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

Table of Contents

LIST OF TABLES

LIST OF FIGURES

Director General's Foreword

Dr Monique Eloit
OIE Director General

On 21 September 2016, the United Nations General Assembly adopted a political declaration aimed at combating the global threat posed by antimicrobial resistance, confirming the necessity of a 'One Health' approach. The Directors General of the tripartite collaboration – OIE, WHO and FAO – supported this declaration, and continue to do so through the work of the Interagency Coordination Group on Antimicrobial Resistance.

In the framework of the Global Action Plan on Antimicrobial Resistance endorsed by the Membership of OIE, FAO and WHO, the OIE has within the collaboration taken the lead to build a global database on the use of antimicrobial agents in animals. As a result of the tremendous efforts of its Member Countries, the first OIE Annual Report on the Use of Antimicrobial Agents in Animals was published in December 2016. This first phase of data collection informed on the global situation of governance of veterinary antimicrobials.

During the 85th General Session in May 2017, the World Assembly of Delegates was informed on results of the Technical Item 1, and adopted Resolution No. 38, 'Global Action to Alleviate the Threat of Antimicrobial Resistance: Progress and Opportunities for Future Activities Under the 'One Health' Initiative'. Among the recommendations of the resolution was the continued dedication of Member Countries to develop monitoring systems on antimicrobials used in animals and contribute to the OIE global database. This commitment was highlighted in the results of the Technical Item 1, where the proportion of Member Countries with no data collection on antimicrobial use in animals fell from 31% before 2015 to 19% after 2015.

The OIE supports its Member Countries in these efforts through the implementation of its Strategy on Antimicrobial Resistance and the Prudent Use of Antimicrobials, published in November 2016. The objectives of this Strategy support those established in the Global Action Plan, and reflect the mandate of the OIE 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.

The OIE's partners acknowledge the establishment of the OIE database on the use of antimicrobials in animals as a major milestone in the global effort to contain antimicrobial resistance. Such a feat was only possible through the contributions and efforts of the 143 OIE Member Countries and 3 non-OIE Member Countries that participated in the data collection in the second phase. The OIE recognises the efforts of the OIE Delegates and the National Focal Points for Veterinary Products in assisting in this extraordinary effort. The OIE also commends participating non-OIE Member Countries who have engaged in the data collection in the second phase.

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

Executive Summary

This second *OIE annual report on the use of antimicrobial agents intended for use in animals* gives the first ever glimpse into the global use of antimicrobial agents adjusted for animal biomass for 2014, and presents the overall findings of the second annual data collection on the use of antimicrobial agents in animals, providing a global and regional analysis from 2013 to 2016.

The template used to collect data was designed to allow all countries to participate, regardless of whether a national data collection system currently exists. In 2016, the second phase of data collection, completed templates were submitted by 143 OIE Member Countries (79% of 180 Member Countries) and 3 non-OIE Member Countries. This indicates progress since the first phase of data collection, whereby 130 Member Countries submitted completed templates.

New in the second phase of data collection, countries were asked to provide information on the barriers faced in reporting quantitative data on antimicrobial agents intended for use in animals. Thirty-eight countries explained their barriers, reporting primarily a lack of regulatory framework, and lack of cooperation between national authorities and with the private sector. Eight countries reported that data were held by national authorities outside of veterinary or agricultural services and therefore could not be accessed for the purpose of the template, most often, by the country's Ministry of Health.

For the responses on the authorisation of antimicrobial agents as growth promoters, a total of 86 out of 146 (59%) responding countries did not authorise any antimicrobial agents for growth promotion in animals in their countries as of 2016. The 60 remaining countries (41%) reported use of antimicrobials for growth promotion, either with direct authorisation of some compounds, or because the country had no regulatory framework on this issue.

One hundred-seven countries of 146 (73%) reported quantitative data for one or more years between 2013 to 2016, an increase compared to the 89 countries providing quantitative data in the first phase. Sources of these data varied among OIE Regions, and were most commonly sales and imports.

New in this report, the first global calculations of animal biomass allowed for an analysis of antimicrobial quantities reported adjusted by a denominator. Animal biomass is calculated as the total weight of the live domestic animals in a given population, used as a proxy to represent those likely exposed to the quantities of antimicrobial agents reported. Animal biomass was therefore calculated for food-producing species of countries reporting quantitative data for the year 2014, primarily using data from the OIE World Animal Health Information System (WAHIS) and the Food and Agriculture Organization Statistics (FAOSTAT). 2014 was the target year of this second phase of data collection, and had the highest number of submissions of quantitative data. From the 60 countries included in the 2014 analysis, the estimated coverage of total animal biomass from four OIE Regions is 47%.

The results of this analysis are presented globally and by OIE Region. The global estimate of antimicrobial agents used in animals in 2014 adjusted for animal biomass, as represented by the quantitative data reported to the OIE from 60 countries during the first two phases of data collection, was 98.97 mg/kg. An approach for an upper level estimate of 134.31 mg/kg was made adjusting by country-level estimates of how much data on antimicrobial agents used in animals they covered in 2014.

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 advises 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.

Acknowledgements

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

The OIE is grateful to all the efforts of the members of the OIE *ad hoc* Group on Antimicrobial Resistance for their input in development of the global database and methodology for calculation of animal biomass: Dr Carolee Carson, Dr Gérard Moulin, Dr Donald Prater, Dr Masumi Sato, Dr Herbert Schneider, Dr Chris Teale and Dr Jordi Torren Edo. Special thanks are also extended to Dr Awa Aidara Kane (WHO) and Dr April Johnson (FAO) for their continued support of the Group. To Dr François Diaz for his dedicated coordination and preparation of the Group as well as his support in communication with French-speaking Member Countries.

The OIE would also like to thank all OIE Member Countries as well as non-OIE Member Countries, Delegates, National Focal Points for Veterinary Products and other governmental officials who contributed to the second 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 Scientific Commission on Animal Diseases who gave their encouragement and support for this initiative since the beginning.

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
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[1]

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.

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 Services: means the governmental and non-governmental organisations that implement animal health and welfare measures and other standards and recommendations in the *Terrestrial Animal Health 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.

[1] 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 combatting 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, the OIE Member Countries officially committed to combat AMR and promote the prudent use of antimicrobials in animals and stated their full support for the Global Action Plan on AMR, developed by WHO in close collaboration with the OIE and 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 in its Member Countries, the OIE engages with National Focal Points for Veterinary Products in its Member Countries. 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 in its Member Countries, and harmonised implementation of OIE standards for responsible and prudent use of antimicrobials.

In many countries today, antimicrobial agents are widely available with virtually no restriction or control. Of the 132 OIE Member Countries assessed through the OIE Performance of Veterinary Services (PVS) Pathway[2] as of November 2017, many do not yet have complete and relevant legislation to ensure appropriate conditions for the import, manufacturing, distribution and use of veterinary medicinal products, including antimicrobial agents. As a result, these products circulate freely, like ordinary goods, and are often falsified or substandard. This inappropriate use of antimicrobial products creates conditions of high risk for the development and spread of resistance.

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 6.7. 'Harmonisation of national antimicrobial resistance surveillance and monitoring programmes'; [5] the *Aquatic Animal Health Code*, Chapter 6.4. 'Development and harmonisation of national antimicrobial resistance surveillance and monitoring programmes for aquatic animals'; [6] and the *Manual of Diagnostic Test and Vaccines for Terrestrial Animals*, Chapter 3.1 'Laboratory methodologies for bacterial antimicrobial susceptibility testing' provide a basis for such surveillance and monitoring [7].

[2] The PVS Gap Analysis Tool ("prescription tool") is a quantitative evaluation of a country's needs and priorities based on the outcome of the independent external evaluation of the country Veterinary Services using the OIE PVS Evaluation Tool. (*http://www.oie.int/en/support-to-oie-members/pvs-gap-analysis/)*

Future work is currently being undertaken to define indicator bacteria relevant to the most commonly raised animal species and to refine recommendations for harmonisation of microbial susceptibility testing in veterinary laboratories.

In addition to surveillance of antimicrobial resistance, surveillance 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 6.8. '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 Member Countries had an official system in place for collecting quantitative data on antimicrobial agents used in animals.

