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

12 rue de Prony 75017 Paris, France
Tel.: 33 (0)1 44 15 18 88 • Fax: 33 (0)1 42 67 09 87 • www.oie.int • oie@oie.int

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Director General's Foreword

Dr Monique Eloit
OIE Director General

During the 87th OIE General Session in May 2019, the World Assembly of Delegates adopted Resolution No. 14: *OIE's Engagement in the One Health Global Effort to Control Antimicrobial Resistance,* which included the decision to establish a permanent Working Group on Antimicrobial Resistance (AMR) to support the implementation of the OIE Global Strategy on Antimicrobial Resistance and the Prudent Use of Antimicrobials and the organisation's capacity to respond to global challenges according to its mandate. The Working Group on AMR held its first meeting in October 2019 and will further guide the collection of data on the use of antimicrobials in animals (AMU).

The need for accurate information on the use of antimicrobial agents in animals is widely recognised. In September 2019, the OIE together with its Tripartite partners – FAO and WHO – provided a report for the UN Secretary General to submit for consideration by Member States at the 74th session of the UN General Assembly. The report was a follow-up on the implementation of the political declaration of the high-level meeting of the General Assembly on antimicrobial resistance and included the recommendations of the Inter-Agency Coordination Group on Antimicrobial Resistance. In his conclusions the Secretary General cited enhancing the collection, analysis and reporting of comparable high-quality AMU and AMR data as one of the ways of addressing challenges at the regional and global levels.

The OIE has taken the lead by creating a global database on the use of antimicrobial agents in animals, in the framework of the Global Action Plan on Antimicrobial Resistance. As a result of the tremendous efforts of its Members, the OIE Annual Reports on the Use of Antimicrobial Agents in Animals have been published every year since December 2016.

The OIE's partners consider the OIE data collection on the use of antimicrobials in animals and the progress achieved by the 152 OIE Members that participated in the data collection in the fourth round to be a major milestone in the global effort to contain antimicrobial resistance. The OIE recognises the efforts of the OIE Delegates and the National Focal Points for Veterinary Products in assisting in this extraordinary effort.

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 2019, the OIE initiated the procedures to create an interactive Information Technology (IT) system for the OIE AMU Data Collection. This system is expected to allow OIE Members to have instant access to their data to guide decisions at the national level. To further support Members, the OIE delivered its first Workshops on the OIE Antimicrobial Use Data Collection in the Americas and Africa to identify suitable data sources, assist in calculating kilograms of active ingredients and get feedback on their needs for the future IT System for the OIE Data Collection.

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

Executive Summary

This fourth *OIE annual report on the use of antimicrobial agents intended for use in animals* provides the global use of antimicrobial agents adjusted for animal biomass for 2016, and interprets the overall findings of the fourth annual data collection on the use of antimicrobial agents in animals, providing a global and regional analysis.

The OIE template used to collect data was designed to allow all countries to participate, regardless of whether a national data collection system currently exists. In 2018, the fourth round of data collection, completed reports were submitted by 152 Members (152 out of 182; 84%), including data reported by one non-contiguous territory[1] of an OIE Member with its own reporting mechanism. One hundred and eighteen reports (118 out of 153; 77%) included quantitative data for one or more years between 2016 to 2018.

In the fourth 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-nine 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. Ten of these countries (10 out of 29; 34%) confirmed that actions will be undertaken in the near future to facilitate their reporting of quantities of antimicrobials to the OIE.

For the responses on the use of antimicrobial agents as growth promoters, a total of 118 responding countries (118 out of 153; 77%) did not use any antimicrobial agents for growth promotion in animals in their countries as of 2018, either with or without legislation or regulations. The remaining countries (35 out of 153; 23%) reported use of antimicrobials for growth promotion; of these, 20 countries (20 out of 35; 57%) had a regulatory framework that either provided a list of antimicrobials that can be used as growth promoters or provided a list of those that should not be used as growth promoters.

The analysis of antimicrobial agents adjusted by animal biomass was performed in 92 countries for the year 2016. The calculations of animal biomass allowed for an analysis of reported antimicrobial quantities adjusted by 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. Animal biomass was calculated for food-producing species of countries reporting quantitative data for the year 2016, primarily using data from the OIE World Animal Health Information System (WAHIS) and the Food and Agriculture Organization Statistics (FAOSTAT). 2016 was the target year of this fourth round of data collection.

The global estimate of antimicrobial agents used in animals in 2016 adjusted by animal biomass, as represented by the quantitative data reported to the OIE from 92 countries, was 144.39 mg/kg. An approach for an upper-level estimate of 153.02 mg/kg was made adjusting by country-level estimates of how much data on antimicrobial agents used in animals they covered in 2016. The 2016 analysis reflects a much stronger global participation in the data collection, with an estimated global biomass coverage of 74%, increased from 68% in 2015.

[1] 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.

As a result of the many challenges that we now know countries face as they advance towards quantitative data collection on antimicrobial use in animals, the OIE continues to advise caution in interpretation and use of quantitative data presented in this report. The report transparently describes the reasons for uncertainty associated with both the complex and simple estimates presented. 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 our Members in developing robust measurement and transparent reporting mechanisms for antimicrobial use, but the challenges for 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 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. OIE 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 data aggregation and analysis.

Acknowledgements

This report was prepared by Dr Delfy Góchez, Dr Gérard Moulin, Dr Morgan Jeannin, and Dr Elisabeth Erlacher-Vindel.

The OIE thanks the contributions from its Antimicrobial Resistance and Veterinary Products Department (Ben Davies, Saija Kalenius, Mduduzi Magongo, Dante Mateo and Jorge Pinto Ferreira), the OIE Capacity Building Department (Camille Loi and Valentyna Sharandak) and OIE Technical Officers in the OIE Regional and Sub-regional representations.

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 fourth annual collection on data of antimicrobial agents used in animals, without which such knowledge and insight could never be gained on the global use of antimicrobial agents in animals.

The OIE thanks the members of the OIE *ad hoc* Group on Antimicrobial Resistance (period of 3-5 July 2018 and 16-18 January 2019) for their input in development of the global database and methodology for calculation of animal biomass for the fourth round of the OIE data collection on antimicrobial agents intended for use in animals (from September 2018 to May 2019).

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
PVS	Performance of Veterinary Services
WAHIS	World Animal Health Information System
WHO	World Health Organization

OIE Glossary[2]

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 *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.

[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 a global level, the mitigation of antimicrobial resistance is crucial for the protection of human, animal, plant and environmental health.

During the 83rd General Session in May 2015, the OIE Members officially committed to combat AMR and promote the prudent use of antimicrobials in animals and stated their full support for Global Action Plan on AMR, developed by the World Health Organisation (WHO) in close collaboration with the OIE and Food and Agriculture Organization of the United Nations (FAO) [2]. One year later, during the 84th General Session, the World Assembly of Delegates directed 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; and (4) Encourage implementation of international standards.

Towards development of these objectives, the OIE engages with National Focal Points for Veterinary Products in OIE Members. During the 76th General Session of the World Assembly of Delegates in May 2008, OIE Delegates were asked to nominate National Focal Points for Veterinary Products, who would provide technical assistance in improving and harmonising national policies for 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 of its Members, and harmonised implementation of OIE standards for responsible and prudent use of antimicrobials.

In many countries, antimicrobial agents remain widely available with virtually no restrictions or controls on their use. Of the 136 OIE Members assessed through an initial OIE Performance of Veterinary Services (PVS) Evaluation[3] up to December 2019, almost three-quarters could not regulate veterinary medicinal products (assessed as 'Level 1') , or had only some capability to exercise regulatory and administrative control over the import, manufacture and market authorisation (registration) of them to ensure their safety and quality. They were unable to ensure their responsible and prudent use in the field ('Level 2'). The absence or low levels of control of veterinary medicinal products leads to the limited control of veterinary products containing antimicrobial agents. These antimicrobial agents 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 conditions of high risk for the development and spread of resistance.

The 7th edition of the OIE PVS Tool includes 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 (NAP) on AMR. Between August 2018 and September

[3] 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.

2019, 17 countries were assessed through PVS Evaluations based on this new edition of the PVS Tool. It is worth highlighting that for 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 Tripartite partners (FAO and WHO).

Currently, very little information is available worldwide on resistance patterns in animal pathogens. Surveillance of antimicrobial resistance in animal pathogens is important to assess the level and evolution of antimicrobial resistance in animals.

The OIE international standards published in the *Terrestrial Animal Health Code*, Chapter 6.8. [5] '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; the *Aquatic Animal Health Code*, Chapter 6.4. [6] 'Development and harmonisation of national antimicrobial resistance surveillance and monitoring programmes for aquatic animals'; and the *Manual of Diagnostic Test and Vaccines for Terrestrial Animals*, Chapter 2.1.1 'Laboratory methodologies for bacterial antimicrobial susceptibility testing' provide a basis for such surveillance and monitoring [7]; during the 87th General Session in May 2019, Members adopted the updates of Chapter 2.1.1, which includes guidance for 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 Member Countries of OIE *Terrestrial Animal Health 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 Member Countries and; (4) to determine what actions are needed and to help the OIE to develop its strategy in this field. A total of 152 out of 178 (85%) OIE Member Countries 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 resulting from the conference to OIE Members included:

- To develop and set up 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 food producing animals (including through medicated feed) with the ultimate aim to create 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]. This global database was created in compliance with Chapters of the *Terrestrial Animal Health Code* (Monitoring of the quantities and usage patterns of antimicrobial agents used in food-producing animals) [8] and of the *Aquatic Animal Health 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.

The OIE launched its first annual data collection on antimicrobial agents intended for use in animals in 2015. The OIE template and guidance documents were developed by the OIE *ad hoc* Group on Antimicrobial Resistance (AMR), 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 the use of antimicrobial agents in animals: Better understanding of global situation* [10], was published in December 2016. In this fourth round of data collection, 153 countries submitted their reports, an increase of 18% since the data collection started in 2015.

As part of the fourth round, the OIE requested quantitative data on antimicrobials used in animals for the 2016 calendar year, but also accepted data from the years 2017 and 2018. The wider timespan of quantitative data collected allows for countries in 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 fourth round of data collection is broad, it was decided for the fourth report analysis of antimicrobial quantities to focus on the year 2016. 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 2016, using quantitative data reported to the OIE by 92 countries during all four rounds of data collection.

In the fifth round of data collection currently underway, the OIE has requested quantitative data for 2017, but will also accept data for 2018 and 2019. 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 fourth 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 to 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 fourth 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 2016; additionally, 2014 and 2015 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 in confidence to the OIE for the purpose of better understanding the global and regional situation of 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 if such data are available online in the OIE template. The list of countries with national reports on veterinary antimicrobial usage that can be accessed publicly can be found in Section 10 of the report, together with the relevant links.

2. Materials and Methods

Every September the OIE invites its Members to participate in the annual data collection of antimicrobial agents intended for use in animals. In order to analyse the antimicrobial quantities reported, the OIE Headquarters developed calculation of an animal biomass. Both materials and methods are summarised and described 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 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 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 in the three official OIE languages (i.e. English, French and Spanish). Following experience from all rounds of data collection, the following changes were made to the OIE template sent during this fourth round:

1. Countries reporting that their antimicrobial quantities covered other commercial poultries (e.g. turkey, duck, etc.) were asked to specify the animals under this category (Baseline Information, Question 26)
2. Countries were asked to provide the list of companion animals covered by the antimicrobial quantities reported (Baseline Information, Question 27 and 28)

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 email in September 2018. The deadline for submission was the 3 December 2018, but responses were accepted on a conditional basis until mid-May 2018.

As with previous rounds of data collection, countries responded to the questionnaire through an Excel document using predefined conditional formulas and analysis tools. This document, 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 answered by any country, and collect information on the current situation of governance of veterinary antimicrobials, such as 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), such as 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 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 contact person within a Member Country were validated by the country's Delegate. Responses were compiled and analysed at OIE Headquarters.

Whenever necessary, staff of OIE Headquarters engaged with respondents for clarification and validation of responses. These questions were addressed to the contact person listed, most often 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. Towards this goal, and in conjunction with the development of the antimicrobial use database, the 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. At this time, 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 U.S. 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 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 (WAHIS[4], FAOSTAT[5]) are point-in-time species-level census data[6] 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 'cycle factor').

Development of the methodology for calculation of an annual animal biomass utilised globally available census data from the OIE WAHIS interface. 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 imputate[7] a data point. The two datasets are therefore similar but can display significant variation.

Where census data were used, the 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 a 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 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 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, 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 from Members, or calculated from animal population data in Eurostat, the statistical office of the European Union.

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4 OIE World Animal Health Information System

5 United Nations Food and Agriculture Organization Statistics

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

7 Imputation is the process used to determine and assign replacement values for missing, invalid or inconsistent data that have failed edits (OECD).

The formulas chosen for calculation of the OIE denominator reflect the best fit estimations using the more general global animal population data (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 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 September 2019: *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 6.3 of the report.

Year of Analysis

2016, the target year of the fourth round of data collection, 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 2016 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:

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

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 according to livestock unit classifications (LSU).[8] 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 a country level, animal biomass was calculated for each of the following species for each country that reported quantitative data to the OIE for 2016.

All weights and biomass figures are measured in kilograms (kg).

[8] 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 (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%.

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

$$census\ population \times [(sub\ regionnal\ mean\ live\ weight \times LSU_{calves} \times P.pop_{calves}) + (sub\ regionnal\ mean\ live\ weight \times LSU_{young\ 1-2yrs} \times P.pop_{young\ 1-2yrs}) + (sub\ regionnal\ mean\ live\ weight \times LSU_{adults} \times P.pop_{adults})\ ]$$

Whereby,

$P.pop_{calves}$, $P.pop_{young\ 1\text{-}2yrs}$, $P.pop_{adults}$ represents respectively 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, as calculated from Eurostat animal population data and considering an anticipated renewal rate of 30%.

LSU_{calves}, $LSU_{young\ 1\text{-}2yrs}$, LSU_{adults} represents respectively the livestock unit ratios (LSU) for calves, young and adults 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 240kg [16]. This weight was adapted by region using livestock unit ratios (Americas = 240kg, Asia, Far East and Oceania = 240 kg, Africa = 192kg);
- 0.09 is the expected percentage of sows in a given swine population, as calculated from Eurostat animal population data.

Poultry biomass was calculated according to the following formula:

$$(live\ weight\ chicken\ \times\ number\ of\ chicken\ slaughtered) + (live\ weight\ turkey\ \times\ number\ of\ turkey\ slaughtered) + (live\ weight\ ducks\ \times\ number\ of\ ducks\ slaughtered) + (live\ weight\ geese\ \times\ number\ of\ geese\ slaughtered)$$

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 75kg [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:

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

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:

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

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

$$standard\ weight\ \times\ census\ population$$

According to the following considerations [19]:

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

Farmed fish biomass was included in the total biomass only for countries that included aquaculture in their reported data on antimicrobials intended for use in animals. Aquaculture data are collected in WAHIS and FAO as tonnes produced annually.

Data on farmed crustaceans, molluscs and amphibians were excluded given the relatively small size of these populations, and inconsistency in their reporting.

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 was 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

Updates were made to the methodology, the live weights and standard weights retained for the calculation, based on updated data and corrections of a detected error in a conversion coefficient. Therefore, the results of the 2014 and 2015 analysis shown in this report may differ from the results of the previous report as they have been recalculated using the updated data to support comparison. More information on the changes carried out to the methodology for the calculation of animal biomass are 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:

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

For a regional and global analysis, country data for both the numerator and denominator, respectively, were summed according to OIE Region before the rate was calculated.

3. Results of the Fourth 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, the OIE template 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 fourth round of data collection, from September 2018 to May 2019, 153 countries submitted completed reports to the OIE Headquarters: 152 from OIE Members (n = 182; 84%) and 1 non-contiguous territory of an OIE Member. The proportion of responses received from the different OIE Regions varies from 50% to 94% (Table 1). The response from the non-contiguous territory was included in the analysis of the Americas for geographical reasons.

For simplicity when reporting results, this section refers to the 152 OIE Member and 1 non-contiguous territory as the 153 countries that responded to the questionnaire during the fourth round of data collection.

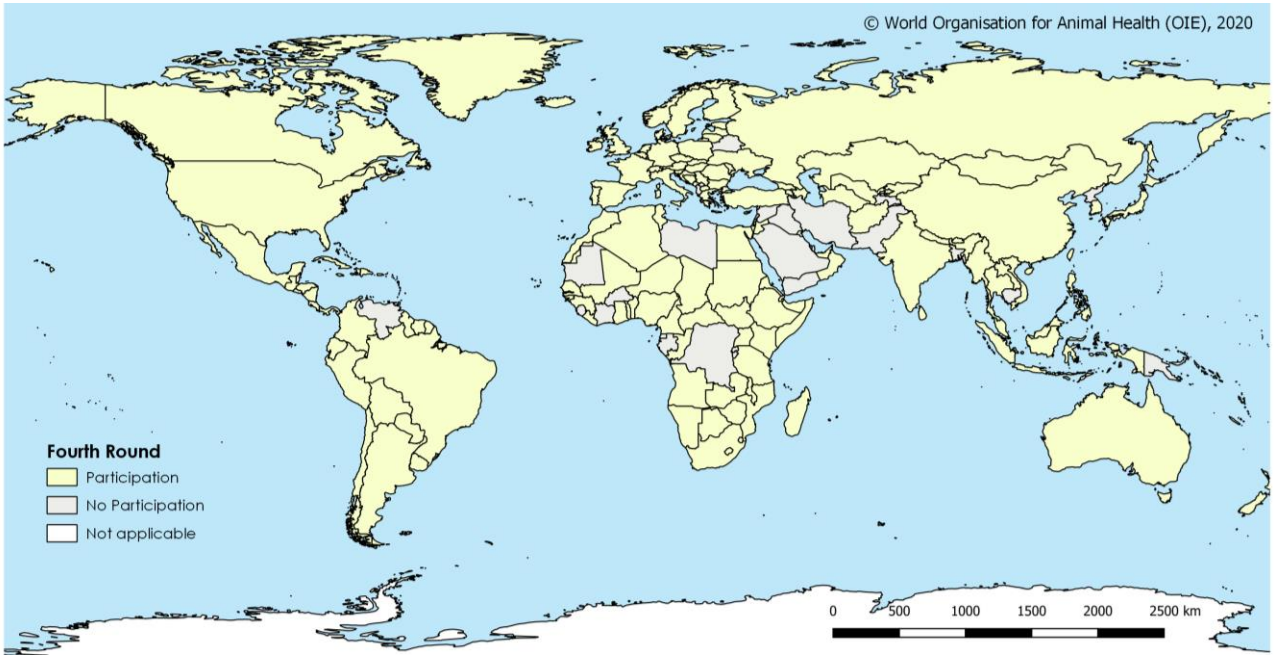
For specific information for the OIE Region, refer to the Annex for each region (Annexes 1-5).

Table 1. Number of Countries that Responded to the OIE Survey in the Fourth 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	44	54	81%
Americas**			
OIE Members	29	31	94%
Non-contiguous territories	1	n/a	n/a
Asia, Far East and Oceania	25	32	78%
Europe	48	53	91%
Middle East	6	12	50%

* *Distribution of countries by OIE Region is done according to the OIE Note de Service 2010/22 – Annex 9*
** *Due to geographic distribution, non-contiguous territories were included in the Americas*

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



Profile of the Contact Person

Each OIE Member must designate a Delegate; most commonly the person selected leads the country's official Veterinary Services. In the 76th General Session, held in May 2008, the World Assembly 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 fourth round of antimicrobial use data collection, the OIE template was most frequently completed by the Member's National Focal Point for Veterinary Products (99 out of 152 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 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 development of data collection systems, where a specific institution may already be mandated to this responsibility (Figure 3).

Figure 2. Contact Person Profile of 152 Members that Submitted the OIE Report in 2018

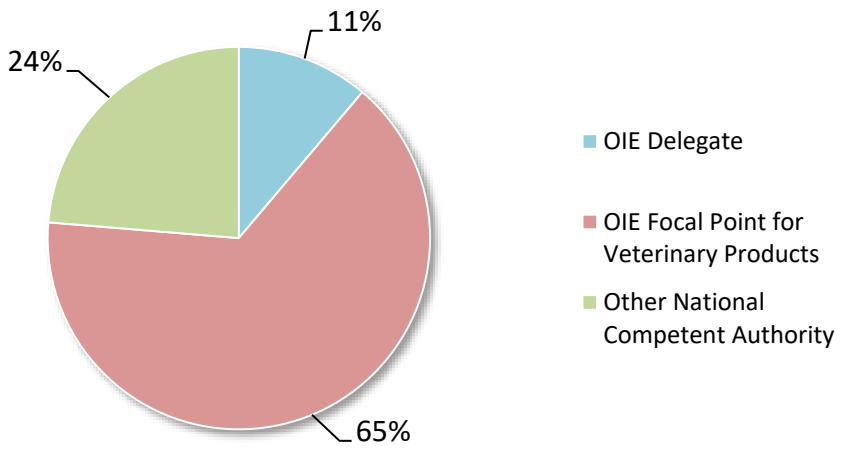
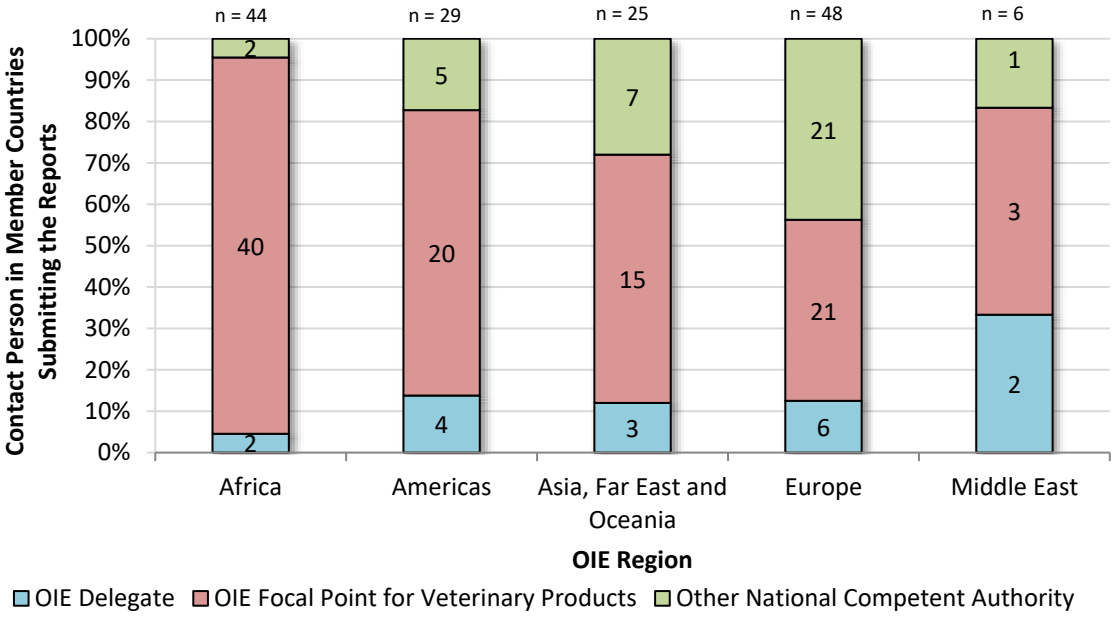


Figure 3. Regional Proportion of Contact Person of 152 Members that Submitted the Response to the OIE Survey in the Fourth Round of Data Collection



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 exists in the country, the template section titled “Baseline Information” can be 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

OIE Template Sections	Countries not able to provide antimicrobial quantities	Countries able to provide antimicrobial quantities		
		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 1.

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

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

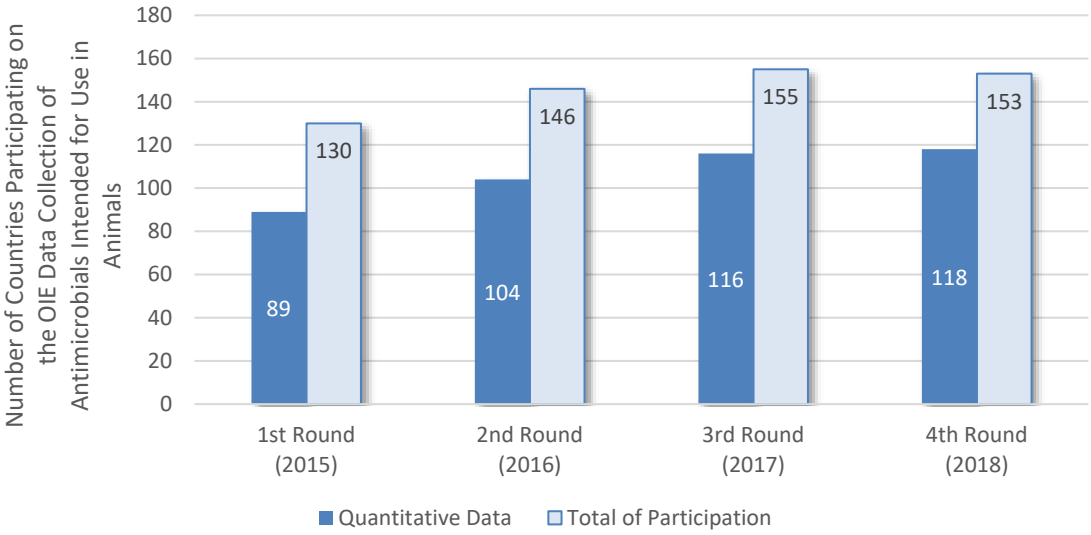
Some countries, where critical errors in the data were identified, were retrospectively removed from previous rounds. As a result, the antimicrobial quantities of some countries have been removed, but their responses related to growth promoters and barriers to the collection of data were retained. The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

Results of the Fourth Round

In the fourth round of data collection, Baseline Information (parts A and B) were completed by 153 countries (152 Members and 1 non-contiguous territory). Of these, two countries submitted data for the first time, and 13 countries, that missed the third-round reporting, renewed their participation in this fourth round. One hundred and one 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, 89 OIE Members reported quantities of antimicrobial agents intended for use in animals (n = 130; 68%). In this fourth round, 118 countries (n = 153; 77%) reported quantitative data, demonstrating growing commitment to development of monitoring systems for veterinary antimicrobial agents (Figure 4).

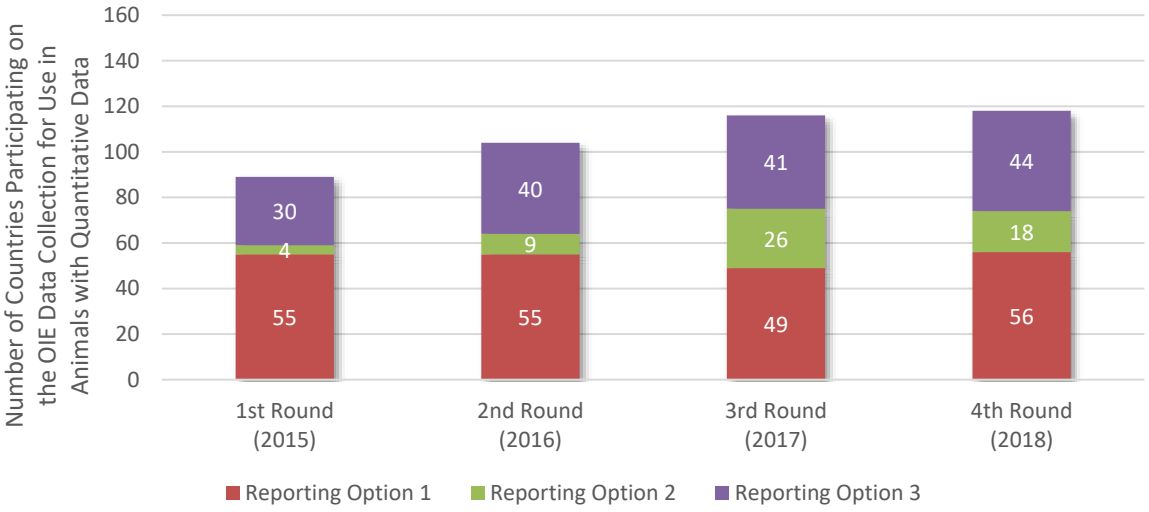
Figure 4. Number of Countries Participating in All Rounds of the Data Collection



Reporting Option 1 allows countries to distinguish antimicrobial quantities by antimicrobial classes and with the possibility to separate by type of use (veterinary medical use or growth promotion [8]) and this option was chosen most frequently by respondents (56 out of 118 countries). Reporting Option 2 allows countries to distinguish quantities of antimicrobial agents by type of use and animal groups (food-producing terrestrial and aquatic species and companion animals) and was chosen by 18 countries. Finally, Reporting Option 3, which allows countries to distinguish antimicrobial quantities by type of use and routes of administration (distinguishing by group of animals is optional), was chosen by 44 countries (Figure 5).

When differentiated by OIE Region, more Members from Europe provided quantitative data (98%) than other OIE Regions and chose more advanced Reporting Options to do so. 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 Fourth Round of Data Collection

Number of countries that responded to the OIE questionnaire	153
Number of countries that provided quantities of antimicrobial agents	118
Number of countries that provided quantitative data for only one year between 2016 and 2018	111
Number of countries that provided quantitative data for more than one year between 2016 and 2018	7

Most countries providing antimicrobial quantities submitted data for only one year between 2016 and 2018 (111 out of 118 countries; 94%). Seven countries submitted quantitative data for more than one year within this timeframe. Given these multiple submissions, 126 responses were provided by 118 countries (Table 3) in the fourth round of data collection.

Fifty-two responses (n = 126; 41%) provided data for 2018 during the fourth round of data collection and not the target year which was 2016 (Figure 6). In previous rounds, the most reported year has been the round's target year, but for this fourth round, there were more non-European countries that reported their antimicrobial quantities, and most of them reported antimicrobial quantities for 2018. These findings reinforce what was presented in previous OIE Reports that most Members in Africa; the Americas; Asia, Far East and Oceania have only recently begun to collect this information and therefore only have access to current information (Figure 7).

