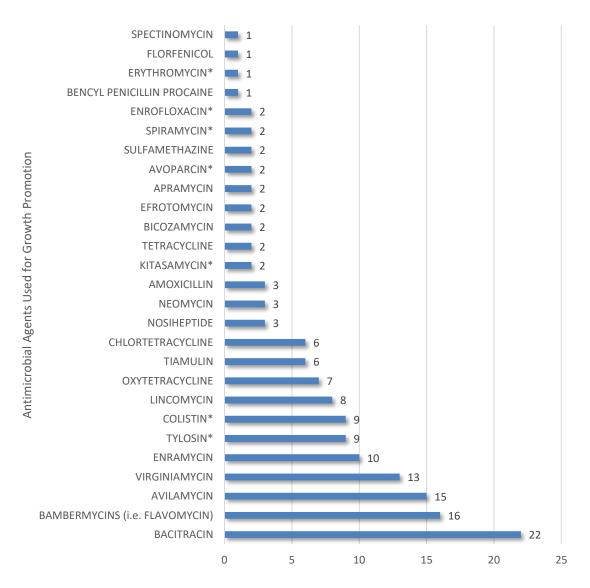
List of antimicrobial agents used for growth promotion

The 42 countries reporting use of antimicrobial agents for growth promotion were further asked for a list of antimicrobial agents (by active ingredient) either authorised as growth promoters or known to be used in cases where legislation on this issue did not exist.

Thirty countries (n = 42; 71%) responded with a list of antimicrobial agents used for growth promotion. The most frequently listed antimicrobial agent was bacitracin, followed by flavomycin and avilamycin, the latter two are currently not used in humans according to the WHO list of critically important antimicrobials. Bacitracin and avilamycin are categorised as a Veterinary Highly Important Antimicrobial Agent and a Veterinary Critically Important Antimicrobial Agent, respectively, according to the *OIE List of Antimicrobial Agents of Veterinary Importance*. Colistin was mentioned by nine countries (Figure 14). By the time this report was published, one country is expected to have banned tylosin for growth promotion.

Analyses at the regional level by antimicrobial class are presented in the annexes by OIE Region (Annexes 1-5).





Number of Countries Reporting Use of Antimicrobial Agents for Growth Promoters in 2019

Thirty-one countries using antimicrobial agents as growth promoters (n = 42; 74%) also provided quantitative data on antimicrobial agents intended for use in animals. Twelve of these countries (n = 31; 39%) could distinguish these quantities by use (i.e. for growth promotion or veterinary medical purposes). During the fifth round, it was found that those countries using the OIE Calculation Tool and using growth promoters, indicated the use of veterinary products for both veterinary medical use and growth promotion purposes; those products presented different doses according to the type of use. As countries are still reporting mainly sales and import data it would be difficult for them to distinguish the quantities by type of use for these products, unless data at the field level are collected.

^{*} The classes in the WHO category of Highest Priority Critically Important Antimicrobials should be the highest priority for countries when phasing out the use of antimicrobial agents as growth promoters.

4. 2017 Analysis of Antimicrobial Quantities

This section provides an analysis of globally reported quantitative data on antimicrobial agents intended for use in animals adjusted by animal biomass, focusing on 2017.

This analysis has been undertaken with the understanding that many countries contributing to the OIE database are in the first stages of development of their national monitoring systems on antimicrobial use in animals. Even for those countries able to provide quantitative information, some data resources may be currently inaccessible, and calculation errors, where present, are still being resolved. Simultaneously, data collection on animal populations is also progressing on the global level. It is expected that these first estimates will be refined over time, and therefore, should be interpreted with caution.

4.1. Antimicrobial Quantities

Regional Representation of Countries Included in the 2017 Analysis

The focus of this section is covering all 2017 data provided during any round of data collection; therefore, the results presented in this section differ from Section 3 that only presented the data provided during the fifth round.

For all rounds of data collection compiled, 103 countries provided validated antimicrobial quantities intended for use in animals for 2017. The regional distribution of countries included in the 2016 analysis is shown in Figure 15. Due to geographical considerations, quantitative data for 2017 of two non-Members and one non-contiguous territory were included in the Americas for the 2017 analysis.

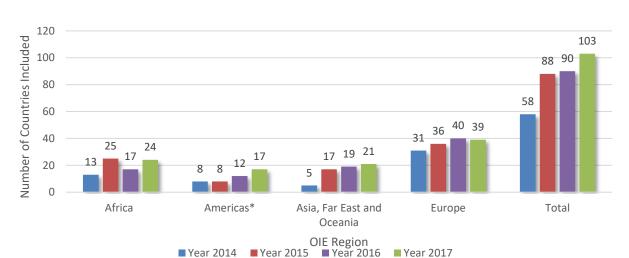


Figure 15. Number of Countries Included in the Antimicrobial Quantities Analysis by OIE Region, from 2014 to 2017

A lack of validated data from the Middle East did not allow for the inclusion of this OIE Region in the regional 2017 analysis, but the data submitted by this region's countries have been included in the global analysis. Future data submissions from this OIE Region may permit a 2017 analysis of antimicrobial quantities adjusted by animal biomass in subsequent reports.

^{*} For 2016 and 2017, a country provided quantities for companion animals only, therefore, this country will be excluded for the section related to animal biomass and the analysis of the mg/kg.

Period of Time Covered

Countries were asked to specify the period of the calendar year covered by their data (e.g., 1 January to 31 December).

For the 103 countries included in the 2017 analysis, one country from Asia, Far East and Oceania did not report the period of time covered so was excluded from this analysis. The average time period covered was 352 days for 102 countries; this information shows that most countries are providing quantitative data for most of a calendar year. Information by the OIE Regions is shown in Table 4.

Table 4. Reported Period of Time Covered by the Antimicrobial Quantities by OIE Region, 2017

OIE Region*	Number of Countries	Mean (days)	Standard Deviation (days)	Maximum (days)	Minimum (days)
Africa	24	351	24	360	270
Americas	17	347	17	360	269
Asia, Far East and Oceania	20	360	13	389	327
Europe	39	353	18	360	86
Global	102	352	20	389	86

^{*}Due to confidentiality issues, the regional data for Middle East were excluded.

Quantitative Data Sources Captured

The OIE template includes an exhaustive list of possible quantitative data sources, in accordance with Chapter 6.9. of the *Terrestrial Code* (Monitoring of the quantities and usage patterns of antimicrobial agents used in food-producing animals) and with Chapter 6.3. of the *Aquatic Code* (Monitoring of the quantities and usage patterns of antimicrobial agents used in aquatic animals). Multiple choices were possible in responding to this question, including the option 'other'.

All countries' data sources were analysed, and all countries where the data duplication was considered to be a risk were then asked to provide clarification on their answers and/or data collection systems. Thirty-four countries' data sources were considered to present a risk of duplication (n = 103; 33%). Following these clarifications, 21 countries (n = 34; 62%) either changed their answers or demonstrated that there was no risk of duplication or overlapping data sources. The remaining countries (13 out of 34; 38%) that did not respond with clarification were excluded from the analysis in Figure 16.

In the Guidance for Completing the OIE Template for the Collection of Data (Annex 7), countries were asked to provide data as close to the point of use (i.e. administration) as possible. However, among the 90 countries that reported validated quantitative data, 'Antimicrobial use data – Farm records' – the category representing on-farm administration of antimicrobials – was only selected as a data source by one country that accompanied those quantities with sales data (Figure 16). All other data sources represent use through what was sold, imported or manufactured for intended administration to animals.

Sources of quantitative data were most commonly sales data, particularly from wholesalers and Marketing Authorisation Holders, which were selected by 25 and 22 countries, respectively. Following sales data, import data as declared by customs authorities was the next most common source of reported quantities of antimicrobial agents intended for use in animals.

For a full explanation of quantitative data sources, see the Guidance for Completing the OIE Template for the Collection of Data (Annex 7).

Number of Countries Reporting Source of Antimicrobial Quantities 10 15 20 Wholesalers 25 Retailers Sales Data Marketing Authorisation Holders 22 **Registration Authorities** Feed Mills **Pharmacies** Farm shops/Agricultural suppliers Industry trade associations Data Sources Puchase Data - Wholesalers Purchase Data Retailers Feed Mills **Pharmacies Agricultural Cooperatives Producer Organisations** Veterinary Medicinal Products **Active Ingredients** 10 Prescription Sales Prescription Farm records Other 15

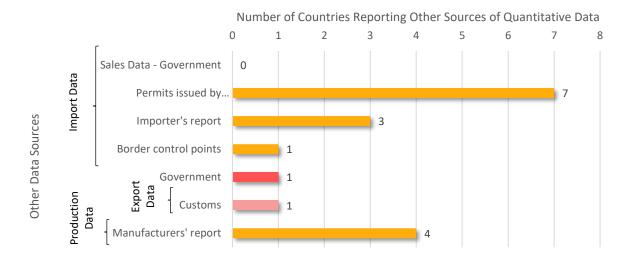
Figure 16. Validated Data Sources Selected by 90 Countries Reporting Quantitative Data in 2017

OTHER DATA SOURCES REPORTED

Fifteen countries (n = 103; 15%) reported 'other' sources of quantitative data from the provided options. When this response was selected, countries were asked to describe these other data sources. The responses were grouped by category.

Other sources of quantitative data most commonly reported were from other levels of import control outside of customs declarations, particularly from permits authorising the importation of antimicrobials as issued by registration authorities (Figure 17). In some countries where the importation of a product is not confirmed after issue of a permit, these quantities may not represent antimicrobial agents actually entering the country and used in the animal population.

Figure 17. 'Other' Source of Data Described by 15 Countries Reporting Quantitative Data in 2017



Data Coverage

In the OIE template for quantitative data collection (Annex 6), countries are asked to estimate the extent to which their data represented overall sales of antimicrobial agents intended for use in animals, as a percentage of the total estimated sales in their country. For example, a hypothetical country may report that the quantitative data reported covers only 80% of all estimated national sales of antimicrobial agents used in animals based on known sources of lacking data. All 90 countries that provided quantitative data with validated data responded to this question.

The global average for quantitative data coverage achieved was 88% (Table 5). This average quantitative data coverage shows that in a number of countries, surveillance systems do not capture the totality of antimicrobial agents intended for use in animals. However, this figure should be interpreted with caution, as data coverage estimations are made subjectively by each country. By definition, this question aims to identify quantitative data that is inaccessible, and therefore the responses can vary in accuracy.

Table 5. Reported Percentage of Antimicrobial Quantity Coverage by OIE Region, 2017

OIE Region	Number of Countries	Mean (%)	Median (%)	Standard Deviation (%)	Minimum (%)	Maximum (%)
Africa	20	82	90	23	30	100+20*
Americas	13	86	98	17	60	100
Asia, Far East and Oceania	18	89	97	14	54	100
Europe	38	93	100	19	10	100
Global	90	88	99	19	10	100+20*

^{*} Some countries export veterinary products to foreign countries. Therefore, to minimise the impact of these products that were not used at a national level; these countries estimated more than 100% coverage, with the understanding the quantities reported overestimate the national antimicrobial usage.

SOURCES NOT CAPTURED BY THE DATA

Of the 90 countries estimating the coverage of their data, 45 countries stated to cover 100% of the data source used to report the data. The 45 countries that did not cover 100% of available quantitative data were asked to provide further information on uncaptured data sources.

Forty-one countries (n = 45; 91%) responded with an explanation on uncaptured data sources. Responses were grouped by category. All countries' uncaptured data sources were analysed and, if needed, further questions were asked on their data collection systems. After the analysis, the uncaptured data sources were validated for 40 countries (n = 45; 89%). The remaining country was excluded from this analysis. Countries could have reported more than one uncaptured data source.

Most uncaptured data sources derive from sales data not provided, particularly those of industry stakeholders that did not respond to government requests for information. Lack of import data was also a significant contributor, reported by 22 countries.

Table 6 describes the quantitative data coverage lost due to a lack of access to data sources, as estimated by 40 countries. This question allows countries to self-report which type of data they were unable to access, and what percentage of total possible available data was estimated to be lost due to this inaccessibility. For countries naming an uncaptured data source, the mean, minimum and maximum reported estimates of related coverage lost are shown. The information in Table 6 highlights which data sources countries consider necessary in order to provide complete coverage. However, these categories may not be relevant in all countries.

Table 6. Estimation of Quantitative Data Not Captured Based on a Lack of Access to Sources, as Reported by 40 Countries in 2017

Sources Estimated Not Captured in Quantitative	Number of Countries	Estim	Estimated Data Coverage Lost		
Data	Naming Uncaptured Data Source	Mean	Minimum	Maximum	
Sales Data					
Partial response from relevant stakeholders	9	35%	13%	70%	
Antibiotics authorised for humans that are used in companion animals	5	7%	0.5%	20%	
Illegal or unofficial veterinary products	2	18%	10%	25%	
Certain food-producing animal species	1	1%	1%	1%	
Companion animals	1	40%	40%	40%	
Veterinary sales	1	15%	15%	15%	
Purchase Data					
Illegal or unofficial veterinary products	1	70%	70%	70%	
Import Data					
Illegal or unofficial veterinary products	8	22%	10%	40%	
Partial data, not from a whole calendar year	3	32%	5%	60%	
Partial data, not for all veterinary products	3	14%	1.5%	30%	
Data from the drug agency under the Ministry of Health	2	45%	45%	50%	
Partial response from relevant stakeholders	2	20%	10%	30%	
Veterinary Products with special licence*	1	20%	20%	20%	
Active ingredients used to manufacture veterinary products	1	30%	30%	30%	
Information lost while transferring data from the national IT system	1	10%	10%	10%	
Partial response from veterinarians	2	3.5%	2%	5%	
Production Data					
Manufacturer's report	1	30%	30%	30%	
Partial response from relevant stakeholders	1	30%	30%	30%	

^{*} For the purpose of this report, 'Veterinary products with special licence' means: veterinary products for self-supply, donation or with special permission from the government.

Antimicrobial Quantities Reported In 2017

Table 7 shows the total tonnage of antimicrobial agents intended for use in animals for 2017, as reported to the OIE during all rounds of data collection.

When the antimicrobial quantities reported adjusted for these coverage estimates (i.e. extrapolation to annual coverage from all data sources to account for partial temporal coverage or missing data sources), the quantities shown in Table 7 were obtained. *These coverage-adjusted figures should be interpreted with caution, as data coverage estimations are made subjectively by each country.* By definition, this question aims to identify quantitative data that is inaccessible, and therefore the responses can vary in accuracy. However, these coverage-adjusted quantities can be considered an upper-level estimate of antimicrobial use in animals.

In order to properly interpret tonnage of antimicrobials reported, the size and composition of each country's animal populations must be considered. For this reason, we refer the reader to Section 4.3, Antimicrobial Quantities Adjusted for Animal Biomass, to interpret differences in regional quantities of antimicrobial agents intended for use in animals.

These regional totals should not be considered representative of the total amounts of antimicrobials consumed in any OIE Region, or in any particular country.

Table 7. Reported Quantity of Antimicrobial Agents Intended for Use in Animals by OIE Region, 2017

OIE Region	Number of Countries Included in Analysis of 2017 Quantitative Data	Quantities Reported (in tonnes)	Quantities Reported Adjusted by Estimated Coverage* (in tonnes)
Africa	24	2,530	2,961
Americas	17	20,312	25,459
Asia, Far East and Oceania	21	55,279	57,191
Europe	39	7,200	7,466
Total	103	85,330	93,092

^{*} Estimated coverage: this refers to the subjective estimates countries made with respect to the extent to which their data represented overall sales of antimicrobial agents intended for use in animals. In this column, the figures were adjusted to represent 100% of the total estimated amount (as further explained in the <u>Data Coverage section</u>, page 41).

Among the 103 countries that provided quantitative data on antimicrobial agents intended for use in animals, tetracyclines were the most commonly reported antimicrobial class (Figure 18).

Aggregated class data 3.0% Others 1.8% Tetracyclines 33.9% Sulfonamides (including trimethoprim) 5.4% Streptogramins 0.1% Quinoxalines 1.1% Polypeptides 11.1% Pleuromutilins 2.8% Penicillins 10.9% **Antimicrobial Classes** Other quinolones 0.5% Orthosomycins 0.1% **Nitrofurans** 0.0% Macrolides 10.4% Lincosamides 1.9% Glycophospholipids 3.3% Glycopeptides 0.0% Fluoroquinolones 3.0% 3-4 gen cephalosporins 0.9% 1-2 gen. cephalosporins 0.1% Cephalosporins (all generations) 1.2% Arsenicals 0.3% **Amphenicols** 4.8% Aminoglycosides 4.4%

Figure 18. Proportion of Antimicrobial Classes Reported for Use in Animals by 103 Countries in 2017

% of Reported Quantities of Antimicrobial Agents Used in Animals by 103 countries

15.0% 20.0% 25.0%

30.0%

HIGH USE OF ANTIMICROBIAL CLASSES

For 2017 data, it was noticed that six countries (n = 103; 6%) allocated more than 70% of their total amount of antimicrobials intended for use in animals to one antimicrobial class (Table 8). Five of these countries (n = 6; 83%) were from Africa.

0.0%

5.0%

10.0%

Countries reporting more than 70% of their amounts for one antimicrobial class were further asked to explain any known reason for the high levels of use for a single antimicrobial class. Three countries provided explanations, with two countries mentioning that tetracyclines were favoured among veterinarians because of a low financial cost. A country with high levels of other quinolones, explained that it was mainly attributed to the large use through oral administration in poultry.

Table 8. Antimicrobial Classes with More than 70% of the Total Amount of Antimicrobials Intended for Use in Animals, by Six Countries in 2017

Antimicrobial Class	Number of Countries with High Levels of Use in a Specific Antimicrobial Class	Antimicrobial Quantities Allocated in the Antimicrobial Class (Tonnes)	Use of the Antimicrobial Class Compared to the Total Amount Reported (% - Mean)
Penicillins	2	33	87.6%
Tetracyclines	3	312	89.7%
Other quinolones	1	293	85.3%

Food-Producing Target Species on the Label of Reported Veterinary Products

Irrespective of whether the data could be differentiated by animal groups, all 103 countries that provided quantitative data were asked to identify the food-producing animal species covered by their data, according to the products target species label, from a list supplied in the OIE template. One country that provided data only for companion animals was excluded from Figure 19. The breakdown of food-producing species included in the reporting countries data sets is shown in Figure 19.

For descriptive purposes, species from the list of options provided in the OIE template were grouped according to the following categories:

A. POULTRY

- a. Layers commercial production for eggs
- b. Broilers commercial productions for meat
- c. Other commercial poultry
- d. Poultry backyard

B. BOVINES

- a. Cattle
- b. Buffaloes (not Syncerus caffer)

C. PIGS

- a. Pigs commercial
- b. Pigs backyard

D. SHEEP AND GOATS

- a. Sheep
- b. Goats
- c. Sheep and goats (mixed flocks)

E. AQUACULTURE

- a. Fish aquaculture production
- b. Crustaceans aquaculture production
- c. Mollusc aquaculture production
- d. Amphibians

In 2017, poultry was mentioned by the 102 countries reporting quantitative data for food-producing species. Bovines, sheep and goats, and pigs were also included by most countries (Figure 19).

120 Number of Countries that Reported Quantities of Antimicrobial Agents Intended for Use in Animals 102 100 98 100 89 80 69 65 59 60 38 40 28 28 20 5 0 Cervidae Karned) Reptiles le B. tocodiles RabbitHares Sheep and Boat's Aduaculture Eduidae other 6.182

Figure 19. Food-Producing Animal Species Included in Quantitative Data Reported by 102 Countries in 2017

Food-Producing Animal Species Covered

Quantitative Data Differentiation by Animal Group

For the purposes of the OIE survey, animal groups are separated into: 'Terrestrial food-producing animals', 'Aquatic food-producing animals' and 'Companion animals'. Multiple choices were possible in responding to this question.

For 2017, 49 countries (n = 103; 48%) provided data differentiated by animal group (Figure 20), this corresponds to the number of countries reporting their antimicrobial quantities through Reporting Options 2 and 3.

Figure 21 shows that more countries were able to report data distinguished by food-producing animals. Usually, countries used more than one animal group to report their antimicrobial quantities.

Most of the data came from sales and imports, and the attribution of antimicrobial quantities by animal group was based on the species types listed on product labels, where this was available and specified. For countries where product labels covered a wide variety of species, it would be more difficult to report quantitative data differentiated by animal group.