The results were presented at the 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 Member Countries 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 6.8. of the *Terrestrial Animal Health Code* (Monitoring of the quantities and usage patterns of antimicrobial agents used in food-producing animals) and 6.3. of the *Aquatic Animal Health Code* (Monitoring of the quantities and usage patterns of antimicrobial agents used in aquatic animals) [8, 9].

In the framework of the Global Action Plan on Antimicrobial Resistance, 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. [10]

The OIE launched its first annual data collection on antimicrobial agents intended for use in animals in OIE Member Countries in the last trimester of 2015. The 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 Member Countries through regional training seminars for OIE National Focal Points for Veterinary Products.

During this first phase of data collection on antimicrobial agents used in animals, 130 Member Countries (72% of the 180 OIE Member Countries) 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*, was published in December 2016. This first report provided a global and regional analysis of qualitative data on the current situation of governance of veterinary antimicrobials, and quantitative data on antimicrobial agents intended for use in animals provided from 2010 to 2015 by participating Member Countries.

The second phase of data collection took place between October 2016 and May 2017, and newly, was distributed to non-OIE Member Countries in the Americas in addition to the OIE's 180 Member Countries[3].

As part of the second phase of the data collection, the OIE requested quantitative data on antimicrobials used in animals for the 2014 calendar year, but also accepted data from the years 2013 to 2016. The wider timespan of quantitative data collected allows for countries in various stages of development of their antimicrobial use surveillance 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 second phase of data collection presented in this report is broad, making comparisons between regions or assessment of trends difficult. Comparison of quantitative data also require a denominator with which to interpret the antimicrobial quantities reported.

To address these challenges, this report initiates a new examination of quantitative data in the context of relevant animal populations, and includes for the first time 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 2014, using quantitative data reported to the OIE by 60 countries during the first two phases of data collection.

In the third phase of data collection, currently underway, the OIE has requested quantitative data for 2015, but will also accept data for 2016 and 2017. Accepting some repeated years of quantitative data from previous phases while continuing engagement with participating countries provides an opportunity for countries to correct and enrich the quality of these data 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 in its Member Countries, as global surveillance on the use of antimicrobial agents becomes more systematic and reliable.

In this second phase of data collection, 143 Member Countries (of 180 Member Countries) and 3 non-OIE Member Countries responded to the OIE questionnaire, with 73% (107 out of 146 countries) providing quantitative data on antimicrobial agents intended for use in animals. Given the outstanding participation of OIE Member Countries and their expressed desire to further increase transparency on antimicrobial agents intended for use in animals, it is expected that more countries will be able to report quantitative information with each successive data collection.

Each year, more countries progress in implementation and development of surveillance systems on antimicrobial agents used in animals. This progress was highlighted in Technical Item 1 of the 85th General Session held in May 2017, titled "Global action to alleviate the threat of antimicrobial resistance: progress and opportunities for future activities under the One Health initiative". This Technical Item was undertaken to inform on the current situation of antimicrobial resistance mitigation initiatives in Member Countries, as reported by each country through a questionnaire. Member Country responses showed an increase in adherence to OIE standards since 2015 for surveillance of antimicrobial use (49% since 2015 compared to 37% before) and resistance (34% since 2015 compared to 25% before) in animals. [11]

[3] During the first and second phases of data collection, the OIE comprised 180 Member Countries. During the 2017 General Assembly, Curaçao officially became an OIE Member Country, bringing the total number to 181. However, as this addition occurred after the completion of the second phase of data collection, mention of the total number of Member Countries throughout this report will refer to 180 countries unless otherwise stated.

These results show that Member Countries are not only developing the needed surveillance systems, but are doing so in compliance with international standards. Following the presentation of the results of the Technical Item, the Assembly adopted Resolution No38, endorsing eleven recommendations for future activities under the 'One Health' initiative. Among these recommendations was one emphasising the significance of continuing the global data collection on the use of antimicrobial agents in animals. [12]

1.2. Scope

This report presents the results of the second phase 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 Member Countries and participating non-OIE Member Countries, 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. Where countries are not able to contribute quantitative data, the report also highlights the barriers they described that impede them in data collection, analysis and/or reporting.

For the first time, in addition to the descriptive analysis of the second phase of data collection, the report now 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 first quantitative analysis is 2014.

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 Member Countries 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 guidelines provided in Annex 8.

The information provided to the OIE by each country was done so in confidence, and for the purpose of better understanding the global and regional situation of the use of antimicrobial agents in animals. This report therefore does not present any data on an individual country level. Nevertheless, Member Countries 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 available can be found in Section 9 of the report, along with the relevant links.

2. Materials and Methods

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:

3. 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).

4. 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 template was translated in the three official OIE languages (i.e. English, French and Spanish). Following experience from the first phase of data collection, the following changes were made to the OIE template:

1. Countries that reported being unable to provide quantitative data on antimicrobial agents used in animals were now asked why the data were not available at this time in their country (Baseline Information; Question 10)
2. The free text box area where countries could notify on the year covered by their quantitative data was changed to pre-defined options of 2013, 2014 and 2015 (Baseline Information; Question 13)
3. Countries were also asked to describe the number of days within a full calendar year covered by their quantitative data (Baseline Information; Question 14)
4. The preselected responses for quantitative data sources were refined to avoid noticed repetitions (Baseline Information; Question 15)
5. 'Companion animals' were added as an optional animal group category for those countries reporting quantitative data on antimicrobial agents (Reporting Option 2 and 3)
6. Countries responding to the Baseline Information sheet were automatically directed to the appropriate Reporting Option given their available data (Baseline Information)

An Annex to the guidance was also provided giving more detailed instructions on mathematical calculations to obtain quantities of active ingredients from antimicrobial products sold. All antimicrobial agents destined for use in animals and contained in the *OIE List of Antimicrobial Agents of Veterinary Importance* [13], in addition to certain antimicrobial agents used only for growth promotion, were reportable.

The updated template (Annex 6) and accompanying guidance documents (Annexes 7 and 8) were sent to all 180 OIE Member Countries and 11 non-OIE Member Countries by email in October 2016. The deadline for submission was set as 1 December 2016, but responses were accepted on a conditional basis until mid-May 2017.

As with the first phase 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 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 '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 (Therapeutic – Growth Promotions), 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 Delegates. 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 scale 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, 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 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 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.

As of 2014, the year of focus for the analysis adjusted for animal biomass, data collected by global animal surveillance databases (WAHIS[4], FAOSTAT[5]) were point in time species-level census data[6] without detail by production class. These data are difficult to interpret given that production classes

[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

within a species can have very different average weights, such as beef cattle and veal calves. Additionally, given that census data are collected at one point in 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').

In development of the methodology for calculation of an annual animal biomass, the underlying effort was to best utilise globally available census data from the OIE WAHIS interface. WAHIS data are reported by National Veterinary Services through 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 yet 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 Member Countries, or calculated from animal population data in Eurostat, the statistical office of the European Union.

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, and shared with Member Countries in the report of the OIE Scientific Commission for Animal Diseases meeting of September 2017.

Year of Analysis

The year for analysis of antimicrobial quantities adjusted for the animal biomass denominator was chosen to be 2014, as this was the target year of the second phase of data collection.

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

2014 was also the year with the most robust information reported as 62 countries reported quantitative data for 2014 during the first two phases of data collection; see Section 4.1, Figure 23). Therefore, countries providing quantitative data on antimicrobial agents intended for use in animals in 2014 during the first or second phases of data collection were included in this additional analysis.

Calculations of Live Weights for All Species

Live weights of animals were calculated using FAOSTAT indigenous slaughter data[8], 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. [14] 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.

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 2014.

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

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

1. Countries were grouped by sub-region as defined by livestock unit classifications.[9] A sub-regional mean live weight was then determined by calculating the average live weight of bovines for countries within the sub-regional grouping;
2. Using the sub-regional mean live weight, a representative weight of the sub-regional bovine population was extrapolated by applying expected population ratios and weights of the bovine production categories (adults, youngstock, calves). Population ratios were determined using an anticipated renewal rate of 30%, and average weights were estimated using livestock unit ratios by production class as defined by Eurostat; [16]

[8] 'Indigenous slaughter' refers to 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*). For an explanation of why this statistic was used, please see the Discussion section of the report.

[9] Livestock units, 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. [15]

The representative weight determined for each sub-region was then multiplied by the census population of bovines for each country within the sub-region.