Figure 6. Years of Quantitative Data Reported in Fourth Round of Data Collection, from 126 Responses Provided by 118 Countries

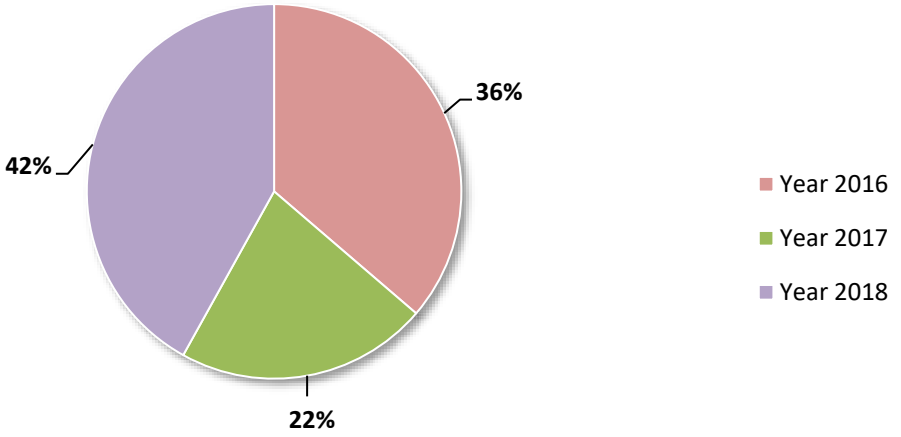
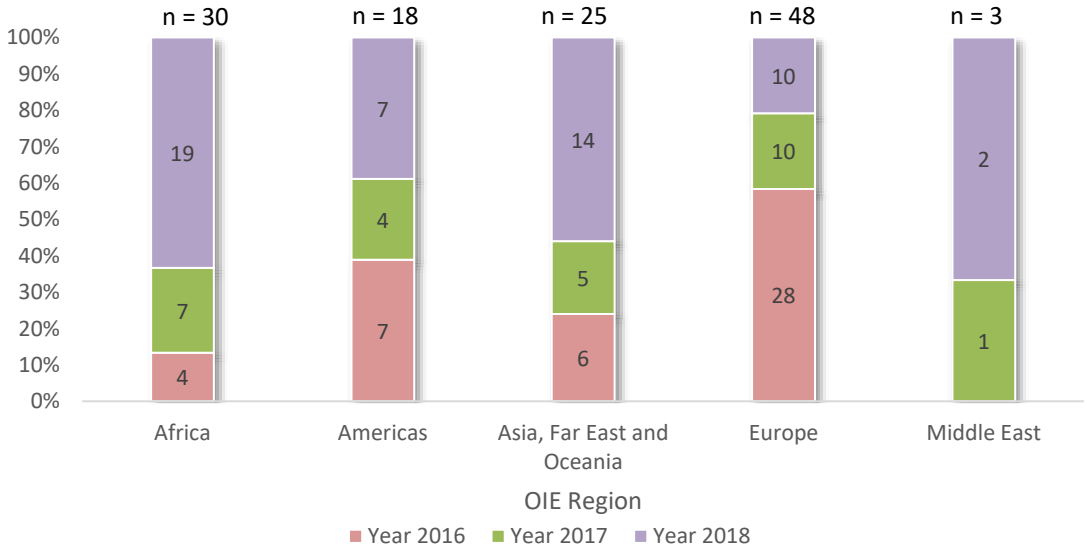


Figure 7. Years of Quantitative Data Reported in Fourth Round of Data Collection, from 126 Responses Provided by 118 Countries by OIE Region



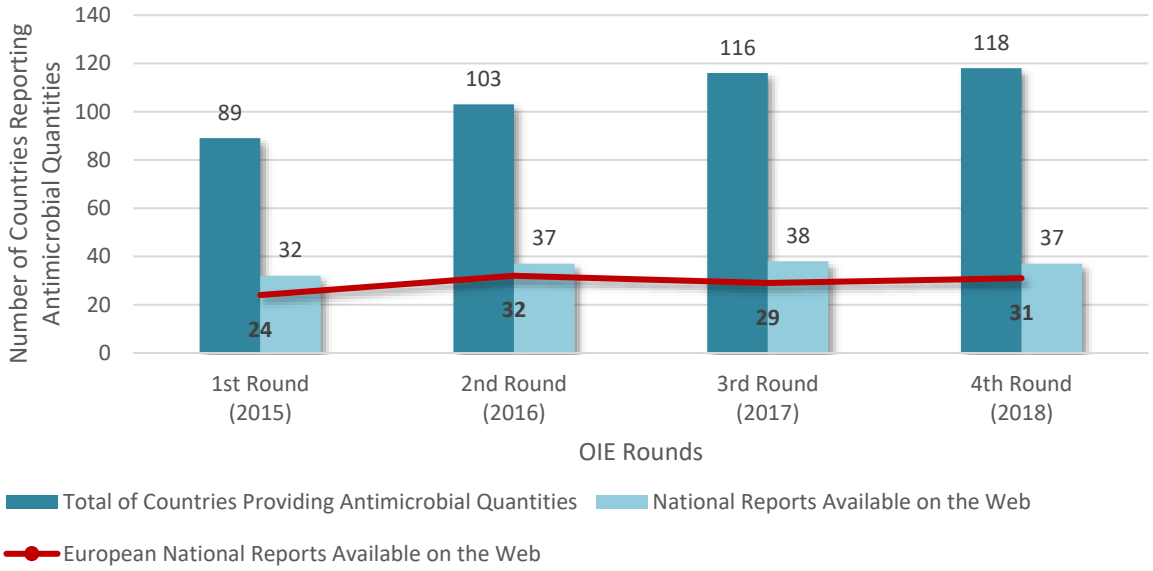
3.4. National Reports Available Online

In the OIE template, countries were asked if a national report for the antimicrobial agents used in animals was available on the Web. In the fourth round of data collection, 81 countries (n = 118; 69%) did not publish online national reports, Europe is the only region where more than 50% of countries' national reports are available on the Web (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 10 of the report, along with the relevant links.

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



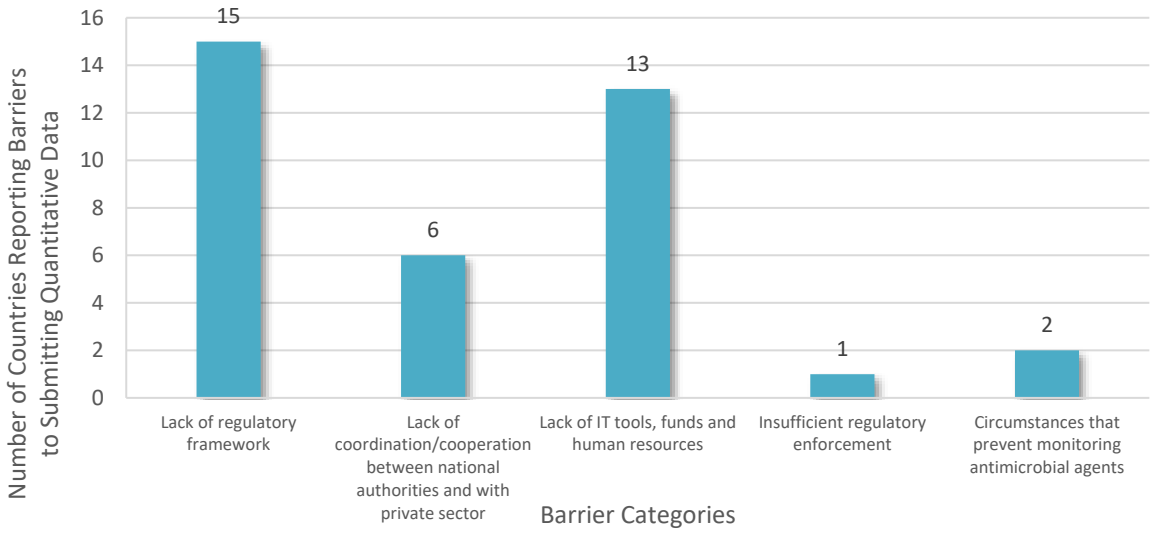
3.5. Country Barriers to Providing Quantities of Antimicrobial Agents in Animals

In the fourth round, progress was observed from 31 countries that had previously reported barriers during the third round. Eight countries progressed from reporting Baseline Information to reporting antimicrobial quantities. Of these eight countries, five had previously indicated that a lack of IT tools and human resources impeded their progress to report the antimicrobial quantities.

Of the countries responding to the fourth round, 35 (n = 153; 23%) provided only Baseline Information with no antimicrobial quantities. Of these, 29 countries (n = 35; 83%) outlined their barriers to reporting antimicrobial quantities. The barriers have been grouped into five categories (Figure 9). Countries tended to report one key barrier, but eight 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.

Figure 9. Country Barriers to Reporting Quantitative Data on Antimicrobial Agents Intended for Use in Animals in 29 Countries in the Fourth Round of Data Collection



Lack of regulatory framework

Eight countries' legislation did not provide a legal basis for collecting data on antimicrobial agents intended for use in animals or, despite relevant legislation, a mechanism for data collection did not exist. Two countries, with a legislation for veterinary products that did not include AMU were already in the process of including the AMU data collection mechanism.

Six countries indicated regulatory framework limitations or absence for the manufacture, registration, distribution, commercialisation and pharmacovigilance of veterinary products. Two of these countries reported that actions were being taken to address the absence of legislation and will work to provide import data.

The Antimicrobial Use Team observed that while the fourth round of data collection was taking place, some countries, that did not provide antimicrobial quantities, participated in the OIE Performance of Veterinary Services (PVS) Pathway[9]. The mission reports had identified the country-barriers for legislation that were reported to the Antimicrobial Use Team.

[9] Chronologically in the OIE PVS Pathway Cycle (https://www.oie.int/fr/solidarite/processus-pvs/), following a PVS Evaluation, countries can request different kind of options, incl. 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 in detailed planning based on their PVS Evaluation results, i.e. determining their priority goals, as well as 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 at obtaining a detailed picture of the current state of the national veterinary legislation and identifying gaps and weakness in that legislation. If the experts of this mission find that the country has sufficient political will and the human and financial resources to successfully undertake it, this 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/).

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

Within this category, three 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 on 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 the responsible use.

Two countries 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

Seven 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 digitalised. For these countries, the time burden would be too great to calculate kilograms of active ingredients for veterinary products. Three of these countries had electronic systems to record the import data and the registration of veterinary products; however, it was identified that the systems did not record the necessary data to be able to calculate kilograms of active ingredient.

The absence of budget to address the AMU Data collection resourcing requirements was raised by two countries. One of these countries falls under the classification of circumstances that prevent monitoring antimicrobial agents.

Four countries were not able to report antimicrobial quantities due to lack of dedicated staff within the Veterinary Authority for the collection and analysis of the data. In some cases, it was noted that other technical staff were potentially available to assist the OIE Focal Point for Veterinary Products for this task. The OIE provides regional seminars to train and prepare Focal Points engagement in the AMU Data Collection process, but the possibility exists for an alternative person, designated by the OIE Delegate or the Focal Point to access OIE training to be equipped to take part in the annual data return.

Insufficient regulatory enforcement

During the fourth round, one country, that had previously cited the category of lack of a regulatory framework, declared that the legislation to collect AMU data had been recently authorised, but it was still not possible to report the antimicrobial quantities due to lack of dedicated staff to collect and analyse the data.

Circumstances that prevent monitoring antimicrobial agents

Two countries reported insecurity and economic crisis in their countries as the main reason that prevented the reporting of antimicrobial quantities in animals.

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 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.

A significant barrier was the lack of IT tools that facilitate the collection and analysis of data. In some countries the records (mainly imports of veterinary products and the information related to their authorisation) did not have all the necessary information to obtain kilograms of active ingredients. By the time this report will be published, the OIE will have already undertaken regional workshops regarding the AMU Data Collection and explored the countries' needs related to IT issues in order to find a solution through the new OIE AMU Data Collection software. It is expected that the future software will assist participating countries in guiding them through the OIE questionnaire and assist in the calculations to obtain kilograms 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 regarding legislation on veterinary products, conducted in 2018 by the OIE Regional Activities Department on all OIE Veterinary Legislation Identification Mission reports existing at that time – i.e. an incomplete legal framework, weaknesses related to the Competent Authority(ies), and inadequate resources to ensure compliance and enforcement. It was also highlighted that there is the need of coordination among the different national authorities that are part of the monitoring of antimicrobial agents.

3.6. Antimicrobial Agents Used for Growth Promotion

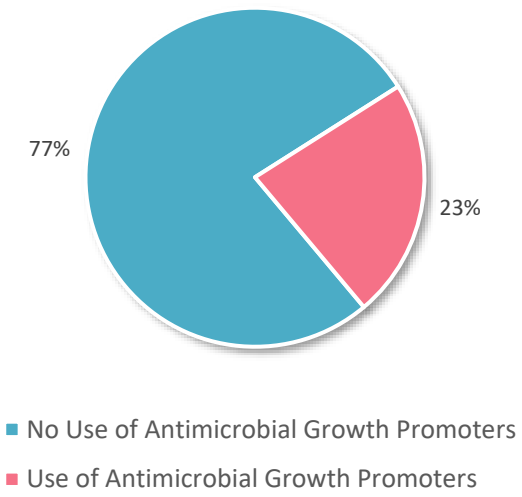
During the 2016 OIE General Session, OIE Members adopted Resolution No 36, "Combating Antimicrobial Resistance through a One Health Approach: Actions and OIE Strategy" agreeing to the recommendation that:

> "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 for reporting as they are mostly used for parasite control and have different regulatory classifications in different countries; however, 16 countries reported the use of these molecules as growth promoters and salinomycin and monensin were mentioned by 12 and 11 countries, respectively.

In this fourth round of data collection, a total of 118 (n = 153; 77%) responding countries did not use any antimicrobial agents for growth promotion in animals in their countries, either with or without legislation or regulations. For further explanation on the legislation, please refer to the following explanatory section. The 35 remaining countries (n = 153; 22%) reported use of antimicrobials for growth promotion. The results of the fourth round show the lowest proportion of countries using growth promoters (35 out of 153 countries, 23%) since the beginning of the OIE global data collection records.

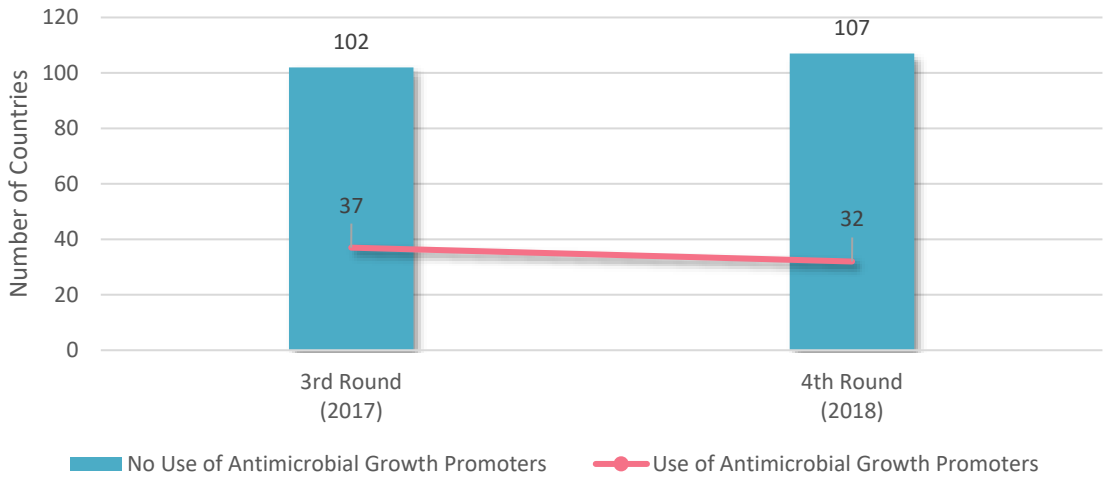
Figure 10. Use of Antimicrobial Growth Promoters in 153 Countries in 2018



During the second round of data collection, where country responses to the question of the authorisation of antimicrobials as growth promoters had changed from the previous year without explanation, further clarifications were 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 use of antimicrobial agents as growth promoters.

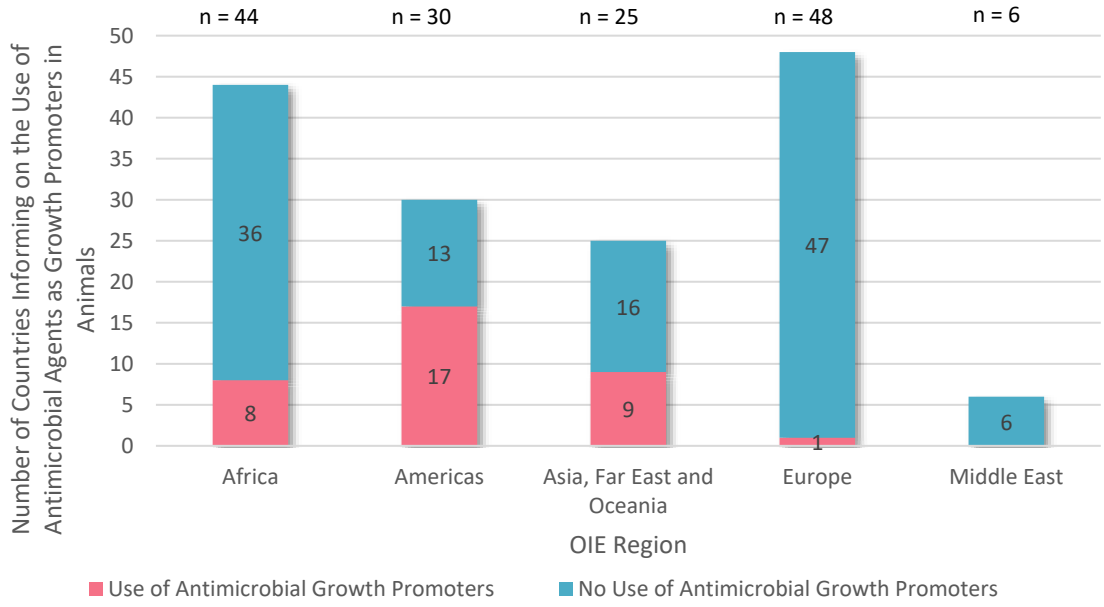
Because the question to understand the use of antimicrobial growth promoters was changed from the third round of the data collection, in order to avoid misunderstandings, Figure 11 only shows the responses of 139 countries that have participated in both the third and fourth round. The results in Figure 11 indicate a decrease of 14% in the number of countries using antimicrobial growth promoters.

Figure 11. Use of Antimicrobial Growth Promoters by Rounds of Data Collection in 139 Countries



When differentiated by OIE Region, the Americas and Asia, Far East and Oceania have the highest proportions of countries using antimicrobial growth promoters (Figure 12). Europe has been working on this issue for many years and this is reflected in the responses provided, where Europe is one of the regions with the lowest percentage of use and authorisation of antimicrobial growth promoters.

Figure 12. Number of Countries Using Antimicrobial Agents for Growth Promotion in Animals in 2018, of 153 Responding Countries, by OIE Region



Regulatory framework for antimicrobial agents used as growth promoters

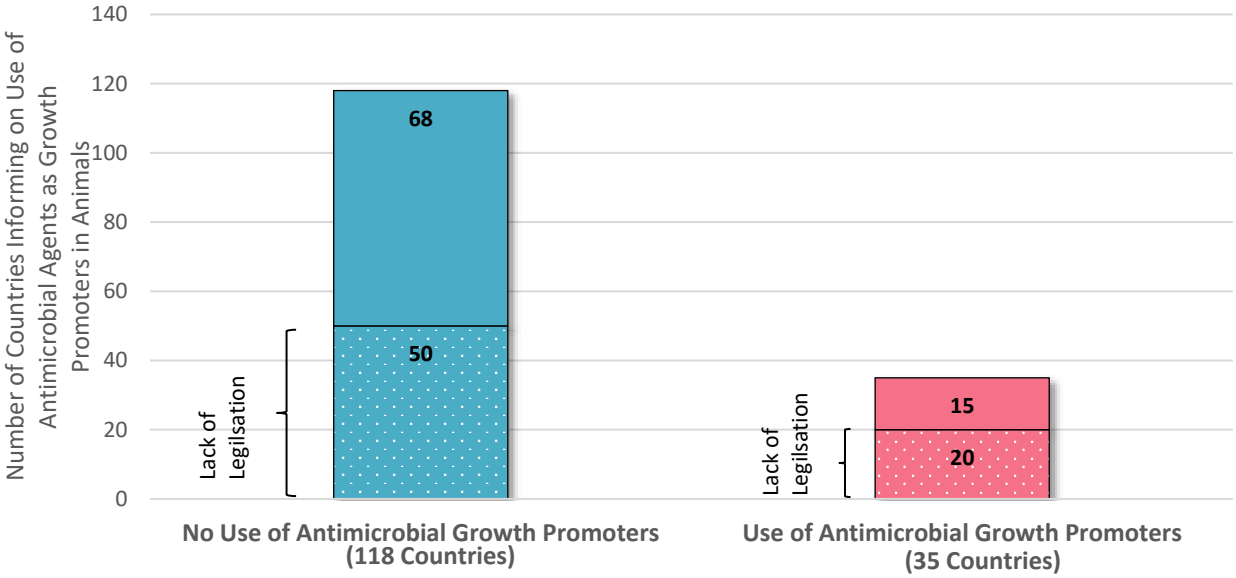
In the OIE template and guidance sent for the fourth round, all countries, regardless of their response to the question relating to use or not of antimicrobial growth promoters, were asked to respond to the following question: *Does your country have legislation/regulations on the use of antimicrobial growth promoters in animals?*

All 70 countries that answered 'Yes' to this question were then asked to indicate which type of legislation/regulations exists 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 13).

As presented in Figure 13, 50 countries stated no use of antimicrobials as growth promoters even though no regulatory framework exists. In some cases (n = 6), the countries stated that these molecules are banned without a regulatory framework; therefore, the OIE asked these countries to provide further information on how antimicrobial growth promoters are 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 in the market: to not allow their import; to monitor the manufacturing companies to only produce antibiotics for veterinary medical use and; to not allow their registration.
- Alternatives to antibiotics were presented to farmers (poultry and pig farmers) emphasizing the need for sanitation and hygiene.

Figure 13. Use of Antimicrobial Growth Promoters by Legislation, in 153 Countries in 2018



Most of the countries reporting the use of antimicrobials as growth promoters do not have a regulatory framework (20 out of 35 countries; 57%).

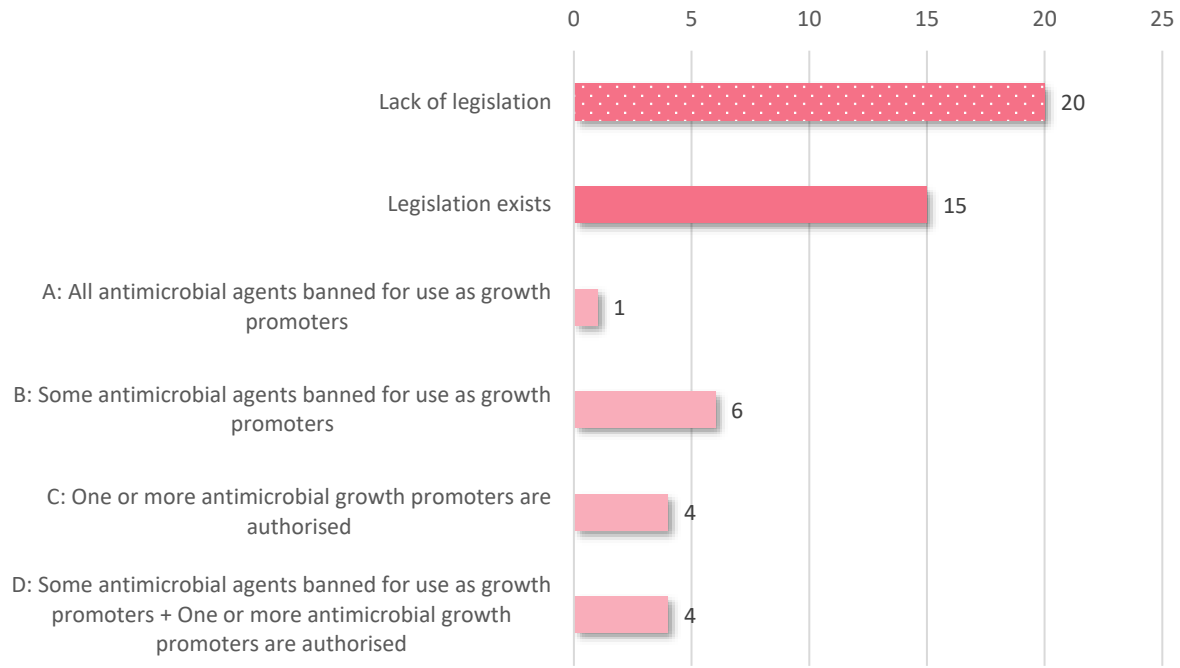
For those 15 countries using antimicrobials as growth promoters with a regulatory framework (n = 35; 43%), the legislation either provides a list of molecules that should not be used as growth promoters (n = 6) or provides a list of antimicrobials that can be used as growth promoters (n = 4) , while in some cases both types of lists have been established (n = 4). It was found that one country with legislation that bans growth promoters reported the use of these molecules in the field (Figure 14), indicating that enforcement of the legislation is needed with feed manufacturers continuing to illegally produce these types of products.

Among the 15 countries using growth promoters within a regulatory framework, some stated to have partially or completely banned all growth promoters for certain animals.

For those 20 countries using growth promoters without a regulatory framework, most of them were found in the Americas (11 out of 17; 65%); followed by Africa (7 out of 8; 88%) and Asia, Far East and Oceania (2 out of 9; 22%). 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 Americas and Asia, Far East and Oceania have improved their countries' regulatory framework on antimicrobial growth promoters.

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

Figure 14. Type of Legislation for Growth Promotion in 35 Countries that Reported the Use of Growth Promoters in 2018



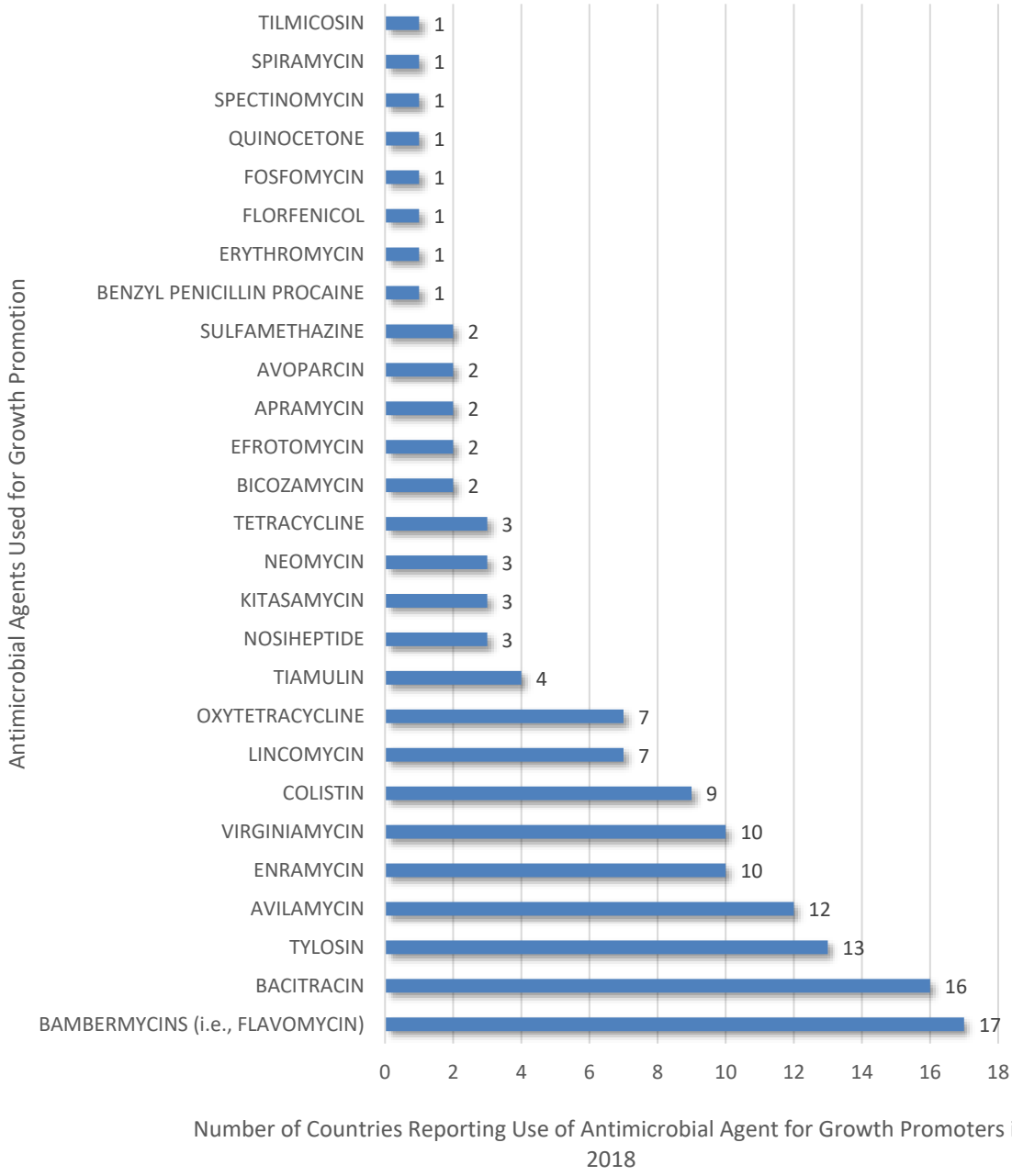
List of antimicrobial agents used for growth promotion

The 35 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.