Figure 20. Differentiation by Animal Groups among 103 Countries Reporting Quantitative Data in 2017

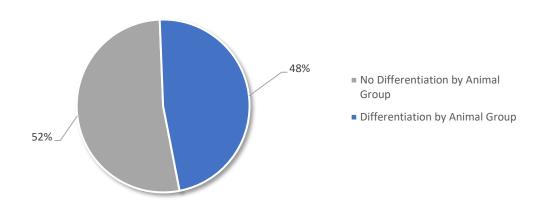
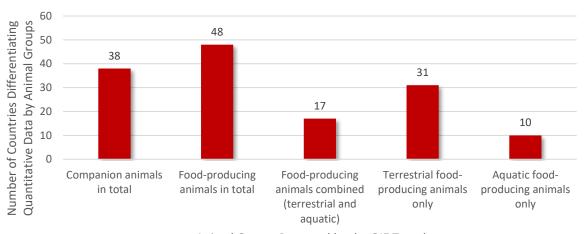


Figure 21. Representation of Quantitative Data from 49 Countries Able to Distinguish by Animal Group in 2017⁹



Animal Groups Proposed by the OIE Template

Fifty-four of those countries reporting quantitative data (n = 103; 52%) were not able to distinguish the amounts of antimicrobial agents by groups of animals. Of these, most (45 out of 54; 83%) reported antimicrobial quantities through Reporting Option 1, which allows reporting for all animal species, and distinguishes quantities only by purpose of use (veterinary medical use or growth promotion [8]). Nine of these countries (n = 54; 17%) used Reporting Option 3, which allows for distinction by type of use, animal groups and route of administration, but provided data only separated by type of use and/or

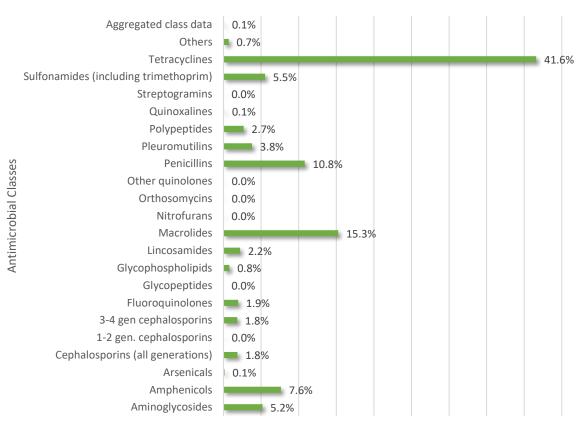
For OIE AMU Database purposes the animal groups proposed to allocate antimicrobial quantities for food-producing animals in Reporting Options 2 and 3 are: aquatic food-producing animals, terrestrial food-producing animals and food-producing animals combined (terrestrial and aquatic). Ideally, the group of food-producing animals combined should sum the quantities provided for the terrestrial and the aquatic food-producing animals; however, there were cases where countries were not able to distinguish between these two animal groups due to veterinary products being labelled for terrestrial and aquatic animals at the same time. As a result of this, the countries only used the group of food-producing animals combined to report quantities. The group of aquatic food-producing animals was only provided if quantities for terrestrial food-producing animals were also reported.

route of administration. This suggests that the labelling of veterinary products in these countries clearly separates out the route of administration but may cover a wide variety of species.

TERRESTRIAL FOOD-PRODUCING ANIMALS

Some countries reported quantities of antimicrobial agents differentiated by group of animals using Reporting Options 2 or 3. Among these countries, tetracyclines were the most commonly reported antimicrobial class used in terrestrial food-producing animals (Figure 22).

Figure 22. Proportion of Antimicrobial Classes by Terrestrial Food-producing Animals as Reported by 31 Countries in 2017



0.0% 5.0% 10.0% 15.0% 20.0% 25.0% 30.0% 35.0% 40.0% 45.0% % of Reported Quantities of Antimicrobial Agents Used in Terrestrial Food-producing Animals by 31 Countries

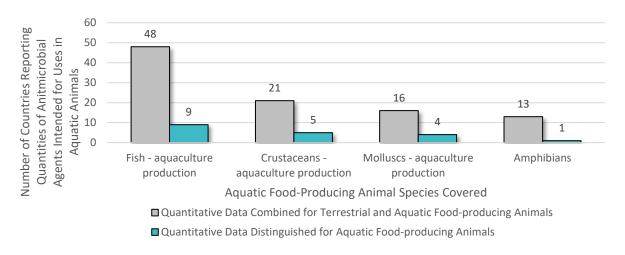
AQUATIC FOOD-PRODUCING ANIMALS

Of the 102 countries that provided quantitative data for food-producing animals in 2017, 59 countries stated that their labelled products also targeted aquatic food-producing animals (n= 102; 58%).

When aquatic food-producing animals were covered, in most cases, quantitative data for aquaculture represented farmed fish. Of the 59 countries that provided amounts of antimicrobial agents under the Aquatic food-producing animals group, 'Crustaceans — aquaculture production', 'Molluscs — aquaculture production' and 'Amphibians' were reported mainly when data for 'Fish — aquaculture production' were also available. Figure 23 highlights the animals included in aquaculture covered by countries reporting quantitative data for aquatic food-producing animals, separated by capacity to distinguish data for terrestrial and aquatic food-producing animals.

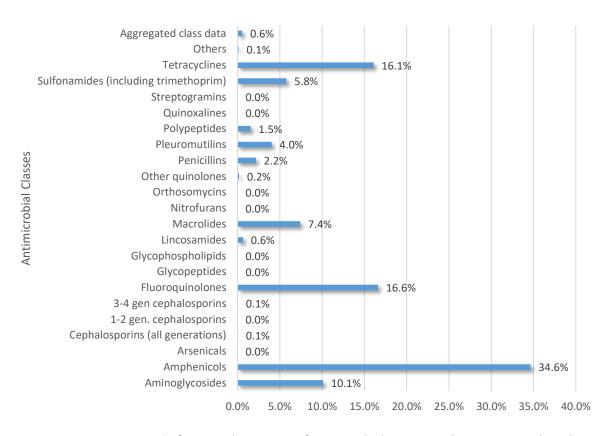
Of the 59 countries providing antimicrobial quantities that covered aquatic animals, ten countries were able to report quantitative data under the Aquatic food-producing animals group separately from other animal groups using mainly Reporting Option 3 (10 out of 59; 17%).

Figure 23. Animals included in Aquaculture covered in the Quantitative Data Reported by 59 Countries in 2017



Of the ten countries, amphenicals were most commonly reported (Figure 24).

Figure 24. Proportion of Antimicrobial Classes by Aquatic Food-producing Animals as Reported by Ten Countries in 2017

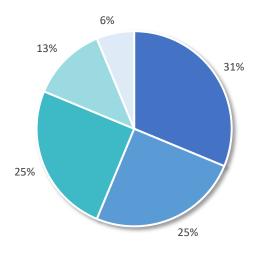


% of Reported Quantities of Antimicrobial Agents Used in Aquatic Food-producing Animals by 10 Countries During the fifth round of the data collection, the OIE Antimicrobial Use Team observed that 22 countries with aquaculture production communicated through OIE-WAHIS or the FAO Fisheries Division did not report antimicrobial quantities for aquatic animals to the OIE (22 out of the 44 countries that did not include aquaculture; 50%). Consequently, some of these countries were asked to clarify if antibiotics were not used in the country's aquaculture sector.

Of the 22 countries, 14 explained that the aquatic production was reported to be insignificant compared to the terrestrial food-producing animals and most often for rudimentary subsistence level. Four countries explained that their lists of authorised products for animals did not report any product for aquaculture; however, in some cases, it was said that the use of antimicrobials at field level may occur. Four other countries explained that another agency rather than the Veterinary Authority controls products for aquaculture, or that aquatic animal producers did not collaborate with the Veterinary Authority (Figure 25).

The OIE will continue to work to understand the barriers that impede countries' data collection provision for aquatic food-producing animals.

Figure 25. Explanations Provided by 14 Countries for not Covering Aquaculture in their Antimicrobial Quantities' Reports in 2017



n = 14

- Insignificant aquaculture production or use of antimicrobials
- Absence of authorised antimicrobial products for aquaculture
- Lack of coordination/cooperation between national authorities and with the private sector
- Antimicrobials banned for aquaculture
- Antimicrobials are used in aquatic animals not intended for consumption

COMPANION ANIMALS

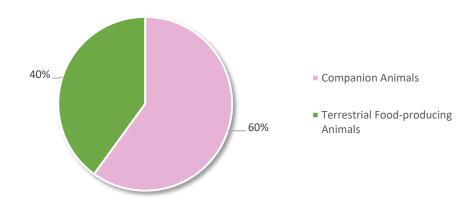
In the first year of the OIE AMU data collection, Members were asked to provide antimicrobial quantities for food-producing animals only. However, some countries additionally reported their data for companion animals. In response to this, the OIE modified its questionnaire to include this group. Since the fourth round of data collection, Members were asked to specify the animals considered companions.

Of the 103 countries which provided quantitative data in 2017, 92 stated that product labels targeted companion animals (n= 103; 89%). Of these 92 countries, 61 provided an answer related to the animals under this group. These 61 countries considered canines and felines as companion animals; of these, 23 countries declared additional species; the most cited being ornamental birds and rabbits (8 countries) followed by equines (7 countries).

The countries reporting equines as companion animals, also reported them as food-producing animals, therefore the OIE further asked where equine's antimicrobial quantities were allocated. Most of the countries reported the equine quantities under companion animals (Figure 26).

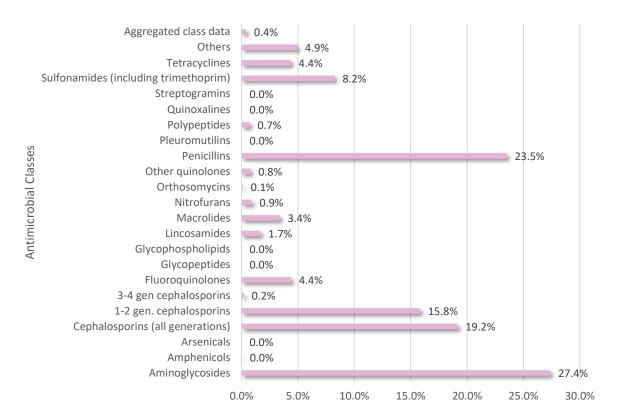
As previously mentioned, countries provided mostly sales and import data, and when differentiating these quantities by animal group, they did so based on the target species declared on the product label. Usually, the horses were grouped together with other major food-producing species, even if they were not destined for human consumption.

Figure 26. Differentiation of Equine Data by Animal Groups among Five Countries Reporting Quantitative Data in 2017



Thirty-eight countries reported quantities of antimicrobial agents differentiated by the group of companion animals using Reporting Options 2 or 3. Among these countries, aminoglycosides were more commonly reported for companion animals (Figure 27).

Figure 27. Proportion of Antimicrobial Classes in Companion Animals as Reported by 38 Countries in 2017



% of Reported Quantities of Antimicrobial Agents Used in Companion Animals by 38 Countries

Routes of administration

For 2017, 40 countries chose to report their quantitative data through Reporting Option 3, the only option which allows for disaggregation of data by route of administration. Among these 40 countries, the majority reported higher amounts of antimicrobial agents used via the oral route, especially for tetracyclines (Figure 28). For the injection route (parenteral route) and other routes, penicillin was more often reported (Figure 29 and 30).

Reporting Option 3 allows for distinction of the data by type of use (veterinary medical use vs growth promotion [8]) and by animal group in addition to route of administration. However, nine countries (n = 40; 22%) using this option distinguished data only by type of use and route of administration, indicating that they were not able to identify which animal groups the agents were being used in. Of the 31 countries (n = 40; 78%) able to distinguish quantitative data by animal group using Reporting Option 3, oral administration was most commonly reported for use in all animal groups.

Figure 28. Proportion of Antimicrobial Quantities (by Antimicrobial Class) Reported for Use in Animals by the Oral Route, Aggregated by 40 Countries in 2017

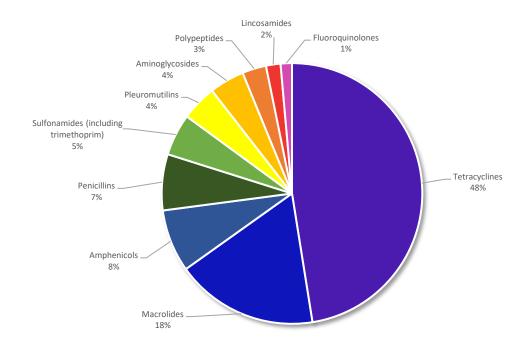
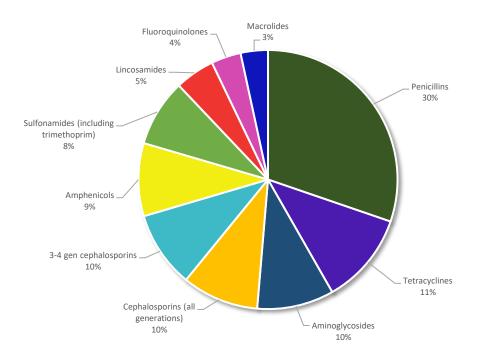


Figure 29. Proportion of Antimicrobial Quantities (by Antimicrobial Class) Reported for Use in Animals by the Injection Route, Aggregated by 40 Countries in 2017



Macrolides Others 3-4 gen cephalosporins Pleuromutilins _ 1% Nitrofurans Amphenicols 2% Sulfonamides (including trimethoprim) 3% Aminoglycoside 4% 1-2 gen. cephalosporins Penicillins 5% 42% Lincosamides 6% Cephalosporins (all generations) Tetracyclines

Figure 30. Proportion of Antimicrobial Quantities (by Antimicrobial Class) Reported for Use in Animals by Other Routes, Aggregated by 40 Countries in 2017

4.2. Animal Biomass

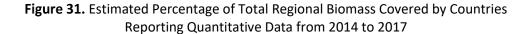
As described in the methodology, animal biomass was calculated for 102 countries providing quantitative data for 2017 during all rounds of data collection. One country that provided data for companion animals only was excluded from the analysis. Aquaculture was included in the biomass for countries reporting that their data covered aquaculture, or could not be distinguished by animal group (n = 63; 62%).

The following figures represent only those countries participating in reporting of quantitative data on antimicrobial agents intended for use in animals and should not be considered representative of global animal populations or biomass, or for any particular OIE Region.

Animal Population Covered by 2017 Data

Figure 31 shows the estimated percentage of the total regional animal biomass covered by the 102 countries included in the analysis of antimicrobial quantities for 2017, compared to the coverage achieved in the 2014, 2015 and 2016 analysis. These estimates were made by calculating the ratio of FAOSTAT meat production figures for the reporting countries relative to the regional total. *It must be highlighted that these estimates were not calculated according to the animal biomass methodology and are solely representative of slaughter data of terrestrial food-producing animals received from the countries.* The number of countries in each OIE Region contributing to this coverage is also included (in brackets).

Globally, the estimated biomass coverage of the responding countries has increased from 36% in 2014 to 83% in 2017. The Americas, Asia and Europe had particularly high animal population coverage for 2017, with responding countries representing 91%, 85% and 79%, respectively, of the regions' total animal biomass. Coverage in Africa also increased to 58% of the region's total.



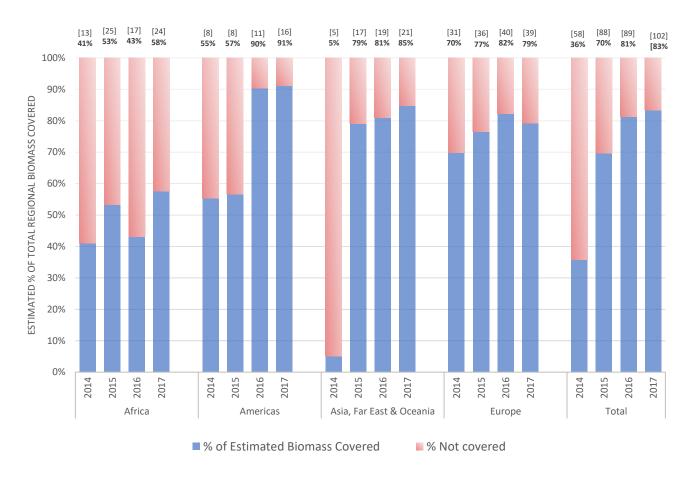
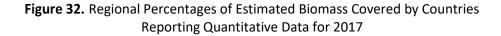
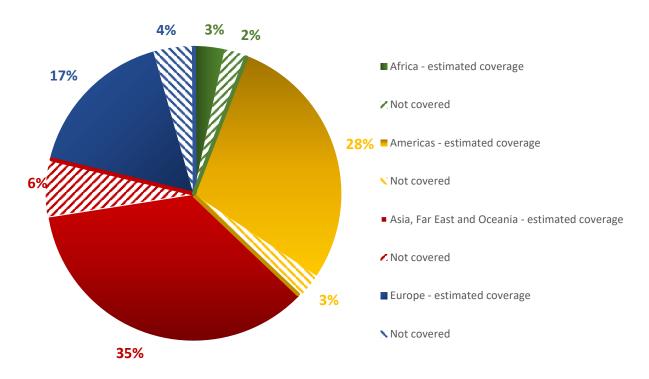


Figure 32 shows the regional distribution of the estimated percentages of regional biomass covered by the 102 countries included in the analysis of antimicrobial quantities for 2017, in comparison to the global biomass estimate. Asia, Far East and Oceania and Americas regions represent a particularly high proportion of the global biomass estimate.





Of the countries providing quantitative data for 2017, 63 (n = 102; 62%) reported that in addition to terrestrial animals, their data covered aquatic food-producing animal species or could not be distinguished by animal group.

As shown in Figure 33, the highest proportion of countries including aquatic food-producing animals in the reported quantitative data on antimicrobial agents was in Europe (85%; 33 of 39 countries). Sixty-two percent of countries in Asia, Far East and Oceania (13/21), 38% of countries in the Americas (6/16), and 29% of countries in Africa (7/24) reported quantitative data that included aquatic food-producing animals.

Europe Asia, Far East and Oceania 13 8 **Americas** 10 Africa 17 5 15 0 10 20 40 45 35 Number of countries ■ Number of Countries including aquaculture ■ Number of Countries not including aquaculture

Figure 33. Countries Including Aquatic Food-Producing Animal Species in Quantitative Data for 2017

Animal Biomass Covered by the 2017 Additional Analysis: Global View

Table 9 shows the animal biomass (in 1,000 tonnes) of farmed animals covered by 2017 quantitative data, as reported to the OIE in all rounds of the data collection.

The figures reported in this table reflect the number of countries that provided quantitative data, and the relative size and average weights of their animal populations in 2017.

Table 9. Animal Biomass Covered by the Quantitative Data Reported to the OIE for 2017 Obtained by the Accumulation of Information from all Rounds of Data Collection, Results for 102 Countries

Year 2017		Africa	Americas	Asia, Far East and Oceania	Europe	Global		
		Number of Countries						
	(tonnes)	24	16	21	39	102		
	(in 1,000)	52,760	169,626	59,794	46,521	328,702		
Bovine Biomass	(relative proportion)	54.0%	59.9%	20.8%	37.1%	41.4%		
	(in 1,000)	1,963	29,744	95,189	35,618	162,514		
Swine Biomass	(relative proportion)	2.0%	10.5%	33.1%	28.4%	20.5%		
	(in 1,000)	4,176	63,472	46,270	26,212	140,130		
Poultry Biomass	(relative proportion)	4.3%	22.4%	16.1%	20.9%	17.7%		
	(in 1,000	7,159	10,445	3,361	3,333	24,298		
Equine Biomass	(relative proportion)	7.3%	3.7%	1.2%	2.7%	3.1%		
	(in 1,000)	9,320	904	2,528	230	12,982		
Goat Biomass	(relative proportion)	9.5%	0.3%	0.9%	0.2%	1.6%		
	(in 1,000)	16,502	4,575	21,523	10,847	53,447		
Sheep Biomass	(relative proportion)	16.9%	1.6%	7.5%	8.6%	6.7%		
	(in 1,000)	20	17	1,766	308	2,111		
Rabbit Biomass	(relative proportion)	0.02%	0.01%	0.61%	0.25%	0.27%		
	(in 1,000)	5,344	74	279	71	5,768		
Camelid Biomass	(relative proportion)	5.5%	0.0%	0.1%	0.1%	0.7%		
	(in 1,000)	0	30	74	65	168		
Cervid Biomass	(relative proportion)	0.00%	0.01%	0.03%	0.05%	0.02%		
Terrestrial Animal	(in 1,000)	97,246	278,886	230,783	123,204	730,120		
Biomass	(relative proportion)	99.6%	98.6%	80.2%	98.2%	92.0%		
Aquaculture	(in 1,000)	387	4,081	57,131	2,203	63,802		
Biomass	(relative proportion)	0.4%	1.4%	19.8%	1.8%	8.0%		
All Species	(in 1,000)	97,633	282,967	287,915	125,407	793,921		
Biomass	(relative proportion)	100%	100%	100%	100%	100%		

Figure 34 shows the global species composition of animals potentially exposed to the antimicrobial quantities reported to the OIE for 2017. These percentages are a function of animal populations in the reporting countries, as well as their average weights.

Across the four OIE Regions covered by the analysis, bovines (41%) make up the largest contribution to animal biomass for the quantitative data reported. Swine (21%) and poultry (18%) also play a significant role, with aquaculture (8%), sheep (7%), equines (3%), and goats (2%) playing relatively minor roles in this analysis. The contributions of rabbits (0.3%), camelids (0.7%) and cervids (0.02%) are negligible for the covered countries.

These percentages may change significantly over time if the numbers or composition of countries in the OIE Regions providing quantitative data changes. This is expected to occur as data reporting capacity of countries increases.