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 (ESVAC 2014). This weight was adapted by region using livestock unit ratios (Americas = 240kg, Asia and the Pacific = 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:

$$\begin{aligned}(live\ weight\ chicken\ \times\ number\ of\ chicken\ slaughtered)\\ +\ (live\ weight\ turkey\ \times\ number\ of\ turkey\ slaughtered)\\ +\ (live\ weight\ ducks\ \times\ number\ of\ ducks\ slaughtered)\\ +\ (live\ weight\ geese\ \times\ number\ of\ geese\ slaughtered)\end{aligned}$$

Equidae biomass was calculated according to the following formula:

$$\begin{aligned}(live\ weight\ horse\ \times\ horse\ census\ population)\\ +\ (live\ weight\ donkey\ \times\ donkey\ census\ population)\\ +\ (live\ weight\ mules\ \times\ mule\ census\ population)\end{aligned}$$

The live weight of horses, donkeys, and mules was calculated for regions where equine slaughter is common and data were available. For regions where equine slaughter is not practiced and/or where data were less available, live weights were adapted using livestock unit ratios.

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

$$(live\ weight\ \times\ number\ slaughtered)\ +\left(census\ population - \frac{number\ slaughtered}{1.5}\right) \times\ 75\ kg$$

Whereby,

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

And $\left(census\ population - \frac{number\ slaughtered}{1.5}\right) \times\ 75\ kg$ 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 small ruminant in Europe is 75kg (ESVAC 2014). This weight was used globally based on livestock unit ratios.

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. [17]

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

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

According to the following considerations: [18]

- Standard weight cervid: 80kg
- Standard weight camel: 600kg
- 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 FAOSTAT 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 would hopefully become feasible.

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 were summed according to OIE Region.

3. Results of the Second Phase of Data Collection

3.1. Global Analysis

General Information

The OIE maintains Regional offices throughout the world, including ones in Africa, the Americas, Asia and the Pacific, Europe and the Middle East. The data collection template was sent to all OIE Member Countries from all OIE Regions. In addition, new in the second phase of data collection, the template was sent to non-OIE Member Countries that asked to be part of the database. The list of all OIE Member Countries is provided in Annex 9.

In the first phase of data collection, launched in October 2015, 130 OIE Member Countries responded to the questionnaire (130/180; 72%). In the second phase of data collection, from October 2016 to May 2017, 146 countries submitted completed templates to the OIE: 143 from OIE Member Countries (79% of 180 Member Countries) and 3 non-OIE Member Countries, demonstrating their increasing commitment to this effort.

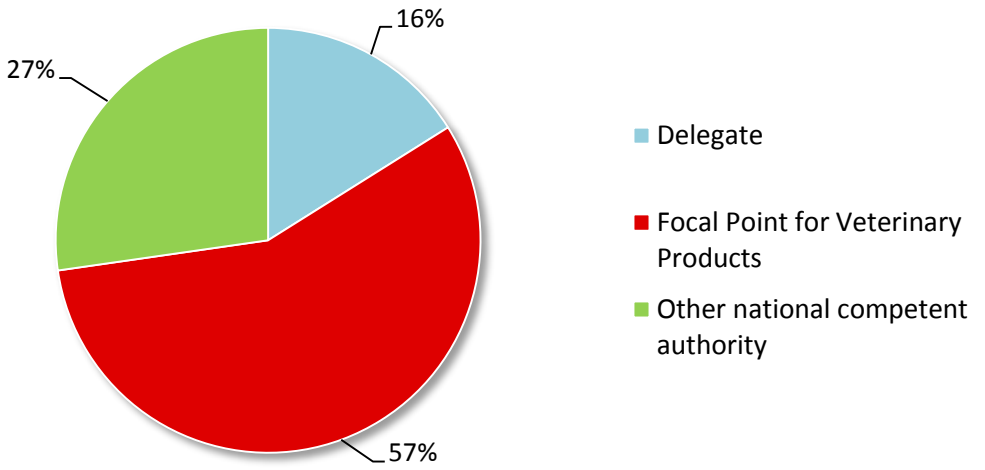
Profile of the Contact Person

Each OIE Member Country 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.

Given that OIE Delegates and National Focal Points only exist in OIE Member Countries, the following analysis on contact persons excludes non-OIE Member Countries.

For the second phase of antimicrobial use data collection, the OIE template was most frequently completed by the Member Country's National Focal Point for Veterinary Products (81 out of 143 Member Countries). This highlights the significant role of OIE Focal Points for Veterinary Products in the success of data collection, and supports the OIE's efforts in conducting regular Focal Point trainings towards establishment of a robust regional and global network of national experts in Veterinary Products (Figure 1).

Figure 1. Contact Person Profile in 143 Member Countries that Submitted the OIE Template in 2016



Reporting Options

The data collection 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, as described in Table 1.

Table 1. Baseline Information Sections and How Countries Respond Based on Available Data

Baseline Information Sections	Countries not able to provide quantitative antimicrobial use data	Countries able to provide quantitative antimicrobial use data
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		✓

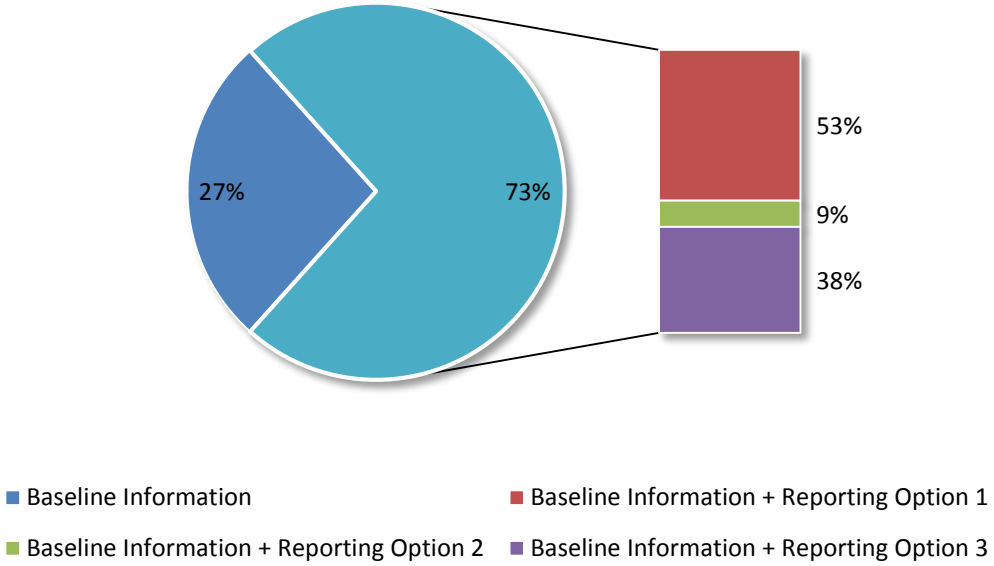
In the second phase of data collection, Baseline Information parts A and B were completed by 146 countries (143 Member Countries and 3 non-OIE Member Countries). Of these, 13 countries were new in the data collection.

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 phase of data collection, 89 OIE Member Countries reported quantities of antimicrobial agents intended for use in animals (89/130 or 68% of Member Countries submitting the template). In second phase of the data collection, 107 countries (107/146 or 73% of countries submitting the template) reported quantitative data, demonstrating growing commitment to development of monitoring systems for veterinary antimicrobial agents.

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. Reporting Option 1 allows countries to distinguish quantities of antimicrobial agents by type of use (therapeutic or growth promotion) and this option was chosen most frequently by respondents (53%; 57 out of 107 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 10 countries. Finally, Reporting Option 3, which allows countries to distinguish quantities of antimicrobial agents by type of use and routes of administration (distinguishing by group of animals is optional), was chosen by 40 countries (Figure 2).

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

Figure 2. Reporting Option Used by 146 Countries in the Second Phase of Data Collection



Country Barriers to Providing Quantities of Antimicrobial Agents in Animals

For the second phase of data collection, a question was added to the template in order to understand the barriers impeding countries from reporting amounts of antimicrobial agents in animals. This information is useful for guiding discussion on overcoming barriers during training Seminars of Focal Points for Veterinary Products and increasing availability of quantitative data in the future, and is also valuable for the Performance of the Veterinary Services (PVS pathway) programme.