Twenty-eight countries (n = 35; 80%) responded with a list of antimicrobial agents used for growth promotion. The most frequently listed antimicrobial agent was Flavomycin, followed by bacitracin and tylosin, the two latter are classified as Veterinary Highly Important Antimicrobial Agent and Veterinary Critically Important Antimicrobial Agent, respectively, according to the *OIE List of Antimicrobial Agents of Veterinary Importance.* Colistin was mentioned by nine countries (Figure 15), less than the 12 countries that reported colistin in 2017. By the time this report was published, one country will have already banned tylosin for growth promotion.

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

Figure 15. Antimicrobial Agents Used for Growth Promotion in Animals in 28 Countries in 2018



Twenty-four countries using antimicrobial agents as growth promoters (n = 35; 69%) also provided quantitative data on antimicrobial agents intended for use in animals. Thirteen of these countries (n = 24; 54%) could distinguish these quantities by use for growth promotion and veterinary medical purposes.

4. 2016 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 2016.

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 a global level. *It is expected that these first estimates will be refined over time, and therefore, should be interpreted with caution.*

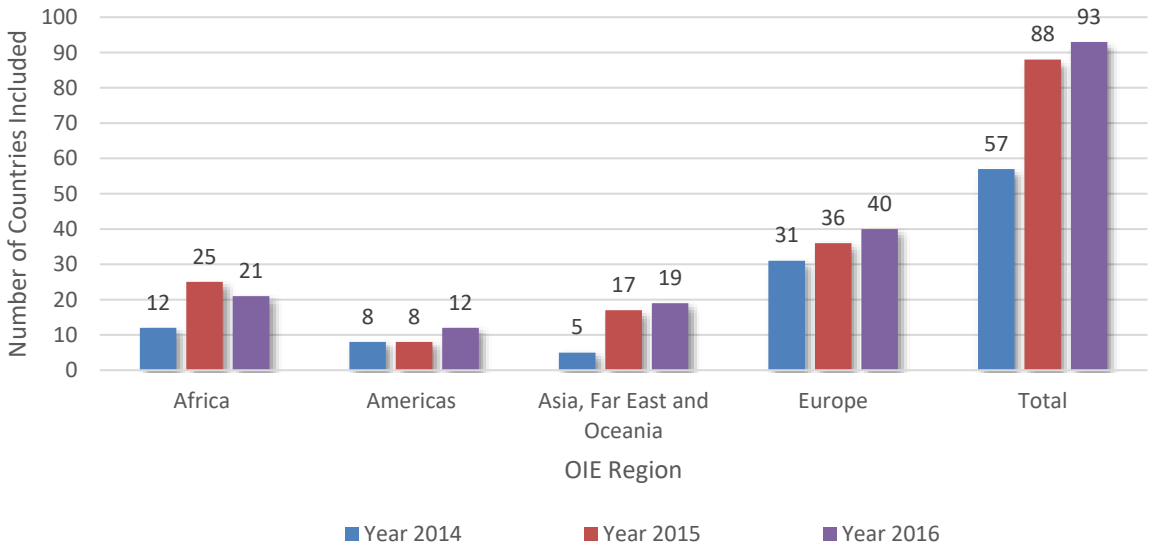
4.1. Antimicrobial Quantities

Regional Representation of Countries Included in the 2016 Analysis

The focus of this section is covering all 2016 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 fourth round.

For all rounds of data collection (4 rounds) compiled, 93 countries provided validated antimicrobial quantities intended for use in animals for 2016. The regional distribution of countries included in the 2016 analysis is shown in Figure 16. Due to geographic considerations, quantitative data for 2016 of two non-contiguous territories were included in the Americas for the 2016 analysis.

Figure 16. Number of Countries Included in the Antimicrobial Quantities Analysis by OIE Region, from 2014 to 2016



A lack of validated data from the Middle East did not allow for the inclusion of this OIE Region in the regional 2016 analysis but have been included in the global analysis. Future data submissions from this

OIE Region may permit a 2016 analysis of antimicrobial quantities adjusted by animal biomass in following reports.

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 93 countries included in the 2016 analysis, one country from Africa did not report the period of time covered so was excluded from this analysis. The average time period covered was 352 days for 92 countries; this information shows that most countries are providing quantitative data for most of a calendar year. Information by the OIE Regions are showed in Table 4.

Table 4. Reported Period of Time Covered by the Antimicrobial Quantities by OIE Region, 2016

OIE Region*	Number of Countries	Mean (days)	Standard Deviation (days)	Maximum (days)	Minimum (days)
Africa	20	335	55	360	119
Americas	12	362	7	387	360
Asia, Far East and Oceania	19	353	16	360	300
Europe	40	357	11	360	300
Global	92	352	29	387	119

*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 Animal Health Code* (Monitoring of the quantities and usage patterns of antimicrobial agents used in food-producing animals) and with Chapter 6.3 of the *Aquatic Animal Health 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 for clarification of their answers and/or data collection systems. Thirty-six countries' data sources were considered to present a risk of duplication (n = 93; 39%). Following these clarifications 18 countries (n = 36; 50%) changed their answers or demonstrated that there was no risk of duplication or overlapping data sources. The remaining countries (18 out of 36; 50%) that did not respond with clarification were excluded from the analysis in Figure 17.

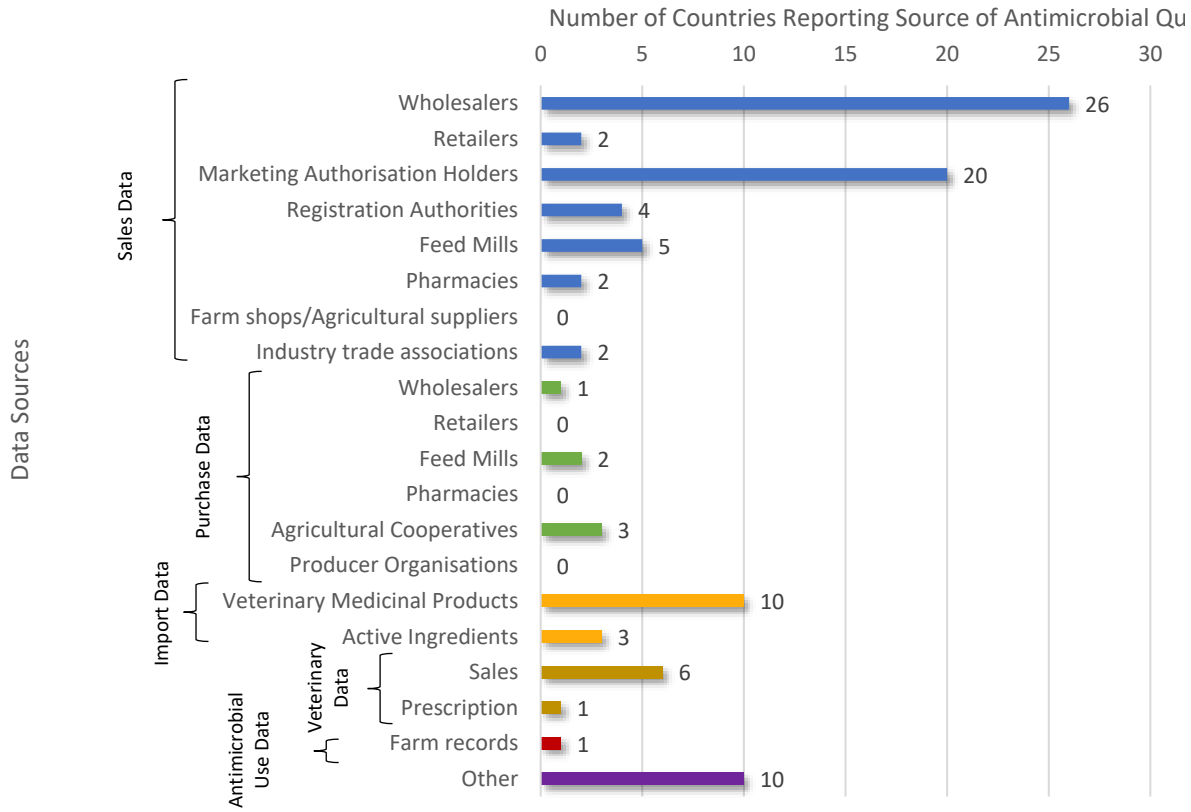
In the Guidance for Completing the OIE template for the Collection of Data (Annex 7), countries were asked to provide data as close to the point of use (i.e., administration) as possible. However, among the 75 countries that reported validated quantitative data, 'Antimicrobial use data – Farm records' – the category representing on-farm administration of antimicrobials – was only selected as a data source by one country (Figure 17). 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 of wholesalers and Marketing Authorisation Holders, which were selected by 26 and 20 countries respectively. Following

sales data, import data as declared by custom 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).

Figure 17. Validated Data Sources Selected by 75 Countries Reporting Quantitative Data in 2016

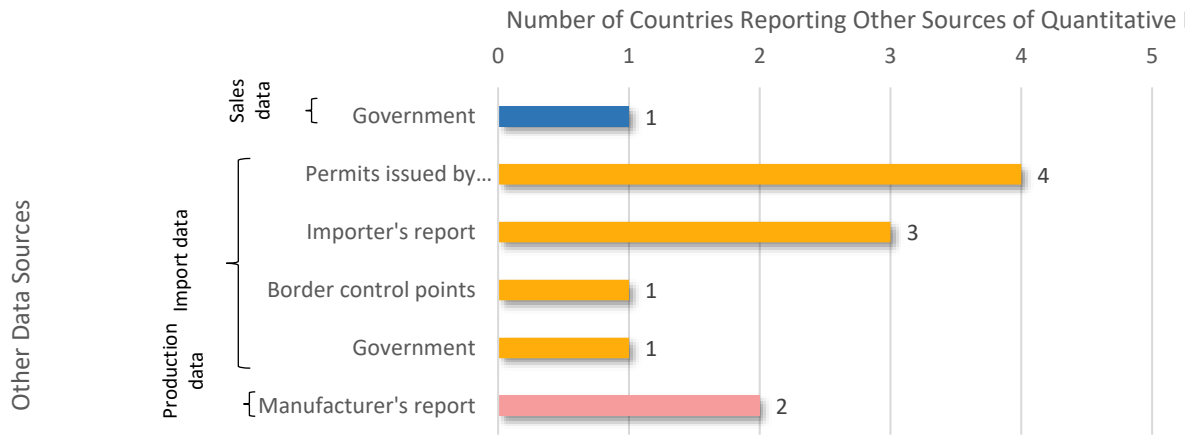


OTHER DATA SOURCES REPORTED

Ten countries (n = 93; 11%) 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 importation of antimicrobials as issued by registration authorities (Figure 18). 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 18. 'Other' Source of Data Described by 10 Countries Reporting Quantitative Data in 2016



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. This question was responded by all 75 countries that provided quantitative data with validated data.

As a global average, quantitative data coverage achieved was 90% (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 Quantities Coverage by OIE Region, 2016

OIE Region	Number of Countries	Mean (%)	Median (%)	Standard Deviation (%)	Minimum (%)	Maximum (%)
Africa	14	73	80	30	5	100
Americas	8	91	97	10	70	100
Asia, Far East and Oceania	16	90	100	14	54	100
Europe	36	96	100	10	55	100
Total	75	90	99	19	5	100

SOURCES NOT CAPTURED BY THE DATA

From the 75 countries estimating the coverage of their data, 28 countries stated to cover 100% of the data source used to report the data. The 47 countries that did not cover 100% of available quantitative data were asked to provide further information on uncaptured data sources.

Forty-two countries (n = 47, 89%) 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 36 countries (n = 47; 77%). The remaining countries (11 out of 47, 23%) were excluded from this analysis. Countries could have reported more than one uncaptured data sources.

Most of the 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 12 countries.

Table 6 describes the quantitative data coverage lost due to lack of access to data sources, as estimated by 36 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 Lack of Access to Sources, as Reported by 36 Countries in 2016

Sources Estimated Not Captured in Quantitative Data	Number of Countries Naming Uncaptured Data Source	Estimated Data Coverage Lost		
		Mean	Minimum	Maximum
Sales Data				
Partial response from relevant stakeholders	10	39%	15%	95%
Antibiotics authorised for humans that are used in companion animals	3	6%	1%	15%
Not all antimicrobial classes were included	2	23%	15%	30%
Illegal or unofficial veterinary products	1	40%	40%	40%
Veterinary products with special license*	1	18%	18%	18%
Companion animals	1	15%	15%	15%
Purchase Data				
Illegal or unofficial veterinary products	3	35%	5%	70%
Import Data				
Illegal or unofficial veterinary products	8	13%	2%	30%
Medicated feed	1	1%	1%	1%
Veterinary Products with special license*	3	14%	10%	18%
Partial data, not from a whole calendar year	2	19%	8%	30%
Companion and zoo animals	1	2%	2%	2%
Production Data				
Manufacturer's report	1	15%	15%	15%

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

Antimicrobial Quantities Reported In 2016

Table 7 shows the total tonnage of antimicrobial agents intended for use in animals for 2016, as reported to the OIE during the first four rounds of data collection.

When the antimicrobial quantities reported were adjusted for these coverage estimates, 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 are only representative of the quantities of antimicrobial agents intended for use in the animals for the animal biomass covered in each OIE Region (shown below in %). *They 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, 2016

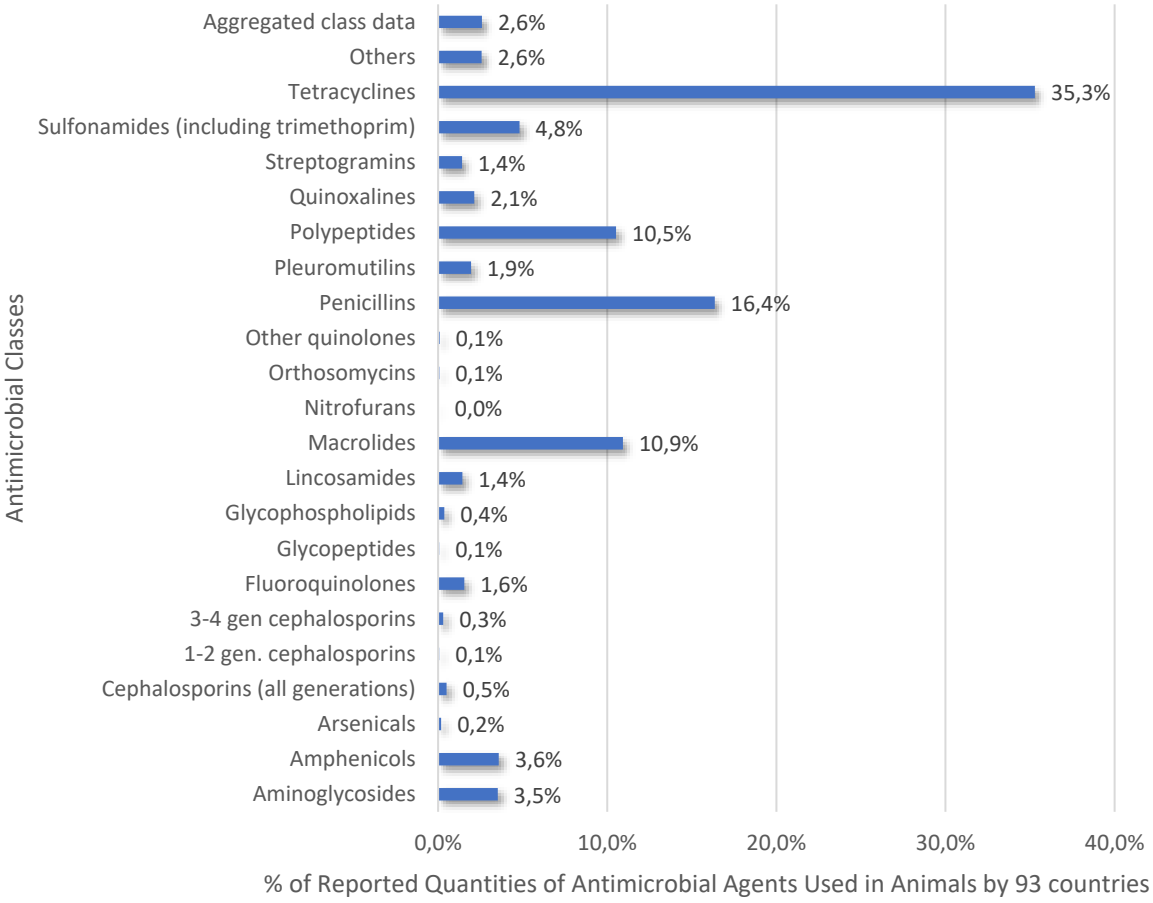
OIE Region	Number of Countries Included in Analysis of 2016 Quantitative Data	% of Total Estimated Biomass Covered*	Quantities Reported (in tonnes)	Quantities Reported Adjusted by Estimated Coverage** (in tonnes)
Africa	20	51%	3,080	3,558
Americas	13	65%	19,940	24,035
Asia, Far East and Oceania	19	81%	60,445	61,170
Europe	40	82%	8,798	9,015
Total	93	74%	92,269	97,784

* *It must be highlighted that the biomass estimates were not calculated according to the animal biomass methodology and are solely representative of slaughter data from the countries.*

** *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 figure was adjusted to represent 100% of the total estimated amount (as further explained in the Data Coverage section, page 41).*

Among the 93 countries that provided quantitative data on antimicrobial agents intended for use in animals, tetracyclines were the most commonly reported antimicrobial class (Figure 19).

Figure 19. Proportion of Antimicrobial Classes Reported for Use in Animals by 93 Countries in 2016



HIGH USE OF ANTIMICROBIAL CLASSES

For 2016 data, it was noticed that eight countries (n = 93; 9%) allocated more than 70% of their total amount of antimicrobials intended for use in animals in one antimicrobial class (Table 8). Five of these countries (n = 8; 63%) were from Africa.

Since the third round of the data collection, 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. For the 2016 analysis, most of the countries reported these data during the second round (six out of eight countries), and therefore they were not asked to provide explanations. For the two countries providing explanations, one country mentioned that tetracyclines were available over-the-counter and were freely-available throughout the country. Another country with high levels of penicillins, explained that it was mainly due to the medicinal policy of the veterinarian's association in the country that states that penicillin is the first choice when selecting antimicrobials.

Table 8. Antimicrobial Classes with More than 70% of the Total Amount of Antimicrobials Intended for Use in Animals, by Eight Countries in 2016

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)
Aminoglycosides	1	0.002	88.2%
Penicillins	1	0.5	82.0%
Polypeptides	1	10.4	89.4%
Sulfonamides	1	7.5	76.5%
Tetracyclines	4	213	83.1%

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

Irrespective of whether the data could be differentiated by animal groups, all 93 countries that provided quantitative data were asked to identify the food producing animal species covered by their data from a supplied list in the OIE template according to the products target species label. One country that provided data only for companion animals was excluded from Figure 20. The breakdown of food producing species included in the reporting countries datasets is shown in Figure 20.

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*)

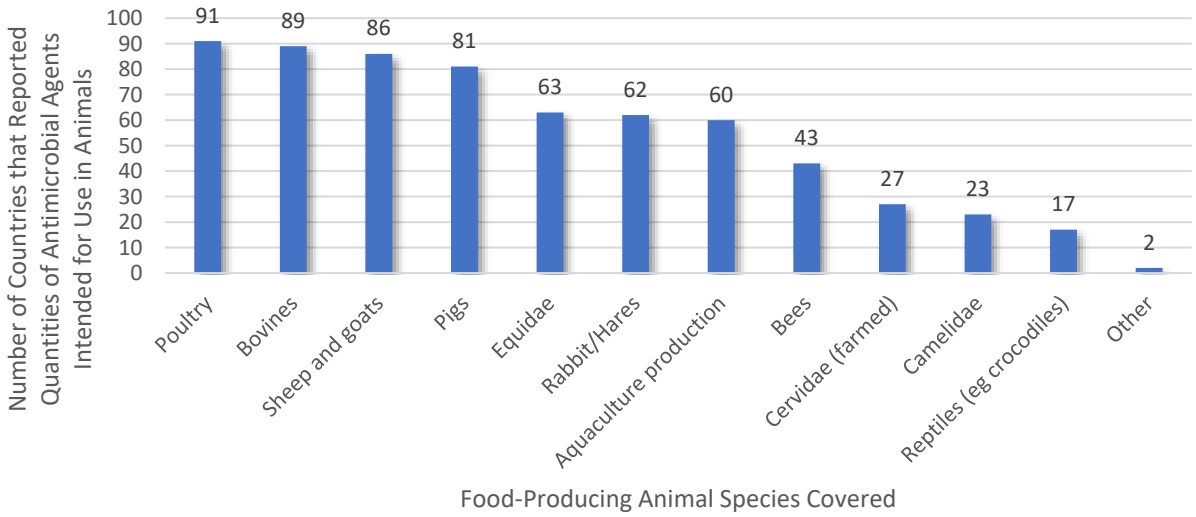
C. PIGS
- *a.* Pigs – commercial
- *b.* Pigs – backyard

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 2016, poultry was mentioned by 91 of the countries reporting quantitative data for food-producing species. Bovines, sheep and goats, and pigs were also included by most countries (Figure 20).

Figure 20. Food-Producing Animal Species Included in Quantitative Data Reported by 92 Countries in 2016



Quantitative Data Differentiation by Animal Groups

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 2016, 43 countries (n = 93; 46%) provided data differentiated by group of animals Figure 21), this corresponds to the number of countries reporting their antimicrobial quantities through Reporting Option 2 and 3.

Figure 22 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 come from sales and imports, and the attribution of antimicrobial quantities by animal group is based on species types represented on product labels, where this is available and specified. For countries where product labels cover a wide variety of species, it would be more difficult to report quantitative data differentiated by animal group.

Figure 21. Differentiation by Animal Groups Among 93 Countries Reporting Quantitative Data in 2016

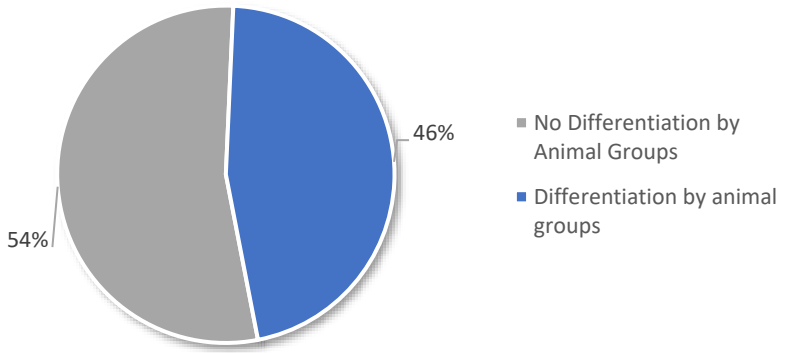
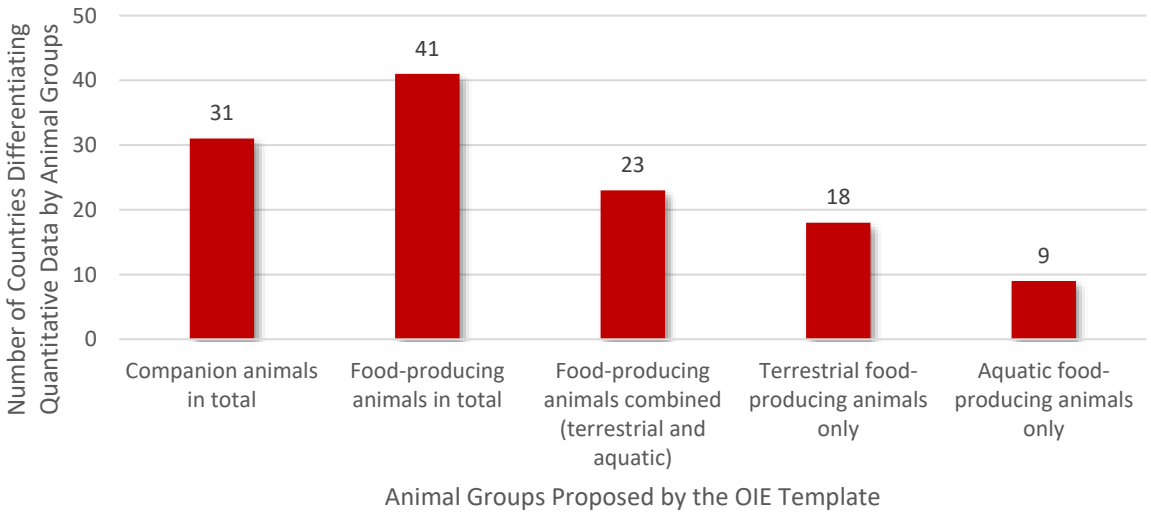


Figure 22. Representation of Quantitative Data from 43 Countries Able to Distinguish by Animal Group in 2016

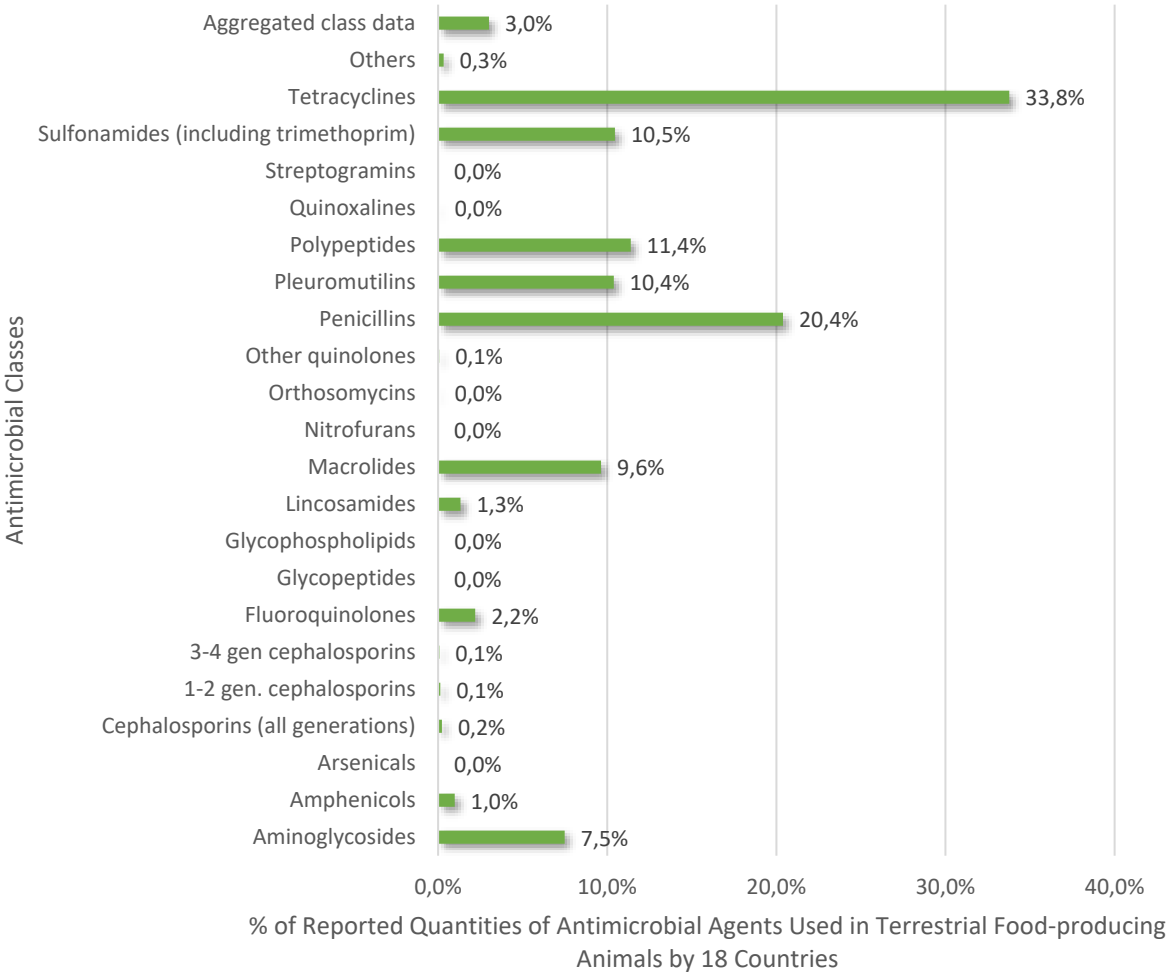


Fifty countries of those reporting quantitative data (n = 93; 54%) were not able to distinguish amounts of antimicrobial agents by groups of animals. Of these, most (41 out of 51; 80%) reported antimicrobial quantities through Reporting Option 1, which allows reporting for all animal species, and distinguishes quantities only by purpose of use (veterinary medical use or growth promotion [8]). Nine of these countries (n = 51; 18%) 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 route of administration. This suggests that the labelling of veterinary products in these countries clearly separates out the routes 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 23).