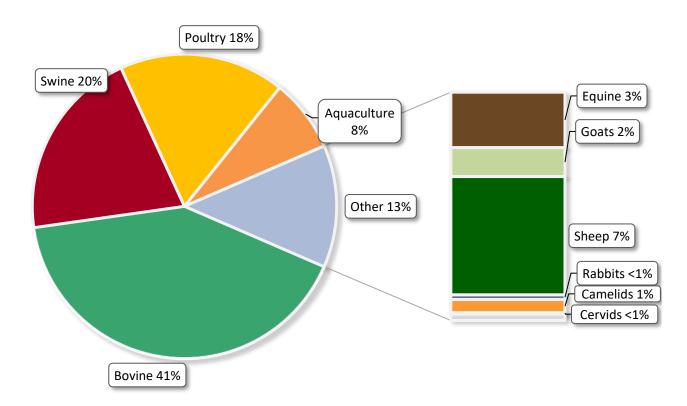


Figure 34. Species Composition of Animal Biomass for 102 Countries Included in 2017 Quantitative Data Analysis

These results should be interpreted with caution for all species for which slaughter data predominantly contributed to the calculation of biomass (swine, poultry, sheep and goats and rabbits). These percentages may underestimate the significance of species that are often slaughtered at places other than slaughterhouses for personal consumption. The amount of slaughter undertaken elsewhere and the extent to which this population is captured in slaughter data is expected to vary significantly between countries and regions.

AQUACULTURE

Aquaculture biomass essentially originates from farmed fish but in this annual report also included data on farmed crustaceans, molluscs and amphibians.

Percentages of aquaculture biomass should also be interpreted with caution as it was only included where countries either reported that their data on antimicrobial agents covered aquaculture, or that they could not distinguish between animal groups. Therefore, the effect of aquaculture on biomass is skewed by the number of countries in that OIE Region for which antimicrobials used in aquaculture were included. These percentages should not be considered representative of global aquaculture production.

For the purposes of the 2017 analysis of quantitative data, aquaculture was most significant in Asia, Far East and Oceania, where aquaculture made up 20% of the covered animal biomass. In Africa, the Americas, and Europe, aquaculture made up 0.4%, 1.4% and 1.8%, respectively, of the covered animal biomass.

CHANGES IN ANIMAL BIOMASS COMPARED TO 2016 ANALYSIS

Populations represented in the animal biomass analysis reflect the number, size and animal population dynamics of the countries reporting data to the OIE during the given year of analysis. In the Americas, Asia and Europe, the estimated percentage of total regional biomass covered remained relatively stable from 2016 to 2017 (Figure 31), with respective increases of +1%, +4% and -3%. Africa had the greatest increase in estimated percentage of total regional biomass covered, from 43% in the up-to date 2016 analysis to 58% in the 2017 analysis. In all regions, the observed species composition of the animal biomass also remained relatively unchanged (between 1% to 3% of changes between animal groups).

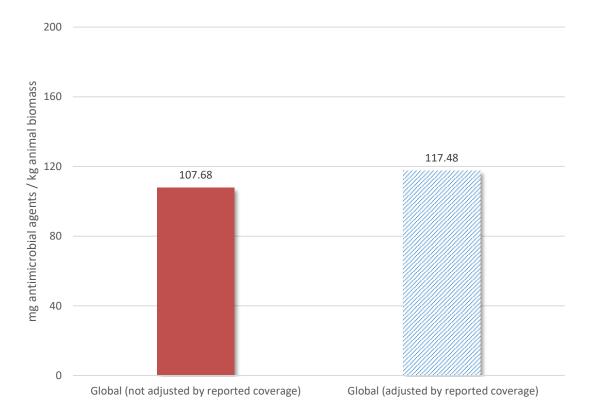
4.3. Antimicrobial Quantities Adjusted by Animal Biomass

2017 Antimicrobial Quantities Adjusted by Animal Biomass, Global View

Figure 35 provides an overview of antimicrobial agents intended for use in animals adjusted by animal biomass. The estimates compile the data of 102 countries providing data for food-producing animals in all rounds of data collection for 2017, from four OIE Regions (Africa; Americas; Asia, Far East and Oceania; and Europe). One country in the Americas that only provided data for companion animals was excluded from this section.

Using this rate (antimicrobial agents reported (mg)/animal biomass (kg)) provides an indicator that remains relevant for the purposes of comparison (e.g. over time and between regions). The first estimate of 107.68 mg/kg represents a global estimate of antimicrobial agents used in animals adjusted by animal biomass, as represented by the quantitative data reported to the OIE from 102 countries during all rounds of data collection. The second estimate of 117.48 mg/kg represents the same quantitative data, additionally adjusted by country-level estimates of how much data on antimicrobial agents intended for use in animals they covered in 2017. These coverage estimates are subjective for each reporting country, but can provide an upper-level estimate of global antimicrobial use in animals. For more detail of coverage estimates, see Section 4.2, Animal Population Covered by 2017 Data.

Figure 35. Global Quantities of Antimicrobial Agents Intended for Use in Animals Based on Data Reported by 102 Countries for 2017, Adjusted by Animal Biomass (mg/kg)



2017 Antimicrobial Quantities Adjusted by Animal Biomass, Regional View

Figure 36 provides a regional view of antimicrobial agents intended for use in animals adjusted by animal biomass of countries within that region. Both estimates for each OIE Region incorporate the data of 102 countries providing data in all rounds of data collection for 2017.

The lower estimate for each OIE Region represents the quantitative data reported to the OIE from that region during all rounds of data collection for 2017, adjusted by animal biomass. The high estimate for each OIE region represents the same quantitative data, additionally adjusted by country-level estimates of how much data on antimicrobial agents intended for use in animals they covered in 2017. These coverage estimates are subjective for each reporting country, but can provide an upper-level approach to global antimicrobial use, including unregulated sources.

Estimates of data coverage were lowest in the Americas, leading to the widest variation between antimicrobial quantities reported and those adjusted by countries' estimates of data coverage. Countries in Europe were the most confident of their data coverage.



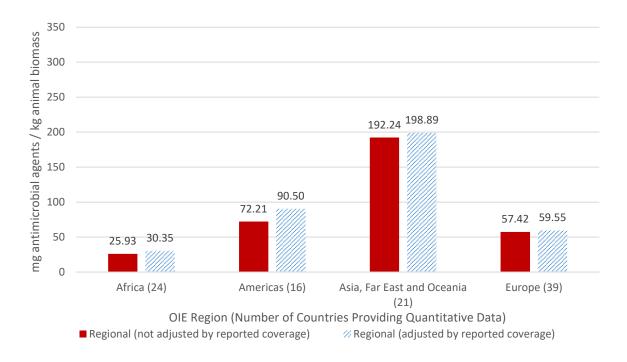


Table 10 displays the same regional figures of antimicrobial quantities adjusted by animal biomass (with the upper-level estimates adjusted by country estimates of data coverage in parentheses). Additionally, some characteristics of the data distribution by OIE Region are provided, including the median, standard deviation and range.

These results show that in 2017, Asia, Far East and Oceania reported the most antimicrobial agents intended for use in animals among the four regions. However, this region also displayed the most variation between individual countries and the highest decrease in antimicrobial quantities used over the years.

Table 10. Antimicrobial Quantities Adjusted by Animal Biomass, by OIE Region, 2017

		% Covered of	Antimicrobial Quantities Adjusted by Animal	Descriptive Statistics		
OIE Region	Number of Countries	Total Regional Estimated Biomass	Biomass (and estimated data coverage) (mg/kg)	Median (mg/kg)	Standard deviation (mg/kg)	Range (mg/kg)
Africa	24	58%	25.93 (30.35)	10.13 (15.00)	35.39 (40.67)	150.29 (150.27)
Americas	16	91%	72.21 (90.50)	63.26 (63.43)	106.34 (158.08)	316.88 (513.54)
Asia, Far East and Oceania	21	85%	192.24 (198.89)	74.61 (77.99)	168.20 (180.75)	584.30 (584.28)
Europe	39	79%	57.42 (59.55)	32.31 (34.35)	66.93 (76.86)	347.27 (364.01)

It is important to interpret the estimates of antimicrobial quantities adjusted by animal biomass (mg/kg) in the context of animal biomass coverage for the region. Estimates for the total estimated regional animal biomass covered by the quantitative data reported for 2017 were calculated and explained in Section 4.2. Changes in reporting countries and in regional animal biomass coverage across years of analysis may significantly change the results. The OIE is working with Members to continue to improve and maintain data coverage in order to allow for an evaluation of trends over time.

Furthermore, since antimicrobial usage differs for different species (as a result of disease burden and husbandry practices), the species composition of regional animal biomass (Table 9) is an additional factor to be taken into account when considering the differences between regions.

Overall, while noting the need for caution in comparison of 2014, 2015, 2016 and 2017 results at global and regional levels due to the differences in the contributing countries, the trends between regions have been maintained. Europe's reported antimicrobial quantities adjusted by animal biomass reduced from 92 mg/kg in 2014 to 57 mg/kg in 2017. These reductions are in line with the results reported by ESVAC for the same years, for those countries that provide it with data. For Africa, the 2017 results are quite similar to those for 2014, 2015 and 2016, despite the new contributions from countries in Africa.

2017 Antimicrobial Quantities Adjusted by Animal Biomass: Distinctions Between Terrestrial and Aquatic Animals

Of the 102 countries that provided quantitative data for food-producing animals in 2017, ten countries were able to report quantitative data under the Aquatic food-producing animals group separately from other animal groups.

These ten countries were able to report their antimicrobial quantities for the group of terrestrial animals separately from the aquatic animals; as a consequence, the OIE was able to perform a separate analysis of the mg/kg by animal groups. It was observed that in four out of ten countries, the mg/kg ratios were higher for the aquatic animals group than the terrestrial animals group. Table 11 presents some characteristics of the data distribution by animal group, including the median, standard deviation and range (with the upper-level estimates adjusted by country estimates of data coverage in parentheses). It is expected that these first figures will be refined over time and should therefore be interpreted with caution and should not be considered representative of global aquaculture production.

Table 11. Antimicrobial Quantities Adjusted by Animal Biomass, by Ten Countries by Terrestrial and Aquatic Animal Groups, 2017

		Descriptive Statistics			
Animal Group	Number of Countries	Mean (mg/kg)	Median (mg/kg)	Standard deviation (mg/kg)	Range (mg/kg)
Terrestrial food-producing animals	10	52.33 (52.75)	26.82 (28.81)	72.18 (72.00)	236.42 (236.42)
Aquatic food-producing animals	10	103.54 (110.06)	21.61 (21.61)	146.68 (160.36)	364.36 (428.66)

5. Updates of Historical Data

The 2014, 2015 and 2016 data were updated based on new information and corrections reported by Members in the fifth round of data collection, and therefore may differ from the results of the previous report.

Changes in the antimicrobial quantities

Corrections to previous antimicrobial quantitative data included recalculations due to identified errors, the addition of previously inaccessible data, and corrections of the calendar year covered by the data submission. For some countries, where errors in calculations were discovered, their data were retrospectively removed from the 2014, 2015 and 2016 analysis pending validation. Two, four and five countries updated the data for 2014, 2015 and 2016, respectively.

Changes in the animal biomass

For the purpose of supporting comparison, all 2014, 2015 and 2016 animal biomass figures have been recalculated using currently available slaughter and live animal data, as these may be retrospectively updated in the databases. All analyses for previous years (2014 to 2016) included in this report reflect the most current information at the time of writing.

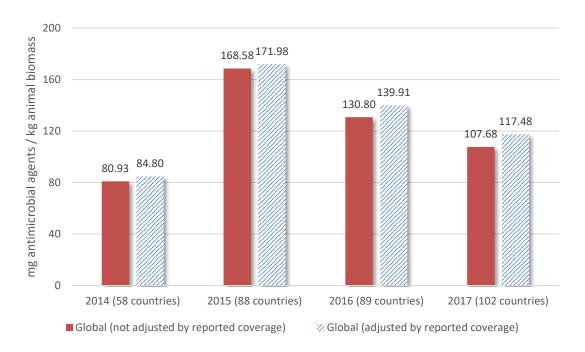
Previously, the biomass for aquatic food-producing animals was restricted to farmed fish biomass. Data on farmed crustaceans, molluscs and amphibians were excluded given the relatively small size of these populations, and inconsistency in their reporting. However, in the 2017 analysis these other aquatic food-producing animals were also included in the aquaculture biomass because certain countries reported antimicrobial quantities intended for use solely in these animal groups. The effect of including these additional animal groups to the animal biomass is estimated to increase the global animal biomass estimation by 3.3% to 3.9%. The results for previous years analysis (2014 to 2016) shown in this report have been recalculated to include these other aquatic food-producing animals to support comparison. Globally, the percentage of variation of the recalculated animal biomass for 2014, 2015 and 2016 compared to the previous report is +2%, +5% and +14%, respectively. These significant variations can be explained by the updates in the number of reporting countries and their respective animal biomass data included in the analysis for previous years. The OIE is working with Members to continue to improve and maintain data coverage in order to allow for an evaluation of trends over time.

Changes in mg/kg results from 2014 to 2016

The updated mg/kg global estimates for 2014 to 2016 are shown in Figure 37. While the 2015 results reflect an apparent increase in antimicrobials used globally, these results cannot be compared to the 2014 analysis and should be interpreted with caution. The 2015 analysis reflects a higher global participation in the data collection, with an increase of 31 reporting countries, and an estimated global biomass coverage of 68%, increased from 35% in 2014. As more countries establish data collection and the global biomass coverage increases, the accuracy of reported data will stabilise and trends over time will become more readily discernible.

The 2014, 2015 and 2016 analysis of antimicrobial quantities adjusted by animal biomass were updated to reflect new information reported by countries in the fifth round of data collection. Some figures were corrected, added or retrospectively removed from the analysis when countries described previous errors in their calculations.

Figure 37. Global Quantities of Antimicrobial Agents Intended for Use in Animals Based on Data Reported by Countries from 2014 to 2017, Adjusted by Animal Biomass (mg/kg)



6. Trends from 2015 to 2017

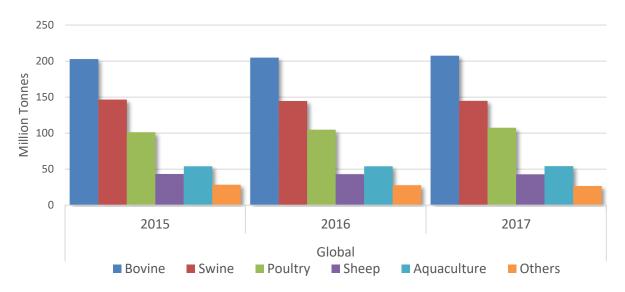
This section presents the changes of the mg/kg, antimicrobial classes and animal biomass in the countries that reported data to the OIE each year from 2015 to 2017. During the 83rd General Session in May 2015, OIE Members adopted Resolution No. 26: "Combating Antimicrobial Resistance and Promoting the Prudent Use of Antimicrobial Agents in Animals" [2] including support for the Global Action Plan on AMR, developed by WHO in close collaboration with the OIE and FAO [9]. The year 2014 was not considered in the analysis because of insufficient representation of countries from the different OIE Regions. Table 12 presents the number of countries by each OIE Region considered for this analysis.

Table 12. Number of Countries that Reported Data to the OIE for Each Year from 2015 to 2017

OIE Region	Number of Countries that Submitted Quantities from 2015 to 2017	Number of OIE Members	Proportion of response (%)
Africa	14	54	26%
Americas			
OIE Members	6	31	19%
Non-contiguous territories	1	n/a	n/a
Asia, Far East and Oceania	15	32	47%
Europe	33	53	62%
Middle East	0	12	0%

Figure 38 presents the evolution of the calculated animal biomass by species for the 69 countries which have reported antimicrobial quantities from 2015 to 2017. Globally, the animal biomass for these countries was relatively stable and has increased of 1.2% from 2015 to 2017. For these 69 countries, the biomass for poultry has shown the greatest increase (6%) followed by bovine (2%). The OIE is continuously working with Members to continue to improve and maintain data coverage in order to allow evaluation of trends over time for a greater number of countries.

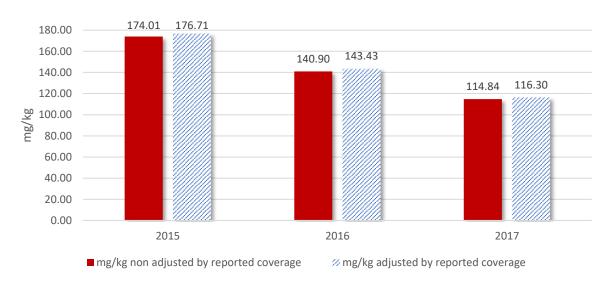
Figure 38. Trends on Time for the Animal Biomass calculated for 69 Countries by species, from 2015 to 2017



Figures 39 and 40 present the mg/kg for all OIE antimicrobial classes reported for the 69 countries¹⁰.

For the 69 countries that reported data to the OIE each year from 2015 to 2017, an overall decrease of 34% in the mg/kg was observed. While all OIE Regions presented a decrease from 2015 to 2017, the Americas reported the most important decrease (36.69%), followed by Asia, Far East and Oceania (34.24%).

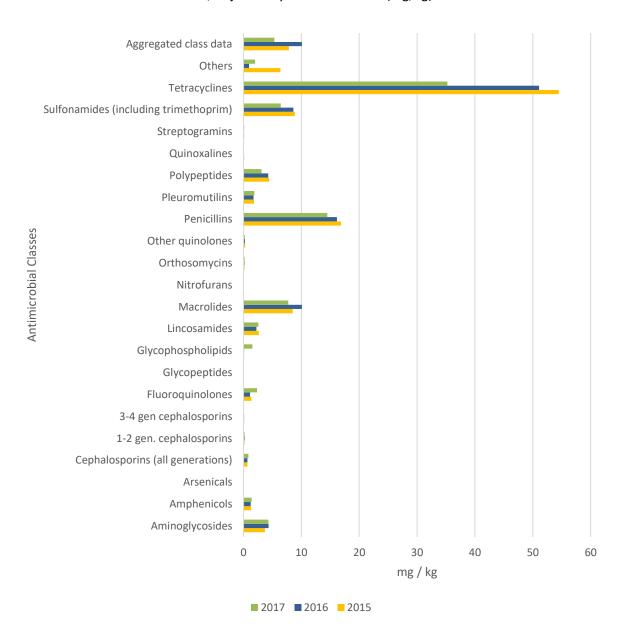
Figure 39. Trends on Time for the Global Quantities of Antimicrobial Agents Intended for Use in Animals Based on Data Reported by 69 Countries from 2015 to 2017, Adjusted by Animal Biomass (mg/kg)



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Antimicrobial quantities intended for use in animals from countries reporting data to the OIE each year from 2015 to 2017 were adjusted for animal biomass (mg/kg). For the regional analyses, country data for both the numerator and the denominator, respectively, were summed according to OIE Regions before the rate was calculated.

Figure 40. Trends over Time for the Antimicrobial Classes Reported by 69 Countries from 2015 to 2017, Adjusted by Animal Biomass (mg/kg)*



^{*} For each antimicrobial class, the summed antimicrobial quantities reported (in mg) in all OIE Regions are divided by the total animal biomass (in kg)

7. Discussion

7.1. Progress Made by Member Countries

During the fifth round of data collection, an increased number of Members were engaged in data reporting compared to the previous rounds.

Of the 156 Members that submitted reports, 139 had also participated during the fourth round of data collection. Among these 139 Members, the following progress was noted:

- Fourteen of those Members graduated from reporting only Baseline Information in the fourth round (n = 35; 40%) to reporting quantitative data on antimicrobial agents used in the animals for the first time. Five Members used Reporting Option 1 which allows distinction by antimicrobial class and by type of use (veterinary medical use or growth promotion). One Member used Reporting Option 2, which allows for a distinction by animal group (terrestrial food-producing, aquatic food-producing and companion animals) in addition to the type of use. Eight countries used Reporting Option 3, which allows for distinction of the quantitative data by type of use, animal groups and routes of administration.
- Twenty of those Members had previously reported quantitative data through Reporting Option 1 or 2 (n = 73; 27%) and progressed to more detailed reporting in this round. Fifteen Members moved from reporting quantities through Reporting Option 1 to one of the two higher-level options: three were found to have switched to Reporting Option 2, and 12 switched to Reporting Option 3. Five Members that had previously reported through Option 2, now used Reporting Option 3.

It is important to note that for this fifth round, all regions showed continued progress; with Africa and the Americas showing the highest number of countries progressing to more detailed reporting levels of their quantitative data. During the fifth round, 25% of the 129 Members providing quantities used the pilot Calculation Tool that the OIE developed and introduced during Regional Workshops for Africa and the Americas. This tool assisted the countries in collecting product information and calculating amounts of active ingredients. Most of the progress demonstrated by countries can be attributed to their use of this newly introduced tool.

The barriers described by the 23 Members unable to provide quantitative data on antimicrobials used in animals in the fifth round of data collection have been described in Section 3.5 of this report. Among this group, three Members (n = 23; 13%) confirmed that action will be taken to facilitate their reporting of quantities of antimicrobials to the OIE in the near future.

7.2. Limitations in the Analysis of Antimicrobial Quantities

All the countries that reported quantities of antimicrobial agents intended for use in animals did so using the template that the OIE created. This document collects essential information to analyse the amounts of antimicrobials (Baseline information, part C, Annex 6). In addition to this document, an annex was provided to perform the calculations to report kilograms per active ingredient (Annex 8).

Data sources

During the fifth round of data collection, 37 of those countries reporting quantitative data (n = 133; 28%) reported data sources indicating the possibility of over-estimated, duplicated or overlapping data (see examples below).

Data duplication or over-estimation was considered to be a risk where the following situations were reported in a country's data sources:

- Import data of active ingredients or manufacturing data reported without taking into account the potential for re-exports;
- Import data of veterinary products reported by a country also providing data on sales of veterinary products (domestic and imported);
- Import, sales or purchase data of veterinary products reported in addition to usage data at farm level;
- Data from wholesalers or Marketing Authorisation Holders in addition to data from retailers, prescriptions, pharmacies or farm records.