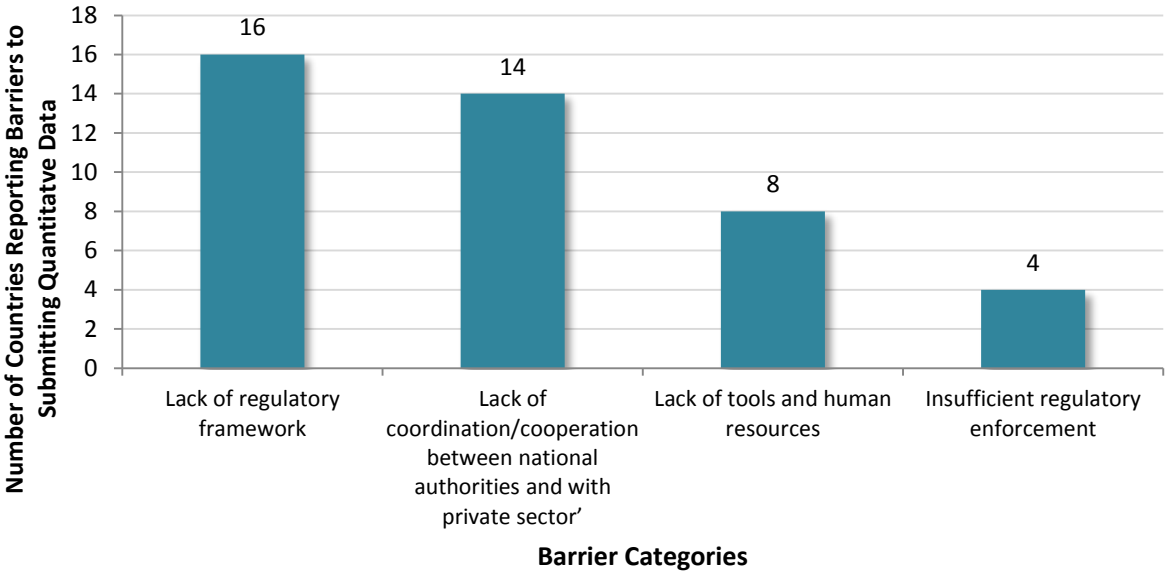
Of the responding countries for the second phase, 39 (39/146; 27%) provided Baseline Information and no quantitative data. Of these, 38 countries (38/39, 97%) explained their barriers to reporting quantities of antimicrobial agents intended for use in animals to OIE.

The barriers highlighted by responding countries have been grouped into four main categories (Figure 3). Usually, countries reported more than one barrier.

Most of the barriers to providing quantitative data on antimicrobial agents intended for use in animals can be grouped into the categories of 'lack of regulatory framework' and 'lack of cooperation between national authorities and with private sector'. The relative importance of these categories may change when analysing the results on a regional level.

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

Figure 3. Country Barriers to Reporting Quantitative Data on Antimicrobial Agents Intended for Use in Animals in 38 Countries in the Second Phase of Data Collection



LACK OF REGULATORY FRAMEWORK:
Seven countries indicated that for the years reported, no regulatory framework existed for the manufacture, registration, distribution, commercialisation and pharmacovigilance of veterinary products. Four countries stated that their legislation did not provide the government with a legal basis for collecting data on antimicrobial agents intended for use in animals, or that despite relevant legislation, a mechanism for collecting such data did not exist.

Five countries under this category reported that actions to address the lack of legislation on veterinary products and/or the monitoring of antimicrobial agents were planned or already in process. Some examples reported include:

- One country notified that a lack of a regulatory framework was already identified and was incorporated into a project within the OIE Veterinary Legislation Support Programme.
- One country informed of a plan to work on legislation pertaining to use of antimicrobial agents in animals and draft a National Action Plan (NAP) on AMR, and asked for the support of the OIE in this process. The Antimicrobial Use Team provided information to the county on several tools that can be used to support development of legislation or the improvement of veterinary services. These tools are also available on the OIE website[10].

[10] http://www.oie.int/en/support-to-oie-members/veterinary-legislation/veterinary-legislation-resources/

- One country reported that WHO has assisted them to draft a NAP on AMR that included a provision for development of regulations on veterinary drug registration, importation and use in food animals.

LACK OF COORDINATION/COOPERATION BETWEEN NATIONAL AUTHORITIES AND WITH PRIVATE SECTOR:

Within this category, 10 countries reported that the relevant data were held by another national authority, outside of the veterinary or agricultural Competent Authority. For these countries, the OIE requested further information on which agencies were involved on the data collection, with the following responses:

- Eight countries (8/10, 80%) indicated the quantities of antimicrobial agents intended for use in animals were under the legal authority of the Ministry of Health, and
- Two countries (2/10, 20%) indicated the data were held by several agencies, but did not give further information on which agencies were involved.

Three countries reported a lack of collaboration and coordination with relevant stakeholders in the country, usually the private sector. For these countries, the lack of collaboration with the private sector was reported in addition to a lack of access to data held by another Governmental Authority and insufficient regulatory framework.

One country explained that in addition to a lack of cooperation with other national authorities and the private sector, the main reason why the data were not available was that AMR and AMU were not until recently of high priority in the country.

LACK OF TOOLS AND HUMAN RESOURCES:

Five 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 captured on paper and were not yet digitalised. These countries informed that the time burden would be too great to calculate kilograms of active ingredients for veterinary products. Two of these countries specified that they were already in the process of implementing data collection software and therefore expected to contribute with quantities of antimicrobials during the third phase of data collection.

Four countries reported that even if the data were available, that no dedicated staff existed in the government for analysis of the data. One of these countries specified that the problem of insufficient dedicated staff was due to economic issues limiting hiring of new staff. Another expressed that the data were already digitalised but that the amounts of antimicrobials by classes could not be calculated from the type of data recorded.

INSUFFICIENT REGULATORY ENFORCEMENT:

Two countries that reported barriers in other categories also stated that the amount of illegal veterinary products on the market impeded calculation of quantities of antimicrobials agents intended for use in animals. One country mentioned two main barriers to accessing quantitative data, which included unlicensed manufacturers and the use of veterinary products by unauthorised persons.

SUMMARY ON BARRIERS:

Most respondents who communicated barriers to the OIE stated that the relevant data (mainly import data) were held by national authorities outside of veterinary or agricultural services and therefore could not be accessed for the purpose of the template. Most often, the data were reported to be managed by the country's Ministry of Health.

In general, most countries unable to report quantitative data also face challenges with issues pertaining to the structure, harmonisation or enforcement of their regulatory framework. Development of a robust regulatory framework within a country should be prioritised to enable monitoring the use of antimicrobial agents in animals. For Member Countries, as emphasised by one respondent, the work of the OIE through the PVS pathway is essential in helping the countries to identify their gaps and to develop stronger legislative and enforcement frameworks.

Antimicrobial Agents Used for Growth Promotion

During the 2016 OIE General Session, Member Countries adopted Resolution No36, "Combating Antimicrobial Resistance through a One Health Approach: Actions and OIE Strategy" agreeing to the recommendation that:

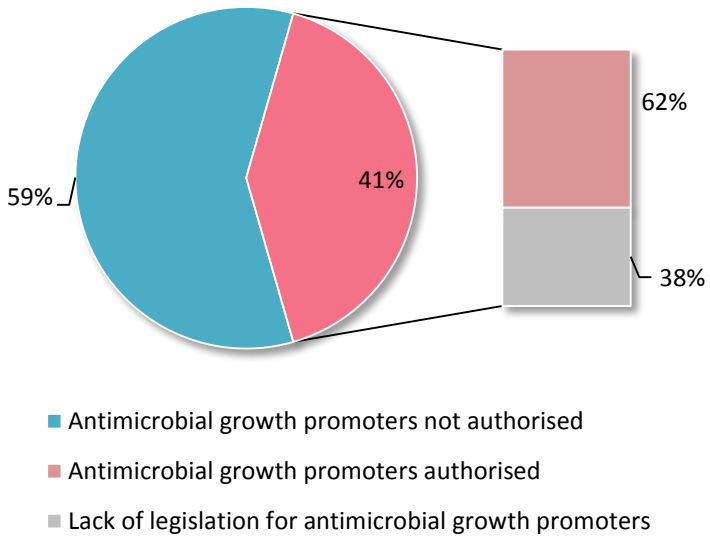
> 5. OIE Member Countries fulfil their commitment under the Global Action Plan to implement policies on the use of antimicrobials in terrestrial and aquatic animals, respecting OIE intergovernmental standards and guidelines on the use of critically important antimicrobial agents, and the phasing out 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 for use 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.