Figure 23. Proportion of Antimicrobial Classes by Terrestrial Food-producing Animals as Reported by 18 Countries in 2016

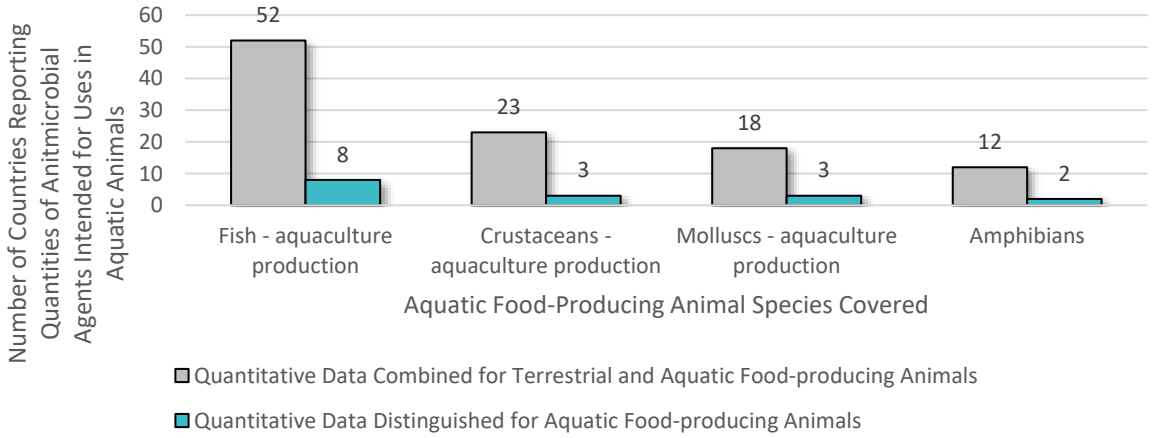


AQUATIC FOOD-PRODUCING ANIMALS

From the 92 countries that provided quantitative data for food-producing animals in 2016, 60 countries stated that their label products targeted aquatic food-producing animals (n= 92, 65%).

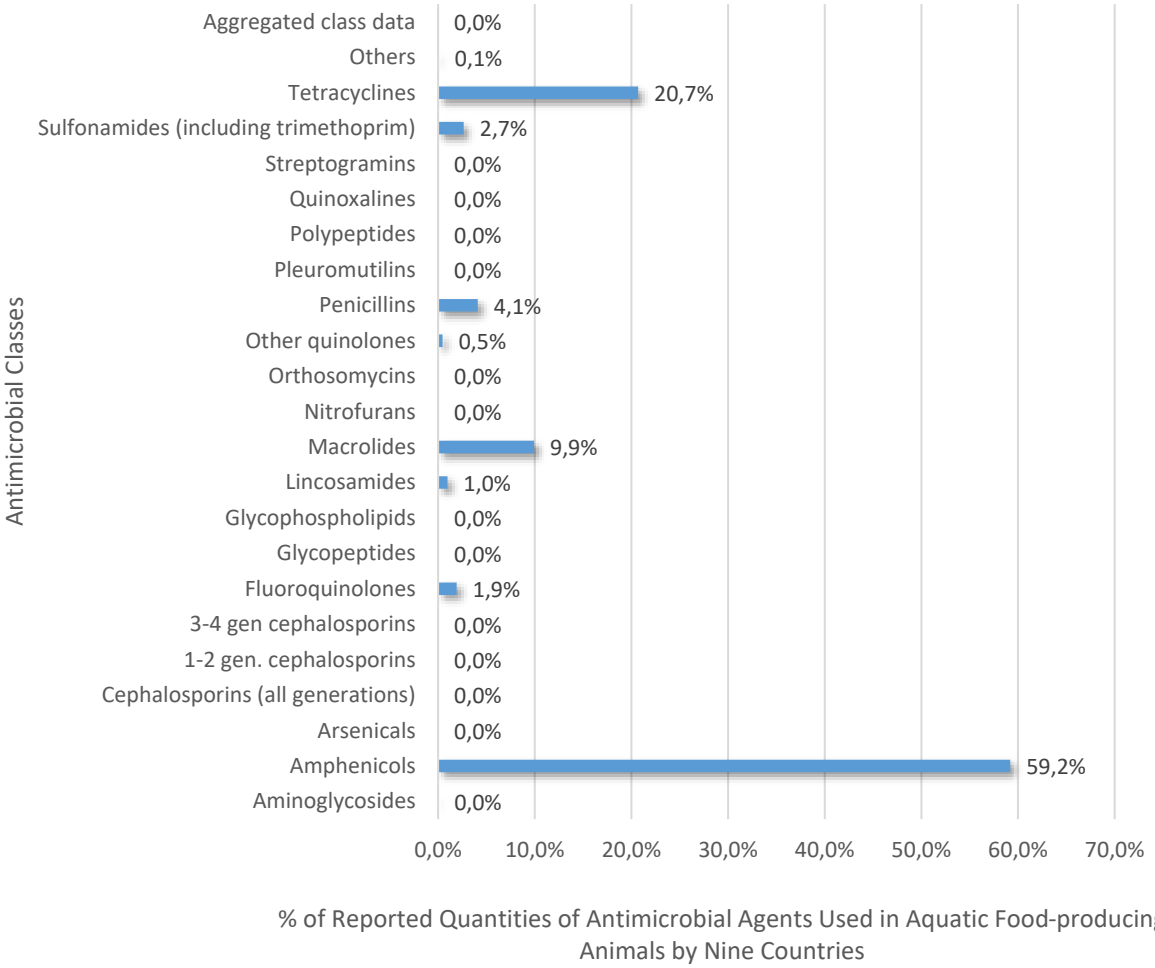
When aquatic food-producing animals are covered, in most cases, quantitative data for aquaculture represents farmed fish. For the 60 countries that provided amounts of antimicrobial agents for 'Aquatic food-producing animals', quantities for 'Crustaceans – aquaculture production', 'Molluscs – aquaculture production' and 'Amphibians' are reported mainly when data for 'Fish – aquaculture production' were also available. Figure 24 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.

Figure 24. Animals included in Aquaculture covered in the Quantitative Data Reported by 60 Countries in 2016



From the 60 countries providing antimicrobial quantities that covered aquatic animals, nine countries were able to report quantitative data for 'Aquatic food-producing animals' separately from other animal groups using mainly Reporting Option 3 (9 out of 60; 15%); four of these nine countries were from Europe. From the nine countries, Amphenicols were most commonly reported (Figure 25).

Figure 25. Proportion of Antimicrobial Classes by Aquatic Food-producing Animals as Reported by Nine Countries in 2016



During the fourth round of the data collection the OIE Antimicrobial Use Team observed that some countries with aquaculture production communicated through WAHIS, did not report antimicrobial quantities for aquatic animals to the OIE AMU Team. Consequently, some of these countries were asked to clarify if antibiotics were not used in the country's aquaculture sector. The following situations were outlined by six countries:

- The country's aquatic production was reported to be insignificant compared to the terrestrial food-producing animals and most often for rudimentary subsistence level. Therefore, the country does not import or distribute veterinary medicinal products for aquatic species.
- The veterinary medicinal products for aquatic animals were under the legal authority of another registration agency in the country.
- The country does not use antimicrobials for aquatic food-producing animals.

The OIE will continue to work in understanding the barriers that imped the countries data collection provision for aquatic food-producing animals.

COMPANION ANIMALS

The first year of the OIE AMU data collection, Members were asked to provide antimicrobial quantities only for food-producing animals. However, some countries additionally reported their data for

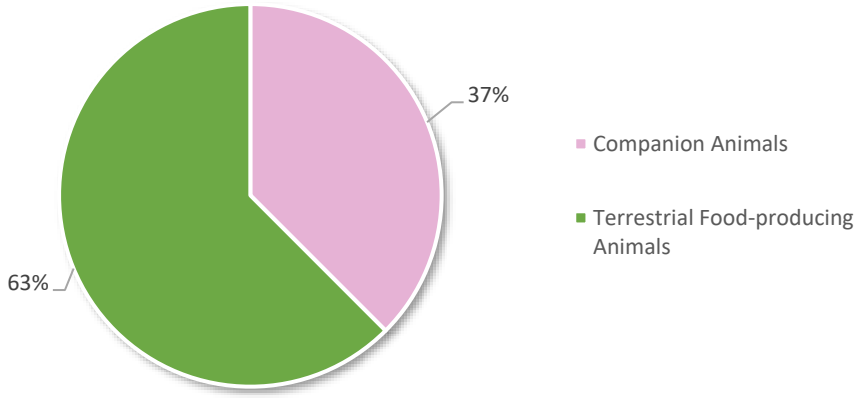
companion animals. In response to this, the OIE modified its questionnaire to include this group. In the fourth round of data collection, Members were asked to specify the animals considered companions.

From the 93 countries who provided quantitative data in 2016, 81 countries stated that products label targeted companion animals (n= 93, 87%). All 81 countries considered canines and felines as pets; of these, 30 countries declared additional species; being the most cited equines (8 countries) followed by ornamental birds (6 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 terrestrial food-producing animals (Figure 26).

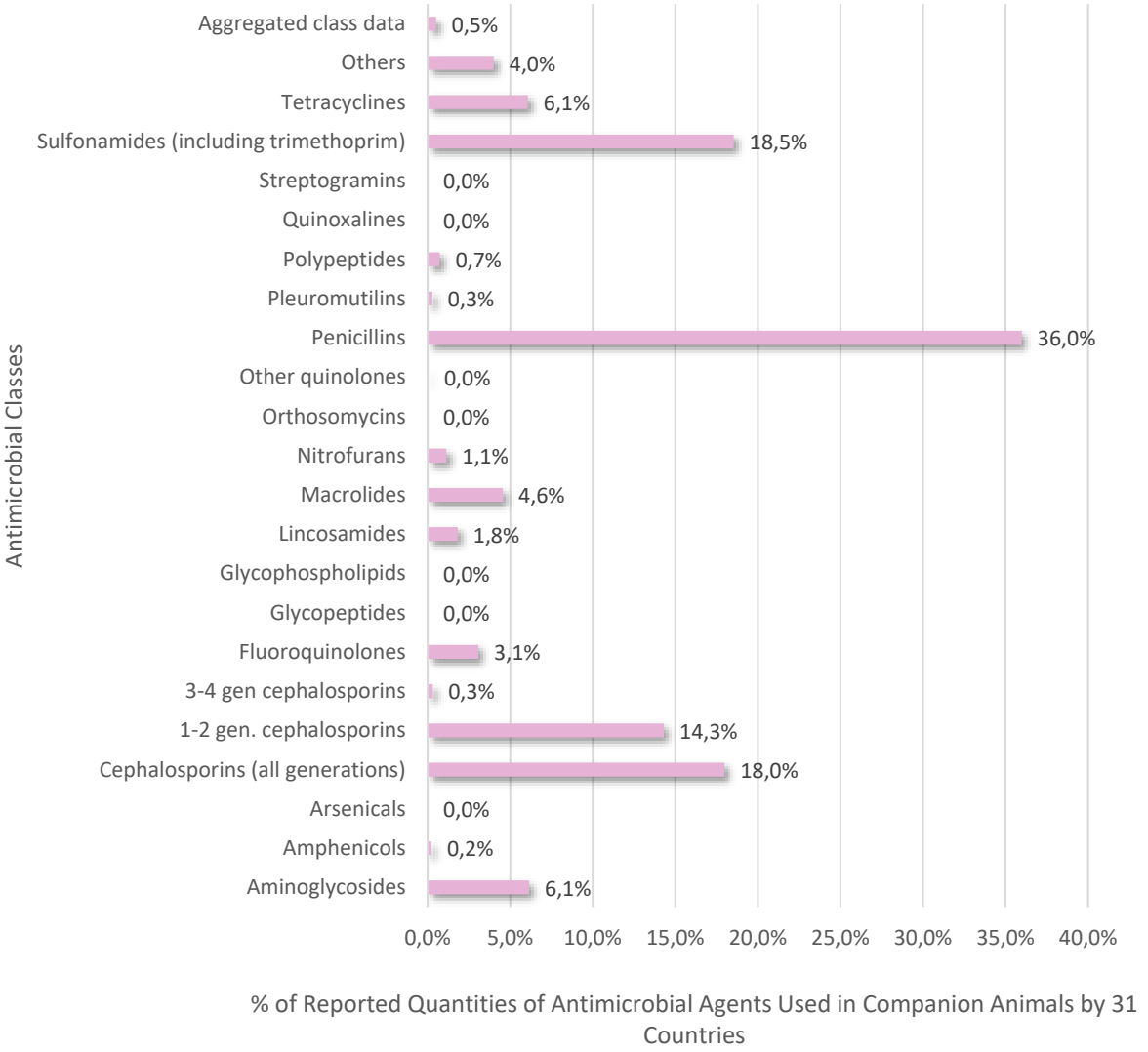
As previously mentioned, countries provided mostly sales and import data, and when differentiating these quantities by animals, they do so based on the target species declared on the product label. Usually the horses will be grouped together with other major food producing species, even if not destined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

Figure 26. Differentiation of Equine Data by Animal Groups Among 11 Countries Reporting Quantitative Data in 2016



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

Figure 27. Proportion of Antimicrobial Classes by Companion Animals as Reported by 31 Countries in 2016



Routes of administration

For 2016, 39 countries chose to report their quantitative data through Reporting Option 3, the only option which allows for distinction of the data by route of administration. Among these 39 countries, a majority reported higher amounts of antimicrobial agents used via 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 animal groups in addition to route of administration. However, nine countries (n = 39; 23%) 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 30 countries (n = 39; 77%) able to distinguish quantitative data by animal groups using Reporting Option 3, injection administration was most commonly reported for use in terrestrial food-producing animals. In aquatic food-producing animals and companion animals, oral administration was reported more commonly.

Figure 28. Proportion of Antimicrobial Quantities (by antimicrobial class) Reported for Use in Animals by the oral route, aggregated by 39 countries in 2016

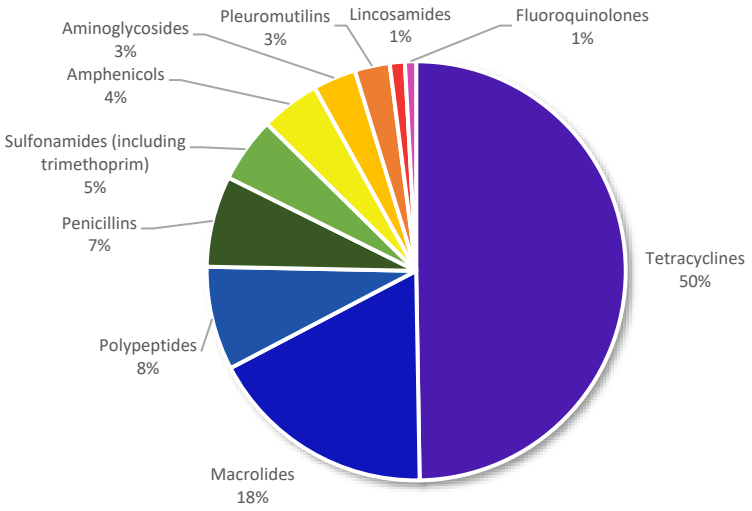


Figure 29. Proportion of Antimicrobial Quantities (by antimicrobial class) Reported for Use in Animals by the injection route, aggregated by 39 countries in 2016

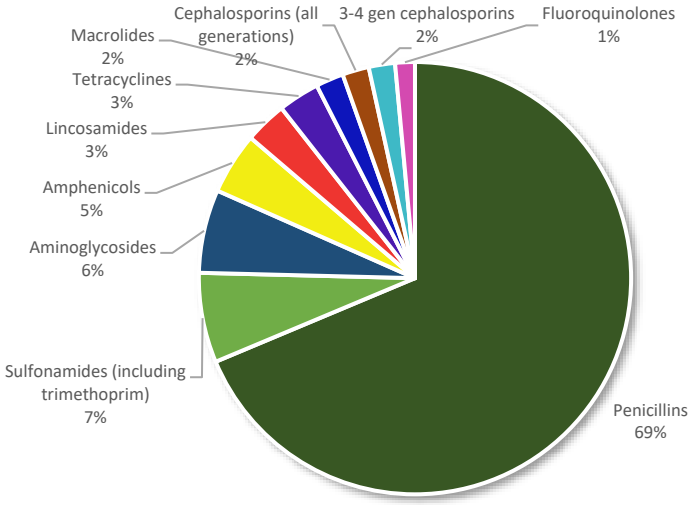
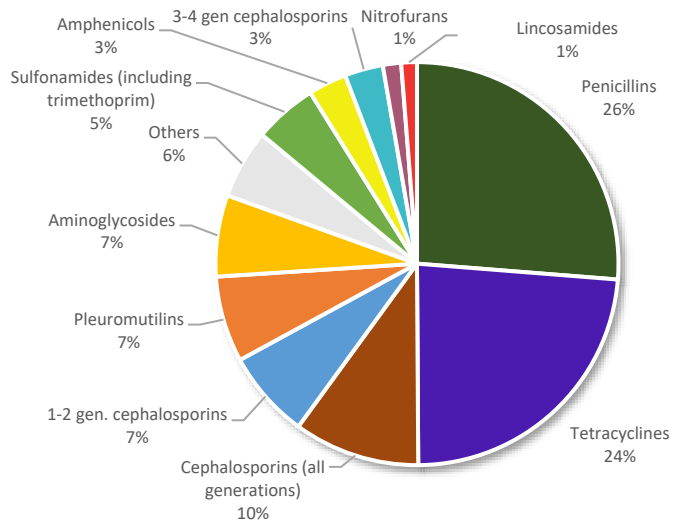


Figure 30. Proportion of Antimicrobial Quantities (by antimicrobial class) Reported for Use in Animals by other routes, aggregated by 39 countries in 2016



4.2. Animal Biomass

As described in the methodology, animal biomass was calculated for 92 countries providing quantitative data for the year 2016 during all rounds of data collection. One country that provided data for companion animals only was excluded from the analysis. Farmed fish were included in the biomass for countries reporting that their data covered aquaculture, or could not be distinguished by animal group (n = 56; 61%)

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 2016 Data

Figure 31 shows the estimated percentage of the total regional animal biomass covered by the 92 countries included in the analysis of antimicrobial quantities for 2016, compared to the coverage achieved in the 2014 and 2015 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 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 35% in 2014 to 75% in 2016. Asia, Far East and Oceania and Europe had particularly high animal population coverage for 2016, with responding countries representing approximately 81% and 82% of the regions' total animal biomass respectively. Coverage in Africa and Americas also increased to 51% and 65% respectively.

Figure 31. Estimated Percentage of Total Regional Biomass Covered by Countries Reporting Quantitative Data for 2014, 2015 and 2016

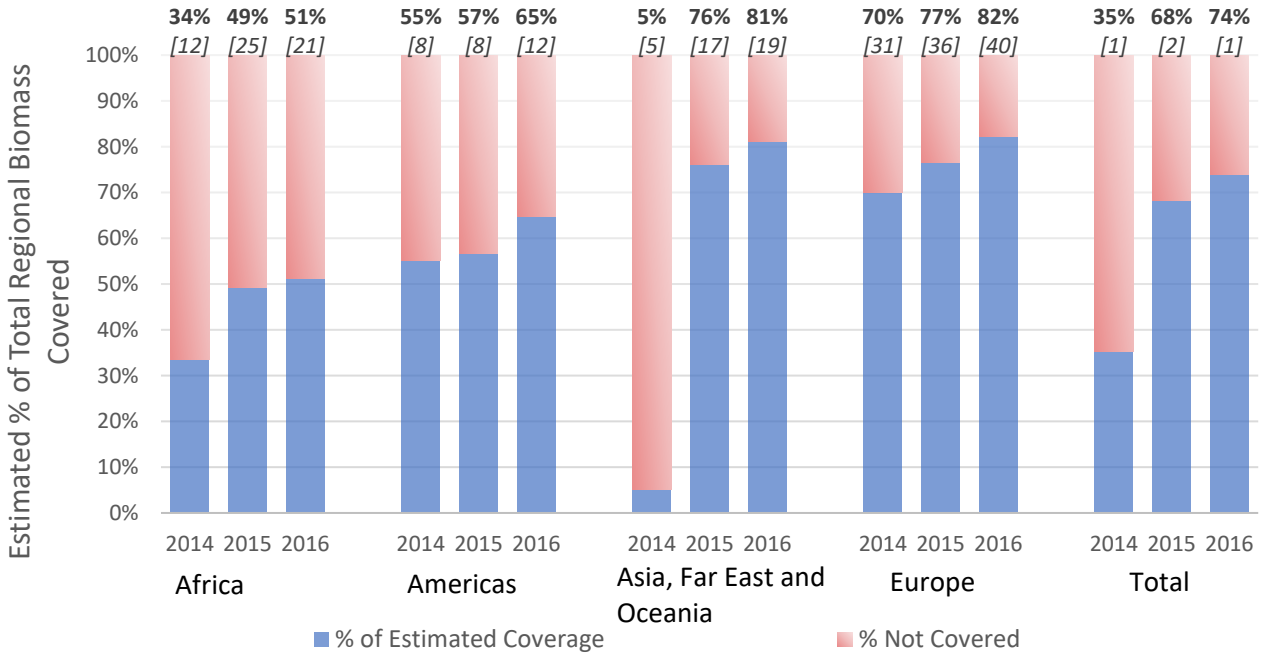
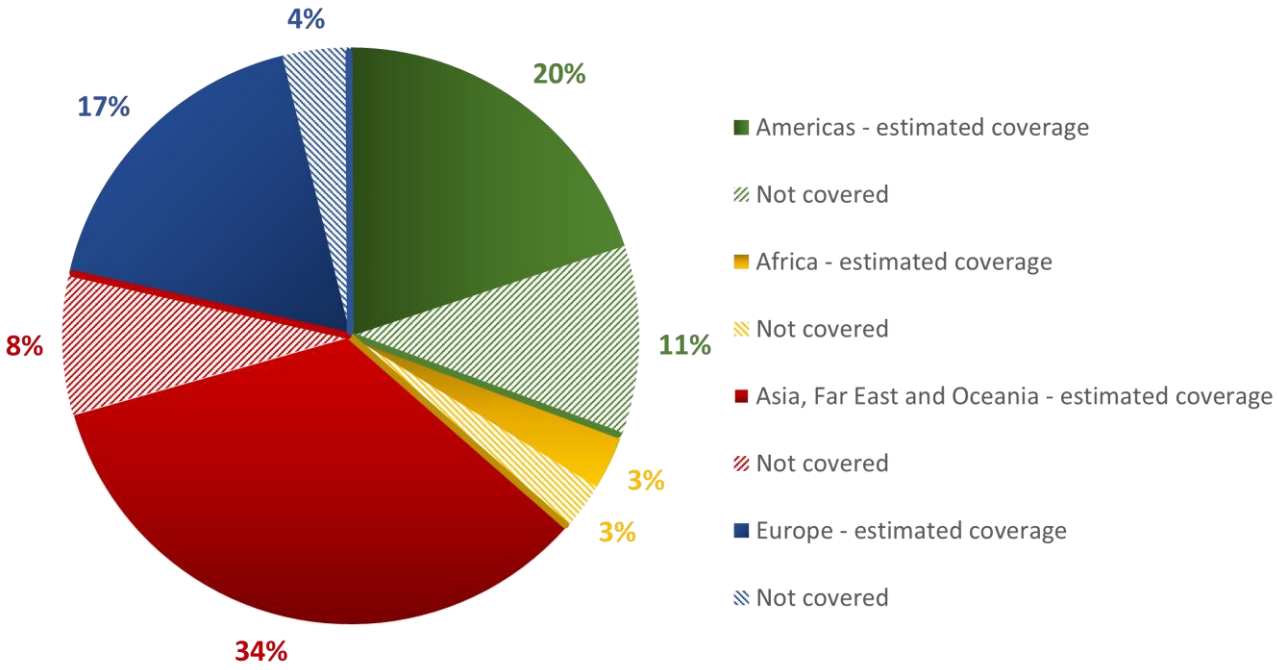


Figure 32 shows the regional distribution of the estimated percentages of regional biomass covered by the 92 countries included in the analysis of antimicrobial quantities for 2016, in comparison to the global biomass estimate. Asia, Far East and Oceania and Americas regions represent a particularly high proportion of the global biomass estimate.

Figure 32. Regional Percentages of Estimated Biomass Covered by Countries Reporting Quantitative Data for 2016

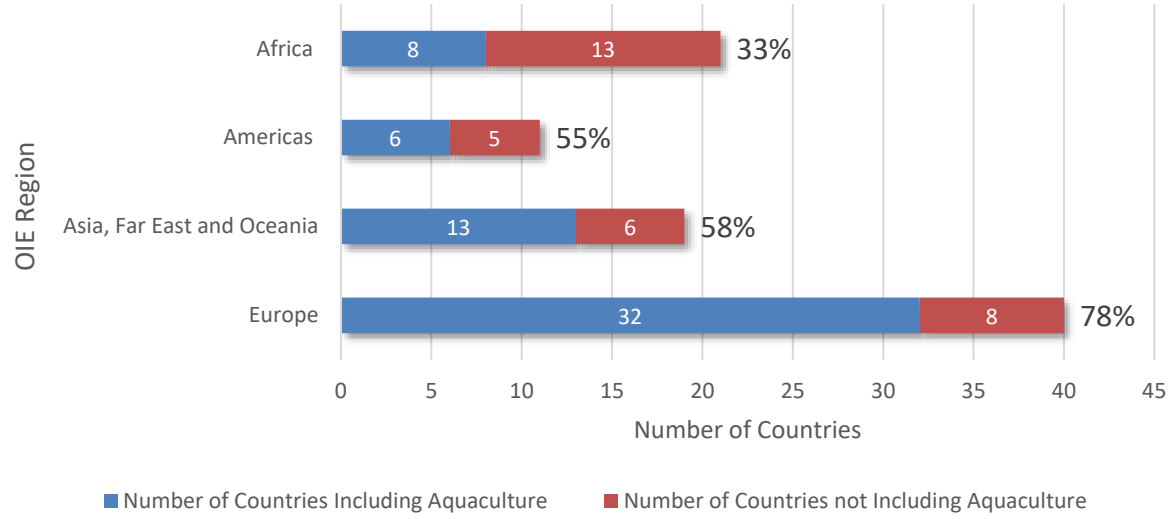


Animal Groups Covered by Data in 2016

Of the countries providing quantitative data for 2016, 60 (n = 92; 65%) 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 (78%; 32 of 40 countries). 58% of countries in Asia, Far East and Oceania (13/19), 55% of countries in the Americas (6/11), and 33% of countries in Africa (8/21) reported quantitative data that included aquatic food-producing animals.

Figure 33. Countries Including Aquatic Food-Producing Animal Species in Quantitative Data for 2016



Animal Biomass Covered by the 2016 Additional Analysis: Global View

Table 9 shows the animal biomass (in 1,000 tonnes) of farmed animals covered by 2016 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 providing quantitative data, the relative size and average weights of their animal populations in 2016.

Table 9. Animal Biomass Covered by Quantitative Data Reported to the OIE for 2016 Obtained by the Accumulation of Information from all Rounds of Data Collection, Results for 92 Countries

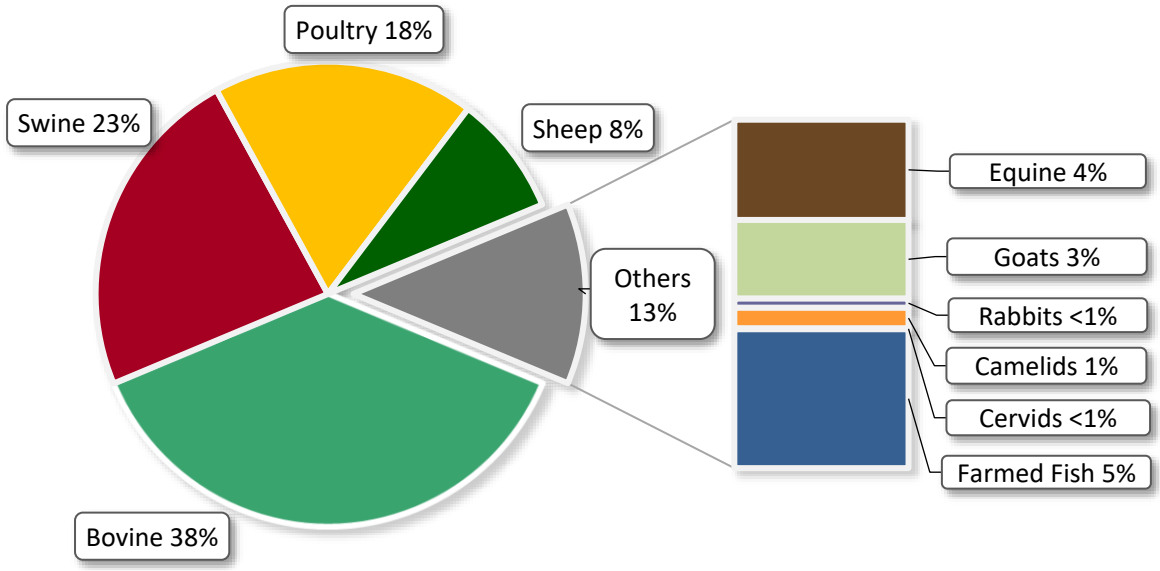
Year 2016		Africa	Americas	Asia, Far East and Oceania	Europe	Global
Number of Countries		21	11	19	40	92
Bovine Biomass	(in 1,000 tonnes)	38,238	95,849	54,832	50,347	239,292
	(relative proportion)	*48.6%*	*55.1%*	*21.6%*	*38.3%*	*37.4%*
Swine Biomass	(in 1,000 tonnes)	1,054	23,443	89,162	35,680	149,339
	(relative proportion)	*1.3%*	*13.5%*	*35.1%*	*27.1%*	*23.4%*
Poultry Biomass	(in 1,000 tonnes)	4,648	42,382	42,763	27,035	116,896
	(relative proportion)	*5.9%*	*24.3%*	*16.8%*	*20.6%*	*18.3%*
Equine Biomass	(in 1,000 tonnes)	7,567	7,226	4,973	3,307	23,133
	(relative proportion)	*9.6%*	*4.2%*	*2.0%*	*2.5%*	*3.6%*
Goat Biomass	(in 1,000 tonnes)	7,954	650	7,640	1,539	18,146
	(relative proportion)	*10.1%*	*0.4%*	*3.0%*	*1.2%*	*2.8%*
Sheep Biomass	(in 1,000 tonnes)	14,654	3,116	23,161	12,326	53,718
	(relative proportion)	*18.6%*	*1.8%*	*9.1%*	*9.4%*	*8.4%*
Rabbit Biomass	(in 1,000 tonnes)	42	25	1,741	314	2,122
	(relative proportion)	*0.1%*	*0.0%*	*0.7%*	*0.2%*	*0.3%*
Camelid Biomass	(in 1,000 tonnes)	4,069	40	399	75	4,760
	(relative proportion)	*5.2%*	*0.0%*	*0.2%*	*0.1%*	*0.7%*
Cervid Biomass	(in 1,000 tonnes)	19	26	82	64	192
	(relative proportion)	*0.02%*	*0.01%*	*0.03%*	*0.05%*	*0.03%*
Terrestrial Animal Biomass	(in 1,000 tonnes)	78,245	172,757	224,754	130,687	607,597
	(relative proportion)	*99.5%*	*99.2%*	*88.4%*	*99.4%*	*95.1%*
Farmed Fish Biomass	(in 1,000 tonnes)	393	1,326	29,516	810	32,045
	(relative proportion)	*0.5%*	*0.8%*	*11.6%*	*0.6%*	*5.0%*
All Species Biomass	(in 1,000 tonnes)	78,638	174,083	254,270	131,496	639,036
	(relative proportion)	*100.0%*	*100.0%*	*100.0%*	*100.0%*	*100.0%*

Figure 34 shows the global species composition of animals potentially exposed to the antimicrobial quantities reported to the OIE for 2016. 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 (38%) make up the largest contribution to animal biomass for the quantitative data reported. Swine (23%) and poultry (18%) also play a significant role, with sheep (8%), farmed fish (5%), equines (4%), and goats (3%) playing relatively minor roles in this analysis. The contributions of rabbits (0.3%), camelids (0.7%), and cervids (0.03%) 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 changed. This is expected to occur as data reporting capacity of countries increases.