Countries where these possible situations were identified were present in all the OIE Regions, however, they were predominant in Asia, Far East and Oceania (n = 12), followed by Africa (n = 10). Countries with these situations decreased from 43% in the fourth round to 28% in the fifth round.

The OIE engages with countries where these risks exist to highlight and clarify possible areas of data duplication or over-estimation. As most of these countries are in the early stages of developing their data collection systems, it is expected that it will take time to develop and implement official processes that provide more accurate data. The OIE continues to work closely with these countries to understand their systems and approach, to support them to address limitations in their data.

Calculation of quantitative data

Wherever possible, the data reported by countries were checked by the OIE against existing reference sources, either using the previous year's reported data or national reports available online. The indicator for this comparison was a calculated 'percentage of change'.

During the fifth round, this analysis could be conducted for 108 countries where data from previous years were available for comparison. In 34 countries (n= 108; 32%), the data varied more than 25% from one year to another, in some countries reaching 100-200% variation, and in others, an even higher percentage of change was observed. Such changes were considered unlikely to reflect the true situation.

In countries with high percentages of unexplained change (>25%), the OIE inquired how the calculations to obtain kg of antimicrobial agents were carried out. Through this process, errors in the calculations were discovered where countries did not follow or misinterpreted the procedure in Annex 8. Errors in the calculations occurred in all OIE Regions. However, Asia, Far East and Oceania presented the highest number of Members experiencing challenges (n = 10), typically among countries new to participation in data collection.

In addition to the analysis of the percentages of change, the OIE developed and piloted a tool to assist countries in performing calculations to obtain amounts of active ingredients. The tool takes into account the different rules when reporting to the OIE: it includes different units of measurement (mg, g, ml, IU, etc.); provides conversion factors; identifies the product data (e.g. molecules names, purpose

of use, target animals and routes of administration as declared on the product label); and allocates them to the different antimicrobial classes of OIE Reporting Options 1, 2 and 3. Of the 133 countries reporting antimicrobial quantities in the fifth round, 25% used the tool for calculating amounts of active ingredients. While using the tool, most of the countries realised that errors had occurred mainly from converting the different units of measurement to kilograms and the conversion factors for IU and derivates or compounds.

Development of antimicrobial monitoring systems

During the fourth round of data collection, 118 countries reported quantitative data on antimicrobial agents intended for use in animals, and 107 of these also participated in the fifth round of data collection. Diverse reasons apply for the 11 countries reverting to not reporting quantitative data.

In the fifth round of data collection, 19 countries (n = 108; 18%) made amendments to the quantitative data they had reported in previous rounds. These amendments corresponded to errors noted in the calculations, or availability of new data, including additional data for months in the year previously not covered, or data from wholesalers or pharmacists newly participating in the data collection. In three specific cases, the data were found to not follow the guidelines to calculate amounts of active ingredients, and were retrospectively deleted from these countries data sets. This error was discovered through countries use of the OIE Calculation Tool.

Taking into account that most countries worldwide are still beginning to report quantitative data on antimicrobials intended for use in animals and that errors in data sources have already been noted that may result in instances of data duplication, *caution is necessary in the interpretation of the results*. As stated in the annual ESVAC report:

'It is generally agreed that it usually takes at least three to four years to establish a valid baseline for the data on sales of veterinary antimicrobial agents. Consequently, the data from countries that have collected such data for the first or even second time should be interpreted with due caution'.

7.3. Limitations in the Estimation of Animal Biomass

The animal biomass methodology was developed with the goal of best representing animal biomass in all OIE Regions, with different animal populations and data collection systems. The biomass figures obtained from this methodology reflect a margin of error, which will be reduced over time as data collection is further refined (see Section 8, Future Developments). Further information can be found in the 'OIE Annual Report on Antimicrobial Agents Intended for Use in Animals: Methods Used' article published in *Frontiers in Veterinary Medicine* in September 2019 [11].

Calculation methodology of average animal weights

Different antimicrobial use surveillance programmes have used various methodologies for the determination of average animal weights to use in the calculation of total biomass. In the ESVAC report [16], estimated average weights at time of treatment are used. The Canadian Integrated Surveillance Program for Antimicrobial Resistance (CIPARS) [20] uses the same standard weights at time of treatment, as well as Canadian standard weights. The surveillance programmes of Japan [21] and the United States of America [22] take a different approach, instead using estimates of average animal weights by production category, rather than focusing the estimates on the time of treatment.

For the purposes of this report, it was determined that the latter approach, using estimates of live average weight without focus on time of treatment, would be most appropriate. The antimicrobial compounds used and their labelling, including target species and production class, varied widely on a global scale, with data on these differences not available. Given these variations, it is not feasible to estimate weights at time of treatment for all countries reporting data to the OIE. Instead, average weights were calculated using globally available slaughter data as reported by FAOSTAT, for all species and regions where these data were available.

The average weights calculated for this report are therefore larger than estimated weights at the time of treatment, resulting in a larger denominator and a decreased relative mg/kg estimate of antimicrobial agents intended for use in animals. Therefore, the results reported in OIE analyses of antimicrobial quantities adjusted by animal biomass are not directly comparable to those of ESVAC or the CIPARS estimates, which are based on treatment weights.

Specificity of data

As described in the methodology, the globally available data sources on animal population, FAOSTAT and OIE-WAHIS, were not systematically reported by production class for 2017. However, it is necessary to stratify species population by production class to better assign average weights, for example, to separate veal calves from adult cattle. The methodology for calculation of biomass therefore utilises some necessary standard animal reproduction rates to extract a best estimate of the population breakdown by production class. These rates will vary between species, countries and production systems, and therefore, are not fully representative of the animal populations of any one country or region.

Animals imported and exported

Imported and exported animals are commonly subtracted and added, respectively, from animal populations when calculating animal biomass, as done by ESVAC and CIPARS. This occurs so that only animals raised in the country, the time during which they would have been treated with antibiotics, are considered. In this report, an effort was made to minimise the effect of animals imported/exported by using the FAOSTAT 'trade of live animals' dataset for the bovine species. In this report, animal biomass for previous years was retrospectively recalculated using the same dataset in order to reduce differences between years of analysis.

Extrapolations within the methodology

Carcass conversion factors: The methodology for the calculation of average animal weight from slaughter data necessitates a conversion factor from carcass weight to live weight at time of slaughter (Section 2.2). Presently, these conversion factors are only available for Europe. It is not currently known how well European conversion factors apply to other countries that may have different breeds, husbandry and slaughter practices, but it is likely that they differ. The significance of this difference and its impact on the accuracy of the biomass calculation for all countries cannot be estimated.

Reproduction rates and weights: Data on reproduction rates were not collected at the time of reporting, nor was slaughter data for cervids, camelids or equids in some regions. Therefore, this information was taken from literature where necessary, or extrapolated from regions where data is available (such as for the live weights of equines). The extent to which these literature and extrapolated weights and reproduction rates represent the true situation in any country is expected to vary.

Animal species not retained in denominator

In the development of the current denominator methodology, it was decided not to include companion animals in the calculation of animal biomass. Data on populations of cats and dogs are available in OIE-WAHIS, and not in FAOSTAT. However, many countries do not report these figures, or report them inconsistently. Another consideration is the need to better understand whether reported cat and dog populations represent owned or stray animals, as this would affect the likelihood of their treatment with antimicrobials.

For the countries where cat and dog populations were available, it was seen that their contribution to overall biomass was minor (<1%). However, as some countries do include antimicrobials used in companion animals in their reported quantitative data, there is expected to be a small effect on results by excluding these species. As excluding them decreases the denominator, the effect, if any, would be a minor increase in antimicrobial quantities adjusted for animal biomass.

In the future, a goal of the AMU data collection would be to provide separate analysis for antimicrobial agents used in companion animals, as more countries are able to report these population data, and distinguish antimicrobial quantities by animal group.

7.4. Barriers to Collect Antimicrobial Quantities

For the countries unable to report antimicrobial quantities, the main barriers reported were the structure or enforcement of their regulatory framework for veterinary products. It was also noted that there are countries that reported the lack of an electronic tool that can collect and analyse data (mainly from imports) that was connected to the information related to the authorisation of veterinary products, in order to perform the calculations of active ingredients (see Section 3.5, Country Barriers to Providing Quantities of Antimicrobial Agents in Animals).

Some countries have described processes under way to facilitate future collection and reporting of antimicrobial use data in animals. Similarly, in line with their commitments made to the Global Action Plan, countries are also in the process of implementing and updating National Action Plans to advance regulations on veterinary antimicrobials and facilitate interactions between sectors. The OIE Calculation Tool will also allow a better collection and analysis of the data. To ensure data quality, investment will be required in prioritised activities supporting the removal of those barriers.

8. Future Developments for the Antimicrobial Use Survey

The OIE will continue working closely with Members to support them in calculating the amounts of active ingredients of antimicrobials. The OIE is also in the process of building an interactive automated system in which Members will report the use of antimicrobial agents in animals and receive support for calculating amounts of active ingredients. This AMU IT system will be accessible online and will help Members with their calculations, reduce errors and improve the quality of data. The AMU IT system will also simplify the reporting process, enable faster reporting and analysis and encourage Members to use their own data to get valuable insights and visualise important information. In 2020, the OIE held dedicated webinars on the OIE AMU Data Collection, and as part of the AMU IT system development process, specific sessions were aimed at understanding Members' user requirements. In 2021, additional workshops will take place to capture the expectations of OIE Members for the new OIE AMU IT System.

The OIE will continue to support improvements to AMU and animal population data quality, and refine its methodology for the calculation of animal biomass based on globally available data, in communication with its Members through its regional offices.

An important step in this process will be achieved through the interface with the OIE-WAHIS. In consultation with the previous OIE *ad hoc* Group on Antimicrobial Resistance, new species and animal sub-categories have been added to the OIE-WAHIS data collection guidelines. These new population sub-categories are now being implemented in OIE-WAHIS and will allow the data on animal biomass to be refined over time.

OIE-WAHIS, the next generation of the WAHIS data collection interface, was launched in March 2021 and will incorporate further updates to the collection of global animal population data. In addition to more sub-categories representing detailed production data where Members can supply it, the interface will also include free text boxes allowing for description of the reported data. OIE-WAHIS will also support the reporting of data on average live weights and the number of animals slaughtered in countries.

Aside from the collection of more detailed global animal population data, additional work is needed to validate some of the conversion factors used in the methodology, which have been frequently extrapolated from European data. Particularly, better understanding potential regional variation in carcass conversion factors (for estimating live weights) and annual multiplication rates of species living less than one year (i.e. 'cycle factor') are necessary to refine the current methodology. The OIE is currently working with its Regional Offices to obtain better estimates on these variables across regions.

9. Conclusions

The OIE AMU Data Collection, the result of a collective effort of OIE Members and participating non-OIE Members, provides critical information for the global effort to promote the responsible and prudent use of antimicrobial agents in animals, and the capacity to measure trends over time. The fifth OIE annual report achieved the highest participation of countries since the first round of the data collection in 2015: a 23% increase in participation and a 55% increase in the number of countries providing antimicrobial quantities. It is the result of a significant commitment by OIE Members to the development of data collection systems on antimicrobial agents intended for use in animals. The decrease in antimicrobial quantities adjusted by animal biomass in all OIE Regions represents countries' commitment to the responsible use of antimicrobials in animals at the country level.

On an annual basis, the OIE highlights not only the reported quantitative data for countries currently able to provide it, but also reflects the current situation of governance of veterinary antimicrobials worldwide, and barriers to quantitative data collection. The OIE analysed the barriers related to the lack of IT tools and developed the OIE Calculation Tool that supported the calculations of 25% of the countries that reported antimicrobial quantities during this fifth round.

Globally, countries continue to develop their AMU monitoring systems and create valid baseline information on the quantities of antimicrobial agents intended for use in animals. During these last five years, countries have updated previously reported information owing to either higher quality data becoming available, or a better understanding and analysis of data sets and countries' situations. The OIE accompanies countries efforts and aims to enhance countries' data ownership through its future OIE AMU IT System.

Simultaneously, as more data on animal populations becomes globally available, it is expected that the methodology for the calculation of animal biomass will be further refined. With the concurrent development of quantitative data collection and calculation of animal biomass, annual reports will refine the comparison of global and regional trends on antimicrobial agents intended for use in animals over time.

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ANNEXES

Annex 1

O Americas, Regional Focus

Annex 3 Asia, Far East and Oceania, Regional Focus

Annex 4 Europe, Regional Focus

Annex 5 Middle East, Regional Focus

Annex 1Annex 6 OIE Template

Annex 7 Guidance for Completing the OIE Template for the Collection of Data on Antimicrobial Agents Used in Animals

Annex 8 Annex to the Guidance for Completing the OIE Template for the Collection of Data on Antimicrobial Agents Used in Animals

Annex 9 Distribution of Members by OIE Region

Africa, Regional Focus

Annex 1. Africa, Regional Focus

Table A1. General Information for Africa during the Fifth Round of Data Collection

General Information for Africa	
Number of OIE Members	54
Number of OIE Members responding to the questionnaire	39 (72%)
Number of OIE Members providing qualitative data only	7 (18%)
Number of OIE Members providing quantitative data	32 (82%)

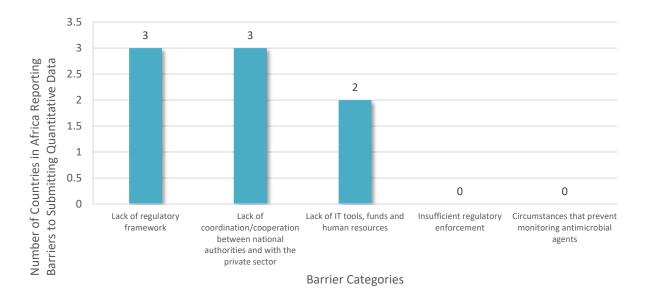
Barriers to Providing Quantities of Antimicrobial Agents in Animals

Seven OIE Members (n= 39; 18%) responded with Baseline Information (qualitative data) and did not provide quantitative data on antimicrobial agents used in animals (Table A1), and six out of seven explained their barriers to reporting quantities of antimicrobial agents used in animals. Countries can report more than one barrier relevant to their situation, and responses for this reporting year were grouped by category (Fig. A1). For further information on the category groupings, please refer to Section 3.5 of this report.

Three countries cited the main impediment to reporting antimicrobial quantities as the lack of a regulatory framework. Of these, two countries describe the absence of a regulatory framework for the manufacture, registration, distribution, commercialization and use of veterinary products. One Member mentioned that it was not a mandatory requirement to collect such data in the country and it was lacking funds.

Three Members described a lack of coordination/cooperation with another national authority, mainly the Ministry of Health, with one also citing the lack of IT tools to assist with data compilation.

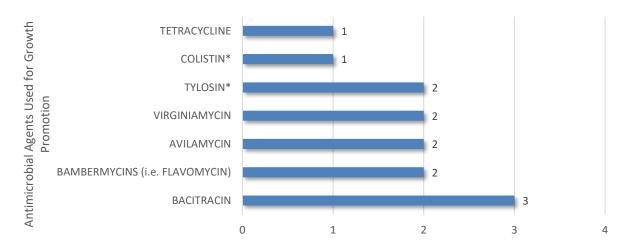
Figure A1. Country Barriers to Reporting Quantitative Data on Antimicrobial Agents Intended for Use in Animals in Six Countries in Africa During the Fifth Round of Data Collection



Antimicrobial Agents Used for Growth Promotion

During 2019, eight African countries (n = 39; 21%) used antimicrobial agents as growth promoters. Of these, four Members (n = 8; 50%) provided a list of antimicrobials used for growth promotion, with bacitracin being the most frequently named (Figure A2). It was noted that of these eight countries only two had legislation regulating for these molecules. It was also observed that of the 30 countries stating that did not use antimicrobials as growth promoters, 21 did not have any legislation or regulation banning the use of these molecules (n = 30; 70%). One country reported that the use of growth promoters in the field was unknown and it also experienced a lack of legislation or regulation for this type of use.

Figure A2. Antimicrobial Growth Promoters Used in Animals in Four Countries in Africa in 2019



Number of Members in Africa Reporting Use of Antimicrobial Agents for Growth Promotion in 2019

^{*} The classes in the WHO category of Highest Priority Critically Important Antimicrobials should be the highest priority for countries when phasing out the use of antimicrobial agents as growth promoters.

2017 Analysis of Antimicrobial Quantities

This section provides additional analysis of reported quantitative data on antimicrobial agents intended for use in animals adjusted by animal biomass, focusing on 2017. This analysis represents the antimicrobial quantities reported to the OIE from 24 countries in Africa during all rounds of data collection.

QUANTITATIVE DATA SOURCES CAPTURED

All African countries' data sources were analysed, and all countries where data duplication was considered to be a risk were asked for clarification of their answers and/or data collection systems. Nine countries' data sources were considered to present a risk of duplication (n = 24; 38%); after clarifications, five countries (n = 9; 56%) changed their answers or proved there was no duplication or overlapping of data sources. Only the remaining countries (four out of nine; 44%) that did not provide clarifications were excluded from the analysis in Figure A3. For a full explanation of quantitative data sources, see the Guidance for Completing the OIE Template for the Collection of Data (Annex 7).

From the list of data source options provided in the OIE template, import data for veterinary products as declared by customs authorities was most commonly chosen. In addition, four Members described other data sources not included in the OIE List, relating to Import data (Figure A4).

Figure A3. Data Sources Selected by 20 African OIE Members Reporting Quantitative Information for 2017

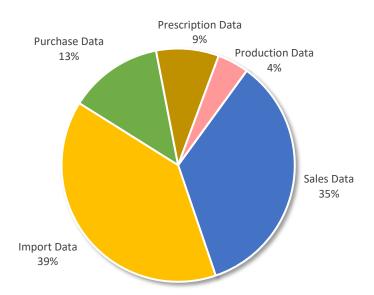
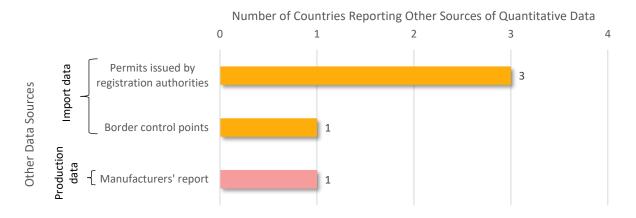


Figure A4. 'Other' Sources of Data as Explained by Four Members in Africa Reporting Quantitative Information for 2017

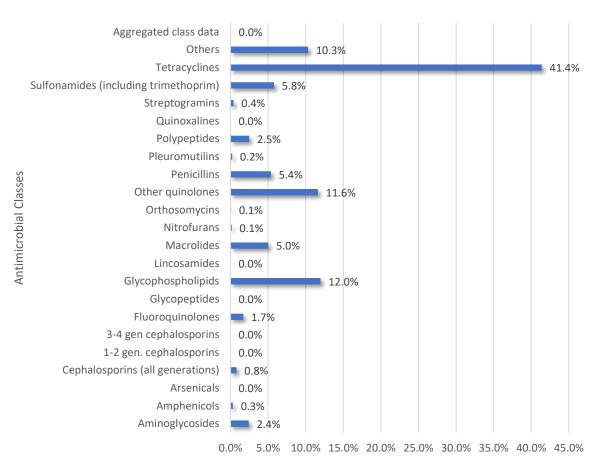


ANTIMICROBIAL QUANTITIES REPORTED IN 2017

For 2017, 24 African countries provided validated antimicrobial quantities intended for use in animals. Of the 24 countries, seven stated a 100% coverage of the data source used to report the data and one country estimated 120% coverage as all import data were covered, but 20% of their total imports were planned for re-exportation to neighbouring countries. The 16 countries that did not cover 100% of available antimicrobial quantity data sources were asked to provide further information on uncaptured data sources. For the 24 countries, the estimated data coverage was 82%. More information on the data coverage for Africa is available in Table 5 of this report.

In Africa, the largest proportion of all reported antimicrobial classes was tetracyclines, followed by glycophospholipids and other quinolones (Figure A5). Under the group of 'others' most of the countries reported fosfomycin and fusidic acid. The *aggregated class data* category is used for confidentiality purposes at the national level and since only one country provided data under this category, the classes cannot be disclosed.

Figure A5. Proportion of Antimicrobial Classes Reported for Use in Animals by 24 African Members in 2017



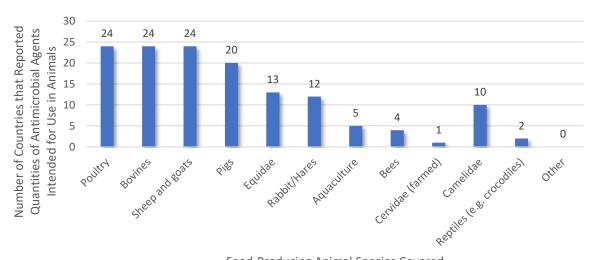
% of Reported Quantities of Antimicrobial Agents Used in Animals by 24 Countries

FOOD-PRODUCING TARGET SPECIES ON THE LABEL OF REPORTED VETERINARY PRODUCTS

Irrespective of whether the data could be differentiated by animal groups, all 24 countries were asked to select the food producing animal species covered by their data from a list supplied in the OIE template and according to the products target species label. For descriptive purposes, some animals were grouped in categories, for more information on the grouping of animals see page 466 of this report.