In this second phase of data collection, a total of 86 out of 146 (59%) responding countries did not authorise any antimicrobial agents for growth promotion in animals in their countries. The 60 remaining countries (41%) reported use of antimicrobials for growth promotion, either with direct authorisation of some compounds, or because the country had no regulatory framework on this issue (Figure 4).

The results of the second phase compared to the first phase, published in 2016, show an apparent decrease in countries that do not authorise antimicrobial agents as growth promoters. Data for the first *OIE Annual report on the use of antimicrobial agents in animals* showed that 96 of 130 (74%) OIE Member Countries did not authorise growth promoters. [19] Where country responses to this question 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. Therefore, the results depicted in Figure 4 should be interpreted with caution, as the variable interpretation of the question likely skewed the results.

Figure 4. Use of Antimicrobial Growth Promoters in 146 Countries in 2016



To improve understanding, for the third phase of data collection currently underway, this question was reworded to obtain clearer results on both legislation and use of antimicrobial agents as growth promotors in the future,[11] which will support reporting of more accurate results.

LACK OF REGULATORY FRAMEWORK FOR ANTIMICROBIAL AGENTS USED AS GROWTH PROMOTERS
In the template and guidance sent for the second phase, countries with no legislation or regulation on the use of antimicrobial growth promoters, but where the use of antimicrobial agents for growth promotion was known to occur, were asked to respond 'Yes' to the question *Are antimicrobial growth promoters authorised for use in your country?*

All 60 countries that answered 'Yes' to this question were then asked for clarification of their answers. Twenty-three countries (23/60; 38%) reported that no regulatory framework for use antimicrobial growth promoters existed in their countries. The following types of insufficient regulatory frameworks were mentioned:

- The country's legislation did not authorise or prohibit of use antimicrobial growth promoters in animals
- The country's legislation on use of antimicrobial agents as growth promoters only covered a limited number of animal species or production classes within a species

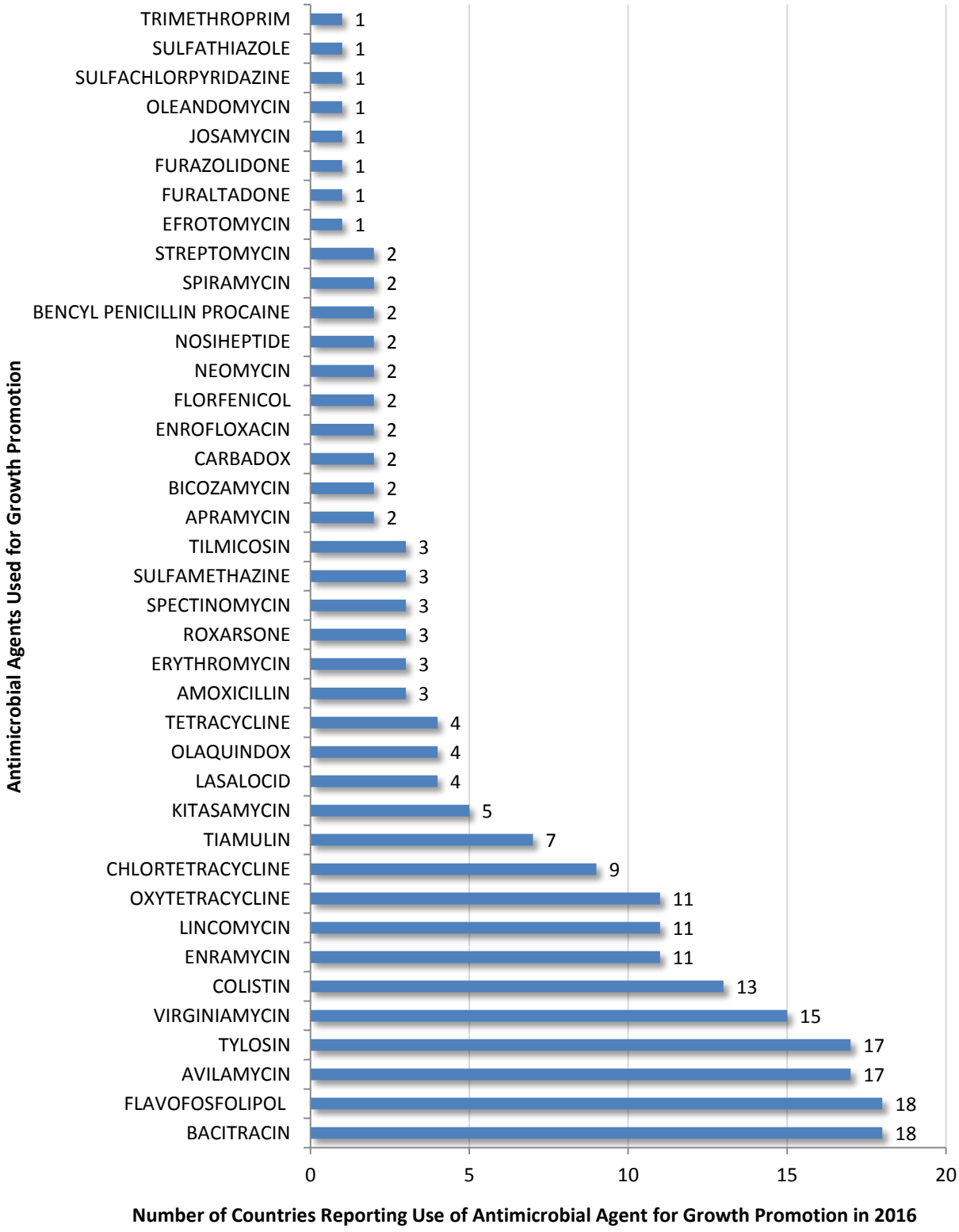
LIST OF ANTIMICROBIAL AGENTS USED FOR GROWTH PROMOTION
The 60 countries reporting use of antimicrobial agents for growth promotion were further asked for a list of antimicrobial agents (by active ingredient) either authorised as growth promoters, or known to be used in cases where legislation on this issue did not exist.

Thirty-three countries (33/60; 55%) responded with a list of antimicrobial agents used for growth promotion. The most frequently listed antimicrobial agents for this purpose were bacitracin and flavophospholipol. Colistin was mentioned by 13 countries (Figure 5).

[11] The updated OIE Template is available at: http://www.oie.int/en/our-scientific-expertise/veterinary-products/antimicrobials/

Three countries provided antimicrobial classes rather than active ingredients used for growth promotion, and so were not included in the analysis for Figure 5. Analysis at a regional level by antimicrobial class is presented in the annexes by OIE Region (Annexes 1-5).

Figure 5. Antimicrobial Agents Used for Growth Promotion in Animals in 33 Countries in 2016



Forty-three of 60 countries using antimicrobial agents as growth promoters (43/60; 72%) also provided quantitative data on antimicrobial agents sold for use in animals. Eleven of these countries (11/43; 26%) could distinguish these quantities by use for growth promotion and therapeutic purposes.

3.2. Antimicrobial Quantities

Using one of the three 'Reporting Option' sections of the data collection template, countries can report national quantities of antimicrobial agents intended for use in animals. In a 2012 OIE questionnaire on Member Country engagement in the issue of AMR[12], 23 Member Countries provided quantitative data to the OIE. In 2015-2016, during the first phase of data collection towards formal establishment of the database, 89 Member Countries provided quantitative data covering any calendar year between 2010 and 2015.

In this second phase of data collection, the number of countries reporting quantitative data increased to 107, covering any calendar year between 2013 and 2016.