Figure 34. Species Composition of Animal Biomass for 92 Countries Included in 2016 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 outside of slaughterhouses for personal consumption. The amount of slaughter undertaken outside slaughterhouses and the extent to which this population is captured in slaughter data is expected to vary significantly between countries and regions.

FARMED FISH

Data on farmed crustaceans, molluscs and amphibians were excluded from the animal biomass analysis given the relatively small size of these populations, and inconsistency in their reporting.

Percentages of farmed fish should also be interpreted with caution as fish biomass 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 farmed fish 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 the global aquaculture production.*

For the purposes of the 2016 analysis of quantitative data, aquaculture was most significant in Asia, Far East and Oceania, where farmed fish made up 12% of the covered animal biomass. In Africa, the Americas, and Europe, farmed fish made up between 0.5% to 0.8% of the covered animal biomass.

CHANGES IN ANIMAL BIOMASS COMPARED TO 2015 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 Africa, Asia and Europe, the estimated percentage of total regional biomass covered remained relatively stable from 2015 to 2016 (Figure 31), with respective increases of +2%, +5% and +6% and the species composition of the animal biomass also remained relatively unchanged (between 1% to 2% of changes between animal groups). Americas had the greatest increase in estimated percentage of total regional biomass covered, from 57% in the up to date 2015 analysis to 65% in the 2016 analysis. This increased

regional coverage resulted in a more significant change in species composition relative to the other regions, notably a relative decrease in representation of bovines (-6%), and relative increase in swine (+4%).

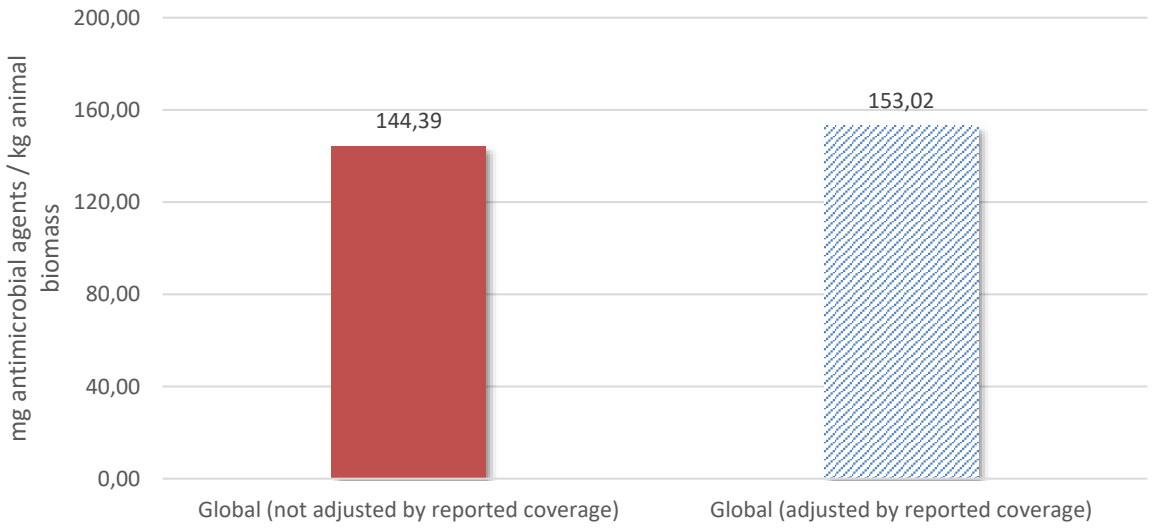
4.3. Antimicrobial Quantities Adjusted by Animal Biomass

2016 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 92 countries providing data for food-producing animals in all rounds of data collection for 2016, 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 comparisons (e.g. over time, and between regions). The first estimate of 144.39 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 92 countries during all rounds of data collection. The second estimate of 153.02 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 2016. These coverage estimates are subjective to each reporting country, but can provide an upper level estimate of global antimicrobial use in animals. For more detail of coverage estimates, see 4.2 Animal Population Covered by 2016 Data (page 54).

Figure 35. Global Quantities of Antimicrobial Agents Intended for Use in Animals Based on Data Reported by 92 Countries for 2016, Adjusted by Animal Biomass(mg/kg)



2016 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 92 countries providing data in all rounds of data collection for 2016.

The lower estimate for each OIE Region represents the quantitative data reported to the OIE from that region during the first four rounds of data collection for 2016, 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 2016. These coverage estimates are subjective to each reporting country, but can provide an upper level approach of 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 country's estimates of data coverage. Countries in Europe, Asia, Far East and Oceania were the most confident of their data coverage.

Figure 36. Quantities of Antimicrobial Agents Intended for Use in Animals Adjusted by Animal Biomass, 2016 Regional Comparison (mg/kg)

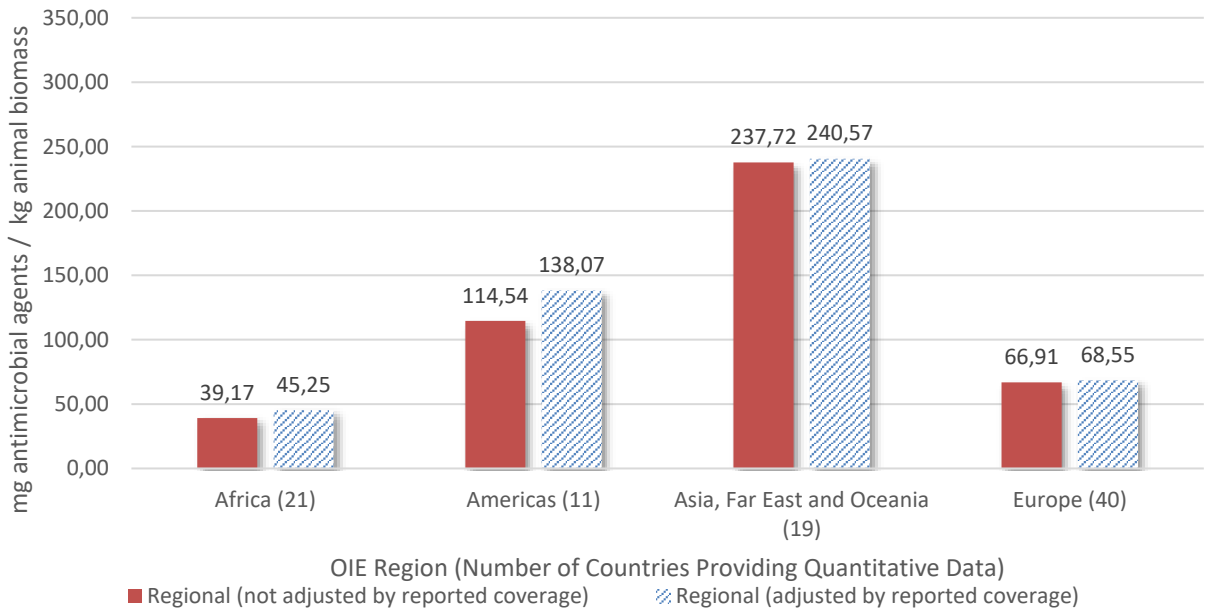


Table 10 displays the same regional figures of antimicrobial quantities adjusted by animal biomass (with the upper level estimates adjusted by country estimates of data coverage in parentheses). Additionally, some characteristics of the data distribution by OIE Region are provided, including the median,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

These results show that in 2016, 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.

Table 10. Antimicrobial Quantities Adjusted by Animal Biomass, by OIE Region, 2016

OIE Region	Number of Countries	% Covered of Total Regional Estimated Biomass	Antimicrobial Quantities Adjusted by Animal Biomass (and estimated data coverage) (mg/kg)	Descriptive Statistics		
				Median (mg/kg)	Standard deviation (mg/kg)	Range (mg/kg)
Africa	21	51%	39.17 (45.25)	6.46 (9.23)	53.75 (61.19)	161.67 (171.15)
Americas	11	65%	114.54 (138.07)	80.11 (112.31)	87.52 (126.51)	326.00 (468.62)
Asia, Far East and Oceania	19	81%	237.72 (240.57)	57.94 (68.16)	153.22 (170.42)	501.82 (501.82)
Europe	40	82%	66.91 (68.55)	33.39 (35.52)	72.59 (75.45)	333.55 (348.53)

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 2016 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 and 2016 results at global and regional level 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 67 mg/kg in 2016. These reductions are in line with the results reported by ESVAC for the same years, for those countries that participate. For Africa, the 2016 results are quite similar to those for 2014 and 2015, despite the new contributions from countries in Africa.

The most notable changes compared to the 2015 and 2016 analysis is for the Americas, where mg/kg results increased. This is unlikely to reflect a dramatically increasing trend in consumption of antimicrobials in this region, but rather is the resulting effect of an increase in the number of countries reporting data and corrections made to historical data submissions.

5. Updates of Historical Data

The 2014 and 2015 data were updated based on new information and corrections reported by Members in the fourth round, 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 and 2015 analysis pending validation. Two and five countries updated the data for 2014 and 2015 respectively.

Changes in the animal biomass

For the purpose of supporting comparison, all 2014 and 2015 animal biomass figures have been recalculated given currently available slaughter and live animal data, as these may be retrospectively updated in the databases. All analysis for 2014 and 2015 included in this report reflects the most current information.

Previously, due to the unavailability of the 'indigenous' slaughter dataset[10], slaughter data not adjusted for trade were used for the 2015 analysis and recalculated for the 2014 analysis. However, in the 2016 analysis the FAOSTAT 'trade of live animals' dataset was included permitting to offset the effect of trade of live bovines on the biomass. The results of the 2014 and 2015 analysis shown in this report have been recalculated using the 'trade of live animals' dataset to support comparison. Globally, the percentage of variation of the recalculated animal biomass for 2014 and 2015 compared to the previous report is respectively +1% and -3%.

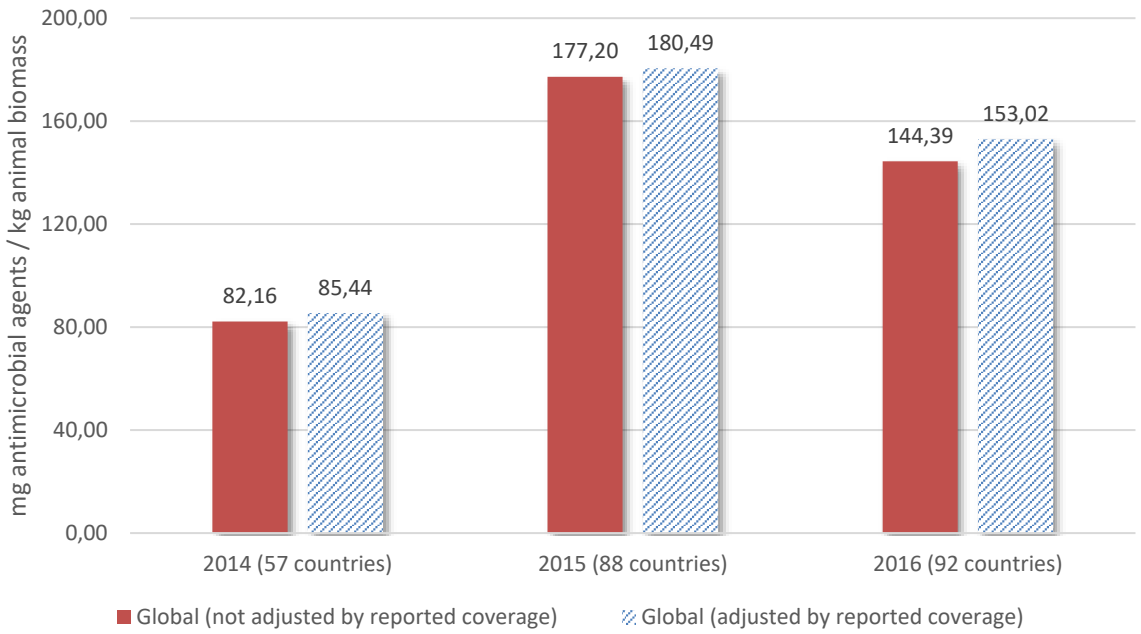
Changes in mg/kg results for 2014 and 2015

The updated mg/kg global estimate for 2014 and 2015 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 be more readily discernible.

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

[10] 'Indigenous slaughter' refers to data on slaughter of animals of native origin. Exported animals are added to the reported figures, and slaughtered animals of foreign origin are excluded. (*FAO Statistics, Livestock statistics; Concepts, definitions and classifications, January 2011*).

Figure 37. Global Quantities of Antimicrobial Agents Intended for Use in Animals Based on Data Reported by Countries for 2014, 2015 and 2016, Adjusted by Animal Biomass (mg/kg)



6. Discussion

6.1. Progress Made by Member Countries

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

Of the 152 Members that submitted reports, 139 had also participated during the third rounds of data collection. Among these 139 Members, the following progress was noted:

- Eight Members (n = 37; 22%) graduated from reporting only Baseline Information to reporting quantitative data on antimicrobial agents used in the animals for the first time. Most of these used Reporting Option 1 (five Member Countries), which allows for distinction of the quantitative data by antimicrobial class and by type of use (veterinary medical use or growth promotion). Two Members used Reporting Option 2, which allows for a distinction by animal group (terrestrial food-producing, aquatic food-producing and companion animals) in addition to type of use. One Member Country reported their quantitative data using Option 3, which allows for distinction of quantitative data by type of use, animal groups and routes of administration.
- Eleven Members (n = 76; 15%) who had previously reported quantitative data through Reporting Option 1 or 2 progressed to more detailed reporting in this round. Ten Members moved from reporting quantities through Reporting Option 1 to one of the two higher level options: five were found to have switched to Reporting Option 2, and five switched to Reporting Option 3. One Member Country that had previously reported through Option 2 now used Reporting Option 3.

It is important to note that for this fourth round, Africa and the Americas, showed the highest number of countries progressing to more detailed reporting of their quantitative data.

The barriers described by the 29 Members unable to provide quantitative data on antimicrobials used in animals in the fourth round of data collection have been described in Section 3.5 of this report. Among this group, 10 Members (n = 29; 34%) confirmed that action will be taken in the near future to facilitate their reporting of quantities of antimicrobials to the OIE.

6.2. 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 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 fourth round of data collection, 51 countries (n = 118; 43%) reported data sources indicating a possibility for 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 a 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 Africa (n = 17), followed by the Americas (n = 12) and Asia, Far East and Oceania (n = 11).

The OIE engages with countries where these situations are noted to highlight and clarify possible areas of data duplication or over-estimation. As most of these countries are in early stages of development of their data collection systems, it is expected that it will take time to implement official processes and to provide accurate data. The OIE is working closely with these countries to understand their systems and 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 fourth round, this analysis could be conducted for 110 countries where data from previous years were available for comparison. In 40 countries (n= 110; 36%), the data varied more than 25% from one year to another, and in some countries reached 100-200% variation; in some cases, an even higher change was observed. Such changes were considered unlikely to reflect the true situation.

In the 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, Africa and Asia presented the highest number of Members experiencing challenges (n = 11; n =11, respectively), and this is consistent with the fact that these regions represent the most recent countries to participate in data collection.

The OIE will continue to work on strengthening data quality with its Members through dedicated Workshops on the OIE Antimicrobial Use Data Collection, including testing a tool to assist in data calculations. These Workshops function as a forum to share experiences with the OIE and peers.

Development of antimicrobial monitoring systems

During the third round of data collection, 116 countries reported quantitative data on antimicrobial agents intended for use in animals, and 100 of these also participated during the fourth round of data collection.

In the fourth round of data collection, eight countries (n = 100; 8%) 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 data from additional months in the year, or data from wholesalers or pharmacists newly participating in the data collection. In two specific cases, the data were found to not follow the guidelines to calculate kilograms of active ingredients, and the data were retrospectively deleted from these countries data sets. The OIE, during the OIE AMU Workshops, has responded to country data calculation errors by developing a tool to assist in the calculations.

Taking into account that most countries worldwide are just 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 some instances of data duplication, *caution is necessary in the interpretation of the results*. As stated in the annual European Surveillance of Veterinary Antimicrobial Consumption (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*.

6.3. 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 7, 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 September 2019 [11].

Calculation methodology of average animal weights

Different antimicrobial use surveillance programmes have used various methodologies for determination of animal average weights towards calculation of total biomass. In the European Surveillance of Veterinary Antimicrobial Consumption (ESVAC) [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 programs of Japan [21] and the United States [22] take a different approach, instead using estimates of average animal weights by production category, rather than focusing the estimates on a time at 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. Antimicrobial compounds used and their labelling, including target species and production class, vary widely on a global scale, with data on these differences unavailable at global scale. 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 time of treatment, resulting in a larger denominator and a decreased relative mg/kg estimate of antimicrobial

agents used 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 WAHIS, are not reported by production class for the year 2016. 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 any one country's or region's animal populations.

Animals imported and exported

Imported and exported animals are commonly subtracted and added, respectively, from animal populations when calculating animal biomass, as done in ESVAC and CIPARS. This is done 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. The corrected 2014 and 2015 results as shown in this report were 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 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 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, and equids in some regions. Therefore, this information was taken from literature where necessary, or extrapolated from regions where data is available (such as in the case of 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 development of the current denominator methodology, it was decided at this time not to include companion animals in the calculation of animal biomass. Data on populations of cats and dogs are available in 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 this denominator, this effect, if any, would be a minor increase in antimicrobial quantities adjusted for animal biomass.

In the future, a goal would be to provide a 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.

6.4. 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 is able to 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).

Many countries have described processes underway 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 developing and implementing National Action Plans to advance regulations on veterinary antimicrobials and facilitate interactions between sectors. Given these developments, it is expected that the reported barriers will be reduced over time, increasing the availability of global antimicrobial use data in animals.

7. Future Developments for the Antimicrobial Use Survey

The OIE will continue working closely with Members to support them in calculating kilograms of active ingredients of antimicrobials. The OIE is also in the process of developing an interactive automated system in which Members will report the use of antimicrobial agents (AMU) in animals and receive support for calculating kilograms 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 October 2019, the OIE started dedicated workshops to the OIE AMU Data Collection, and as part of the AMU IT system development process, specific working sessions were organised during these workshops to understand user requirements. In 2020 additional workshops will take place in order to cover the expectation of all OIE Members for the future OIE AMU IT System.

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

An important step in this process will be achieved through interface with the OIE World Animal Health Information and Analysis System (WAHIS). In consultation with the 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 the OIE WAHIS and will allow to refine the data on animal biomass over time.

OIE-WAHIS, the next generation of the WAHIS data collection interface, is currently in development 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 are able to supply it, the interface will also include free text boxes allowing for description of the reported data. OIE-WAHIS will also additionally support the reporting of data on average live weights and number of animals slaughtered in the countries.

Aside from collection of more detailed global animal population data, more 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.

8. Conclusions

This report 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. This global OIE programme, the first of its kind, highlights not only reported quantitative data where countries are currently able to provide it, but also reflects the current situation of governance of veterinary antimicrobials worldwide, and barriers to quantitative data collection. This information is critical to the global effort to promote the responsible and prudent use of antimicrobial agents in animals, and the capacity to measure trends over time. Additionally, this report provides core global level indicator data for the Monitoring and Evaluation Framework of the Global Action Plan (GAP) on Antimicrobial Resistance [23], and at country level the data can be used to frame indicators under antimicrobial resistance National Action Plans (NAPs) Monitoring and Evaluation systems.

Contributions to the database have continued to grow, with increasing engagement from countries. The OIE also commends the participating non-contiguous territories for their invaluable efforts, and will continue to support their engagement with the data collection. The results from the fourth round of data collection have demonstrated a growing capacity worldwide for collection of higher quality data.

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

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ANNEXES

Annex 1. Africa, Regional Focus

Table A1. General Information for Africa During the Fourth Round of Data Collection

General Information for Africa	
Number of OIE Members	54
Number of OIE Members responding to the questionnaire	44 (81%)
Number of OIE Members providing only qualitative data	17 (39%)
Number of OIE Members providing quantitative data	27 (61%)

Barriers to Providing Quantities of Antimicrobial Agents in Animals

Seventeen OIE Members (n= 44; 39%) responded with Baseline Information (qualitative data) and did not provide quantitative data on antimicrobial agents used in animals (Table A1), and 13 explained their barriers to reporting quantities of antimicrobial agents used in animals. Countries could report more than one barrier relevant to their situation, and responses were grouped by category (Figure A1). For further information on the category groupings, please refer to section 3.5 of this report.

More than half of the responses from Africa (8 out of 13; 62%) mentioned that the main impediment to reporting antimicrobial quantities was the lack of a regulatory framework. Of these, four countries (n = 8; 50%) describe the absence of regulatory framework for the manufacture, registration, distribution, commercialization and use of veterinary products; one of these countries had just started to supervise the border points, distributors and veterinarians for the imports and sales of veterinary products. Four Members mentioned that it was not mandatory to collect such data in their countries; with one that had previously provided antimicrobial quantities, stating the lack of an official mechanism to collect the data had prevented the collection and report of the antimicrobial quantities during this fourth round.

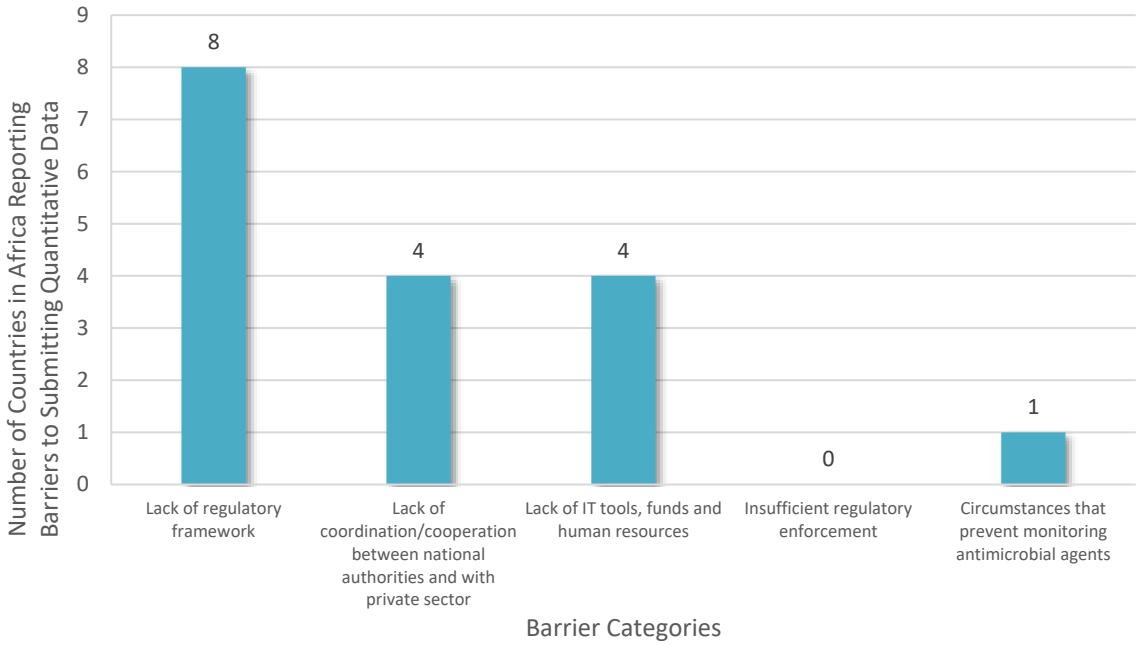
Four Members described a lack of coordination/cooperation with the Ministry of Health. One country expected to provide antimicrobial quantities in the future with the Veterinary Authority already having established a mechanism with the Ministry of Health.

Two Members reported insufficient funds for collecting the antimicrobial quantities with one country explaining that available funds would be used to develop and implement the National Action Plan (NAP) on AMR.

One African Member explained its main challenge in data collection was that import records were only available as hardcopies and that staff availability was insufficient to digitalise the data, perform the calculations and analyse the results. Another country reported that the software used to collect the import records does not capture the necessary information to calculate kilograms of active ingredients for the veterinary products.

One country explained that even if funds were available for hiring staff to collect, collate and analyse the data, the country's current situation prevented the allocation of funds for such activity.

Figure A1. Country Barriers to Reporting Quantitative Data on Antimicrobial Agents Intended for Use in Animals in 13 Countries in Africa During the Fourth Round of Data Collection



FUTURE OF THE OIE DATA COLLECTION - WORKSHOP RESULTS

After the fourth round of data collection, to facilitate addressing the barriers to providing quantities of antimicrobial agents in animals, the OIE conducted a regional workshop on the OIE data collection database in Eastern and Southern Africa, in Mombasa, Kenya on the 29th to the 31st of October 2019. As outlined in section 7 of this report, in the future, the OIE will have developed a software solution for the annual data collection. This workshop included a working group session dedicated to the future of the OIE Data Collection and provided the opportunity to take into consideration the needs of stakeholders in designing and developing the future AMU IT System.

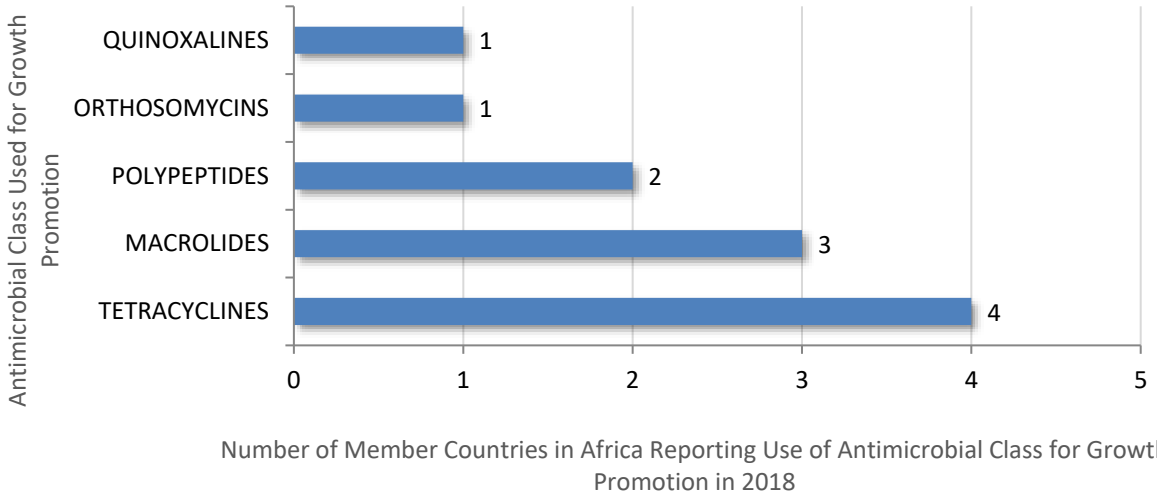
The OIE Focal Points for Veterinary Products and the AMR focal point from the animal sector (if different from the OIE Focal Point for Veterinary Products) with a representative of the national drug regulatory authority from each country were present in the workshop. This should allow enhanced collaboration and support inclusion of AMU as an important component of countries NAP on AMR.

Overall, the participants confirmed the need to integrate calculations and error detection mechanism to ensure better data quality. Readily accessible data and a dynamic data analysis tool were also considered crucial by participants to inform key decisions and their NAPs on AMR. This will improve accessibility and visibility of data for stakeholder's use.

Antimicrobial Agents Used for Growth Promotion

During 2018, eight African countries (n = 44; 19%) used antimicrobial agents as growth promoters. Of these, five Members (n = 8; 63%) provided a list of antimicrobials used for growth promotion, with tetracyclines most commonly named (Figure A2). It was noted that from these eight countries only one had legislation for these molecules. It was also observed that from the 36 countries stating no use of antimicrobials as growth promoters, 28 did not have any legislation or regulation to ban these molecules (n = 36, 78%).

Figure A2. Antimicrobial Growth Promoters Used in Animals in Five Countries in Africa in 2018



2016 Analysis of Antimicrobial Quantities

This section provides an additional analysis of reported quantitative data on antimicrobial agents intended for use in animals adjusted by animal biomass, focusing on 2016. This analysis represents the antimicrobial quantities reported to the OIE from 21 countries in Africa during all four 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. Fourteen countries' data source were considered to present a risk of duplication (n = 21, 67%); after clarifications, seven countries (n = 14; 50%) changed their answers or proved there was no duplication or overlapping of data sources. The remaining countries (7 out of 14; 50%) that did not provide clarification were excluded only 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 custom authorities was most commonly chosen, with four Members (n = 16; 25%) selecting this option. In addition, four Members described other data source not provided in the OIE List, relating to Import data as well (Figure A4).