In the 24 African Members that reported quantitative data on antimicrobial agents intended for use in animals for 2017, the food-producing species most frequently covered by the data were poultry, sheep and goats, and bovines (Figure A6). Within the four regions analysed, Africa is one of the regions were Camelidae were more commonly named by Members.

Figure A6. Food-Producing Animal Species Included in Quantitative Data Reported by 24 African Members in 2017

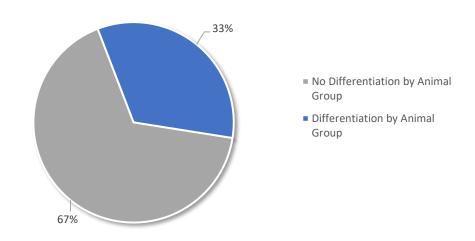


Food-Producing Animal Species Covered

QUANTITATIVE DATA DIFFERENTIATION BY ANIMAL GROUP

Most of the quantitative data from the African Members cannot be differentiated by animal group. This result corresponds with the African Region's predominant use of Reporting Option 1, which does not allow for differentiation by animal group (Fig. A7). For the eight African countries (n = 24; 33%) that were able to distinguish antimicrobial quantities by animal groups, data were mainly provided for terrestrial food-producing animals.

Figure A7. Differentiation by Animal Group among 24 Members in Africa Reporting Quantitative Data in 2017



ANIMAL BIOMASS

In Africa, sheep, goat and equine biomass are relatively more significant, compared to the other regions, contributing 17%, 10% and 8%, respectively, to the total biomass. In contrast, the proportions of swine and poultry, 2% and 4%, respectively, are the lowest among all regions. It can be underlined that camelids, totalling 5%, are also proportionally more significant in Africa than in other regions.

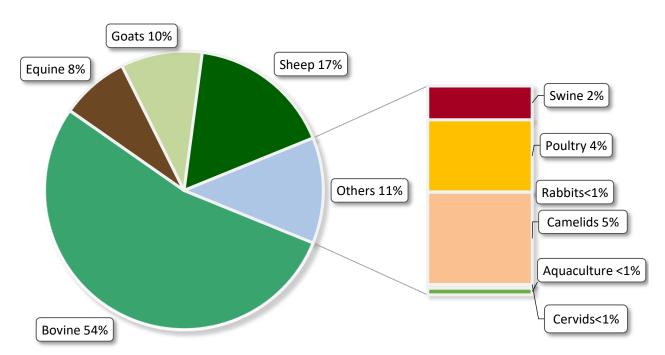


Figure A8. Species Composition of Animal Biomass for the 24 Countries in Africa Included in 2017 Quantitative Data Analysis

ANTIMICROBIAL QUANTITIES ADJUSTED BY ANIMAL BIOMASS

In Africa, the mg/kg estimate for 2017 for 24 countries is 25.93 mg/kg, with an upper-level estimate of 30.35 mg/kg when adjusted by estimated coverage. From all OIE Regions, Africa has the lowest mg/kg estimate.

Changes in mg/kg results from 2014 to 2016

The updated mg/kg estimate for 2014 for 13 African countries is 32.72 mg/kg, with an upper-level estimate of 41.56 mg/kg when adjusted by estimate coverage.

The updated mg/kg estimate for 2015 for 25 African countries is 32.56 mg/kg, with an upper-level estimate of 37.97 mg/kg when adjusted by estimate coverage.

The updated mg/kg estimate for 2016 for 17 African countries is 37.04 mg/kg, with an upper-level estimate of 43.97 mg/kg when adjusted by estimate coverage.

Annex 2. Americas, Regional Focus

Table A2. General Information for the Americas during the Fifth Round of Data Collection

General Information for the Americas	
Number of countries*	35
Number of countries responding to the questionnaire	35 (100%)
Number of countries providing qualitative data only	11 (31%)
Number of countries providing quantitative data	24 (69%)

^{*31} OIE Members, one non-contiguous territory and three non-OIE Members

Since the second round of the data collection, the OIE questionnaire has been sent to non-OIE Members and non-contiguous territories that have asked to participate in the data collection survey.

In the Americas, 35 countries (n = 35; 100%) submitted completed reports to OIE Headquarters: 31 from OIE Members, one non-contiguous territory and three non-OIE Members. The response from the non-contiguous territory was included in the analysis of the Americas for geographical reasons (Table A2).

Barriers to Providing Quantities of Antimicrobial Agents in Animals

Eleven countries (n = 35; 31%) responded with Baseline Information (qualitative data) and no quantitative data on antimicrobial agents used in animals. Of these, ten countries (n = 11; 91%) explained their barriers to reporting antimicrobial quantities. Countries can report more than one barrier relevant to their situation, and responses were grouped by category (Figure A9). For further information on the category groupings, please refer to Section 3.5 of this report.

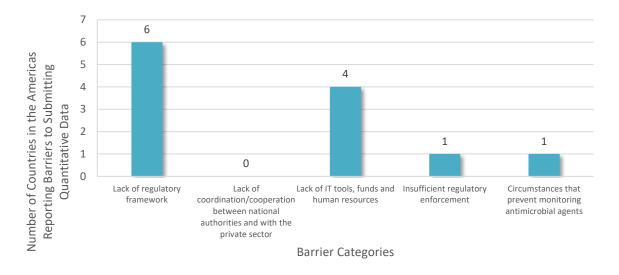
More than half of the responses in the Americas (6 out of 10 countries; 60%) mentioned that the main impediment to reporting antimicrobial quantities was the lack of regulatory frameworks. Four countries explained that no legislation existed for veterinary medicinal products, one of these countries noted that importers do not register and import veterinary products as the market is too small and falls below the minimum quantities for bulk purchase, and therefore, human medicines are used for animals. This country also mentioned that veterinarians import small quantities exclusively for use in livestock and poultry that are difficult to track. Two countries explained that the main barrier was that their legislations/regulations did not require the monitoring of antimicrobial use, so there were no regulations or guidelines on data collection procedure or stakeholder obligations.

Four responses were grouped in the category of lack of IT tools, funds and human resources. In this category, three countries explained that even if IT tools for the registration and importation of veterinary products existed, the following reasons would impede the reporting of quantities:

- The registration and the importation systems were not integrated;
- The registration system only partially recorded the necessary data to perform the calculations (e.g. active ingredients, strength of each active ingredient and package size/presentation);
- The import customs system did not record the package size/presentation of the veterinary products, but the weight of the shipment (in tonnes or kilograms). This created confusion in certain countries that reported the shipment weights to the OIE rather than the calculated weights of active ingredients.

Two countries cited the lack of human resources in their offices as an impediment to them collecting the data. One of these countries also mentioned the lack of an IT Tool, and the other noted that the COVID-19 situation had further impacted the lack of staff and activities for the drug agency.

Figure A9. Country Barriers to Reporting Quantitative Data on Antimicrobial Agents Intended for Use in Animals in 10 Countries in the Americas during the Fifth Round of Data Collection



Antimicrobial Agents Used for Growth Promotion

Twenty countries (n = 35; 57%) in the Americas used antimicrobial agents as growth promoters in 2019. Of these, 18 countries (n = 20; 90%) provided a list of antimicrobials used for growth promotion, with bacitracin most commonly named (Figure A10).

lonophores were excluded from reporting as they are mostly used for parasite control and have different regulatory classifications in different countries; however, 12 countries in the Americas reported the use of these molecules as growth promoters, where monensin and salinomycin were mentioned by eight countries and narasin by four countries.

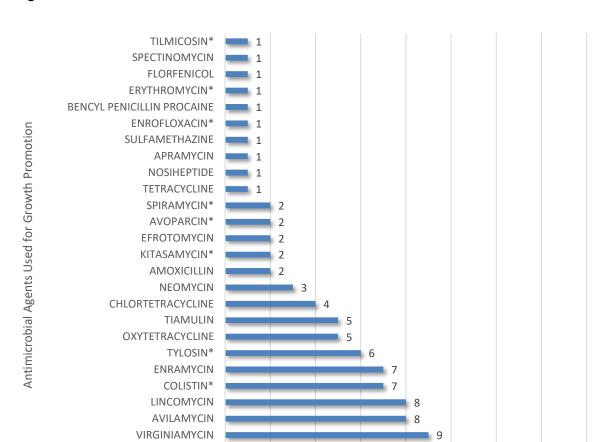


Figure A10. Antimicrobial Growth Promoters Used in 18 Countries in the Americas in 2019

Number of Countries in the Americas Reporting Use of Antimicrobial Agents for Growth Promotion in 2019

6

10

12

15

16

14

4

As mentioned in previous reports, the Americas is the OIE Region with most countries reporting a lack of legislation or regulation for antimicrobials used as growth promoters (12 out of 20 countries, 60%). However, the following cases were noted:

- Some countries are working in cooperation with pharmaceutical companies for the voluntary removal of growth promotion claims from the labels of all products that are considered to be Medically Important Antimicrobials in human medicine.
- A partial ban on growth promoters for specific animals (e.g. cattle and aquatic animals) or for colistin only.

2017 Analysis of Antimicrobial Quantities

BAMBERMYCINS (i.e. FLAVOMYCIN)

BACITRACIN

This section provides additional analysis of reported quantitative data on antimicrobial agents intended for use in animals adjusted by animal biomass, focusing on 2017. This analysis represents the antimicrobial quantities reported to the OIE from 17 countries in the Americas during all rounds of data collection.

^{*} The classes in the WHO category of Highest Priority Critically Important Antimicrobials should be the highest priority for countries when phasing out the use of antimicrobial agents as growth promoters.

QUANTITATIVE DATA SOURCES CAPTURED

All countries' data sources in the Americas were analysed, and countries where data duplication was considered to be a risk were asked for clarification of their answers and/or data collection systems. Six countries' data sources (n = 17, 35%) were considered to present a risk of duplication; after the clarifications, two countries (n = 6; 33%) changed their original data sources. Only the remaining countries (4 out of 6; 67%) that did not provide clarification were excluded from the analysis in Figure A11. For a full explanation of quantitative data sources, see the Guidance for Completing the OIE Template for the Collection of Data (Annex 7).

From the list of data source options provided in the OIE template, import and sales data were the main data sources used by the countries in the Americas (Figure A11).

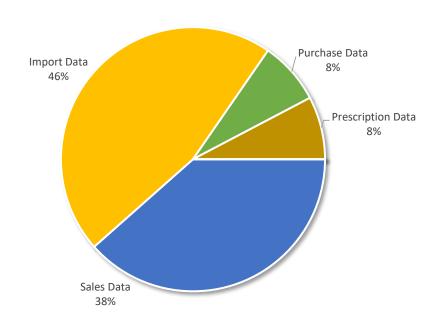


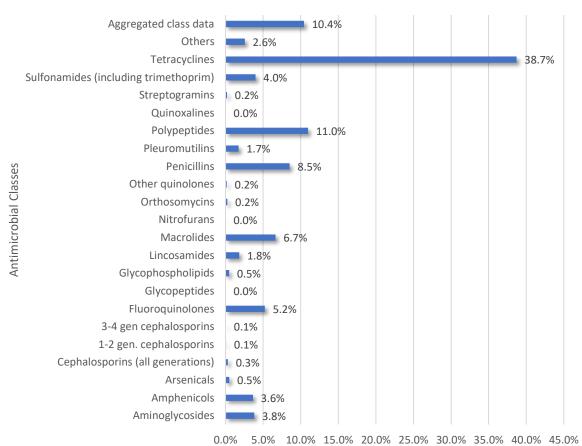
Figure A11. Data Sources Selected by 13 Countries in the Americas Reporting Quantitative Information for 2017

ANTIMICROBIAL QUANTITIES REPORTED IN 2017

For 2017, 17 countries in the Americas provided validated antimicrobial quantities intended for use in animals. Of the 17 countries, seven stated 100% coverage of the data source used to report the data. The ten countries that did not cover 100% of available antimicrobial quantity data sources were asked to provide further information on uncaptured data sources. For the 17 countries, the estimated data coverage was 86%. More information on the data coverage for the Americas is available in Table 5 of this report.

In the Americas, the largest proportion of all reported antimicrobial classes were tetracyclines, followed by polypeptides and the *aggregated class data* (Figure A12). The *aggregated class data* category is used for confidentiality purposes at the national level and since very few countries provided data under this category, the classes cannot be disclosed.

Figure A12. Proportion of Antimicrobial Classes Reported for Use in Animals by 17 Countries in the Americas 2017



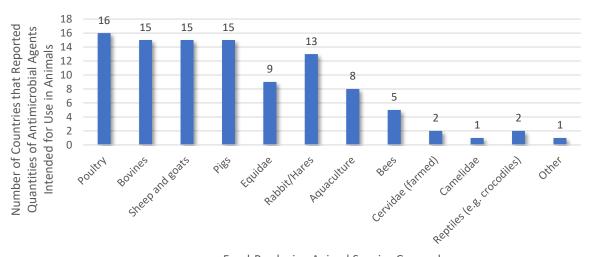
% of Reported Quantities of Antimicrobial Agents Used in Animals by 17 Countries

FOOD-PRODUCING TARGET SPECIES ON THE LABEL OF REPORTED VETERINARY PRODUCTS

Irrespective of whether the data could be differentiated by animal groups, all 17 countries were asked to select the food-producing animal species covered by their data from a list supplied in the OIE template and according to the products target species label. For descriptive purposes, some animals were grouped in categories, for more information on the grouping of animals see page 46 of this report.

One country reported data for companion animals only and was excluded from this analysis. In the 16 countries from the Americas that reported antimicrobial quantities for 2017, the food-producing species most frequently covered by the data were poultry, bovines, pigs, and sheep and goats (Figure A13).

Figure A13. Food-Producing Animal Species Included in Quantitative Data Reported by 16 Countries in the Americas in 2017

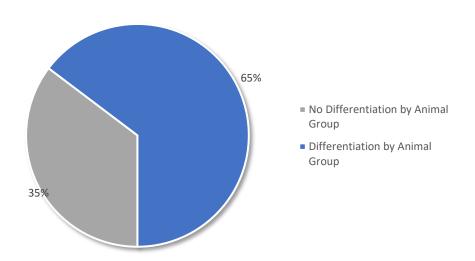


Food-Producing Animal Species Covered

QUANTITATIVE DATA DIFFERENTIATION BY ANIMAL GROUP

Most of the quantitative data from the Americas can be differentiated by animal group (Figure A14). For the countries that were able to distinguish antimicrobial quantities by animal group, data were mainly provided for food-producing animals (aquatic and terrestrial combined) and companion animals.

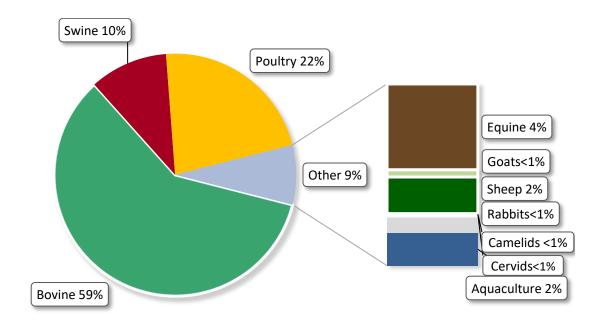
Figure A14. Differentiation by Animal Groups among 16 Members in the Americas Reporting Quantitative Data in 2017



ANIMAL BIOMASS

The bovine species make an important contribution (60%) to the total biomass of the Americas. In comparison to other regions, small ruminants (sheep and goats), have a relatively low impact on the region's biomass.

Figure A15. Species Composition of Animal Biomass for the 16 Countries in Americas Included in 2017 Quantitative Data Analysis



ANTIMICROBIAL QUANTITIES ADJUSTED BY ANIMAL BIOMASS

In the Americas, the mg/kg estimate for 2017 for 16 countries is 72.21 mg/kg, with an upper-level estimate of 90.50 mg/kg when adjusted by estimated coverage.

Changes in mg/kg results from 2014 to 2016

The updated mg/kg estimate for 2014 for eight countries in the Americas is 90.20 mg/kg, with an upper-level estimate of 94.04 mg/kg when adjusted by estimate coverage.

The updated mg/kg estimate for 2015 for eight countries in the Americas is 99.83 mg/kg, with an upper-level estimate of 102.90 mg/kg when adjusted by estimate coverage.

The updated mg/kg estimate for 2016 for 11 countries in the Americas is 89.16 mg/kg, with an upper-level estimate of 108.90 mg/kg when adjusted by estimate coverage.

Annex 3. Asia, Far East and Oceania, Regional Focus

Table A3. General Information for Asia during the Fifth Round of Data Collection

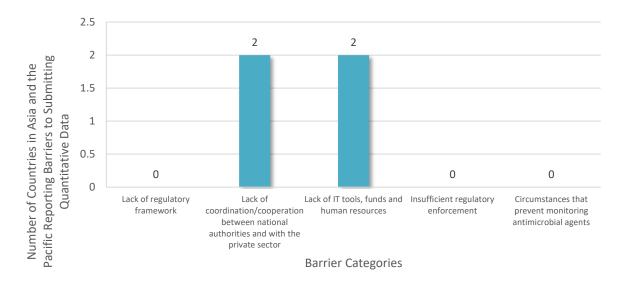
General Information for Asia, Far East and Oceania	
Number of OIE Members	32
Number of OIE Members responding to the questionnaire	31 (97%)
Number of OIE Members providing qualitative data only	5 (16%)
Number of OIE Members providing quantitative data	26 (84%)

Barriers to Providing Quantities of Antimicrobial Agents in Animals

For the fifth round, five countries responded with Baseline Information (qualitative data) and no quantitative data on antimicrobial agents used in animals. Of these, four countries explained their barriers to reporting antimicrobial quantities. Countries can report more than one barrier relevant to their situations, and these responses were grouped by category (Figure A16). For further information on the category groupings, please refer to Section 3.5 of this report.

Two countries mentioned that the main impediment to reporting antimicrobial quantities was the lack coordination and cooperation between different entities: one mentioned other national authorities and the other one, coordination with the pharmaceutical sector. Two other countries had initially intended to send quantities to the OIE, but during the exchanges it was found that their import systems did not record the package size/presentation of the veterinary products. Their systems recorded the weight of the shipment (in tonnes or kilograms) and this created confusion among the countries. The OIE shared the OIE Calculation Tool with these countries and can assist them in the submission of quantitative data in future rounds if necessary.

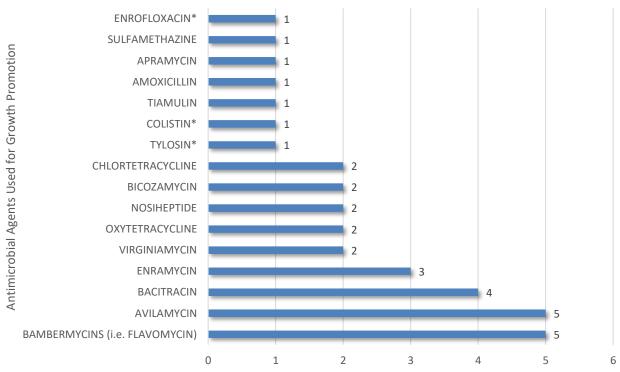
Figure A16. Country Barriers to Reporting Quantitative Data on Antimicrobial Agents Intended for Use in Animals in Four Countries in Asia, Far East and Oceania during the Fifth Round of Data Collection



Antimicrobial Agents Used for Growth Promotion

Twelve Members (n = 31; 39%) reported the use of antimicrobials as growth promoters. Of these, eight Members (n = 12; 66%) provided a list of utilised agents, the most frequently listed antimicrobial agents for this purpose were bambermycin (i.e. flavomycin) and avilamycin (Figure A17).

Figure A17. Antimicrobial Growth Promotors Used in Animals in Asia, Far East and Oceania in 2019 as reported by Eight Members



Number of Members in Asia, Far East and Oceania Reporting Use of Antimicrobial Agents for Growth Promotion in 2019 * The classes in the WHO category of Highest Priority Critically Important Antimicrobials should be the highest priority for countries when phasing out the use of antimicrobial agents as growth promoters.

2017 Analysis of Antimicrobial Quantities

This section provides additional analysis of reported quantitative data on antimicrobial agents intended for use in animals adjusted by animal biomass, focusing on 2017. This analysis represents the antimicrobial quantities reported to the OIE from 21 countries in Asia, Far East and Oceania during all four rounds of data collection.

QUANTITATIVE DATA SOURCES CAPTURED

All countries' data sources in Asia, Far East and Oceania were analysed, and all countries where data duplication was considered a risk were asked for clarification on their answers and/or data collection systems. Ten countries' data sources (n = 21; 48%) were considered to present a risk of duplication; after clarifications, seven countries (n = 10; 70%) changed their answers or proved there was no duplication or overlapping of data sources. Only the remaining countries (3 out of 10; 30%) that did not provide clarifications were excluded from the analysis of data sources in Figure A18. For a full explanation of quantitative data sources, see the Guidance for Completing the OIE Template for the Collection of Data (Annex 7).

From the list of data source options provided in the OIE template, import data was most commonly chosen (Figure A18). In addition, five Members described other data source not included in the OIE List, relating mainly to import data (Figure A19).