Years of Quantitative Data Reported

Table 2. Breakdown of Country Response Types in Second Phase of Data Collection

Number of countries that responded to the OIE questionnaire	146
Number of countries that provided quantities of antimicrobial agents	107
Number of countries that provided quantitative data for only one year between 2013 and 2016	98
Number of countries that provided quantitative data for more than one year between 2013 and 2016	9

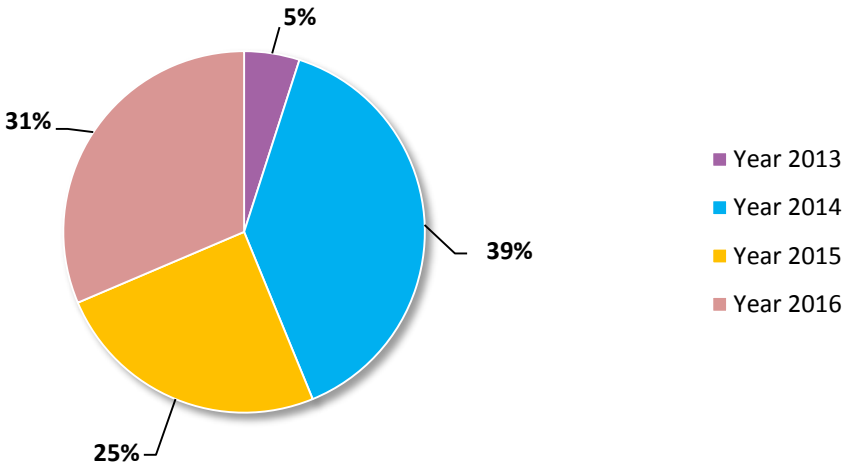
For this second phase of data collection, countries were requested to provide quantitative data for 2014, but data were accepted for any year from 2013 onwards. The OIE also accepted multiple submissions from any country who wished to provide data for more than one year.

Most countries providing quantitative data (97 out of 107; 92%) submitted data for only one year between 2013 and 2016. Nine countries submitted quantitative data for more than one year within this timeframe. Given these multiple submissions, 121 responses were provided by 107 countries (Table 2) in the second phase of data collection.

Forty-eight countries (48/121; 39%) provided data for 2014 (Figure 6).

[12] See introduction for background on the 2012 Questionnaire

Figure 6. Years of Quantitative Data Reported in Second Phase of Data Collection, from 121 Responses Provided by 107 Countries



The following analysis describes the results from the 107 countries that provided quantitative data during the second phase of data collection, covering any year between 2013 and 2016.

Period of Time Covered

In the second phase of data collection, a new question was added to the template asking countries to specify the length of the calendar year covered by their data (e.g., 1 January to 31 December). This question was added as some countries informed during the first phase that their quantitative data only covered a certain number of days.

A response to the question on time period was provided by 101 out of 107 countries reporting quantities of antimicrobials intended for use in animals. Globally, the average time period covered was 345 days; this information shows that most countries are providing quantitative data for most of a calendar year.

Quantitative Data Sources Captured

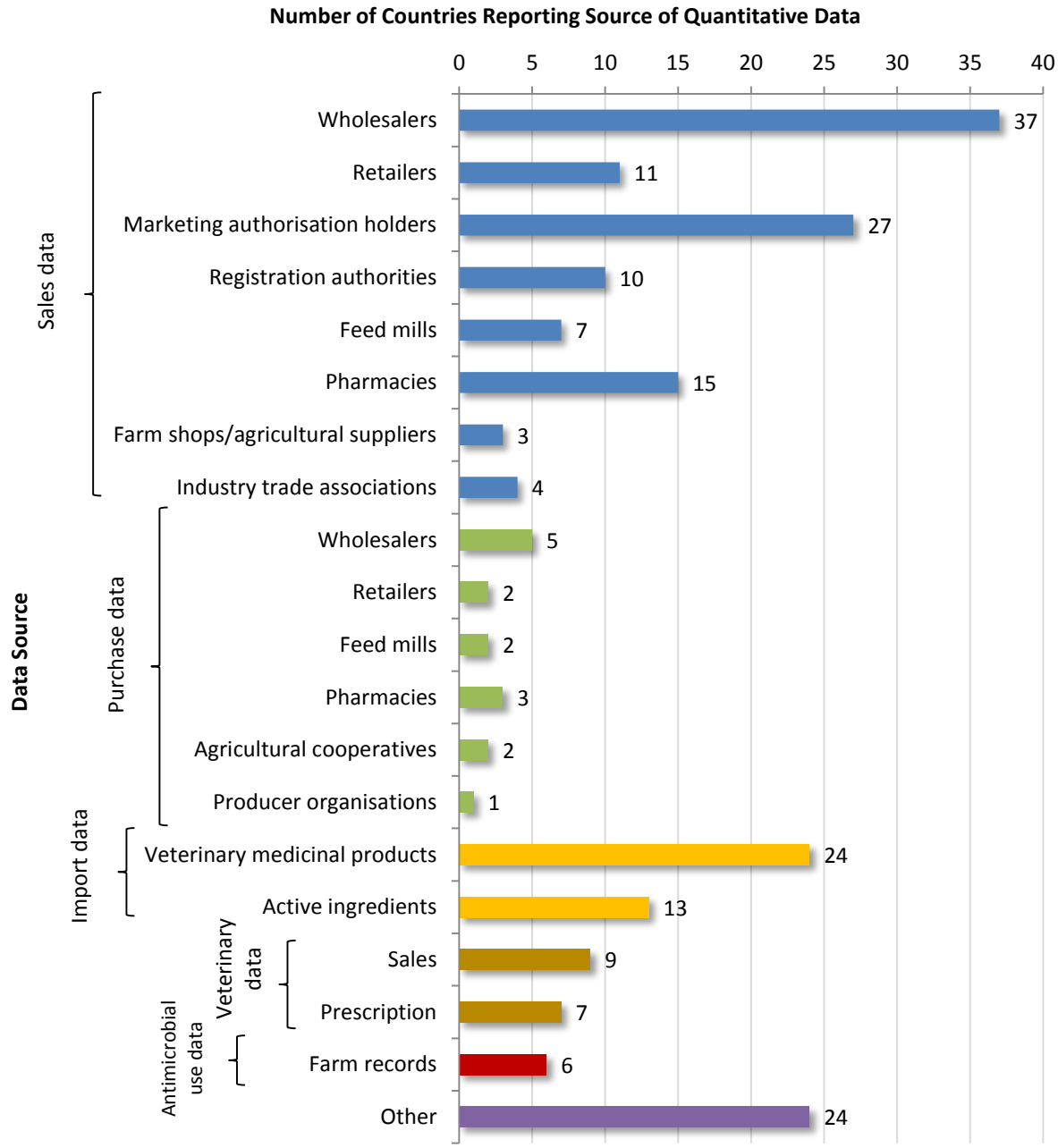
The OIE data collection template includes an exhaustive list of possible quantitative data sources, in accordance with Chapter 6.8 of the *Terrestrial Animal Health Code* (Monitoring of the quantities and usage patterns of antimicrobial agents used in food-producing animals) and with Chapter 6.3 of the *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'.

In the Guidance for Completing the OIE Template for the Collection of Data, countries were asked to provide data from as close to the point of use (i.e., administration) as possible. However, among the 107 countries that reported quantitative data, 'Antimicrobial use data – Farm records' – the category representing on-farm administration of antibiotics – was only selected as a data source by 6 countries (Figure 7). 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 37 and 27 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 7. Data Sources Selected by 107 Countries Reporting Quantitative Data from 2013-2016