Figure A3. Data Sources Selected by 16 African OIE Members Reporting Quantitative Information for 2016

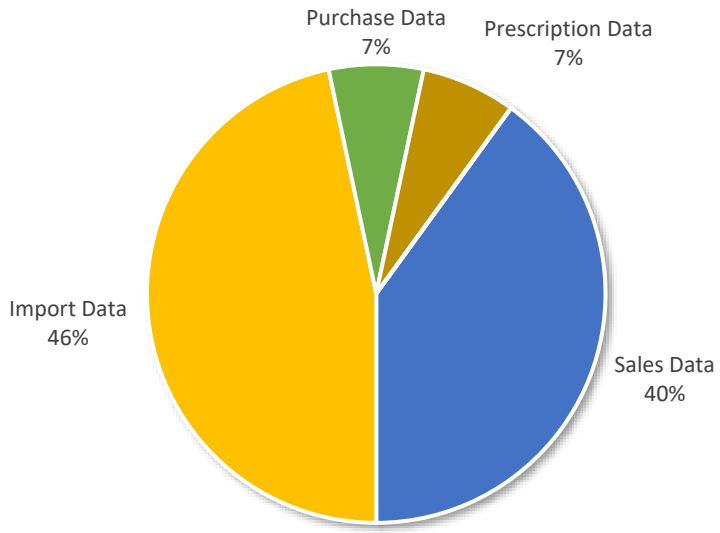
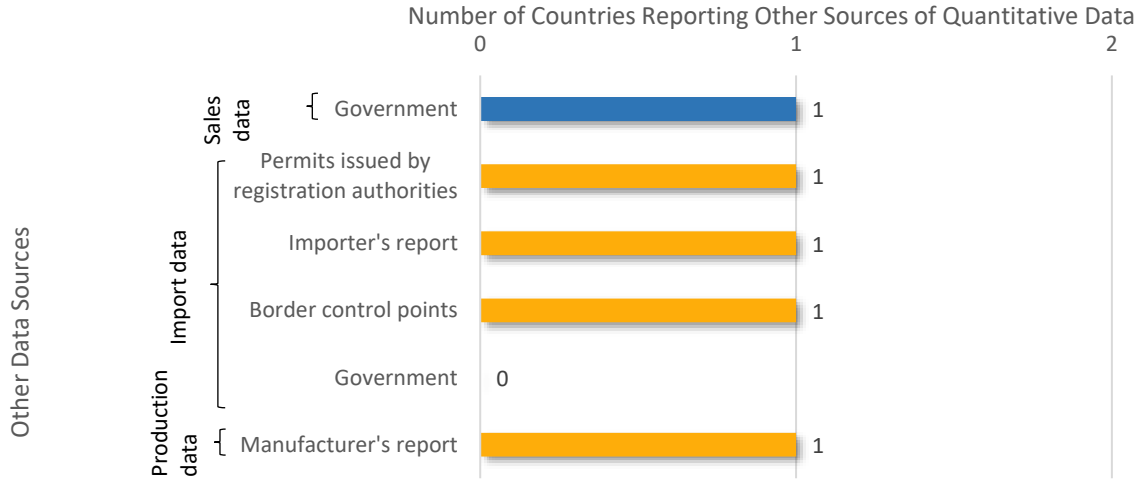


Figure A4. 'Other' Source of Data as Explained by four Members in Africa Reporting Quantitative Information for 2016

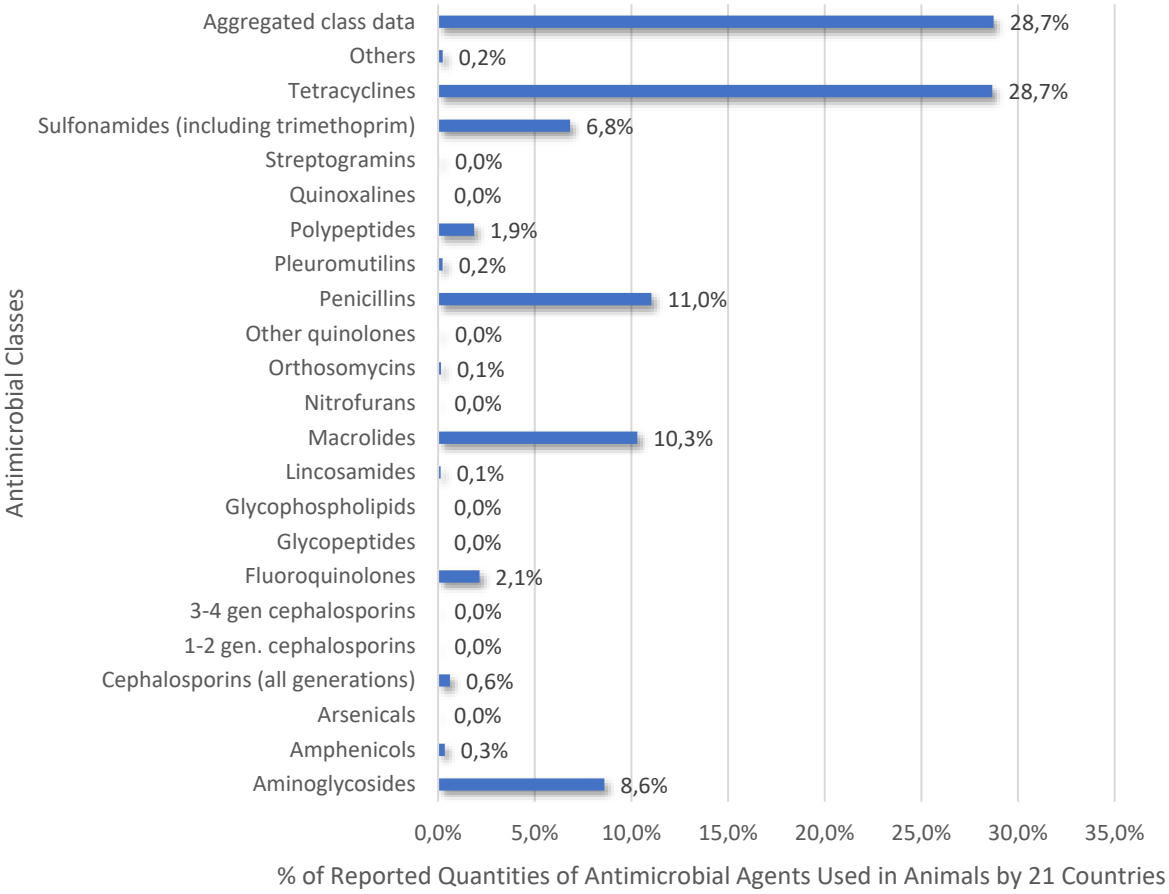


ANTIMICROBIAL QUANTITIES REPORTED IN 2016

For 2016, 21 African countries provided validated antimicrobial quantities intended for use in animals. From the 21 countries, four stated to cover 100% of the data source used to report the data. The 17 countries that did not cover 100% of available antimicrobial quantities were asked to provide further information on uncaptured data sources. For the 21 countries, the data coverage achieved was 73%. More information for 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 penicillins and macrolides (Figure A5). Under the group of others most of the countries reported fosfomycin and salinomycin. The *aggregated class data* category is used for confidentiality purposes at national level; under this category, data were submitted mainly for glycopeptides, glycophospholipids and quinoxalines.

Figure A5. Proportion of Antimicrobial Classes Reported for Use in Animals by 21 African Members in 2016

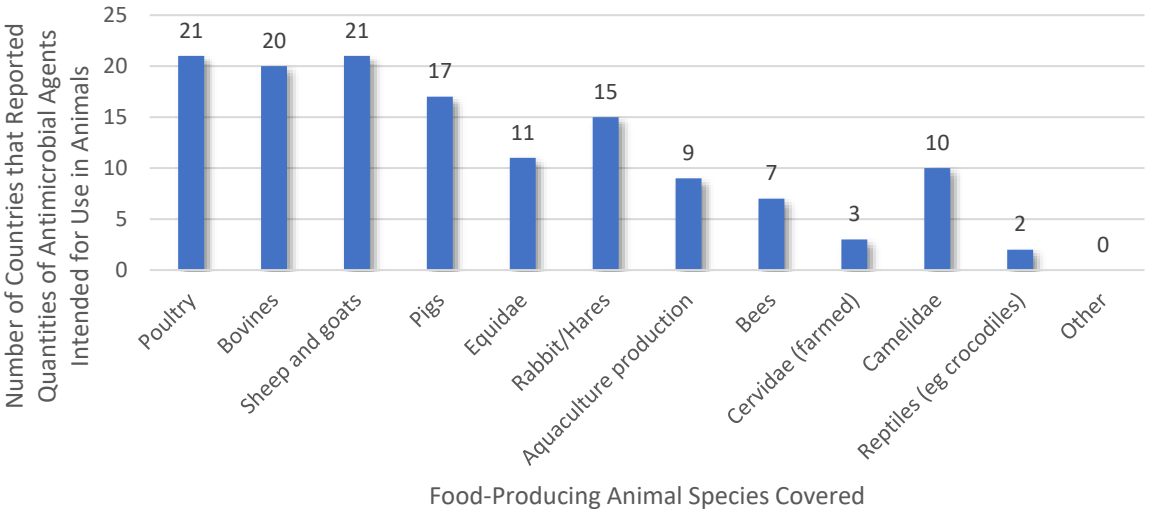


FOOD-PRODUCING TARGET SPECIES ON THE LABEL OF REPORTED VETERINARY PRODUCTS

Irrespective of whether the data could be differentiated by animal groups, all 21 countries were asked to pick 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 in categories, for more information on the grouping of animals see page 45 of this report.

In the 21 African Members that reported quantitative data on antimicrobial agents intended for use in animals for 2016, the food-producing species most frequently covered by the data were poultry, sheep and goats and bovines (Figure A6). Among the poultry production types, 'layers - commercial production for eggs' were named by all African countries (n = 21; 100%). Within the four regions analysed, Africa is one of the regions were Camelidae were more commonly named by Members.

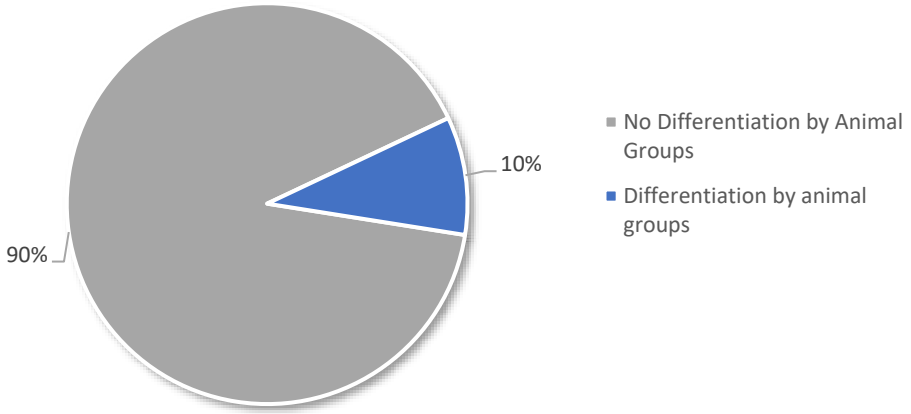
Figure A6. Food-Producing Animal Species Included in Quantitative Data Reported by 21 African Members in 2016



QUANTITATIVE DATA DIFFERENTIATION BY ANIMAL GROUPS

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 (Figure A7). For the two African countries (n = 21; 10%) that were able to distinguish antimicrobial quantities by animal groups, data were mainly provided for terrestrial food-producing animals.

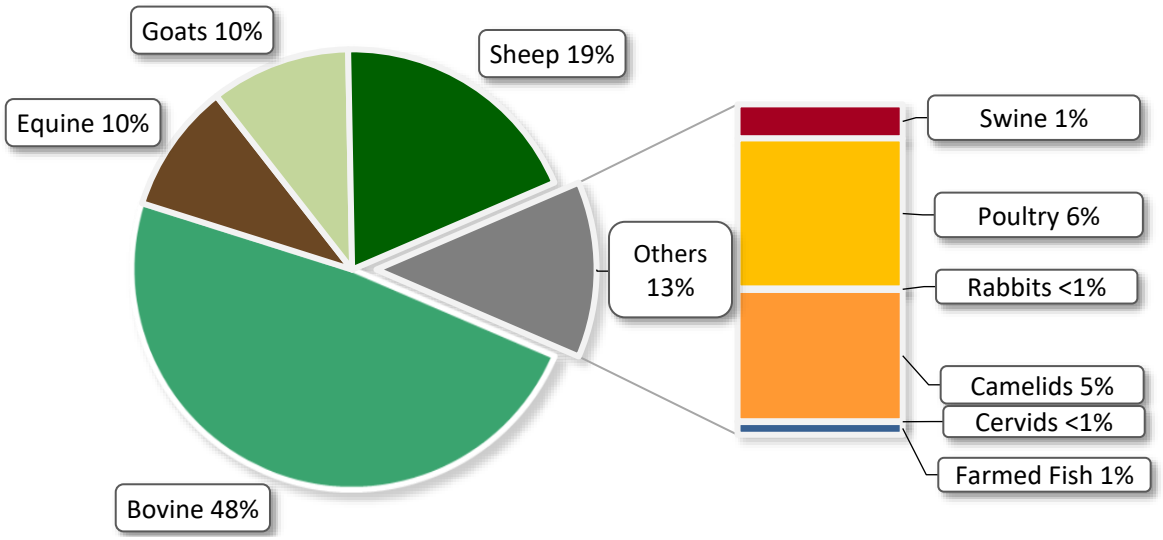
Figure A7. Differentiation by Animal Groups Among 21 Members in Africa Reporting Quantitative Data in 2016



ANIMAL BIOMASS

In Africa, sheep, goat and equine biomass are relatively more significant, compared to the other regions, contributing respectively 19%, 10% and 10% to the total biomass. In contrast, the proportions of swine and poultry, respectively 1% and 6%, are the lowest among all regions. It can be underlined that camelids are also proportionally more significant in Africa than in other regions.

Figure A8. Species Composition of Animal Biomass for the 21 Countries in Africa Included in 2016 Quantitative Data Analysis



ANTIMICROBIAL QUANTITIES ADJUSTED BY ANIMAL BIOMASS

In Africa, the mg/kg estimate for 2016 for 21 countries is 39.17 mg/kg, with an upper level estimate of 45.25 mg/kg when adjusted by estimated coverage. From all OIE Regions, Africa has the lowest mg/kg estimate.

Changes in mg/kg results for 2014 and 2015

The updated mg/kg estimate for 2014 for 12 African countries is 35.86 mg/kg, with an upper level estimate of 42.13 mg/kg when adjusted by estimate coverage.

The updated mg/kg estimate for 2015 for 25 African countries is 38.21 mg/kg, with an upper level estimate of 45.45 mg/kg when adjusted by estimate coverage.

Annex 2. Americas, Regional Focus

Table A2. General Information for the Americas During the Fourth Round of Data Collection

General Information for the Americas	
Number of countries*	32
Number of countries responding to the questionnaire	30 (94%)
Number of countries providing only qualitative data	12 (40%)
Number of countries providing quantitative data	18 (60%)

*31 OIE Members and 1 non-contiguous territory

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, 30 countries (n = 31; 94%) submitted completed reports to OIE Headquarters: 29 from OIE Members and one non-contiguous territory. 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 Antimicrobials Agents in Animals

Twelve countries (n = 30; 40%) responded with Baseline Information (qualitative data) and no quantitative data on antimicrobial agents used in animals. Of these, 11 countries (n = 12; 92%) explained their barriers to reporting antimicrobial quantities. Countries could 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.

Half of the responses in the Americas (6 out of 11 countries; 55%) mentioned that the main impediment to reporting antimicrobial quantities was the lack of regulatory frameworks. Two countries explained that there was no legislation for the veterinary medicinal products, one of these countries said 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. Four countries explained that the main barrier was that their legislations/regulations do not require the monitoring of antimicrobial use, so there are no regulations or guidelines on data collection procedure or stakeholder obligations. Two out of these four countries are planning to provide antimicrobial quantities in the upcoming rounds.

The other half of the responses were grouped in the category of lack of IT tools, funds and human resources. In this category, five countries explained that even if IT tools for the registration and importation of veterinary products already existed, the following reasons impeded the reporting of quantities:

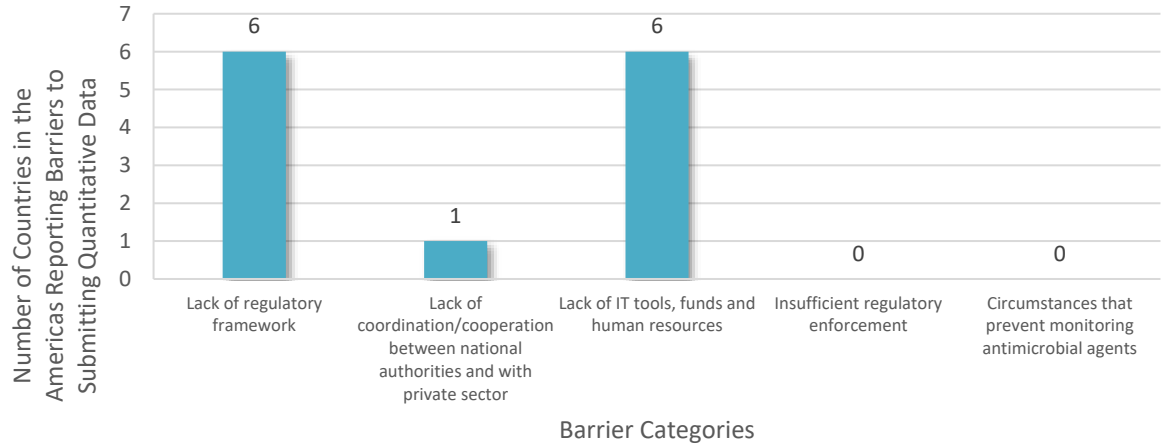
- There was no integration between the registration and the importation system;
- The registration system only partially records the necessary data to perform the calculations (e.g. active ingredients, strength of each active ingredient and package size/presentation);
- The import customs system does not record the package size/presentation of the veterinary products, but the system records 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 out of the five countries stated that they will amend their IT situation in order to report import data in the future.

One country that already had an IT tool for the registration of veterinary products integrated with import data, reported that the main barrier was the lack of dedicated staff to perform the calculations and analyse the data.

One country that had previously reported sales of antimicrobial quantities, explained that for the fourth round, the Veterinary Authority could not get the data from the wholesalers, but will attempt to reinforce this collaboration with the private sector in the future.

Figure A9. Country Barriers to Reporting Quantitative Data on Antimicrobial Agents Intended for Use in Animals in 11 Countries in the Americas During the Fourth Round of Data Collection



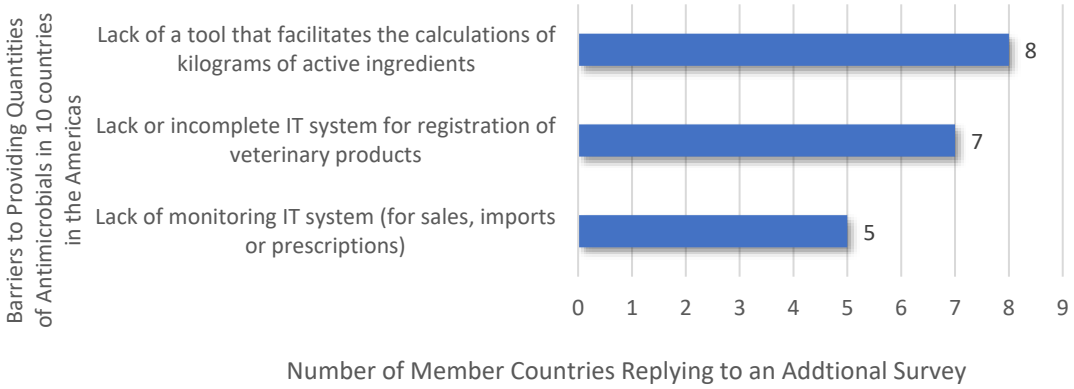
ADDITIONAL SURVEY ON THE BARRIERS TO REPORTING ANTIMICROBIAL QUANTITIES

As part of addressing the barriers in providing quantities of Antimicrobial Agents in Animals, the Regional Office in the Americas conducted a survey of 17 countries in the region at the end of the fourth round of data collection (first semester of 2019) to understand countries' barriers related to IT system or tools. Ten countries (n = 17; 59%) replied to the survey where multiple selections were possible. The results are shown in Figure A10.

Eight countries reported that the main barrier was the absence of a tool that facilitates the calculations of kilograms of active ingredients. Seven reported issues related to the registration of the veterinary medicinal products, mainly the absence of an IT system for the registration of these goods. Two countries explained that their IT systems where not built to monitor antimicrobial quantities. These IT challenges combined with staffing constraints impeded the calculations and analysis of the data.

In September 2019, the OIE conducted a Workshop in the Americas where a tool was tested and presented to the Members to support them in the calculations of kilograms of active ingredients. The tool was well received by the Members and several stated their willingness to use the tool for the 5th data collection round that started in September 2019. The methodology of this tool was based on instructions provided in Annex 8 of this report, and will be one of the key components of the future IT System of the AMU Data Collection.

Figure A10. Survey results about the availability of various systems in 10 countries in the Americas

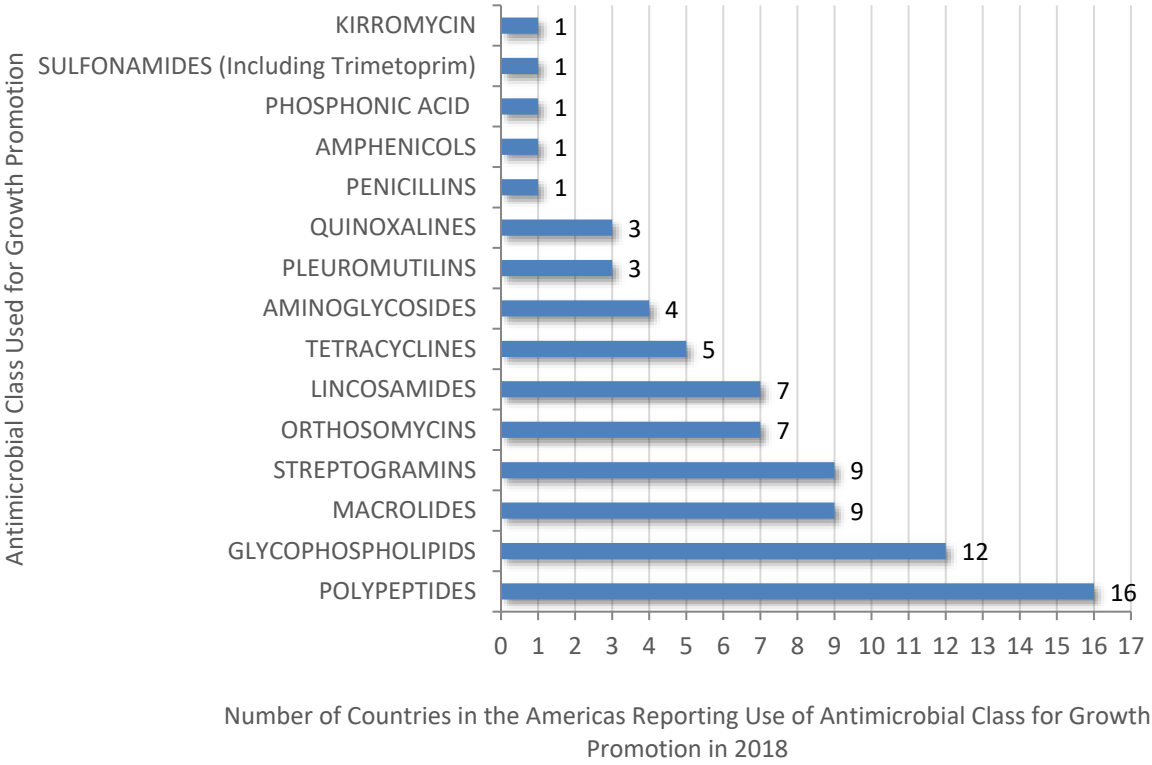


Antimicrobial Agents Used for Growth Promotion

Seventeen countries (n = 30; 57%) in the Americas used antimicrobial agents as growth promoters in 2018. Of these, 16 countries (n = 17; 94%) provided a list of antimicrobials used for growth promotion, with polypeptides most commonly named (by 16 countries); of these seven mentioned colistin (Figure A11).

Ionophores were excluded for reporting as they are mostly used for parasite control and have different regulatory classifications in different countries; however, 11 countries in the Americas reported the use of these molecules as growth promoters, where monensin was mentioned by eight countries and salinomycin and halquinol by seven and four countries, respectively.

Figure A11. Antimicrobial Growth Promoters Used in 16 Countries in the Americas in 2018



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 (6 out of 17 countries, 35%). However, the following cases were noted:

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

2016 Analysis of Antimicrobial Quantities

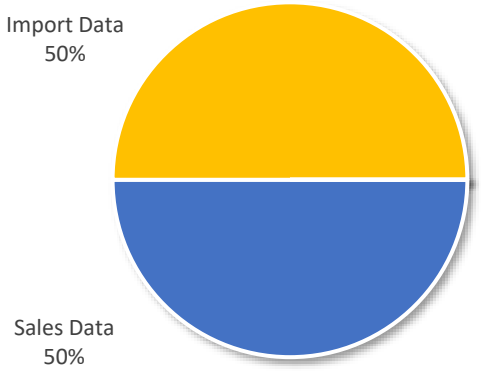
This section provides an additional analysis of reported quantitative data on antimicrobial agents intended for use in animals adjusted by animal biomass, focusing on 2016. This analysis represents the antimicrobial quantities reported to the OIE from 12 countries in the Americas during all rounds of data collection.

QUANTITATIVE DATA SOURCES CAPTURED

All countries' data sources in the Americas 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. Five countries' data source (n = 12, 42%) were considered to present a risk of duplication; after the clarifications, one country (n = 5; 20%) changed its original data source. The remaining countries (4 out of 5; 80%) that did not provide clarification were excluded only from the analysis in Figure A12. 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 only data sources use by the countries in the Americas (Figure A12).

Figure A12. Data Sources Selected by Eigth Countries in the Americas Reporting Quantitative Information for 2016

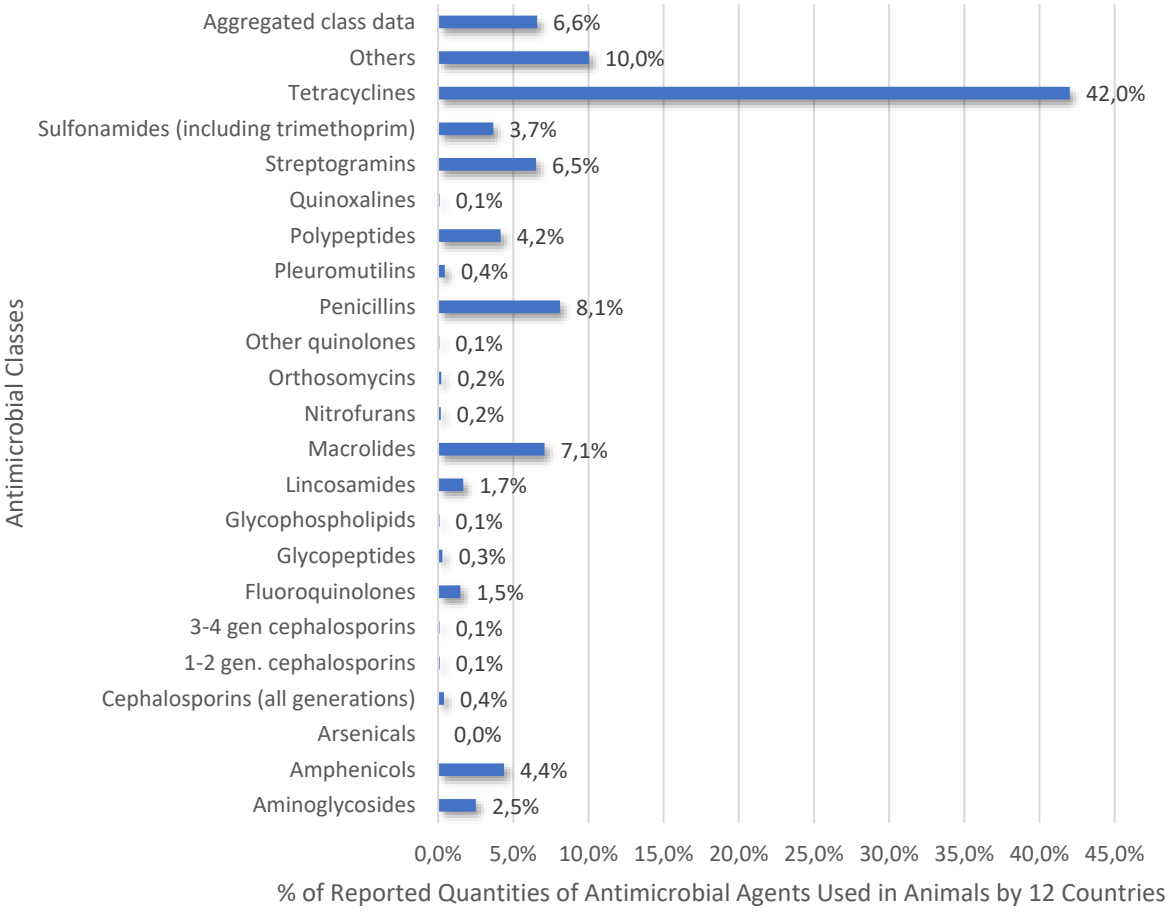


ANTIMICROBIAL QUANTITIES REPORTED IN 2016

For 2016, 12 countries in the Americas provided validated antimicrobial quantities intended for use in animals. From the 12 countries, three stated to cover 100% of the data source used to report the data. The nine countries that did not cover 100% of available antimicrobial quantities were asked to provide further information on uncaptured data sources. For the 12 countries, the data coverage achieved was 91%. More information for 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 penicillins and macrolides (Figure A13). Under the group of others most of the countries reported fosfomycin.