Figure A18. Data Sources Selected by 18 Countries in Asia, Far East and Oceania Reporting Quantitative Information for 2017

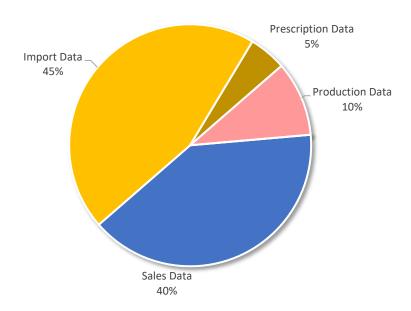
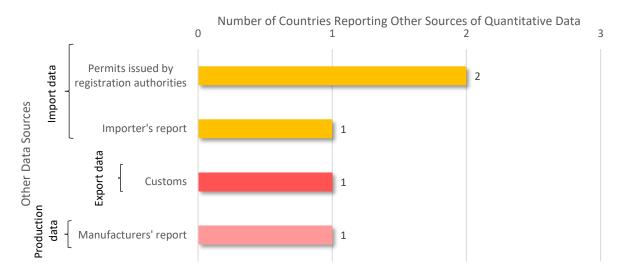


Figure A19. 'Other' Sources of Data as Explained by Five Members in Asia, Far East and Oceania Reporting Quantitative Information for 2017

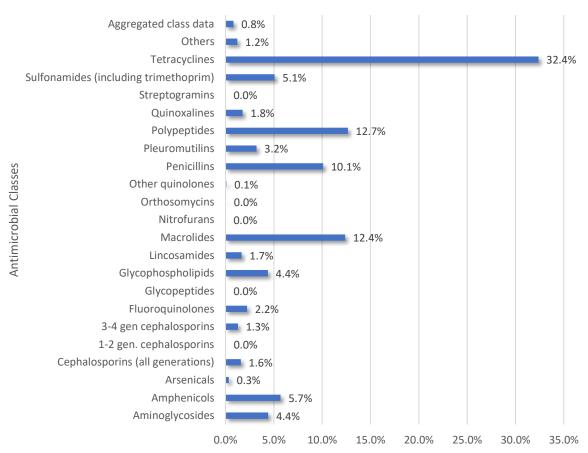


ANTIMICROBIAL QUANTITIES REPORTED IN 2017

For 2017, 21 countries in Asia, Far East and Oceania provided validated antimicrobial quantities intended for use in animals. Of these 21 countries, eight stated 100% coverage of the data sources used to report the data. The 13 countries that did not cover 100% of available antimicrobial quantities data sources were asked to provide further information on uncaptured data sources. For the 21 countries, the estimated data coverage was 89%. More information on the data coverage for Asia, Far East and Oceania, is available in Table 5 of this report.

In Asia, Far East and Oceania, the largest proportion of all reported antimicrobial classes were tetracyclines, followed by polypeptides and macrolides (Figure A20).

Figure A20. Proportion of Antimicrobial Classes Reported for Use in Animals by 21 Members in Asia, Far East and Oceania in 2017



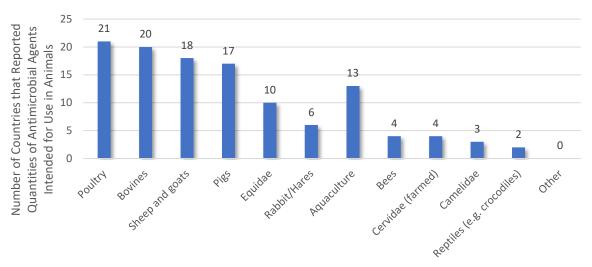
% of Reported Quantities of Antimicrobial Agents Used in Animals by 21 Countries

FOOD-PRODUCING TARGET SPECIES ON THE LABEL OF REPORTED VETERINARY PRODUCTS

Irrespective of whether the data could be differentiated by animal groups, all 21 countries were asked to select the food-producing animal species covered by their data from a supplied list in the OIE template and according to the products target species label. For descriptive purposes, some animals were grouped into categories, for more information on the grouping of animals see page 46 of this report.

Of the 21 countries from Asia, Far East and Oceania that reported antimicrobial quantities for 2017, the food-producing species most frequently covered by the data were poultry, bovines, sheep and goats, and swine (Figure A21). Asia, Far East and Oceania is the second OIE region that has more countries whose data cover aquaculture.

Figure A21. Food-Producing Animal Species Included in Quantitative Data Reported by 21 Countries in Asia, Far East and Oceania in 2017

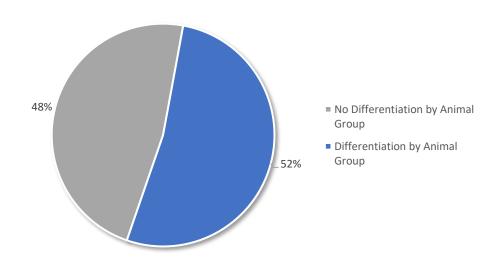


Food-Producing Animal Species Covered

QUANTITATIVE DATA DIFFERENTIATION BY ANIMAL GROUP

Most of the quantitative data from Asia, Far East and Oceania can be differentiated by animal group (Figure A22). For the countries that were able to distinguish antimicrobial quantities by animal group, data were mainly provided for food-producing animals (terrestrial and aquatic combined).

Figure A22. Differentiation by Animal Groups among 21 Members in Asia, Far East an Oceania Reporting Quantitative Data in 2017



ANIMAL BIOMASS

In contrast to the three other regions, the species contributing the most to the total biomass in Asia is swine, totalling 33% of the biomass followed by 21% for bovines. Moreover, the relative importance of aquaculture, reaching 20% of the animal biomass, exceeds the other regions. However, as detailed previously, percentages of aquaculture should be interpreted with caution as the aquaculture biomass

was only included for those countries reporting that their data on antimicrobial agents covered aquaculture. Therefore, the effect of aquaculture on biomass is skewed by the number of countries in that OIE Region for which antimicrobials used in aquaculture were included. In addition, the aquaculture biomass for aquatic food-producing animals is essentially composed of farmed fish but this annual report also includes, for the first-time data on farmed crustaceans, molluscs and amphibians.

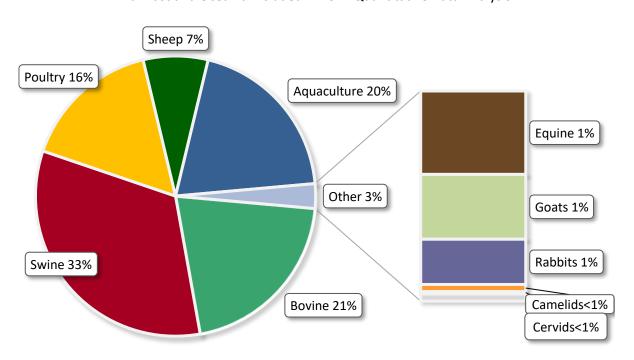


Figure A23. Species Composition of Animal Biomass for the 21 Countries in Asia, Far East and Oceania Included in 2017 Quantitative Data Analysis

ANTIMICROBIAL QUANTITIES ADJUSTED BY ANIMAL BIOMASS

In Asia, Far East and Oceania, the mg/kg estimate for 2017 of 21 countries is 192.24mg/kg, with an upper level estimate of 198.89 mg/kg when adjusted by estimated coverage.

Changes in mg/kg results from 2014 to 2016

The updated mg/kg estimate for 2014 for five Asian countries is 94.71 mg/kg, with an upper-level estimate of 94.71 mg/kg when adjusted by estimate coverage.

The updated mg/kg estimate for 2015 for 17 Asian countries is 291.80 mg/kg, with an upper-level estimate of 294.20 mg/kg when adjusted by estimate coverage.

The updated mg/kg estimate for 2016 for 19 Asian countries is 227.53 mg/kg, with an upper-level estimate of 230.09 mg/kg when adjusted by estimate coverage.

Annex 4. Europe, Regional Focus

Table A4. General Information for Europe during the Fifth Round of Data Collection

General Information for Europe	
Number of OIE Members	53
Number of OIE Members responding to the questionnaire	48 (91%)
Number of OIE Members providing qualitative data only	1 (2%)
Number of OIE Members providing quantitative data	47 (98%)

Barriers to Providing Quantities of Antimicrobial Agents in Animals

For the fifth round of data collection, only one contributing country in Europe did not report antimicrobial quantities. This country explained that relevant legislation was being harmonised with that of the European Union, and, once concluded the country expected to report antimicrobial quantities for the sixth round of data collection.

Antimicrobial Agents Used for Growth Promotion

From Europe, two countries (n = 48; 4%) reported the use of antimicrobial growth promoters in animals, but did not send the list of the molecules used for this purpose. One country (n = 48; 2%) reported that the use of growth promoters in the field was unknown and cited a lack of legislation or regulation for these molecules.

2017 Analysis of Antimicrobial Quantities

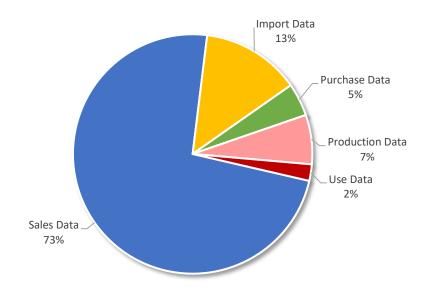
This section provides additional analysis of reported quantitative data on antimicrobial agents intended for use in animals adjusted by animal biomass, focusing on 2017. This analysis represents the antimicrobial quantities reported to the OIE from 39 countries in Europe during all four rounds of data collection.

QUANTITATIVE DATA SOURCES CAPTURED

All countries' data sources in Europe were analysed, and all countries where data duplication was considered a risk were asked for clarification of their answers and/or data collection systems. Seven countries' data sources (n = 39; 18%) were considered to present a risk of duplication; after clarifications, six countries (n = 7; 86%) changed their answers or proved there was no duplication or overlapping of data sources. Only the one remaining country (one out of seven; 14%) that did not provide a clarification to the OIE was excluded from the analysis in Figure A24. For a full explanation of quantitative data sources, see the Guidance for Completing the OIE Template for the Collection of Data (Annex 7).

From the list of data source options provided in the OIE template, sales data for veterinary products as declared by wholesalers was most commonly chosen, with 19 Members (n= 38; 50%) selecting this option (Figure A24).

Figure A24. Data Sources Selected by 38 Countries in Europe Reporting Quantitative Information for 2017

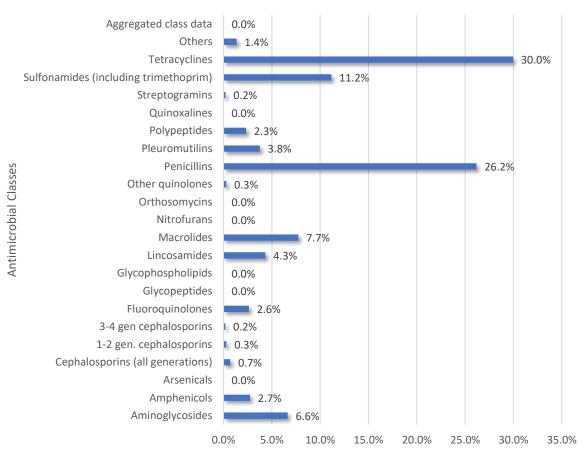


ANTIMICROBIAL QUANTITIES REPORTED IN 2017

For 2017, 39 countries in Europe provided validated antimicrobial quantities intended for use in animals. Of the 39 countries, 26 stated 100% coverage of the data source used to report the data. The 13 countries that did not cover 100% of available antimicrobial quantities were asked to provide further information on uncaptured data sources. For the 39 countries, the estimated data coverage was 93%. For more information on the data coverage for Europe, please refer to Table 5 of this report.

In Europe, the largest proportion of all reported antimicrobial classes were tetracyclines, followed by penicillins and sulfonamides (Figure A25).

Figure A25. Proportion of Antimicrobial Classes Reported for Use in Animals by 39 European Members in 2017



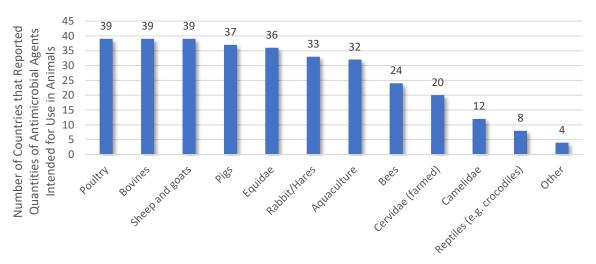
% of Reported Quantities of Antimicrobial Agents Used in Animals by 39 Countries

FOOD-PRODUCING TARGET SPECIES ON THE LABEL OF REPORTED VETERINARY PRODUCTS

Irrespective of whether the data could be differentiated by animal group, all 39 countries were asked to identify the food producing animal species covered by their data from a list supplied in the OIE template and according to the products target species label. For descriptive purposes some animals were grouped into categories, for more information on the grouping of animals see page 46 of this report.

In the 39 countries from Europe that reported antimicrobial quantities for 2017, the food-producing species most frequently covered by the data were poultry, bovines, sheep and goats (Figure A26). Europe is the OIE region that is providing the most data covering aquaculture.

Figure A26. Food-Producing Animal Species Included in Quantitative Data Reported by 39 Countries in Europe in 2017

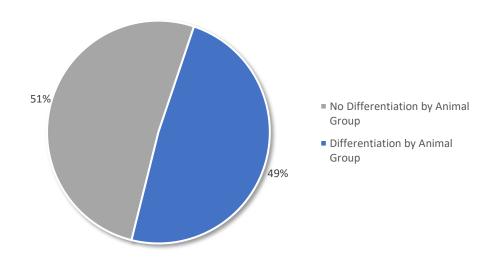


Food-Producing Animal Species Covered

QUANTITATIVE DATA DIFFERENTIATION BY ANIMAL GROUPS

Half of the quantitative data from Europe can be differentiated by animal group (Figure A27). For the countries that were able to distinguish antimicrobial quantities by animal groups, data were mainly provided for food-producing animals (terrestrial and aquatic combined).

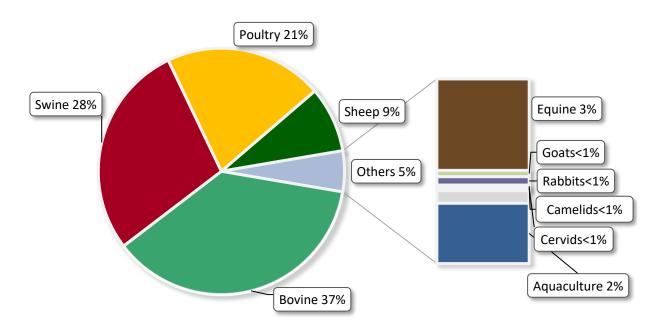
Figure A27. Differentiation by Animal Groups among 39 Members in Europe Reporting Quantitative Data in 2017



ANIMAL BIOMASS

The relative species composition of animal biomass in Europe is very similar to the global composition of animal biomass, with the four main species, bovine, swine, poultry and sheep, representing more than 95% of the total biomass of the region.

Figure A28. Species Composition of Animal Biomass for the 39 Countries in Europe Included in 2017 Quantitative Data Analysis



ANTIMICROBIAL QUANTITIES ADJUSTED BY ANIMAL BIOMASS

In Europe, the mg/kg estimate for 2017 for 39 countries is 57.42 mg/kg, with an upper-level estimate of 59.55 mg/kg when adjusted by estimated coverage.

Changes in mg/kg results from 2014 to 2015

The updated mg/kg estimate for 2014 for 31 European countries is 92.22 mg/kg, with an upper-level estimate of 94.11 mg/kg when adjusted by estimate coverage.

The updated mg/kg estimate for 2015 for 36 European countries is 77.40 mg/kg, with an upper-level estimate of 81.32 mg/kg when adjusted by estimate coverage.

The updated mg/kg estimate for 2016 for 40 European countries is 67.45 mg/kg, with an upper-level estimate of 69.11 mg/kg when adjusted by estimate coverage.

Annex 5. Middle East, Regional Focus

Table A5. General Information for the Middle East during the Fifth Round of Data Collection

General Information for the Middle East	
Number of OIE Members	12
Number of OIE Members responding to the questionnaire	7 (58%)
Number of OIE Members providing qualitative data only	3 (43%)
Number of OIE Members providing quantitative data	4 (57%)

Due to confidentiality concerns, most variables included in the survey cannot be published in this report for the Middle East as the data represents only a small number of countries (Table A5). Higher participation in the Middle East Region in the future would allow a more in-depth study of the data.

Barriers to Providing Quantities of Antimicrobial Agents in Animals

During the fifth round, three Members (n = 7; 43%) responded with Baseline Information (qualitative data) and no quantitative data and explained the barriers to reporting quantities of antimicrobial agents used in animals (Table A5). For further information on the category groupings, please refer to Section 3.5 of this report.

One country explained that the country security situation affected its ability to obtain sales data for veterinary medicinal products. Another country outlined that an IT system was being developed and it was expected that the antimicrobial quantities would be reported for the sixth round of data collection.

Annex 6. OIE Template

Q	ı	the contract of the contract o	ould be completed by all OIE Member Countries ***
	1		
	_		microbial Agents Use Data Collection
1	+		<free field="" text=""></free>
2	1	Name (First name, SURNAME)	<free field="" text=""></free>
		Role with respect to the OIE	OIE Delegate
3			OIE Focal Point for Veterinary Products
			Other
4	_	Organisation	<free field="" text=""></free>
5	+	Organisation's Address	<free field="" text=""></free>
7	_	Country Phone Number	<free field="" text=""> <free field="" text=""></free></free>
8	-		<free field="" text=""></free>
-			eral Information
	Q		n in your country. Responses should not be linked to the year of
			al quantities reported.
	4	Are data on the amount of antimicrobial agents	Amounts available - Yes
9	i	ntended for use in animals available?	Amounts available - No
	P	Please indicate why the data are not available at	Amounts are made to
10) t	his time in your country, if the answer to Question	<free field="" text=""></free>
	9) is 'No'	
	١,	Are antimicrobial agents used for growth	Yes
11		promotion purposes in animals in your country?	□ No
		romotion purposes in animals in your country.	Unknown
	0	Ooes your country have legislation/regulations	Legislation/regulation exists - Yes
12		on antimicrobial agents as growth promoters in	Legislation/regulation does not exist - No
	а	nimals?	
		f your country has legislation/regulation on	All antimicrobial agents banned for use as growth promoters
13	2	Intimicrobial agents as growth promoters in	Some antimicrobial agents banned for use as growth promoters
		nimals, could you please indicate the	One or more subjusticabled arough accounts are subjusted for use
	a	ppropriate case that applies in your country?	One or more antimicrobial growth promoters are authorised for use
	P	Please provide a list of antimicrobial agents used	
14	1	or authorised as growth promoters, if any	<free field="" text=""></free>
щ	If v	your response to Question Q is 'Ne' places kindly se	and this template, once validated by the OIE Delegate and with your
	ı, y		o the OIE Antimicrobial Use Team at:
			icrobialuse@oie.int
		If your response to Question 9 is 'Yes',	please kindly complete Section C " <u>Data Collection</u> ".
		C. Data collection of Antimic	robial Agents Intended for Use in Animals
		*** Please provide data for 2017 If you have data	for another year, please select the year from the list below ***
			2017 (target year)
	15	Year for which data apply	2018
	_	(Please select only one year per template)	2019
		Time period for which data are provided	
	16	(e.g., 1 January to 31 December 2017)	<free field="" text=""></free>

17	Data source	Sales data Sales data - Wholesalers
		☐ Sales data - Retailers
		Sales data - Marketing Authorisation Holders
		Sales data - Registration Authorities
		Sales data - Feed Mills
		Sales data - Pharmacies
		Sales data - Farms Shops/Agricultural Suppliers Sales data - Industry Trade Associations
		Purchase data
		Purchase data - Wholesalers
		Purchase data - Retailers
		☐ Purchase data - Feed Mills
		☐ Purchase data - Pharmacies
		Purchase data - Agricultural Cooperatives
		Purchase data - Producer Organisations
		Import data Import data - Customs declarations - Veterinary Medicinal Product
		Import data - Customs declarations - Active Ingredient
		Veterinary data
		Veterinary data - Sales
		☐ Veterinary data - Prescriptions
		Antimicrobial use data
		Antimicrobial use data - Farm Records Other data source(s)
		Other
18	Clarification of the data source, if your response to Question 17 is 'Other'	<free field="" text=""></free>
19	Estimated coverage of accessible data out of total amount (in %)	0%
20	Explanation of estimated coverage	<free field="" text=""></free>
21	Is the information extrapolated from	☐ Data extrapolated from representatives samples - Yes
	Is the information extrapolated from representative samples?	☐ Data extrapolated from representatives samples - Yes ☐ Data extrapolated from representatives samples - No
	Is the information extrapolated from representative samples?	☐ Data extrapolated from representatives samples - Yes ☐ Data extrapolated from representatives samples - No
22	-	
22	representative samples? Explanation of extrapolations carried out, if your response to Question 21 is 'Yes'	Data extrapolated from representatives samples - No
	representative samples? Explanation of extrapolations carried out, if your	Data extrapolated from representatives samples - No <free field="" text=""></free>
22	representative samples? Explanation of extrapolations carried out, if your response to Question 21 is 'Yes'	Data extrapolated from representatives samples - No <free field="" text=""> Data differentiated by animal group - Yes</free>
22	representative samples? Explanation of extrapolations carried out, if your response to Question 21 is 'Yes'	Data extrapolated from representatives samples - No <free field="" text=""> Data differentiated by animal group - Yes Data differentiated by animal group - No Data with no differentiation (all animals combined) Data for terrestrial and aquatic food animals (all food-producing animals</free>
22	representative samples? Explanation of extrapolations carried out, if your response to Question 21 is 'Yes' Can data be differentiated by animal group?	Data extrapolated from representatives samples - No <free field="" text=""> Data differentiated by animal group - Yes Data differentiated by animal group - No Data with no differentiation (all animals combined)</free>
22	representative samples? Explanation of extrapolations carried out, if your response to Question 21 is 'Yes'	Data extrapolated from representatives samples - No <free field="" text=""> Data differentiated by animal group - Yes Data differentiated by animal group - No Data with no differentiation (all animals combined) Data for terrestrial and aquatic food animals (all food-producing animals combined) Data for terrestrial food-producing animals and companion animals (combined)</free>
22	representative samples? Explanation of extrapolations carried out, if your response to Question 21 is 'Yes' Can data be differentiated by animal group?	Data extrapolated from representatives samples - No <free field="" text=""> Data differentiated by animal group - Yes Data differentiated by animal group - No Data with no differentiation (all animals combined) Data for terrestrial and aquatic food animals (all food-producing animals combined) Data for terrestrial food-producing animals and companion animals (combined)</free>