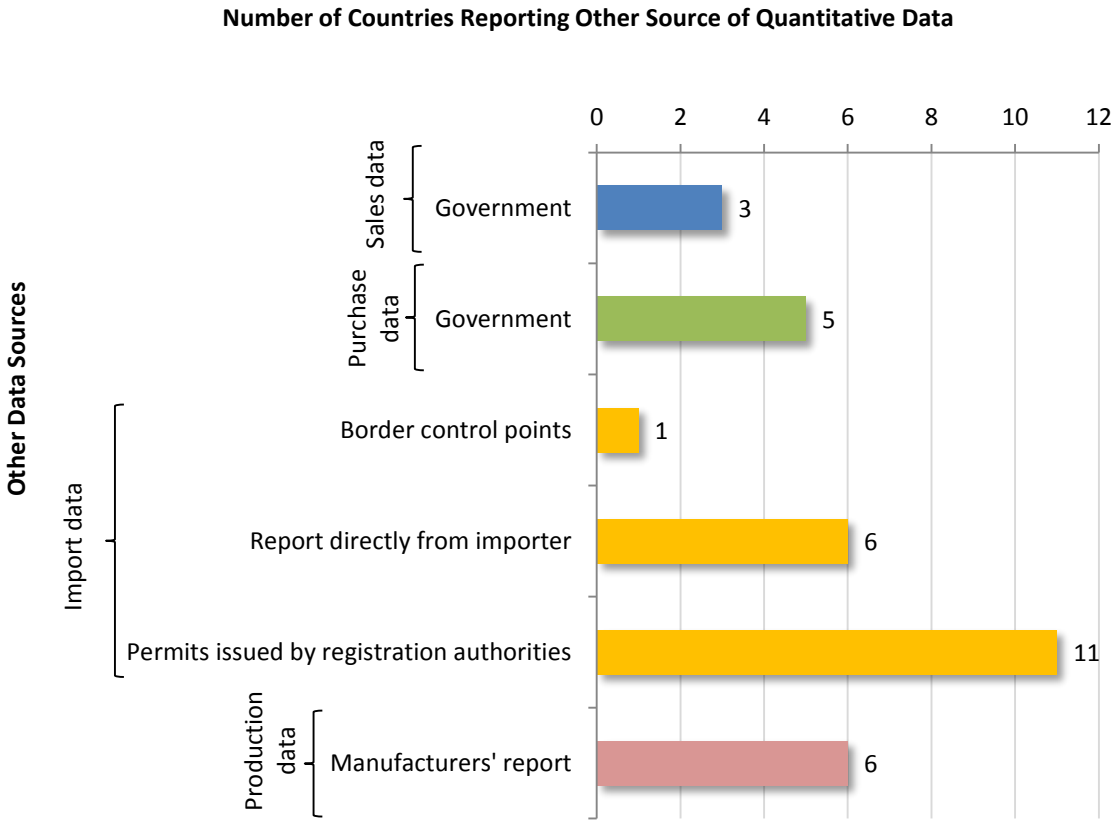


OTHER DATA SOURCES REPORTED

Twenty-four countries (24 of 107; 22%) 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 8). 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 8. 'Other' Source of Data Described by 24 Countries Reporting Quantitative Data from 2013-2016



Quantitative Data Sources Not Captured

Countries were 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 sales in their country. This question was responded to by 103 out of 107 countries that provided quantitative data.

As a global average, quantitative data coverage achieved was 84.5%. 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.

SOURCES NOT CAPTURED BY THE DATA

Countries that did not cover 100% of available quantitative data (60/103; 58%) were asked to provide further information on uncaptured data sources. Responses were grouped by category.

Most of the uncaptured data sources derive from unobtained sales data, 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 20 countries.

Table 3 describes the quantitative data coverage lost due to lack of access to data sources, as estimated by 60 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. This information highlights which data reporting countries deemed necessary to access in order to provide a complete dataset, though these categories may not be relevant to another country's situation.

Table 3. Estimation of Quantitative Data Not Captured Based on Lack of Access to Sources, as Reported by 60 Member Countries in Second Phase of Data Collection

Sources Estimated Not Captured in Quantitative Data	Number of Countries Naming Uncaptured Data Source	Estimated Data Coverage Lost		
		Mean	Minimum	Maximum
Sales data - Illegal or unofficial veterinary products	13	14.5%	5.0%	30.0%
Sales data - Partial response from relevant stakeholders	5	27.3%	2.0%	65.0%
Sales data - Veterinary products with special license*	5	12.8%	0.5%	33.0%
Sales data - Veterinary products	5	15.0%	10.0%	20.0%
Sales data - For all food-producing animal species	2	25.0%	15.0%	35.0%
Sales data - Companion animals	2	8.8%	7.5%	10.0%
Sales data - Selected regions in the country	2	35.0%	20.0%	50.0%
Sales data - Medicated feed	1	1.0%	1.0%	1.0%
Purchase data - Partial response from relevant stakeholders	4	20.2%	12.5%	33.0%
Import data – Illegal or unofficial veterinary products	10	8.6%	0.5%	15.0%
Import data – Ministry of Health and human pharmacies	5	21.0%	10.0%	60.0%
Import data - Partial response from relevant stakeholders	5	20.0%	20.0%	20.0%
Import data - Active ingredient	1	20.5%	5.0%	70.0%
Production data - Manufacturer's report	5	16.0%	15.0%	20.0%
Production data - Partial response from relevant stakeholders	2	11.3%	10.0%	12.5%
Production data - Feed mills for self-supply	1	20.0%	20.0%	20.0%
Antimicrobial use data - Farm records	4	15.0%	5.0%	25.0%

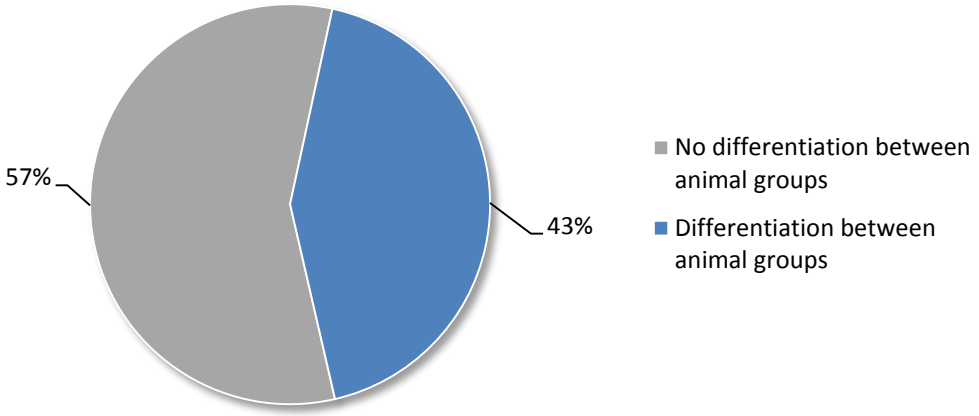
* For the purpose of this report, 'Veterinary products with special license' means: veterinary products for self-supply, donation or with special permission from the government

Quantitative Data Differentiation by Animal Groups

The majority of countries reporting quantitative data (63 of 107; 59%) were unable to distinguish which groups of animals the reported antimicrobial quantities were intended to be used in (Figure 9). For the purposes of the OIE database, animal groups are separated into: 'Terrestrial food-producing animals', 'Aquatic food-producing animals' and 'Companion animals'.

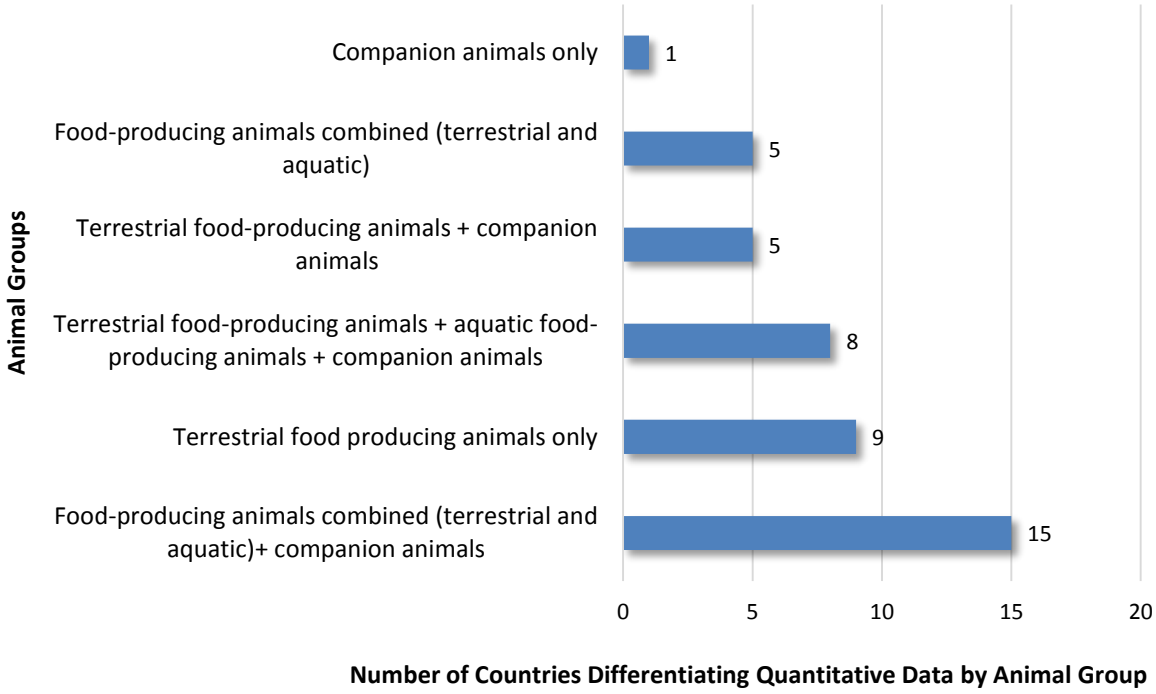
Most of the data comes from sales and imports and the attribution of antimicrobial quantities by animal group is based on species types represented on product labels, where this is available and specified. For countries where product labels cover a wide variety of species, it would be more difficult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

Figure 9. Differentiation by Animal Groups Among 107 Countries Reporting Quantitative Data from 2013-2016



Forty-three countries of those reporting quantitative data (43 of 107, 40%) were able to distinguish amounts of antimicrobial agents by groups of animals. Multiple options were possible when choosing differentiation by animal groups (Figure 10). Most countries were able to report data for companion animal separately from data for food-producing animals, though many were not able to distinguish antimicrobials used in aquatic and terrestrial food-producing species.