Figure A13. Proportion of Antimicrobial Classes Reported for Use in Animals by 12 Countries in the Americas 2016

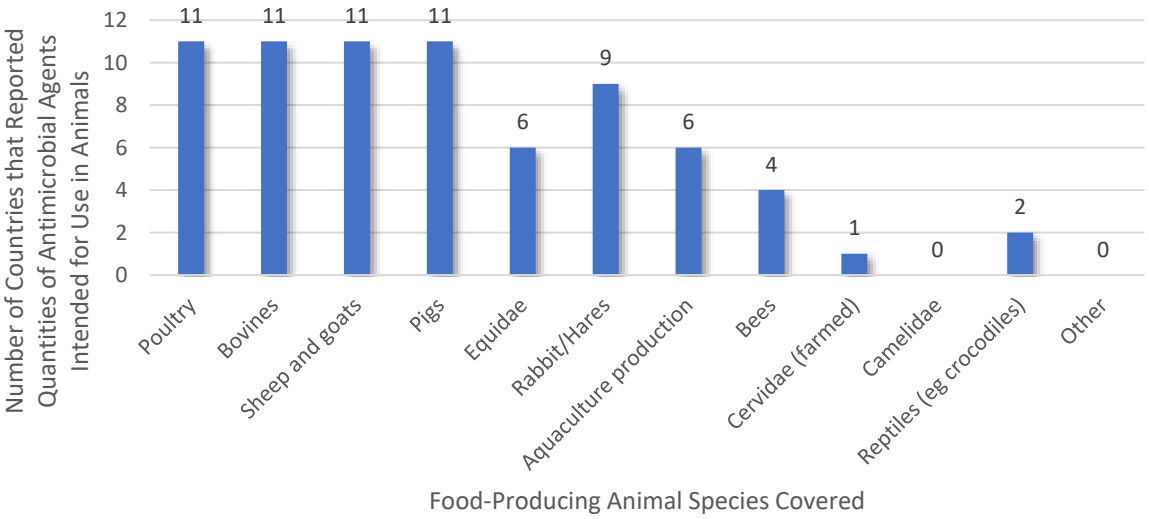


FOOD-PRODUCING TARGET SPECIES ON THE LABEL OF REPORTED VETERINARY PRODUCTS

Irrespective of whether the data could be differentiated by animal groups, all 12 countries were asked to pick 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 in categories, for more information on the grouping of animals see page 45 of this report.

One country reported data only for companion animals, and it was excluded from this analysis. In the 11 countries from the Americas that reported antimicrobial quantities for 2016, the food-producing species most frequently covered by the data were poultry, bovines, pigs and sheep and goats (Figure A14).

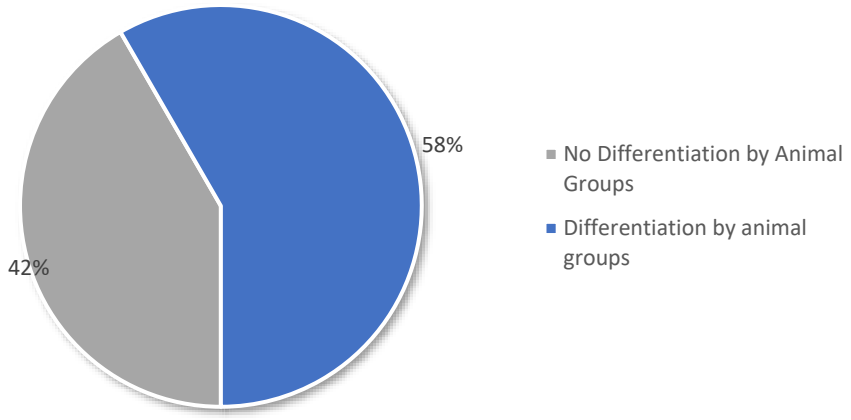
Figure A14. Food-Producing Animal Species Included in Quantitative Data Reported by 11 Countries in the Americas in 2016



QUANTITATIVE DATA DIFFERENTIATION BY ANIMAL GROUPS

Most of the quantitative data from the Americas can be differentiated by animal group (Figure A15). For the countries that were able to distinguish antimicrobial quantities by animal groups, data were equally provided for terrestrial food-producing animals and companion animals.

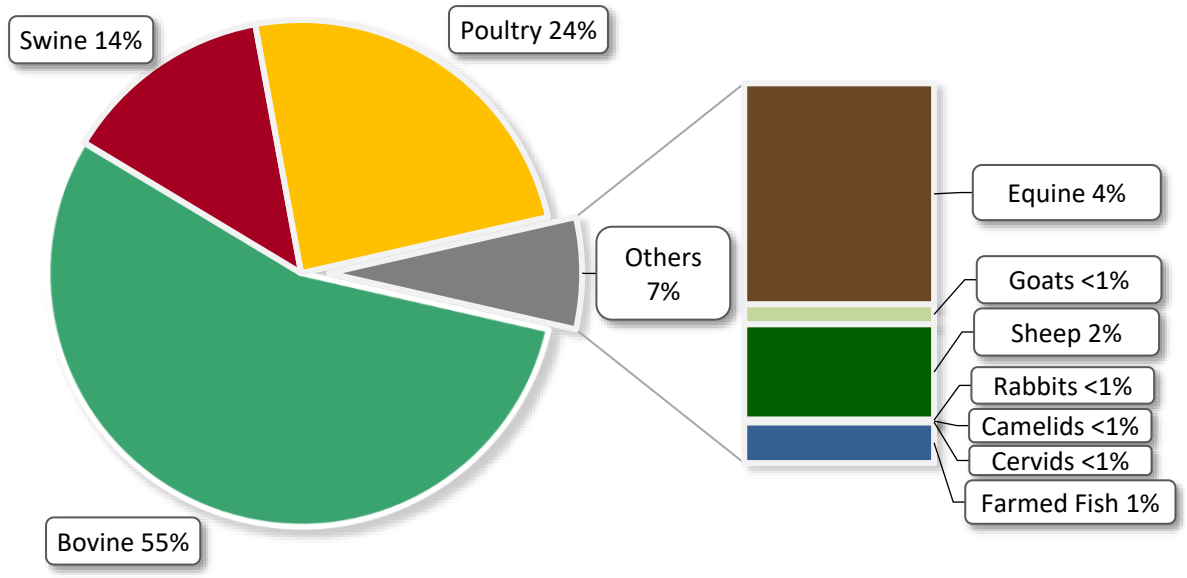
Figure A15. Differentiation by Animal Groups Among 21 Members in the Americas Reporting Quantitative Data in 2016



ANIMAL BIOMASS

The bovine species make an important contribution (55%) to the total biomass of Americas. Small ruminants, sheep and goats, in comparison to other regions have a relatively lower impact on the region's biomass.

Figure A16. Species Composition of Animal Biomass for the 11 Countries in Americas Included in 2016 Quantitative Data Analysis



ANTIMICROBIAL QUANTITIES ADJUSTED BY ANIMAL BIOMASS

In the Americas, the mg/kg estimate for 2016 for 11 countries is 114.54mg/kg, with an upper level estimate of 138.07 mg/kg when adjusted by estimated coverage.

Changes in mg/kg results for 2014 and 2015

The updated mg/kg estimate for 2014 for eight countries in the Americas is 87.80 mg/kg, with an upper level estimate of 91.53 mg/kg when adjusted by estimate coverage.

The updated mg/kg estimate for 2015 for eight countries in the Americas is 96.82 mg/kg, with an upper level estimate of 99.80 mg/kg when adjusted by estimate coverage.

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

Table A3. General Information for Asia During the Fourth 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	25 (78%)
Number of OIE Members providing only qualitative data	2 (8%)
Number of OIE Members providing quantitative data	23 (92%)

Barriers to Providing Quantities of Antimicrobial Agents in Animals

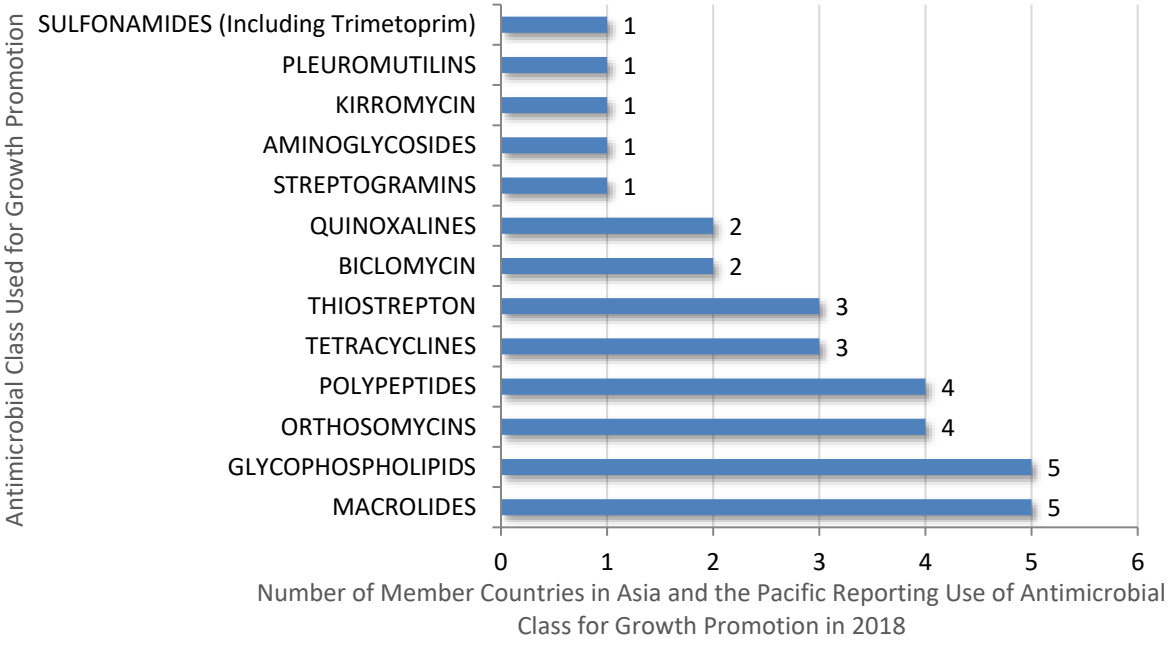
It was noted from the previous data collection round that three countries reporting regulatory framework and cooperation barriers with other agencies managed to report antimicrobial quantities in the fourth round.

For the fourth round, two countries in Asia did not report antimicrobial quantities. One country reported the barrier to be agricultural suppliers not reporting sales data to the Veterinary Authority and not keeping records of the veterinary products dispensed.

Antimicrobial Agents Used for Growth Promotion

Nine Members (n = 25; 36%) reported use of antimicrobials as growth promoters. Of these, seven Members (n = 25; 28%) provided a list of utilised agents, the most frequently listed antimicrobial agents for this purpose were macrolides and glycophospholipids, followed by orthosomycins and polypeptides (Figure A17).

Figure A17. Antimicrobial Growth Promotors Used in Animals in Asia, Far East and Oceania in 2018 as reported by Seven Members



2016 Analysis of Antimicrobial Quantities

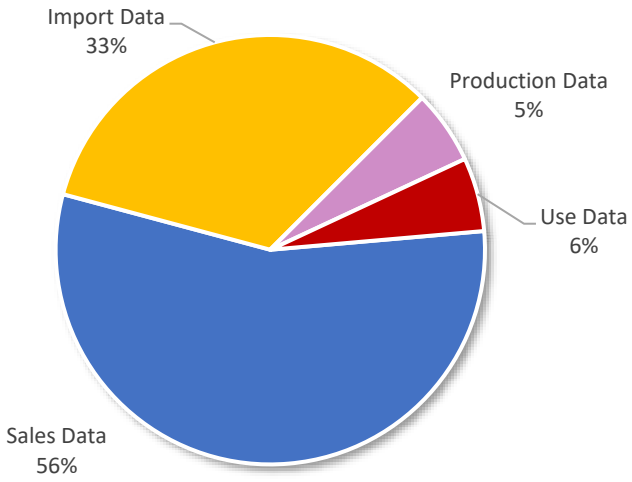
This section provides an additional analysis of reported quantitative data on antimicrobial agents intended for use in animals adjusted by animal biomass, focusing on 2016. This analysis represents the antimicrobial quantities reported to the OIE from 19 countries in Asia, Far East and Oceania during 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 of their answers and/or data collection systems. Ten countries' data sources (n = 19, 53%) were considered to present a risk of duplication; after the clarifications, seven countries (n = 10; 70%) changed their answers or proved there was no duplication or overlapping of data sources. The remaining countries (3 out of 10; 30%) that did not provide clarification were excluded only 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, sales data for veterinary products declared by Marketing Authorisation Holders was most commonly chosen, with four Members (n = 16; 25%) selecting this option (Figure A18).

Figure A18. Data Sources Selected by 16 Countries in Asia, Far East and Oceania Reporting Quantitative Information for 2016

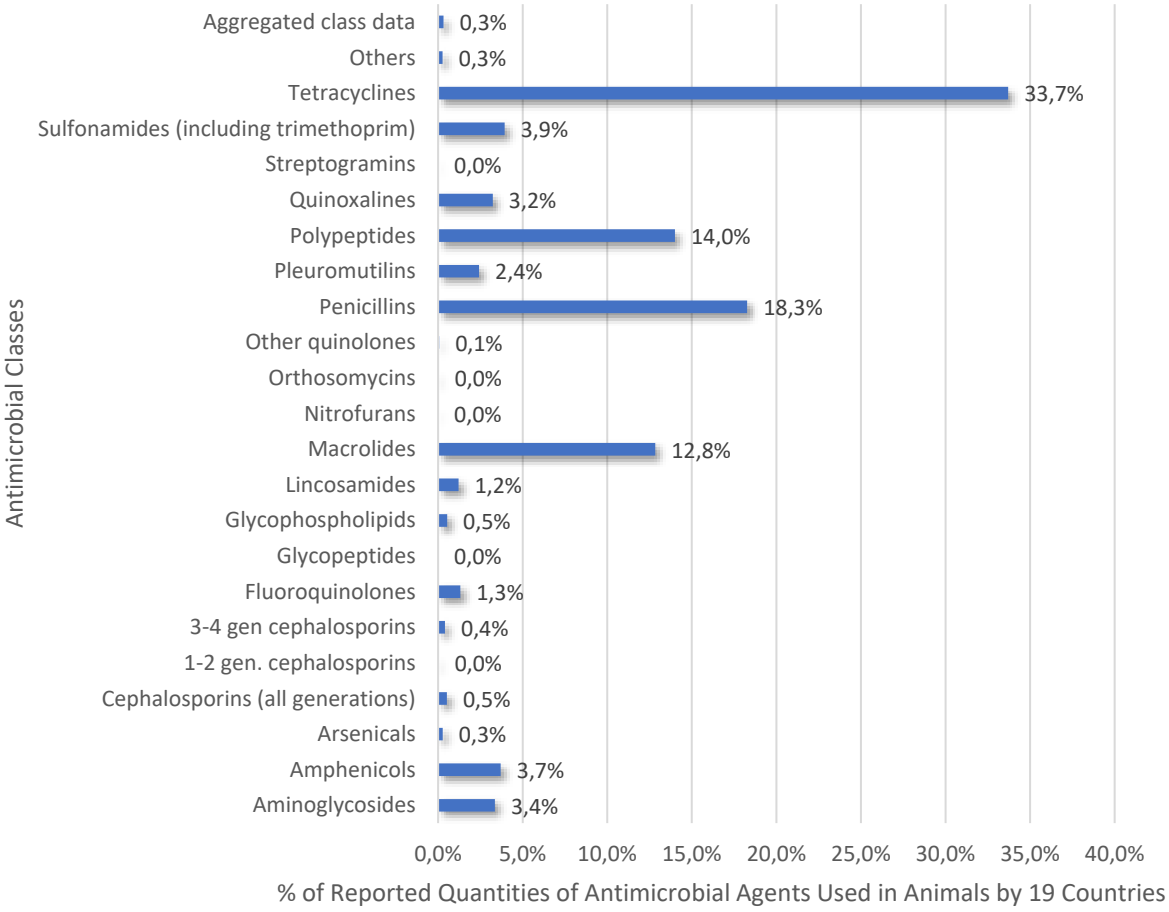


ANTIMICROBIAL QUANTITIES REPORTED IN 2016

For 2016, 19 countries in Asia, Far East and Oceania provided validated antimicrobial quantities intended for use in animals. From the 19 countries, eight stated to cover 100% of the data source used to report the data. The 11 countries that did not cover 100% of available antimicrobial quantities were asked to provide further information on uncaptured data sources. For the 19 countries, the data coverage achieved was 90%. More information for the data coverage for Asia, Far East and Oceania, is available in Table 5 of this report.

In the Asia, Far East and Oceania, the largest proportion of all reported antimicrobial classes were tetracyclines, followed by penicillins and polypeptides (Figure A19).

Figure A19. Proportion of Antimicrobial Classes Reported for Use in Animals by 19 Members in Asia, Far East and Oceania in 2016

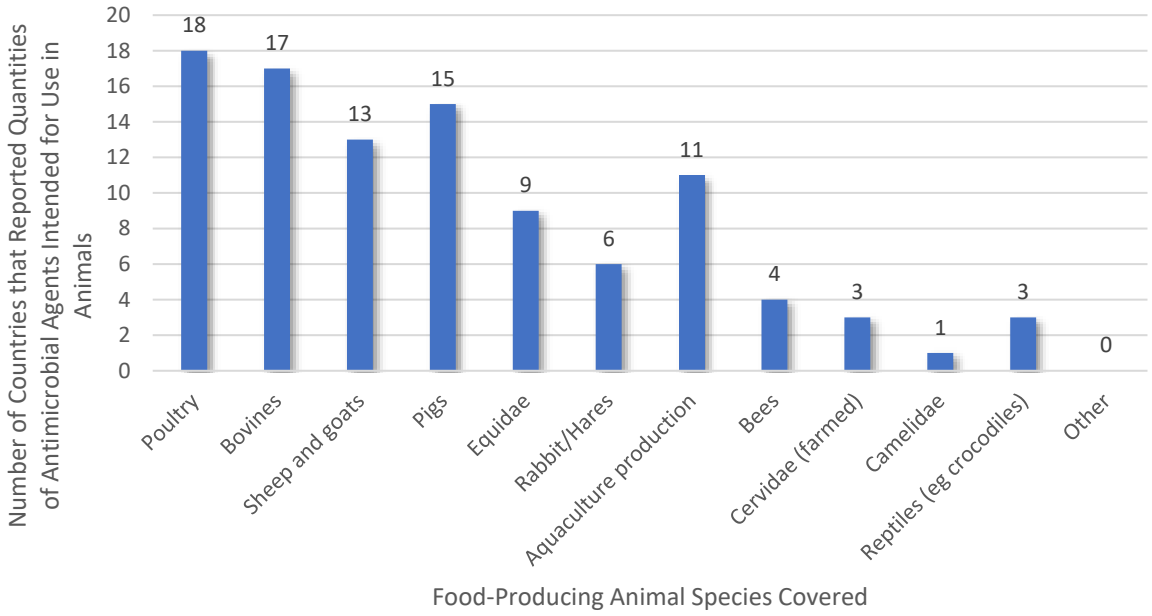


FOOD-PRODUCING TARGET SPECIES ON THE LABEL OF REPORTED VETERINARY PRODUCTS

Irrespective of whether the data could be differentiated by animal groups, all 19 countries were asked to pick 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 in categories, for more information on the grouping of animals see page 45 of this report.

Of the 19 countries from Asia, Far East and Oceania that reported antimicrobial quantities for 2016, the food-producing species most frequently covered by the data were poultry, bovines and pigs (Figure A20). Asia, Far East and Oceania is the second OIE region that is providing data that cover aquaculture.

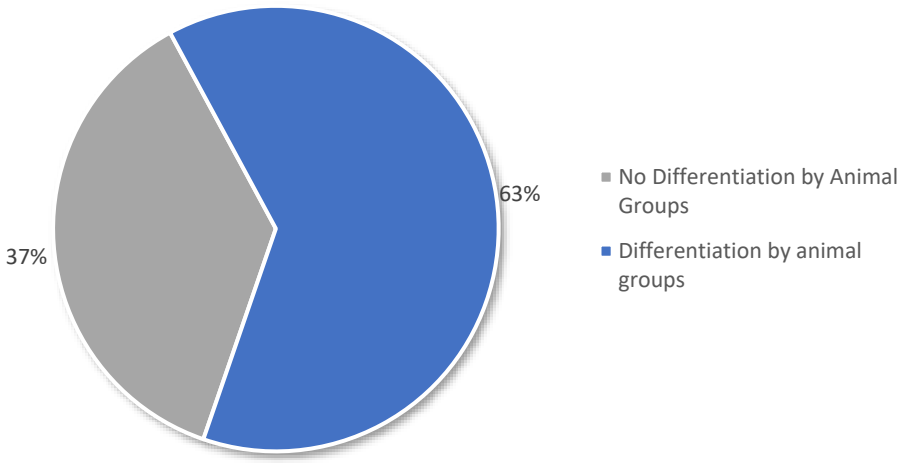
Figure A20. Food-Producing Animal Species Included in Quantitative Data Reported by 19 Countries in Asia, Far East and Oceania in 2016



QUANTITATIVE DATA DIFFERENTIATION BY ANIMAL GROUPS

Most of the quantitative data from Asia, Far East and Oceania can be differentiated by animal group (Figure A21). For the countries that were able to distinguish antimicrobial quantities by animal groups, data were mainly provided for terrestrial food-producing animals.

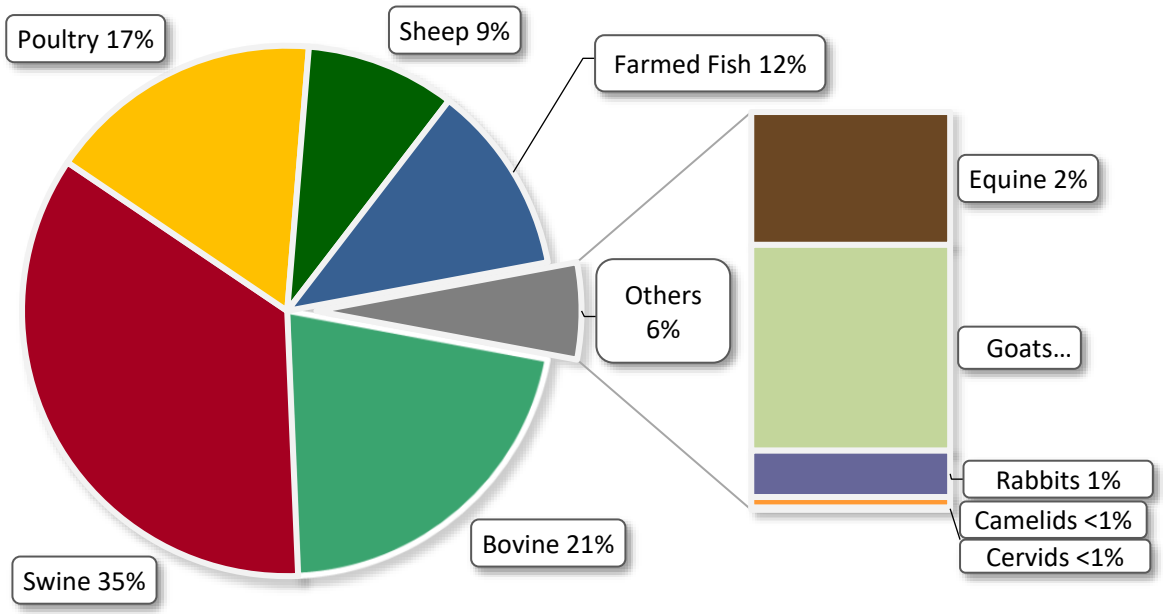
Figure A21. Differentiation by Animal Groups Among 19 Members in Asia, Far East an Oceania Reporting Quantitative Data in 2016



ANIMAL BIOMASS

In contrast to the three other regions, the species contributing the most to the total biomass in Asia are swine, totalising 35% of the biomass followed by 21% for bovines. Moreover, the relative importance of farmed fish, reaching 12% of the animal biomass, exceeds the other regions. However, as detailed previously, *percentages of farmed fish should be interpreted with caution as fish biomass was only included where countries reported that their data on antimicrobial agents covered aquaculture*. Therefore, the effect of farmed fish on biomass is skewed by the number of countries in that OIE Region for which antimicrobials used in aquaculture were included.

Figure A22. Species Composition of Animal Biomass for the 19 Countries in Asia, Far East and Oceania Included in 2016 Quantitative Data Analysis



ANTIMICROBIAL QUANTITIES ADJUSTED BY ANIMAL BIOMASS

In Asia, Far East and Oceania, the mg/kg estimate for 2016 of 19 countries is 237.72mg/kg, with an upper level estimate of 240.57 mg/kg when adjusted by estimated coverage.

Changes in mg/kg results for 2014 and 2015

The updated mg/kg estimate for 2014 for five Asian countries is 97.36 mg/kg, with an upper level estimate of 97.36 mg/kg when adjusted by estimate coverage.

The updated mg/kg estimate for 2015 for 17 Asian countries is 321.49 mg/kg, with an upper level estimate of 323.14 mg/kg when adjusted by estimate coverage.

Annex 4. Europe, Regional Focus

Table A4. General Information for Europe During the Fourth 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 only qualitative data	1 (2%)
Number of OIE Members providing quantitative data	47 (98%)

Barriers to Providing Quantities of Antimicrobial Agents in Animals

It was noted that from the previous third round of data collection, out of six countries previously reporting Baseline Information (qualitative data), three were able to report antimicrobial quantities while two countries did not participate in the fourth round.

For the fourth 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 fifth round of data collection.

Antimicrobial Agents Used for Growth Promotion

From Europe, only one country (n = 48; 2%) reported the use of antimicrobial growth promoters in animals. This country reported to have legislation that only banned some antimicrobial agents as growth promoters and could not provide the list of those molecules actually used for this purpose.

It was noted that one country that previously reported the use of growth promoters, banned all antimicrobials for growth promotion purposes in 2018.

2016 Analysis of Antimicrobial Quantities

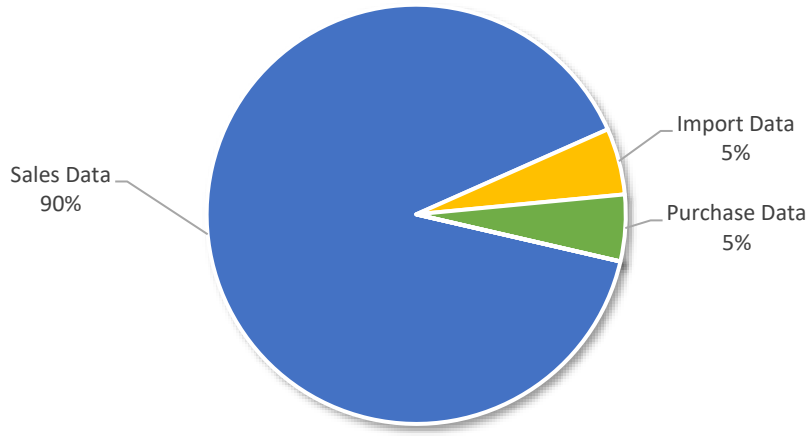
This section provides an additional analysis of reported quantitative data on antimicrobial agents intended for use in animals adjusted by animal biomass, focusing on 2016. This analysis represents the antimicrobial quantities reported to the OIE from 40 countries in Europe during all four rounds of data collection.

QUANTITATIVE DATA SOURCES CAPTURED

All countries' data sources in Europe were analysed, and all countries where the data duplication was considered to be a risk were asked for clarification of their answers and/or data collection systems. Seven countries' data source (n = 40, 18%) were considered to present a risk of duplication; after clarifications, three countries (n = 7; 43%) changed their answers or proved there was no duplication or overlapping of data sources. The remaining countries (4 out of 7; 57%) that did not provide clarification to the OIE were excluded only from the analysis in Figure A23. 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 21 Members (n= 36, 58%) selecting this option (Figure A23).