25	Food-producing animal species covered by the	☐ Cattle
25	information on antimicrobial quantities	Pigs - commercial
	imormation on antimicropial quantities	
		☐ Pigs - backyard ☐ Sheep
		Goats
		Sheep and goats (mixed flocks)
		Layers - commercial production for eggs
		Broilers - commercial production for meat
		Other commercial poultry
		Poultry - backyard
		☐ Buffaloes (excluding Syncerus caffer)
		Cervidae (farmed)
		☐ Camelidae
		☐ Equidae
		Rabbits
		Bees - Honey
		Fish - aquaculture production
		☐ Crustaceans - aquaculture production
		Molluscs - aquaculture production
		Amphibians
		Reptiles (e.g., crocodiles)
		Other
		□ All
	Clarification of other species considered to be food-	
26	producing, if your response to Question 25 is	<free field="" text=""></free>
	' <u>Other commercial poultry</u> ' or ' <u>Other</u> '	
		Canines
27	Companion animal species covered by	Felines
	antimicrobial quantities, if any	Other
	Clarification of other species considered to be	
28	companion animals, if your response to Question	<free field="" text=""></free>
20	27 is 'Other'	Specient period
	27.15 GUICE	
29	Can data be differentiated by route of	Data differentiated by route of administration - Yes
	administration?	Data differentiated by route of administration - No
	National report(s) on sales/use of antimicrobial	Report available on the web - Yes
30	agents in animals available on the web?	_ ·
		Report available on the web - No
	Please provide the link to the report, if the answer	6 6
31	to Question 30 is 'Yes'	<free field="" text=""></free>

According to your responses to the questions abo	ove, you are invited to fill in the following Reporting Option:
REPORTING OPTION	Appropiate for your Country
Option 1	<u>NO</u>
Option 2	<u>NO</u>
Option 3	<u>NO</u>

OIE 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

t: dical Use Growth Promotion	ecies All animal species (kg)				0																					0	List all classes for which the amounts were combined, using whenever possible the 'Antimicrobial class' terms or the terminology of the OIE list of antimicrobial agents of veterinary importance. Substances included in the data aggregation that are not part of the recommended terminology should also be listed. If one class was reported that needs to remain confidential, please enter 'Confidential'.	Describe the class or classes reported as 'Others', using whenever possible the terminology of the OIE list of antimicrobial agents of veterinary importance.	Please describe the calculations carried out in addition to the ones recommended by the OIE in sections 1 and 2 of the annex to the instructions for the completion of the OIE template.
Amount: Veterinary Medical Use (including prevention of clinical signs)	All animal species (kg)	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0			0	0	0	List all classes for which t possible the 'Artimicrobi of antimicrobial agents of the data aggregation that should also be listed. If or confidential, please ente	Describe the class or class possible the terminology veterinary importance.	Please describe the calcul recommended by the OIE instructions for the compl
Overall Amount: Veterinary Medical Use + Growth Promotion	All animal species (kg)																										dree text field>	dree text field>	dree text field>
	Antimicrobial Class	Aminoglycosides	Amphenicols	Arsenicals	Cephalosporins (all generations)	1-2 gen. cephalosporins	3-4 gen cephalosporins	Fluoroquinolones	Glycopeptides	Glycophospholipids	Lincosamides	Macrolides	Nitrofurans	Orthosomycins	Other quinolones	Penicillins	Pleuromutilins	Polypeptides	Quinoxalines	Streptogramins	Sulfonamides (including	Tetracyclines	0.042	Others	Aggregated class data	Total kg	If 'Aggregated class data' are reported, please list the classes combined	if 'Others' are reported under 'Antimicrobial class', please list the classes reported	Please report any additional calculations applied

OIE 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

	Overall Amount:			A A.			
	Veterinary Medical Use + Growth Promotion		(inc	Amount: Veterinary Medical Use (including prevention of clinical signs)	Use al signs)		Amount: Growth Promotio
Antimicrobial Class	All animal species (kg)	All animal species (kg)	Companinon 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			i
Amphenicols	0	0		0			
Arsenicals	0	0		0			
Cephalosporins (all generations)	0	0	0	0	0	0	
1-2 gen. cephalosporins	0	0		0			
3-4 gen cephalosporins	0	0		0			
Fluoroquinolones	0	0		0			
Glycopeptides	0	0		0			
Glycophospholipids	0	0		0			
Lincosamides	0	0		0			
Macrolides	0	0		0			
Nitrofurans	0	0		0			
Orthosomycins	0	0		0			
Other quinolones	0	0		0			
Penicillins	0	0		0			
Pleuromutilins	0	0		0			
Polypeptides	0	0		0			
Quinoxalines	0	0		0			
Streptogramins	0	0		0			
Sulfonamides (including trimethoprim)	0	0		0			
Tetracyclines	0	0		0			
Others	0	0		0			
Aggregated class data	0	0		0			
Total kg	0	0	0	0	0	0	
If 'Aggregated dass data' are reported, oplease list the classes combined	dree text field>	List all classes forv terms or the termi included in the dat listed. If one class v	which the amount inology of the OIE a aggregation tha was reported that	List all dasses for which the amounts were combined, using whenever possible the 'Antimicrobial class' terms or the terminology of the OIE list of antimicrobial agents of veterinary importance. Substances included in the data aggregation that are not part of the recommended terminology should also be listed. If one class was reported that needs to remain confidential , please enter 'Confidential'.	ieneverpossible the', of veterinary importa mended terminology s ial, please enter' Conf	Antimicrobial class' nce . Substances ihould also be idential'.	
If 'Others' are reported under 'Antimicrobial class', please list the classes reported	dree text field>	Describe the class list of antimicrobia	or classes reporte Il agents of veterir	Describe the class or classes reported as 'Others', using whenever possible the terminology of the OIE list of antimicrobial agents of veterinary importance.	ver possi ble the termii	nology of the OIE	
y additional calculations	cfree text field>	Please describethe 1 and 2 of the anne	e calculations carr ex to the instructi	Please describe the calculations carried out in addition to the ones recommended by the OIE in sections 1 and 2 of the annex to the instructions for the completion of the OIE template.	nes recommended by '	the OIE in sections	

OIE template for the collection of data on antimicrobial agents intended for use in animals Reporting option 3 - Overall amount sold for/used in animals by antimicrobial class, with the possibility to separate by type of

	Overall Amount: Veterinary Medical Use + Growth Promotion							Vete (including	Amount: Veterinary Medical Use (including prevention of dinical signs)	cal Use							Amount: Growth Promotion
	All Animal Species		All animal species		ပ	Companion animals	sı	All fo (ter	All food-producing animals (terrestrial and aquatic)	imals tic)	Terrestri	Terrestrial food-producing animals	animals	Aquatic	Aquatic food-producing animals		All food-producing animals (terrestrial and aquatic)
Antimicrobial Class	All routes (kg)	Oral route (kg)	Injection route (kg)	Other routes (kg)	Oral route (kg)	Injection route Other routes (kg)	Other routes (kg)	Oral route (kg)	Injection route Other routes (kg)	Other routes (kg)	Oral route (kg)	Injection route (kg)	Other routes (kg)	Oral route (kg)	Injection route Other routes (kg)	Other routes (kg)	All routes (kg)
Aminoglycosides	6	0	0	0				0	0	0							
Amphenicols	6	0	0	0				0	0	0							
Arsenicals	0	0	0	0				0	0	0							
Cephalosporins (all generations)	0	0	0 0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
1-2 gen. cephalosporins	0	0	0 0	0				0	0	0							
3-4 gen cephalosporins	0	0	0 0	0				0	0	0							
Fluoroquinolones	0	0	0	0				0	0	0							
Glycopeptides	6	0	0 0	0				0	0	0							
Glycophospholipids	0	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							
Orthosomycins	0	0	0 (0				0	0	0							
Other quinolones	0	0	0 0	0				0	0	0							
Penicillins	0	0	0 0	0				0	0	0							
Pleuromutilins	0	0	0	0				0	0	0							
Polypeptides	0	0	0	0				0	0	0							
Quinoxalines	0	0	0	0				0	0	0							
Streptogramins	0	0	0	0				0	0	0							
Sulfonamides (including trimethoprim)	6	0	0	0				0	0	0							
Tetracyclines	0	0	0 0	0				0	0	0							
Others	0	0	0 0	0				0	0	0							
Aggregated class data	0	0	0 (0				0	0	0							
Total kg	Ö	0	0	0	0	0	0	0	o	0	0	0	0	0	0	0	0
		1		1		1				Ì	1						

If 'Aggregated class data' are reported, please list the classes combined	<free field="" text=""></free>	List all classes for which the amounts were combined, using whenever possible the 'Antimic obiaid ass' terms or the terminology of the OIE list of antimicrobial agents of veterinary importance. Substances included in the data aggregation that are not part of the recommended terminology should also be listed. If one class was reported that needs to remain confidential, please enter 'Confidential'.
If 'Others' are reported under Antimicrobial class', please list the classes reported	<free field="" text=""></free>	Describe the class or classes reported as 'Others', using whenever possible the terminology of the OIE list of antimicrobial agents of veterinary importance.
Please report any additional calculations applied	cfree text field>	Please describe here calculations carried out in addition to the ones recommended by the OIE in sections 1 and 2 of the annex to the instructions for the compilation of the OIE template.

Annex 7. Guidance for Completing the OIE Template for the Collection of Data on Antimicrobial Agents Used in Animals

Antroduction

The OIE proposes to collect data on <u>antimicrobial agents</u> intended for use in animals from OIE Member Countries implementing Chapter 6.9, "Monitoring of the quantities and usage patterns of antimicrobial agents used in food-producing animals" of the OIE *Terrestrial Animal Health Code* and Chapter 6.3 "Monitoring of the quantities and usage patterns of antimicrobial agents used in aquatic animals" of the OIE *Aquatic Animal Health Code*, and to contribute to the global effort against antimicrobial resistance.

Member Countries 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 "OIE template"), the OIE seeks to collect data on antimicrobial agent intended for use in animals from all OIE Member Countries in a harmonised way. Using a phased approach, the OIE will initially focus on sales11 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 the OIE List of antimicrobial agents of veterinary importance 12, 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. The OIE places highest priority on food-producing animals; however, data on all animals, including companion 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., <u>chemical compound</u> 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', 'companion animals', 'all food-producing animals', 'terrestrial food-producing animals', and 'aquatic food-producing animals'.

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

Please contact <u>antimicrobialuse@oie.int</u> for any question on the OIE template.

Required information and choices for reporting

As noted before, OIE Member Countries 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 the OIE template: 'Baseline Information', 'Reporting Option 1', 'Reporting Option 2', and 'Reporting Option 3'.

^{&#}x27;Sales', in the context of the OIE data collection on antimicrobial agents used in animals, should be interpreted to include data on import of antimicrobial agents for use in animals.

https://www.oie.int/fileadmin/Home/eng/Our_scientific_expertise/docs/pdf/AMR/A_OIE_List_antimicrobials_July2019.pdf

The Baseline Information sheet allows participation of all Member Countries: and should be completed by all. On this sheet, some fields are formatted in *italics and grey;* these fields are optional, but Member 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, or the sheet labelled Reporting Option 2 or the sheet labelled Reporting Option 3 should be completed – only one of the three Reporting Options should be selected.

-Baseline Information

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

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

	Field name	Information to be provided
		Contact Person for Antimicrobial Agents Use Data Collection
	(Please	provide the contact details of the person entering the information)
1	Title	Salutation (e.g., Dr, Ms, Mr).
2	Name	First or given name, SURNAME or FAMILY NAME.
3	Role with respect to	Please choose either 'Delegate', 'National Focal Point for Veterinary Products'
	the OIE	or 'Other' to describe your relation to the OIE.
4	Organisation	Name of the organisation for which you work, administrative subunit, and
		position.
5	Organisation's	Full mailing address of your organisation.
	Address	
6	Country	Country name.
7	Phone Number	Please provide the telephone number in the format "(country code) phone
		number".
8	Email Address	Email address where you can best be reached.

		B. General Information
	Questions 9 to 14 are rel	ated to the current situation in your country. Responses should not be linked to the year of antimicrobial quantities reported.
9	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 is available for part of your country, choose 'Yes'.
10	Please indicate why the data are not available at this time in your country, if the answer to Question 9 is 'No'	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'.
11	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'.
12	Does your country have legislation/regulations on antimicrobial	Please respond by ticking either 'Legislation/regulation exists - Yes' or 'Legislation/regulation does not exist - No'.

	agents as growth promoters in animals?	
13	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'.
14	Please provide a list of antimicrobial agents used or authorised as growth promoters, if any	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.
If d	ata on the amount of antim	nicrobial agents intended for use in animals are not available in your country, the completion of the OIE template is terminated after completing Question 14 of the Baseline Information sheet.
	C. Dat	a Collection of Antimicrobial Agents Intended for Use in Animals
15	Year for which data apply (Please select only one year per template)	(Reserved to the Countries where data are available) Please provide data for 2017. If you have data for another year, please select the year from the list. We will accept data for other years, but not from before 2017. If you would like to provide data for additional years, please fill out one template per year of data. If you have found calculation errors in data already submitted to the OIE for previous years, we ask that you please send an updated data template to the Antimicrobial Use Team.
16	Time period for which data are provided (e.g., 1 January to 31 December 2017)	Please provide further information regarding the reporting year, especially if the data only covers a portion of the calendar year.
17	Data source	Please describe the origin of the data on antimicrobial sales 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 <i>OIE Terrestrial Code</i> and Chapter 6.3 of the <i>OIE Aquatic Code</i> provide more detail on potential sources of such information. Possible data sources include: • 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 is 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. 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

18	Clarification of the data source, if your response to Question 17 is 'Other'	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. Ideally, the source of information should be as close to the point of use as possible. 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. If under Data source the option 'Other' is selected, please explain here which source of information was used.
19	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 sales for use in animals (percentage of the total sales in your country in relation to overall use).
20	Explanation of estimated coverage	Please explain in this field which data were not captured on the antimicrobial agents used in animals reported for your country in the OIE template. 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).
21	Is the information extrapolated from representative samples?	Please indicate whether the data provided in your report have been extrapolated from representative samples.
22	Explanation of extrapolations carried out, if your response to Question 21 is 'Yes'	Please explain in this field the nature of any extrapolations that were carried out in order to provide the data recorded in the OIE template.
23	Can data be differentiated by animal group?	Please respond by ticking 'Yes' or 'No'. For the purposes of the database, animal group means: 'Terrestrial food-producing animals', 'Aquatic food-producing animals' or 'Companion animals'. If your data is differentiated by any of these groups, please select 'Yes'.
24	Animal groups covered by the data	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 companion animals', 'Data for terrestrial food-producing animals and companion animals (combined)', 'Data for terrestrial food-producing species', 'Aquatic food-producing animals', 'Data for aquatic food-producing animals' and 'Data for companion animals'. Multiple selections are possible.
25	Food-producing animal species covered by the information on antimicrobial quantities	Animal species considered to be food-producing animals vary between countries. The OIE needs to gain an understanding of how this difference impacts the antimicrobial quantities reported to the OIE and future reporting of summary quantities by the OIE. Please indicate which animals are considered to be food-producing animals covered by the quantities. Multiple selections are possible.
26	Clarification of other species considered to be food-producing, if	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.

÷			
ı		your response to	
ı		Question 25 is 'Other	
ı		<u>commercial poultry'</u>	
L		or ' <u>Other'</u>	
ı	27	Companion animal	The OIE needs to gain an understanding of how this difference could impacts
ı		species covered by	the antimicrobial quantities reported to the OIE and future reporting of summary
ı		the information on	quantities by the OIE. Please indicate which animals are considered to be
ı		<u>antimicrobial</u>	companion animals covered by the quantities. Multiple selections are possible.
L		<u>quantities</u>	
I	28	Clarification of other	Please provide any explanations you may feel necessary to explain which animal
ı		species considered to	species covered by the data are considered companion animals (e.g. horses).
ı		be companion	
ı		animals, if your	
ı		response to Question	
ı		27 is 'Other'	
Γ	29	Can data be differen-	Please respond by ticking either 'Yes' or 'No'.
ı		tiated per route of	
L		administration?	
ſ	30	National report(s) on	Please respond by ticking either 'Yes' or 'No'.
ı		sales/use of	
ı		antimicrobial agents	
ı		in animals available	
L		on the web?	
ľ	31	Please provide the	If answer is 'Yes' to Question 30, please insert the link to the site where the
I		link to the report, if	report is available on the internet.
ı		your response to	
		Question 30 is 'Yes'	

Classes of antimicrobial agents for reporting

All antimicrobial classes used in animals (for <u>veterinary medical</u> including prevention of clinical signs, as well as growth promotion, whether classified as veterinary medicines or not, <u>with the exception of ionophores</u>) should be included in the table by the reporting OIE Member Country.

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 nitarsone, 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).		
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	ds Includes bambermycin (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.		
Polypeptides	Includes bacitracin, colistin, polymyxin B and others.		

Antimicrobial class	Guidance		
Quinoxalines	Includes carbadox, olaquindox and others.		
Streptogramins Includes virginiamycin, pristinamycin, and others.			
Sulfonamides (includ- Includes all sulfonamides, as well as trimethoprim and similar compounds ing trimethoprim)			
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	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 confidential (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 the OIE template. In cases where the amounts sold for more than one class are reported as aggregated data, please enter <agg> in the table for those substances for which sales quantities have been included in the aggregated amount, and list the names of the classes of antimicrobial agents that cannot be reported individually in the free-text field called 'If 'Aggregated class data' are reported, please list here the classes combined' located underneath the table collecting the antimicrobial quantities.</agg>		

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

Field name	Information to be provided
If 'Aggregated class data' are reported, please list the classes combined	If for your country there are Aggregated class data , please list the names of the classes of antimicrobial agents that cannot be reported individually. If sales for only one antimicrobial class that needs to remain confidential are reported as Aggregated class data , please enter the word 'Confidential' in this free-text field. Whenever possible, use the 'Antimicrobial class' terms explained above or the terminology of the <i>OIE List of antimicrobial agents of veterinary importance</i> . Aggregated data may include substances that are not mentioned in the definition of 'Antimicrobial classes for use in animals'. In such cases, please specify any additional classes of antimicrobials which are included in the reported amount for Aggregated class data that are not listed in the table.
If 'Others' are reported under terminology of the OIE List of antimicrobial agents of veterinary importations the classes reported as 'Others', using whenever terminology of the OIE List of antimicrobial agents of veterinary importations the classes reported as 'Others', using whenever terminology of the OIE List of antimicrobial agents of veterinary importations.	
Please report any additional calculations applied	Please describe calculations carried out in addition to the ones recommended by the OIE in Sections 1 and 2 of the Annex to the Guidance for completing the OIE 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
- % weight per volume (% w/v)

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', please enter the three letters <AGG> in the table for all classes, for which quantities sold have been summarised.

Ideally, the OIE is interested in the amount of <u>active ingredient</u> (moiety), that is, the substance as listed in the *OIE 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, the OIE 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 the OIE 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 the OIE 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 OIE Member Countries 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.

Reporting Option 1

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

The sheet Reporting Option 1 is designed for the reporting of data on amount or type of antimicrobial agents used <u>in all animals</u>. 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 below).

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 (Growth Promotion + Veterinary Medical)" for each class.

Reporting Option 2

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

If the data can be differentiated by use in all food-producing animals, companion 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 therapeutic 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", "Companion 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.

Reporting Option 3

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

If the data can be differentiated <u>by route of administration</u>, Reporting Option 3 is the appropriate choice. Further differentiation by antimicrobial class, by use in companion animals, food-producing species and, where possible, by use in terrestrial and aquatic food-producing species as well as veterinary medical, including prevention of clinical signs, or growth promotion, is possible.

In the category of "Veterinary Medical (including prevention of clinical signs)", the OIE is interested in differentiating the proportion of sales by route of administration for mass treatment (e.g., via feed) versus those more suited for treatment of individual animals (e.g., injection route, other routes). If sales for veterinary medical can be sub-divided by route of administration, please report the quantities used for each route of administration. If further differentiation by animal group is possible, then it should be reported if the data are available.

For Reporting Option 3, "Growth Promotion" can be reported jointly for terrestrial and aquatic food-producing animals.