Figure A23. Data Sources Selected by 36 Countries in Europe Reporting Quantitative Information for 2016

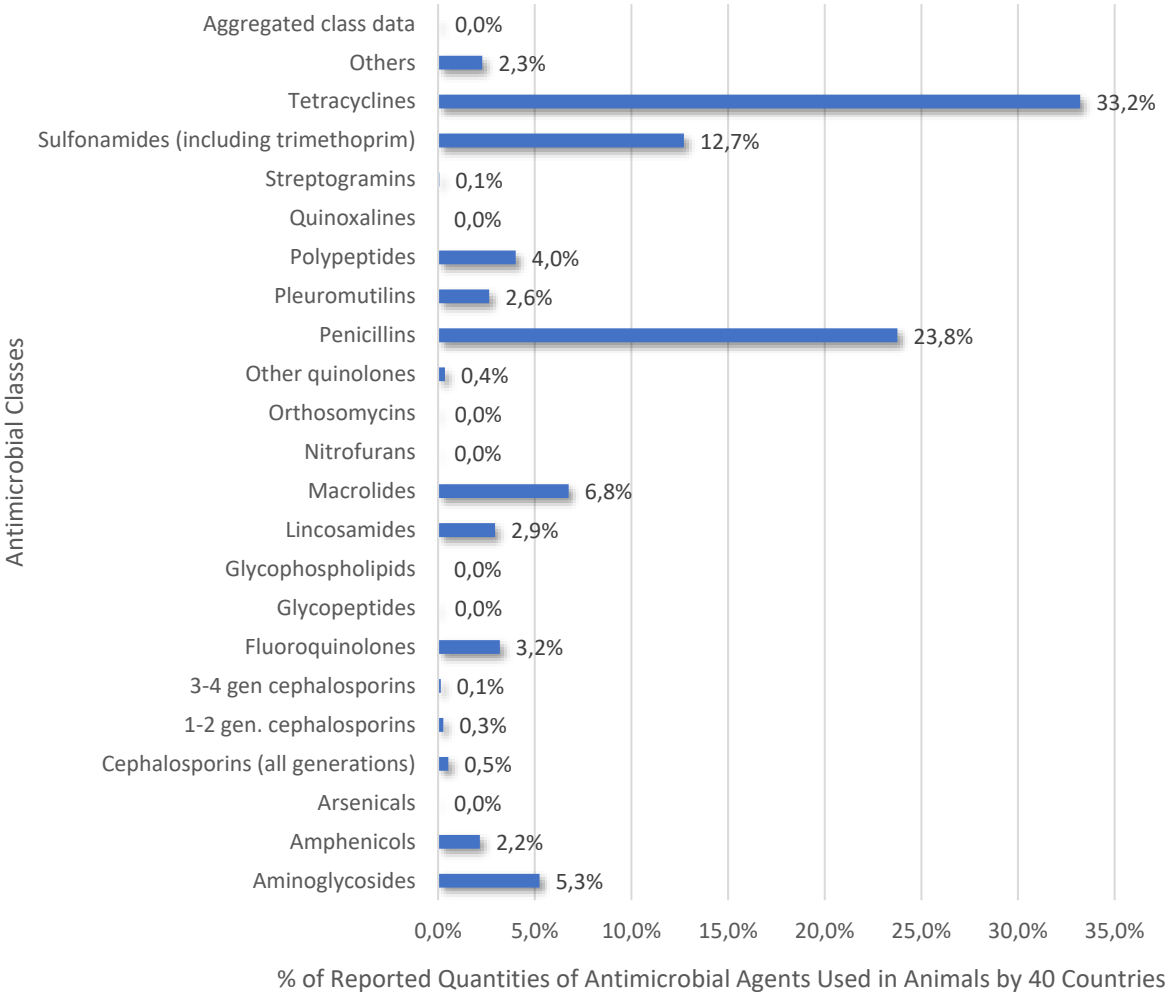


ANTIMICROBIAL QUANTITIES REPORTED IN 2016

For 2016, 40 countries in Europe provided validated antimicrobial quantities intended for use in animals. From the 40 countries, 28 stated to cover 100% of the data source used to report the data. The 12 countries that did not cover 100% of available antimicrobial quantities were asked to provide further information on uncaptured data sources. For the 40 countries, the data coverage achieved was 96%. If you would like to have more information for 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 A24).

Figure A24. Proportion of Antimicrobial Classes Reported for Use in Animals by 40 European Members in 2016

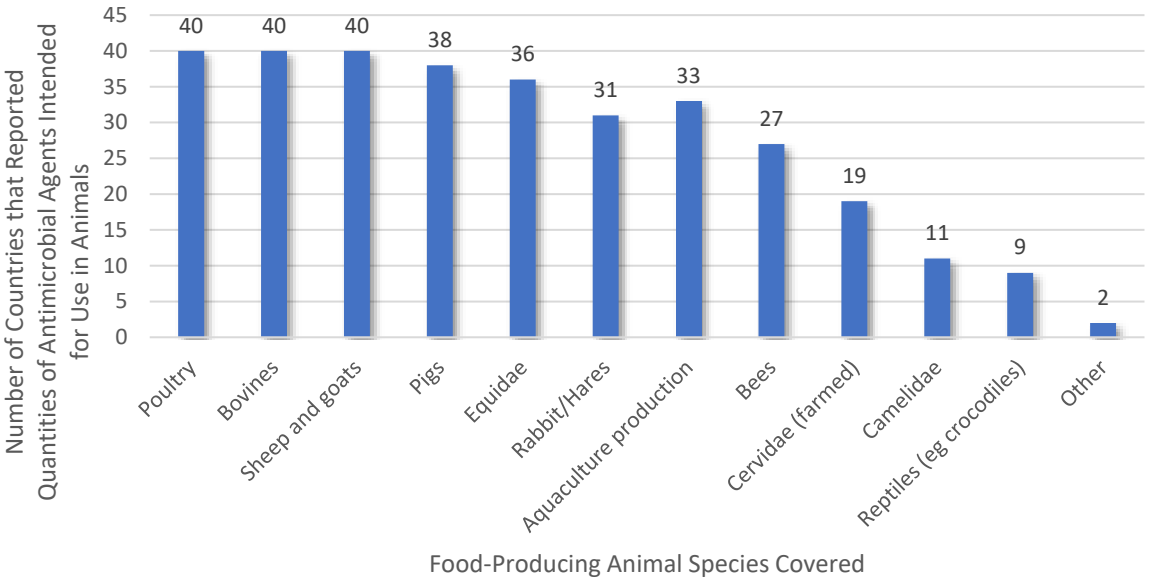


FOOD-PRODUCING TARGET SPECIES ON THE LABEL OF REPORTED VETERINARY PRODUCTS

Irrespective of whether the data could be differentiated by animal groups, all 40 countries were asked to pick 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 in categories, for more information on the grouping of animals see page 45 of this report.

In the 40 countries from Europe that reported antimicrobial quantities for 2016, the food-producing species most frequently covered by the data were poultry, bovines, sheep and goats (Figure A25). Europe is the OIE region that is providing the most data covering aquaculture.

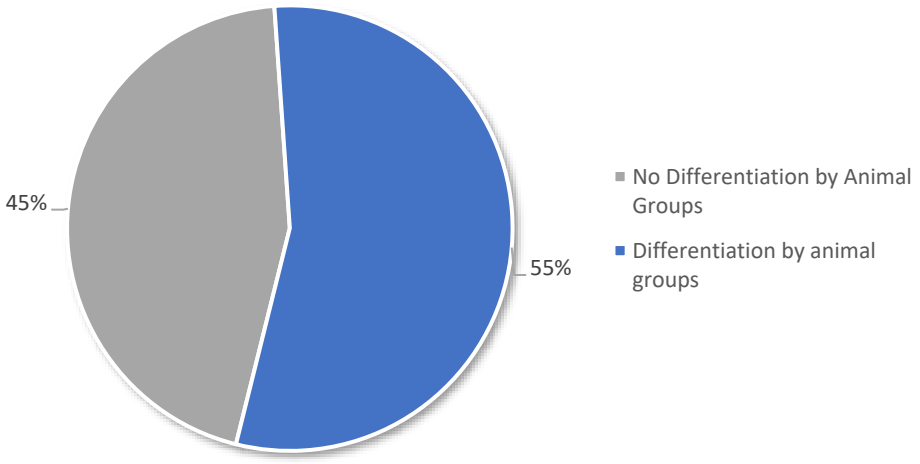
Figure A25. Food-Producing Animal Species Included in Quantitative Data Reported by 40 Countries in Europe in 2016



QUANTITATIVE DATA DIFFERENTIATION BY ANIMAL GROUPS

Most of the quantitative data from Europe can be differentiated by animal group (Figure A26). For the countries that were able to distinguish antimicrobial quantities by animal groups, data were mainly provided for terrestrial food-producing animals.

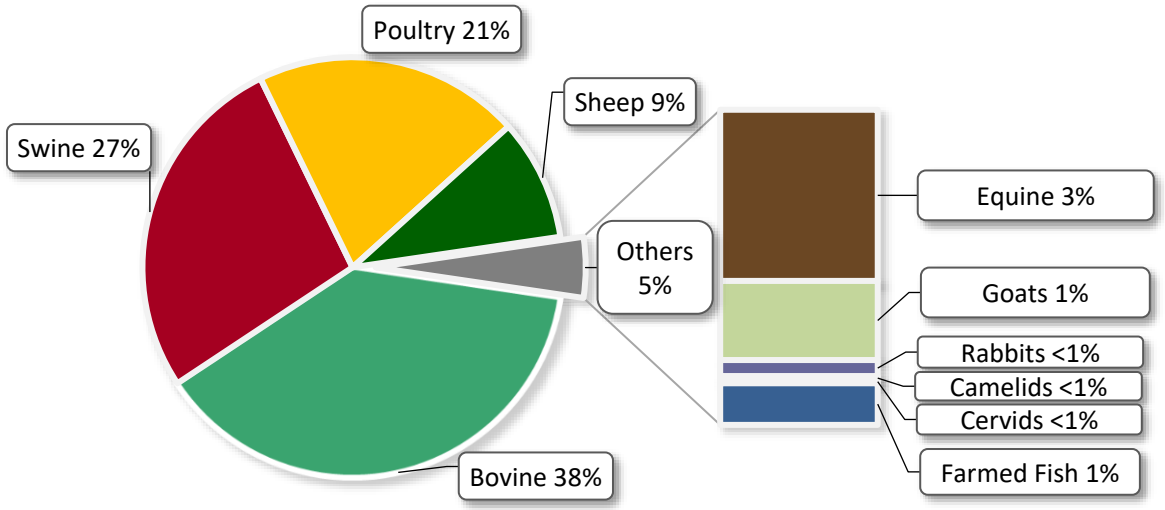
Figure A26. Differentiation by Animal Groups Among 40 Members in Europe Reporting Quantitative Data in 2016



ANIMAL BIOMASS

The relative species composition of the 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 A27. Species Composition of Animal Biomass for the 40 Countries in Europe Included in 2016 Quantitative Data Analysis



ANTIMICROBIAL QUANTITIES ADJUSTED BY ANIMAL BIOMASS

In Europe, the mg/kg estimate for 2016 for 40 countries is 66.91 mg/kg, with an upper level estimate of 68.55 mg/kg when adjusted by estimated coverage.

Changes in mg/kg results for 2014 and 2015

The updated mg/kg estimate for 2014 for 31 European countries is 92.23 mg/kg, with an upper level estimate of 94.13 mg/kg when adjusted by estimate coverage.

The updated mg/kg estimate for 2015 for 36 European countries is 77.38 mg/kg, with an upper level estimate of 81.29 mg/kg when adjusted by estimate coverage.

Annex 5. Middle East, Regional Focus

Table A5. General Information for the Middle East During the Fourth Round of Data Collection

General Information for the Middle East	
Number of OIE Members	12
Number of OIE Members responding to the questionnaire	6 (50%)
Number of OIE Members providing only qualitative data	3 (50%)
Number of OIE Members providing quantitative data	3 (50%)

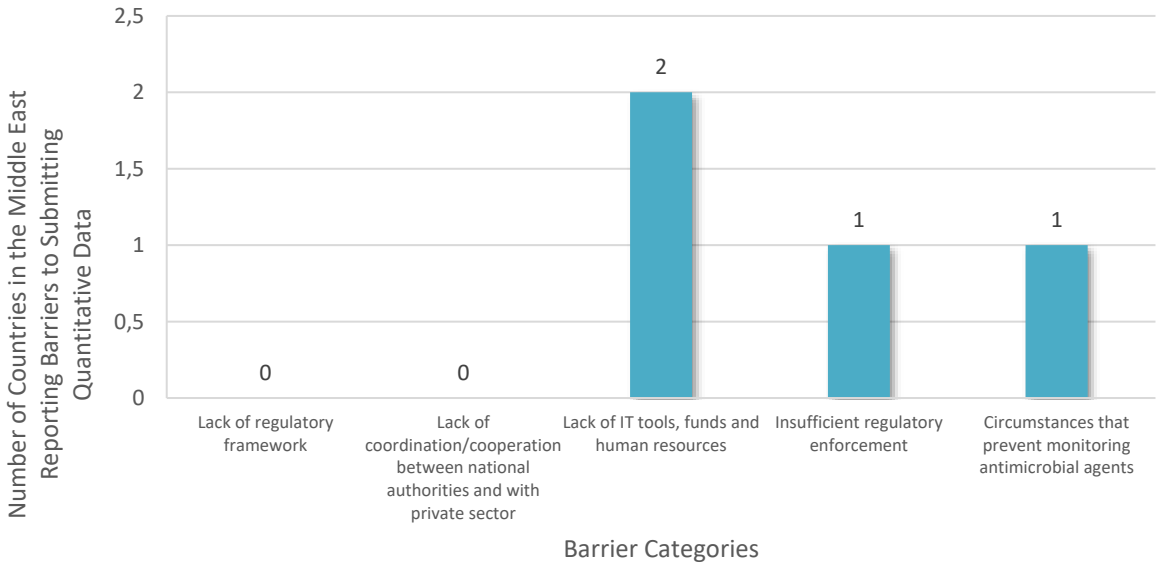
Due to confidentiality concerns, most variables included in the survey cannot be published in this report for the Middle East as the data represents only a small number of countries (Table A5). Higher participation in the Middle East Region in the future would allow a more in-depth study of the data.

Barriers to Providing Quantities of Antimicrobial Agents in Animals

During the third round, three Members (n = 6; 50%) 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 despite legislation having been approved during the fourth round, few staff were allocated to the office for the registration of veterinary medicines. Another country, that had previously reported antimicrobial quantities, mentioned that they were having problems with their IT System and that prevented their ability to calculate the kilograms of active ingredients. A third country explained that the country security situation effected their ability to obtain sales data for veterinary medicinal products (Figure A28).

Figure A28. Country Barriers to Reporting Quantitative Data on Antimicrobial Agents Intended for Use in Animals in three Members in the Middle East During the Fourth Round of Data Collection



Annex 6. OIE Template

Q	*** This sheet of the OIE template should be completed by all OIE Member Countries *** Please refer to the Guidance document for further instructions.	
A. Contact Person for Antimicrobial Agents Use Data Collection		
1	**Title**	<free text field>
2	**Name (First name, SURNAME)**	<free text field>
3	**Role with respect to the OIE**	☐ OIE Delegate ☐ OIE Focal Point for Veterinary Products ☐ Other
4	**Organisation**	<free text field>
5	**Organisation's Address**	<free text field>
6	**Country**	<free text field>
7	**Phone Number**	<free text field>
8	**Email Address**	<free text field>
B. General Information		
*Questions 9 to 14 are related 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?**	☐ Amounts available - Yes ☐ Amounts available - No
10	*Please indicate why the data are not available at this time in your country, if the answer to Question 9 is 'No'*	*<free text field>*
11	**Are antimicrobial agents used for growth promotion purposes in animals in your country?**	☐ Yes ☐ No ☐ Unknown
12	**Does your country have legislation/regulations on antimicrobial agents as growth promoters in animals?**	☐ Legislation/regulation exists - Yes ☐ Legislation/regulation does not exist - No
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?**	☐ All antimicrobial agents banned for use as growth promoters ☐ Some antimicrobial agents banned for use as growth promoters ☐ One or more antimicrobial growth promoters are authorised for use
14	***Please provide a list of antimicrobial agents used or authorised as growth promoters, if any***	*<free text field>*
*If your response to Question 9 is '**No**', please kindly send this template, once validated by the OIE Delegate and with your OIE Delegate in copy, to the OIE Antimicrobial Use Team at:* antimicrobialuse@oie.int *If your response to Question 9 is **'Yes'**, please kindly complete Section C "Data Collection".*		
C. Data collection of Antimicrobial Agents Intended for Use in Animals		
*** Please provide data for **2016** If you have data for another year, please select the year from the list below ***		
15	**Year for which data apply** (Please select only one year per template)	☐ 2016 (target year) ☐ 2017 ☐ 2018
16	**Time period for which data are provided** (e.g., 1 January to 31 December 2016)	<free text field>

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 text field>*
19	**Estimated coverage of accessible data out of total amount (in %)**	**0%**
20	*Explanation of estimated coverage*	<free text field>
21	**Is the information extrapolated from representative samples?**	☐ Data extrapolated from representatives samples - Yes ☐ Data extrapolated from representatives samples - No
22	*Explanation of extrapolations carried out, if your response to Question 21 is 'Yes'*	*<free text field>*
23	**Can data be differentiated by animal group?**	☐ Data differentiated by animal group - Yes ☐ Data differentiated by animal group - No
24	**Animal groups <u>covered by the data</u>**	☐ 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) ☐ Data for terrestrial food-producing animals ☐ Data for aquatic food-producing animals ☐ Data for companion animals

25	**Food-producing animal species covered by the information on antimicrobial quantities**	☐ Cattle ☐ Pigs - commercial ☐ 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
26	*Clarification of other species considered to be food-producing, if your response to Question 25 is 'Other commercial poultry' or Other'*	*<free text field>*
27	**Companion animal species covered by antimicrobial quantities, if any**	☐ Canines ☐ Felines ☐ Other
28	*Clarification of other species considered to be companion animals, if your response to Question 27 is 'Other'*	*<free text field>*
29	**Can data be differentiated by route of administration?**	☐ Data differentiated by route of administration - Yes ☐ Data differentiated by route of administration - No
30	**National report(s) on sales/use of antimicrobial agents in animals available on the web?**	☐ Report available on the web - Yes ☐ Report available on the web - No
31	*Please provide the link to the report, if the answer to Question 30 is 'Yes'*	*<free text field>*

According to your responses to the questions above, you are invited to fill in the following Reporting Option:		
REPORTING OPTION	**Appropiate for your Country**	
Option 1	NO	If you answered 'No' to Question 23, then Reporting Option 1 may be the best adapted Reporting Option for the data you can report.
Option 2	NO	If you answered 'Yes' to Question 23, then Reporting Option 2 may be the best adapted Reporting Option for the data you can report.
Option 3	NO	If you answered 'Yes' to Question 23 and Question 27, then Reporting Option 3 may be the best adapted Reporting Option for the data you can report.

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

	Overall Amount: **Veterinary Medical Use + Growth Promotion**	Amount: **Veterinary Medical Use** (including prevention of clinical signs)	Amount: **Growth Promotion**
Antimicrobial Class	**All animal species (kg)**	**All animal species (kg)**	**All animal species (kg)**
Aminoglycosides	0		
Amphenicols	0		
Arsenicals	0		
Cephalosporins (all generations)	0	0	0
1-2 gen. cephalosporins	0		
3-4 gen cephalosporins	0		
Fluoroquinolones	0		
Glycopeptides	0		
Glycophospholipids	0		
Lincosamides	0		
Macrolides	0		
Nitrofurans	0		
Orthosomycins	0		
Other quinolones	0		
Penicillins	0		
Pleuromutilins	0		
Polypeptides	0		
Quinoxalines	0		
Streptogramins	0		
Sulfonamides (including trimethoprim)	0		
Tetracyclines	0		
Others	0		
Aggregated class data	0		
Total kg	0	0	0

*If **'Aggregated class data'** are reported, please list the classes combined*	*<free text field>*	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'.
*If **'Others'** are reported under 'Antimicrobial class', please list the classes reported*	*<free text field>*	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*	*<free text field>*	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.

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: **Veterinary Medical Use + Growth Promotion**	Amount: **Veterinary Medical Use** (including prevention of clinical signs)					Amount: **Growth Promotion**
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			
Amphenicols	0	0		0			
Arsenicals	0	0		0			
Cephalosporins (all generations)	0	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	0

*If **'Aggregated class data'** are reported, please list the classes combined*	*<free text field>*	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'.
*If **'Others'** are reported under 'Antimicrobial class', please list the classes reported*	*<free text field>*	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*	*<free text field>*	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.

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	Amount: Veterinary Medical Use (including prevention of clinical signs)															Amount: Growth Promotion
	All Animal Species	All animal species			Companion animals			All food-producing animals (terrestrial and aquatic)			Terrestrial food-producing animals			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 (kg)	Other routes (kg)	Oral route (kg)	Injection route (kg)	Other routes (kg)	Oral route (kg)	Injection route (kg)	Other routes (kg)	Oral route (kg)	Injection route (kg)	Other routes (kg)	All routes (kg)
Aminoglycosides	0	0	0	0				0	0	0							
Amphenicols	0	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
1-2 gen. cephalosporins	0	0	0	0				0	0	0							
3-4 gen cephalosporins	0	0	0	0				0	0	0							
Fluoroquinolones	0	0	0	0				0	0	0							
Glycopeptides	0	0	0	0				0	0	0							
Glycophospholipids	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							
Penicillins	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)	0	0	0	0				0	0	0							
Tetracyclines	0	0	0	0				0	0	0							
Others	0	0	0	0				0	0	0							
Aggregated class data	0	0	0	0				0	0	0							
Total kg	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

*If **'Aggregated class data'** are reported, please list the classes combined*	*<free text field>*	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'.
*If **'Others'** are reported under 'Antimicrobial class', please list the classes reported*	*<free text field>*	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	*<free 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

Introduction

The OIE proposes to collect data on antimicrobial agents intended for use in animals from OIE Member Countries implementing Chapter 6.8, "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 **sales**[11] 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., chemical compound as declared on the product label, that is to be calculated from the available information as explained in the Annex to this Guidance document), animals are grouped into 'all animal species', '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 antimicrobialuse@oie.int 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

[11] **'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.

[12] http://www.oie.int/fileadmin/Home/eng/Our_scientific_expertise/docs/pdf/AMR/A_OIE_List_antimicrobials_May2018.pdf

Reporting Options are proposed, using different individual sheets of the OIE template: 'Baseline Information', 'Reporting Option 1', 'Reporting Option 2', and 'Reporting Option 3'.

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
	A. 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 the OIE**	Please choose either 'Delegate', 'National Focal Point for Veterinary Products' 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 Address**	Full mailing address of your organisation.
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 related 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 agents as growth promoters in animals?**	Please respond by ticking either 'Legislation/regulation exists - Yes' or 'Legislation/regulation does not exist - No'.
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 data on the amount of antimicrobial 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. Data Collection of Antimicrobial Agents Intended for Use in Animals (Reserved to the Countries where data are available)		
15	**Year for which data apply** (Please select only one year per template)	Please provide data for **2016**. 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 2016. 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 2016)	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 6.8 of the *OIE Terrestrial Code* and Chapter 6.3 of the *OIE Aquatic Code* 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 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 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.
18	*Clarification of the data source, if your response to Question 17 is 'Other'*	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 your response to Question 25 is 'Other commercial poultry' or 'Other'*	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.
27	**Companion animal species covered by the information on antimicrobial quantities**	The OIE needs to gain an understanding of how this difference could 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 companion animals covered by the quantities. Multiple selections are possible.
28	*Clarification of other species considered to be companion animals, if your response to Question 27 is 'Other'*	Please provide any explanations you may feel necessary to explain which animal species covered by the data are considered companion animals (e.g. horses).
29	**Can data be differentiated per route of administration?**	Please respond by ticking either 'Yes' or 'No'.
30	**National report(s) on sales/use of antimicrobial agents in animals available on the web?**	Please respond by ticking either 'Yes' or 'No'.
31	*Please provide the link to the report, if your response to Question 30 is 'Yes'*	If answer is 'Yes' to Question 30, please insert the link to the site where the report is available on the internet.

Classes of antimicrobial agents for reporting

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

Antimicrobial class	Guidance
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	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.
Quinoxalines	Includes carbadox, olaquindox and others.
Streptogramins	Includes virginiamycin, pristinamycin, and others.
Sulfonamides (including trimethoprim)	Includes all sulfonamides, as well as trimethoprim and similar compounds.
Tetracyclines	Includes chlortetracycline, doxycycline, tetracycline, and oxytetracycline.
Others	All others not covered, including coumarin antimicrobials, e.g., novobiocin, fusidic acid, kirromycins, phosphonic acids like fosfomycin, rifamycins, thiostrepton.
Aggregated class data	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.

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 *OIE List of antimicrobial agents of veterinary importance*.

Field name	Information to be provided
	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 'Antimicrobial class', list the classes reported	Please 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	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 active ingredient (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 in all animals. Data may be reported overall for all animal species, but can be separated by antimicrobial class and possibly by type of use (veterinary medical including prevention of clinical signs, or growth promotion; see definitions 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, species group and **route of administration.**

If the data can be differentiated by route of administration, 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 lead to elevated 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 intramammary 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 (according to the new version of Chapter 6.9 of the *Terrestrial Code*, adopted during the 86th OIE General Session)**
  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 (according to the new version of Chapter 6.9 of the *Terrestrial Code*, adopted during the 86th OIE General Session)**
  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
l	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.

Step 1: 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) $Pack\ content = 100\ g/kg\ x\ 20\ kg = 2000\ g$

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 mg/ml x 100 ml = 30000 mg = 30 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 mg/ml x 250 ml = 75000 mg = 75 g
Pack content: (a) 6 x 75 g = 450 g,
(b) 10 x 75 g = 750 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

$$\text{Content of antimicrobial agent per package in } mg = Content\ of\ antimicrobial\ agent\ \ in\ IU\ \text{x}\ conversion\ factor$$

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

Table 2: Conversion of International Units (IUs) of certain antimicrobial agents into mg and relevant active entities, based on the ESVAC conversion factors[13]

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).

Converting % w/w: 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.

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

[13] http://www.ema.europa.eu/ema/pages/includes/document/open_document.jsp?webContentId=WC500189269

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)

Converting % w/v: 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.

Table 3: 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 factors[14]

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.

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

[14] http://www.ema.europa.eu/ema/pages/includes/document/open_document.jsp?webContentId=WC500189269

Annex 9. Distribution of Members by OIE Region

AFRICA (54)

1. ALGERIA
2. ANGOLA
3. BENIN
4. BOTSWANA
5. BURKINA FASO
6. BURUNDI
7. CAMEROON
8. CABO VERDE
9. CENTRAL AFRICAN (REP.)
10. CHAD
11. COMOROS
12. CONGO (REP. OF THE)
13. CONGO (DEM. REP. OF THE)
14. CÔTE D'IVOIRE
15. DJIBOUTI
16. EGYPT
17. EQUATORIAL GUINEA
18. ERITREA
19. ESWATINI
20. ETHIOPIA
21. GABON
22. GAMBIA
23. GHANA
24. GUINEA
25. GUINEA-BISSAU
26. KENYA
27. LESOTHO
28. LIBERIA
29. LIBYA
30. MADAGASCAR
31. MALAWI
32. MALI
33. MAURITANIA
34. MAURITIUS
35. MOROCCO
36. MOZAMBIQUE
37. NAMIBIA
38. NIGER
39. NIGERIA
40. RWANDA
41. SAO TOME AND PRINCIPE
42. SENEGAL
43. SEYCHELLES
44. SIERRA LEONE
45. SOMALIA
46. SOUTH AFRICA
47. SOUTH SUDAN (REP. OF)
48. SUDAN
49. TANZANIA
50. TOGO
51. TUNISIA
52. UGANDA
53. ZAMBIA
54. ZIMBABWE

AMERICAS (31)

1. ARGENTINA
2. BAHAMAS
3. BARBADOS
4. BELIZE
5. BOLIVIA
6. BRAZIL
7. CANADA
8. COLOMBIA
9. COSTA RICA
10. CUBA
11. CURACAO
12. CHILE
13. DOMINICAN (REP.)
14. ECUADOR
15. EL SALVADOR
16. GUATEMALA
17. GUYANA
18. HAITI
19. HONDURAS
20. JAMAICA
21. MEXICO
22. NICARAGUA
23. PANAMA
24. PARAGUAY
25. PERU
26. SAINT LUCIA
27. SURINAME
28. TRINIDAD AND TOBAGO
29. UNITED STATES OF AMERICA
30. URUGUAY
31. VENEZUELA

MIDDLE EAST (12)

1. AFGHANISTAN
2. BAHRAIN
3. IRAQ
4. JORDAN
5. KUWAIT
6. LEBANON
7 OMAN
8. QATAR
9. SAUDI ARABIA
10. SYRIA
11. UNITED ARAB EMIRATES
12. YEMEN

ASIA, FAR EAST AND OCEANIA (32)

1. AUSTRALIA
2. BANGLADESH
3. BHUTAN
4. BRUNEI
5. CAMBODIA
6. 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)
14. LAOS
15. MALAYSIA
16. MALDIVES
17. MICRONEISA (FED. STATES OF)
18. MONGOLIA)
19. MYANMAR
20. NEPAL
21. NEW CALEDONIA
22. NEW ZEALAND
23. PAKISTAN
24. PAPUA NEW GUINEA
25. PHILIPPINES
26. SINGAPORE
27. SRI LANKA
28. TAIPEI (CHINESE)
29. THAILAND
30. TIMOR LESTE
31. VANUATU
32. VIETNAM

EUROPE (53)

1. ALBANIA
2. ANDORA
3. ARMENIAA
4. AUSTRIA
5. AZERBAIJAN
6. BELARUS
7. BELGIUMS
8. BOSNIA AND HERZEGOVINA
9. BULGARIA
10. CROATIA
11. CYPRUS
12. CZECH REP.
13. DENMARK
14. ESTONIA
15. FINLAND
16. FRANCE
17. GEORGIA
18. GERMANY
19. GREECE
20. HUNGARY
21. ICELAND
22. IRELAND
23. ISRAEL
24. ITALY
25. KAZAKHSTAN
26. KYRGYZSTAN
27. LATVIA
28. LIECHTENSTEIN
29. LITHUANIA
30. LUXEMBOUR
31. MALTA
32. MOLDOVA
33. MONTENEGRO
34. NETHERLANDS (THE)
35. NORTH MACEDONIA
36. NORWAY
37. POLAND
38. PORTUGAL
39. ROMANIA
40. RUSSIA
41. SAN MARINO
42. SERBIA
43. SLOVAKIA
44. SLOVENIA
45. SPAIN
46. SWEDEN
47. SWITZERLAND
48. TAJIKISTAN
49. TURKEY
50. TURKMENISTAN
51. UKRAINE
52. UNITED KINGDOM
53. UZBEKISTAN