Column label	Guidance			
Oral route	Includes all orally administered pharmaceutical forms, including "in water" or			
	"in feed" administration, but also oral bolus administration.			
Injection route Includes all forms of parenteral administration that readily lea				
	blood levels of the active ingredient, such as subcutaneous, intramuscular,			
	intravenous, including intravenous infusion (intravenous drips).			
Other routes Summarises all other routes of administration, including i				
	preparations, and, mostly for aquatic animals, the bath route where an animal			
	or a group of animals immersed in a solution containing the active ingredient.			

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 the *OIE 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 *OIE Terrestrial Code* and the *OIE 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 the OIE 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 the *OIE 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 the OIE 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 *OIE Terrestrial Code* and the *OIE 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.

Annex 8. Annex to the guidance for completing the OIE template for the collection of data on antimicrobial agents used in animals

Considerations on converting content of antimicrobial active ingredients in veterinary medicines into kilograms

Calculating the quantities to report in kilogram (kg)

Data on antimicrobial agents intended for use in animals comes in different forms. The OIE template for the collection of data on antimicrobial agents used in animals (OIE template) is designed to collect data on the amounts of chemical compound as declared on the product label. The information may vary, ranging from bulk quantities of antimicrobial agents to numbers of packs of a veterinary medicinal product. The content of antimicrobial agents in such products can be stated in a number of possible ways. It will be necessary, where appropriate, to calculate the required data to populate the OIE template.

Detailed instructions are provided to harmonise some aspects of data reporting:

- Transformation of bulk quantities (section 1); use this section if you need to convert quantities of raw material, e.g. from import data into the required format.
- Data on veterinary medicinal products (section 2), including conversion from International Units (IU) to kg (section 2. (ii))
- Recommendations are made in section 3 for further optional conversions, aimed at achieving refined reporting of active entities, the ultimately desired format. If such calculations are made, they should be reported in the OIE template in the free text field provided on the sheets for Reporting Option 1, 2 and 3.

The following abbreviations and symbols will be used:

Symbol/abbreviation	Explanation
Strength	amount of antimicrobial agent per unit of veterinary product
% w/v	per cent weight per volume
mg	milligram
g	gram
kg	kilogram
t	ton (metric)
ml	millilitre
1	litre

1. For data on bulk quantities

Such information is usually sourced from customs, import or other bulk trading. It will likely come as a weight in a number of possible units (e.g. metric tons) of chemical compound and needs to be converted to kg. When conversion into kg is necessary, follow the steps below. If additional conversion factors are needed, please contact the OIE at antimicrobialuse@oie.int.

<u>Step 1:</u> Multiply the amount of antimicrobial agent, i.e. the chemical compound as declared on the product label with the appropriate conversion factor from the table 1 below.

Antimicrobial agent (kg) = antimicrobial agent (unit Z) x conversion factor

Table 1: Converting weight units into kg

Unit reported (unit Z)	Conversion factor to kg (for multiplication)
Metric ton	1000
Imperial ton (long)	1016
Imperial ton (short)	907.18
Stone (Imperial)	6.35
Imperial Pound	0.4536
Ounce	0.0283

2. For data on veterinary medicinal products

For veterinary medicinal products containing antimicrobial agents, data on quantities sold is likely to be available as numbers of packages of product sold, with each package containing a specified quantity of medicinal product with a specified amount of antimicrobial agent. In such cases, the amount of antimicrobial agent (chemical compound as declared on the product label) per package needs to be calculated first, and subsequently the result needs to be multiplied with the number of packages of the presentation sold to obtain the overall amount of antimicrobial agent, which should be reported in kg.

The most common ways to indicate the content of the antimicrobial agent(s) of a veterinary medicinal product are:

- (i) Strength in mg or g of the active ingredient per volume or weight or other unit, (for example: ml, l, kg, tablet),
- (ii) Strength in International Units (IU) per weight, volume or other unit,
- (iii) Strength in per cent (%) weight per weight (w/w) or weight per volume (w/v).

Each situation requires a different kind of mathematical conversion.

2. (i) – content of antimicrobial active ingredient (antimicrobial agent) stated in milligram per volume or weight or other unit (for example millilitre, litre, kilogram, tablet) of content

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

Multiply the amount of antimicrobial agent (chemical compound as declared on the product label) per unit of content, that is, the strength of the product, with the total number of units contained in the package

Content of antimicrobial agent per package

= Strength (amount antimicrobial agent per unit)x number of units per package

Example A:

Tiamulin 100 g/kg premix for medicated feeding stuff; package sizes: (a) 1 kg, (b) 5 kg and (c) 20 kg

Calculation of content of antimicrobial agent, tiamulin, per package:

- (a) Pack content = 100 g/kg x 1 kg = 100 g
- (b) Pack content = 100 g/kg x 5 kg = 500 g
- (c) $Pack content = 100 g/kg \times 20 kg = 2000 g$

Example B:

Tetracycline intrauterine tablet containing 2000 mg tetracycline hydrochloride per tablet; package sizes: (a) carton with 1 blister of 5 intrauterine tablets, (b) carton with 4 blisters of 5 intrauterine tablets each (20 tablets), (c) carton with 20 blisters of 5 intrauterine tablets each (100 tablets).

Calculation of content of antimicrobial agent, tetracycline, per package:

```
(a) Pack content = 2000 mg  x  5 = 2 g x  5 = 10 g
(b) Pack content = 2000 mg  x  20 = 2 g x  20 = 40 g
(c) Pack content = 2000 mg  x  100 = 2 g x  100 = 200 g
```

Example C:

Tilmicosin 300 mg/ml solution for injection for cattle; package sizes: containers of 100 ml and 250 ml; packs of (a) 6, (b) 10 and (c) 12 units of 100 ml and 250 ml.

Calculation of content of antimicrobial agent, tilmicosin, per package:

(a) Container content =
$$300 \text{ mg/ml} \times 100 \text{ ml} = 30000 \text{ mg} = 30 \text{ g}$$

Pack content: (a) 6 x 30 g = 180 g ,

(b) 10 x 30 g = 300 g

(c) 12 x 30 g = 360 g

(b) Container content = $300 \text{ mg/ml} \times 250 \text{ ml} = 75000 \text{ mg} = 75 \text{ g}$

Pack content: (a) 6 x 75 g = 450 g ,

(b) 10 x 75 g = 7500 g

(c) 12 x 75 g = 900 g

- Step 2: Sum up the antimicrobial agent contained in all presentations and packages sold

 Convert all contents of antimicrobial agent calculated under step 1 to the same weight unit and add up the total
- Step 3: If necessary: convert the total sum of antimicrobial agent contained in all packages of all presentations sold to kg

 Multiply the result from step 2 with an appropriate conversion factor to achieve the result in kg

2. (ii) – content of antimicrobial agent (chemical compound as declared on the product label) in International Units (IU) per weight, volume or other unit (for example millilitre, litre, kilogram, tablet) of content

Where the strength of the antimicrobial agent in the veterinary medicinal product is stated International Units (IU) per unit of finished product, an additional conversion step is necessary to obtain results in mg, g, or kg. Table 2 is used to convert content of antimicrobial agents declared in IU on the product label into mg for reporting to the OIE: either divide the total number of IUs of an antimicrobial agent by the value in the column 'International Units (IU) per mg' for this agent in table 2, or, if multiplication is preferred, multiply the total number of IUs with the conversion factor listed for the agent. To convert mg values into kg, please multiply the result of the conversion with 1×10^{-6} equalling 0.000001.

For some antimicrobial agents in veterinary medicinal products, the IU content or strength may be stated in respect to the active entity rather than to the chemical compound actually included; for example: a product may contain penethamate hydroiodide, or procaine benzylpenicillin, but the stated strength in IU refers to benzylpenicillin (product X containing penethamate hydroiodide, equivalent to xx IU benzylpenicillin, or, product Y containing procaine benzylpenicillin, equivalent to yy IU benzylpenicillin). For such cases, use the conversion factor for the relevant active entity listed in table 2 (in the examples used: benzylpenicillin). To convert mg values into kg, please multiply the result of the conversion with 1×10^{-6} equalling 0.000001.

If additional conversion factors are needed or have been used, please contact the OIE at antimicrobialuse@oie.int.

Step 1: Calculating the content of antimicrobial agent per package in IU

Multiply the amount of IU antimicrobial agent per unit of content with the total number of units contained in the package

Content of antimicrobial agent per package in IU

= Strength (amount IU antimicrobial agent per unit) x number of units per package

Step 2: Converting the content of antimicrobial agent per package in IU into mg

Content of antimicrobial agent per package in mg

= Content of antimicrobial agent in IU x conversion factor

Steps 3-4: Follow steps 2-3 described for (i)

<u>Table 2</u>: Conversion of International Units (IUs) of certain antimicrobial agents into mg and relevant active entities, based on the ESVAC conversion factors¹³

Antimicrobial agent in the veterinary medicine	Antimicrobial active entity for reporting to OIE	International Units per mg	Conversion factor to mg for multiplication
Bacitracin	Bacitracin	74	0.013514
Benzylpenicillin (penicillin G)	Benzylpenicillin	1666.67	0.0006
Chlortetracycline	Chlortetracycline	900	0.001111
Colistin methane sulfonate sodium (colistimethate sodium INN)	Colistin	12700	0.000079
Colistin sulfate	Colistin	20500	0.000049
Dihydrostreptomycin	Dihydrostreptomycin	820	0.00122
Erythromycin	Erythromycin	920	0.001087
Gentamicin	Gentamicin	620	0.001613
Kanamycin	Kanamycin	796	0.001256
Neomycin	Neomycin	755	0.001325
Neomycin B (Framycetin)	Neomycin B (Framycetin)	670	0.001492
Oxytetracycline	Oxytetracycline	870	0.001149
Paromomycin	Paromomycin	675	0.001481
Polymyxin B	Polymyxin B	8403	0.000119
Rifamycin	Rifamycin	887	0.001127
Spiramycin	Spiramycin	3200	0.000313
Streptomycin	Streptomycin	785	0.001274
Tobramycin	Tobramycin	875	0.001143
Tylosin	Tylosin	1000	0.001
Tetracycline	Tetracycline	950	0.001

2. (iii) – content of antimicrobial agent (chemical compound as declared on the product label) in per cent (%) weight per weight (w/w) or weight per volume (w/v) of content

The amount of antimicrobial agent contained in a veterinary medicine concerned may be stated in per cent weight per weight (% w/w) (example 1: product X contains tylosin 100% w/w or, example 2, product Y contains amoxicillin 22.2 % w/w) or in per cent weight per volume (% w/v) (example: product Z contains procaine benzylpenicillin 30% w/v). Such figures first need to be converted into mg/g, g/g, or mg/ml, followed by the calculations described under (i).

<u>Converting % w/w:</u> Conversion calculations are performed by relating the content of antimicrobial agent to 1 g of the finished product. Divide the percentage value by 100 to obtain the amount of antimicrobial agent in g per g finished product.

value antimicrobial agent in g per gram finished product =
$$\frac{\frac{value (\%)}{100} \times g}{1 \text{ g (finished product)}}$$

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Example 1: Product X containing 100% w/w tylosin will contain 100/100 x g = 1 g tylosin per

g finished product.

Example 2: Product Y containing 22.2% w/w amoxicillin will contain 22.2/100 = 0.222 g

amoxicillin per g finished product.

Continue with Steps 1-3 of (i)

<u>Converting % w/v</u>: Conversion is based on the assumption that 1 ml of the products weighs 1000 mg. Multiply the percentage value with 10 to obtain the content in mg/ml.

value antimicrobial agent in g per ml finished product = $\frac{value (\%)x \ 10 \ x \ mg}{1 \ ml \ (finished \ product)}$

Example: Product Z containing 30% w/v benzylpenicillin will contain (30 x 10 x mg)/1ml,

equal to 300 mg/ml benzylpencicillin.

Continue with Steps 1-3 of (i)

3. Additional recommendations for further conversions of quantities of antimicrobial agents

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. However, OIE Member Countries may wish to carry out further calculations to report amounts of active entity. If such further calculations are carried out, please describe them in the OIE template.

(i) Calculating the total amount expressed in weight of chemical compound as declared on the product label of a veterinary medicinal product into antimicrobial active entity (e.g. salt into base)

This step may be carried out once the steps described in section 1 or section 2. (i) have been completed.

As an example, for the antimicrobial agent tiamulin that is often available in the form of tiamulin hydrogen fumarate (the chemical compound as declared on the product label), the conversion formula to tiamulin (the active entity) would be:

Salt (including base): Tiamulin hydrogen fumarate MW 609.8

Base: Tiamulin MW 493.7

Conversion factor = MW base/MW salt (including base) = 0.81

Multiply the final result in kg obtained by following steps 1 to 3 with the appropriate conversion factor

```
Content of active entity (kg)
= Content of chemical compound as listed on the label (kg)
x conversion factor
```

(ii) The antimicrobial agent is in the form of a prodrug, expressed in weight

Where the antimicrobial agent contained in the veterinary medicinal product is a long-acting salt (example: benethamine benzylpenicillin) or a pro-drug (example: penethamate hydroiodide) and the content is stated in weight in reference to the actual chemical compound (example: product x contains 500 mg/ml benzylpenicillin benzathine), an additional conversion step as described below is needed to calculate the amount of active entity. When the antimicrobial agent is described in reference to the active entity (example: product y contains cloxacillin benzathine equivalent to 500 mg cloxacillin activity) the conversion using a prodrug conversion factor described below is not necessary.

Taking the prodrug conversion factors used by the European Surveillance of Veterinary Antimicrobial Consumption (ESVAC) program managed by the European Medicines Agency, as a starting point, table 3 lists the suggested conversion factors for relevant long-acting salts and prodrugs. The amount of the actual chemical compound as declared on the product label (example: benzylpenicillin benzathine) needs to be multiplied with the prodrug conversion factor to obtain the corresponding amount of the active entity (example: benzylpenicillin.

If additional conversion factors are needed or have been used, please contact the OIE at antimicrobialuse@oie.int.

<u>Table 3</u>: Conversion of content stated in mg, g or kg of long-acting salts and prodrugs of antimicrobial agents in the veterinary product into corresponding mg, g or kg antimicrobial active entity for reporting to the OIE, based on the ESVAC conversion factors¹⁴

Antimicrobial agent (prodrug)	Active entity	Prodrug conversion factor for multiplication
Benethamine benzylpenicillin	Benzylpenicillin	0.65
Benzathine benzylpenicillin	Benzylpenicillin	0.74
Cefapirin benzathine	Cefapirin	0.41
Cefalexin benzathine	Cefalexin	0.36
Cloxacillin benzathine	Cloxacillin	0.43
Oxacillin benzathine	Oxacillin	0.69
Penethamate hydroiodide	Benzylpenicillin	0.63
Procaine benzylpenicillin	Benzylpenicillin	0.61

Step 1-3: As described in section 2. (i)

Step 4: Multiply the final result in kg obtained by following steps 1 to 3 with the appropriate conversion factor listed in table 3

Antimicrobial agent (active entity)(kg)

= antimicrobial agent (chemical compound as declared on the product label)(kg)

x prodrug conversion factor

For bulk quantities of antimicrobial agents in form of prodrugs, the additional step 2 described below should be applied after the calculations described in section 1.

Step 2: If the antimicrobial agent is a long-acting salt or prodrug listed in table 3 above, additionally multiply with the corresponding conversion factor.

Antimicrobial agent (active entity)(kg)

= $Step\ 1$ antimicrobial agent (chemical compound as declared on the product label) kg $x\ prodrug\ conversion\ factor$

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Annex 9. Distribution of Members by OIE Region

AFRICA (54)	AMERICAS (31)	ASIA, FAR EAST AND OCEANIA (32)	EUROPE (53)
1. ALGERIA	1. ARGENTINA	1. AUSTRALIA 2. BANGLADESH 3. BHUTAN 4. BRUNEI 5. CAMBODIA 6. CHINA (PEOPLE'S REP. OF)	1. ALBANIA
2. ANGOLA 3. BENIN 4. BOTSWANA 5. BURKINA FASO	2. BAHAMAS	2. BANGLADESH	2. ANDORA
3. BENIN	3. BARBADOS	3. BHUTAN	3. ARMENIAA
4. BOTSWANA	4. BELIZE	4. BRUNEI	4. AUSTRIA
5. BURKINA FASO	5. BOLIVIA	5. CAMBODIA	5. AZERBAIJAN
6. BURUNDI	6. BRAZIL	6. CHINA (PEOPLE'S REP. OF)	6. BELARUS
7. CAMEROON	7. CANADA	7. FIJI	7. BELGIUMS
8. CABO VERDE	1. ARGENTINA 2. BAHAMAS 3. BARBADOS 4. BELIZE 5. BOLIVIA 6. BRAZIL 7. CANADA 8. COLOMBIA 9. COSTA RICA	8. INDIA	8. BOSNIA AND HERZEGOVINA
9. CENTRAL AFRICAN (REP.)	9. COSTA RICA	9. INDONESIA	9. BULGARIA
10. CHAD	10. CUBA	10. IRAN	10. CROATIA
11. COMOROS	11. CURACAO	11. JAPAN	11. CYPRUS
12. CONGO (REP. OF THE)	12. CHILE	0. CHINA (PEOPLE'S REP. OF) 7. FIJI 8. INDIA 9. INDONESIA 10. IRAN 11. JAPAN 12. KOREA (REP. OF) 13. KOREA (DEM. PEOPLE'S REP. OF)	12. CZECH REP.
13. CONGO (DEM. REP. OF THE)	13. DOMINICAN (REP.)	13. KOREA (DEM. PEOPLE'S REP. OF)	13. DENMARK
14. CÔTE D'IVOIRE	13. DOMINICAN (REP.) 14. ECUADOR 15. EL SALVADOR 16. GUATEMALA	14. LAOS	14. ESTONIA
15. DJIBOUTI	15. EL SALVADOR	15. MALAYSIA	15. FINLAND
16. EGYPT	16. GUATEMALA	16. MALDIVES	16. FRANCE
17. EQUATORIAL GUINEA	17 CHVANA	17 MICRONFISA (FFD STATES OF)	17 GEORGIA
18. ERITREA	18. HAITI	18. MONGOLIA)	18. GERMANY
19. ESWATINI	19. HONDURAS	19. MYANMAR	19. GREECE
20. ETHIOPIA	20. JAMAICA	20. NEPAL	20. HUNGARY
21. GABON	17. GUYANA 18. HAITI 19. HONDURAS 20. JAMAICA 21. MEXICO 22. NICARAGUA 23. PANAMA 24. PARAGUAY 25. PERU	18. MONGOLIA) 19. MYANMAR 20. NEPAL 21. NEW CALEDONIA 22. NEW ZEALAND 23. PAKISTAN 24. PAPUA NEW GUINEA 25. PHILIPPINES	21. ICELAND
22. GAMBIA	22. NICARAGUA	22. NEW ZEALAND	22. IRELAND
23. GHANA	23. PANAMA	23. PAKISTAN	23. ISRAEL
	24. PARAGUAY	24. PAPUA NEW GUINEA	24. ITALY
24. GUINEA 25. GUINEA-BISSAU 26. KENYA	25. PERU	25. PHILIPPINES	25. KAZAKHSTAN
26. KENYA	26. SAINT LUCIA	26. SINGAPORE	26. KYRGYZSTAN
27. LESOTHO	27. SURINAME	27. SRI LANKA	27. LATVIA
28. LIBERIA	28. TRINIDAD AND TOBAGO	28. TAIPEI (CHINESE)	28. LIECHTENSTEIN
29. LIBYA	29. UNITED STATES OF AMERICA	29. THAILAND	29. LITHUANIA
30. MADAGASCAR	30. URUGUAY	30. TIMOR LESTE	30. LUXEMBOUR
31. MALAWI	31. VENEZUELA	31. VANUATU	31. MALTA
32. MALI		32. VIETNAM	32. MOLDOVA
33. MAURITANIA 34. MAURITIUS			33. MONTENEGRO
34. MAURITIUS	MIDDLE EAST (12)		34. NETHERLANDS (THE)
35. MOROCCO			35. NORTH MACEDONIA
36. MOZAMBIQUE	1. AFGHANISTAN		36. NORWAY
37. NAMIBIA	2. BAHRAIN		37. POLAND
38. NIGER	3. IRAQ		38. PORTUGAL
39. NIGERIA	4. JORDAN	25. PHILIPPINES 26. SINGAPORE 27. SRI LANKA 28. TAIPEI (CHINESE) 29. THAILAND 30. TIMOR LESTE 31. VANUATU 32. VIETNAM	39. ROMANIA
40. RWANDA	5. KUWAIT		40. RUSSIA
41. SAO TOME AND PRINCIPE	6. LEBANON		41. SAN MARINO
42. SENEGAL			
43. SEYCHELLES	8. QATAR		43. SLOVAKIA
44. SIERRA LEONE	9. SAUDI ARABIA		44. SLOVENIA
45. SOMALIA	10. SYRIA		45. SPAIN
46. SOUTH AFRICA	11. UNITED ARAB EMIRATES		46. SWEDEN
47. SOUTH SUDAN (REP. OF)	12. YEMEN		47. SWITZERLAND
48. SUDAN			48. TAJIKISTAN
49. TANZANIA			49. TURKEY
50. TOGO			50. TURKMENISTAN
51. TUNISIA			51. UKRAINE
52. UGANDA			52. UNITED KINGDOM
53. ZAMBIA			53. UZBEKISTAN

54. ZIMBABWE