Figure 10. Representation of Quantitative Data from 43 Countries Able to Distinguish by Animal Group from 2013-2016



Sixty-three countries of those reporting quantitative data (63 of 107; 59%) were not able to distinguish amounts of antimicrobial agents by groups of animals. Of these, most (54 of 63; 86%) reported antimicrobial quantities through Reporting Option 1, which allows reporting for all animal species, and distinguishes quantities only by purpose of use (therapeutic or growth promotion). Nine of these countries (9 of 63; 14%) 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 route of administration. This suggests that the labelling of veterinary products in these countries more clearly separates how the product should be administered than what species it should be applied in.

Eight countries (8 of 44; 18%) were able to report quantitative data for 'Aquatic food-producing animals' separately from other animal groups using Reporting Option 3.

Food-Producing Animal Species Covered by Quantitative Data

Animal species produced for food varies between countries. Understanding these differences between countries is necessary for planning analysis of reported antimicrobial quantities adjusted for animal biomass (see section 4).

The 107 countries that provided quantitative data were asked to pick the food producing animal species covered by their data from a supplied list in the OIE template. The breakdown food producing species included in the reporting countries datasets is shown in Figure 11.

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

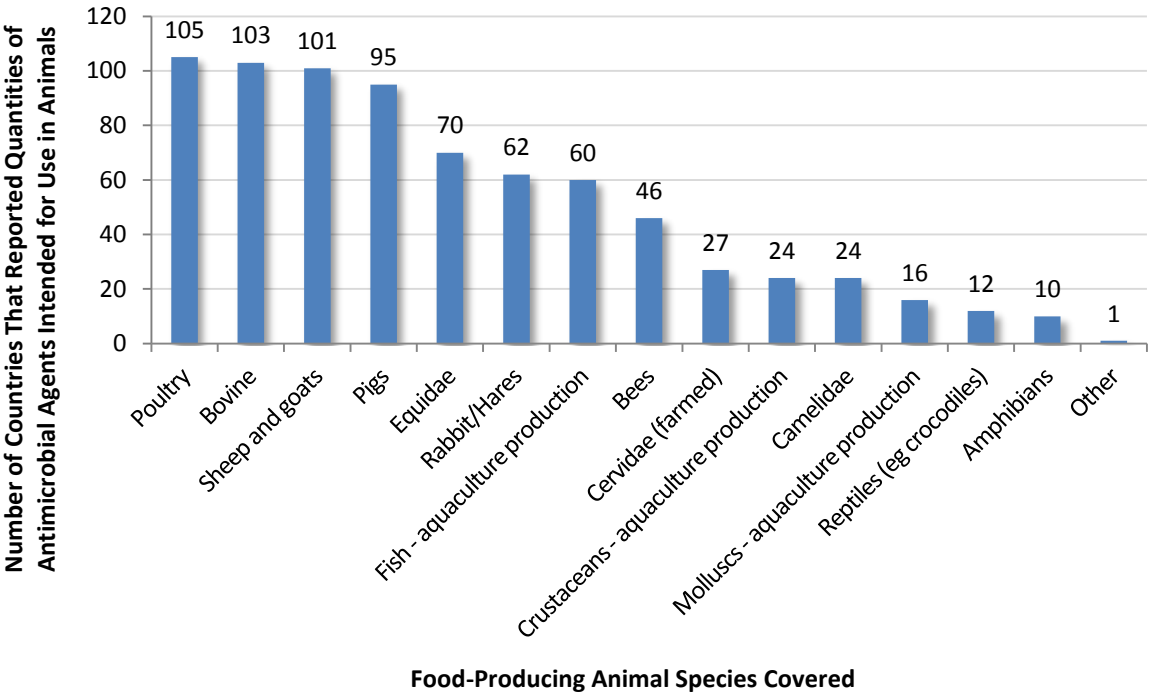
C. SHEEP AND GOATS
- *a.* Sheep
- *b.* Goats
- *c.* Sheep and goats (mixed flocks)

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

One country that provided data for companion animals only was excluded from Figure 11.

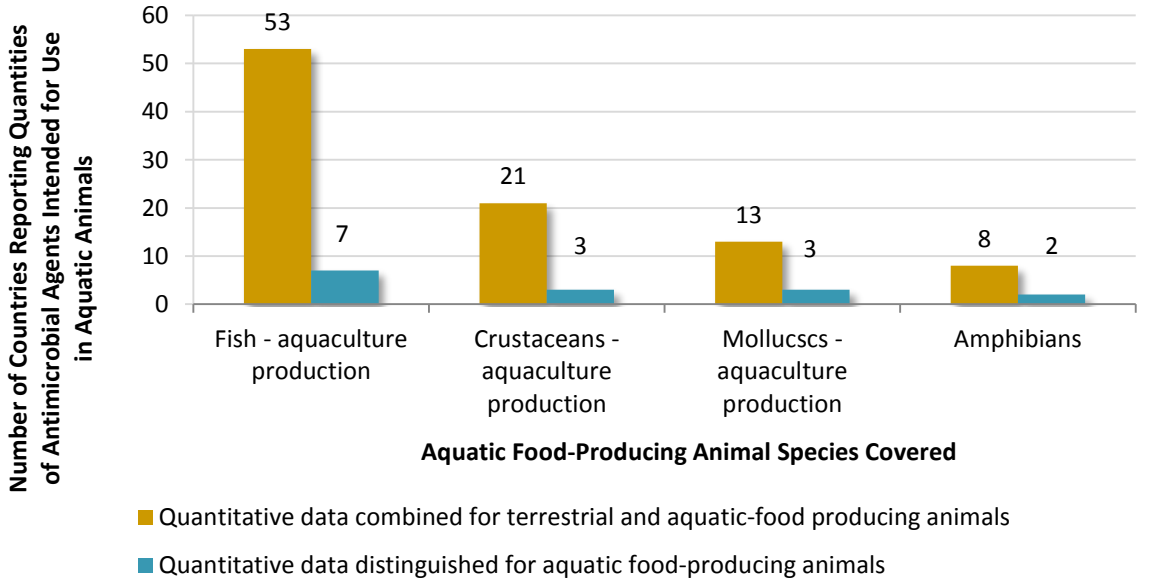
In the second phase of data collection, poultry was mentioned by all 106 countries reporting quantitative data for food-producing species. Cattle, sheep and goats, and pigs were also included by most countries (Figure 11).

Figure 11. Food-Producing Animal Species Included in Quantitative Data Reported by 106 Countries from 2013-2016



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 only when data for 'Fish – aquaculture production' were also available. Figure 12 highlights the aquatic food-producing species covered by countries reporting quantitative data, separated by capacity to distinguish data for terrestrial and aquatic food-producing animals.

Figure 12. Aquatic Food-Producing Animal Species Included in Quantitative Data Reported by 60 Countries from 2013-2016



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 second phase of data collection, 65% of countries did not publish national reports on quantities of antimicrobial agents used in animals online (70/107), Europe is the only region where more than 50% of countries' national reports are available on the Web. The OIE encourages all Member Countries to publish their own national reports on the sales or use of antimicrobial agents in animals, to ensure transparency and to assess trends.

Routes of Administration

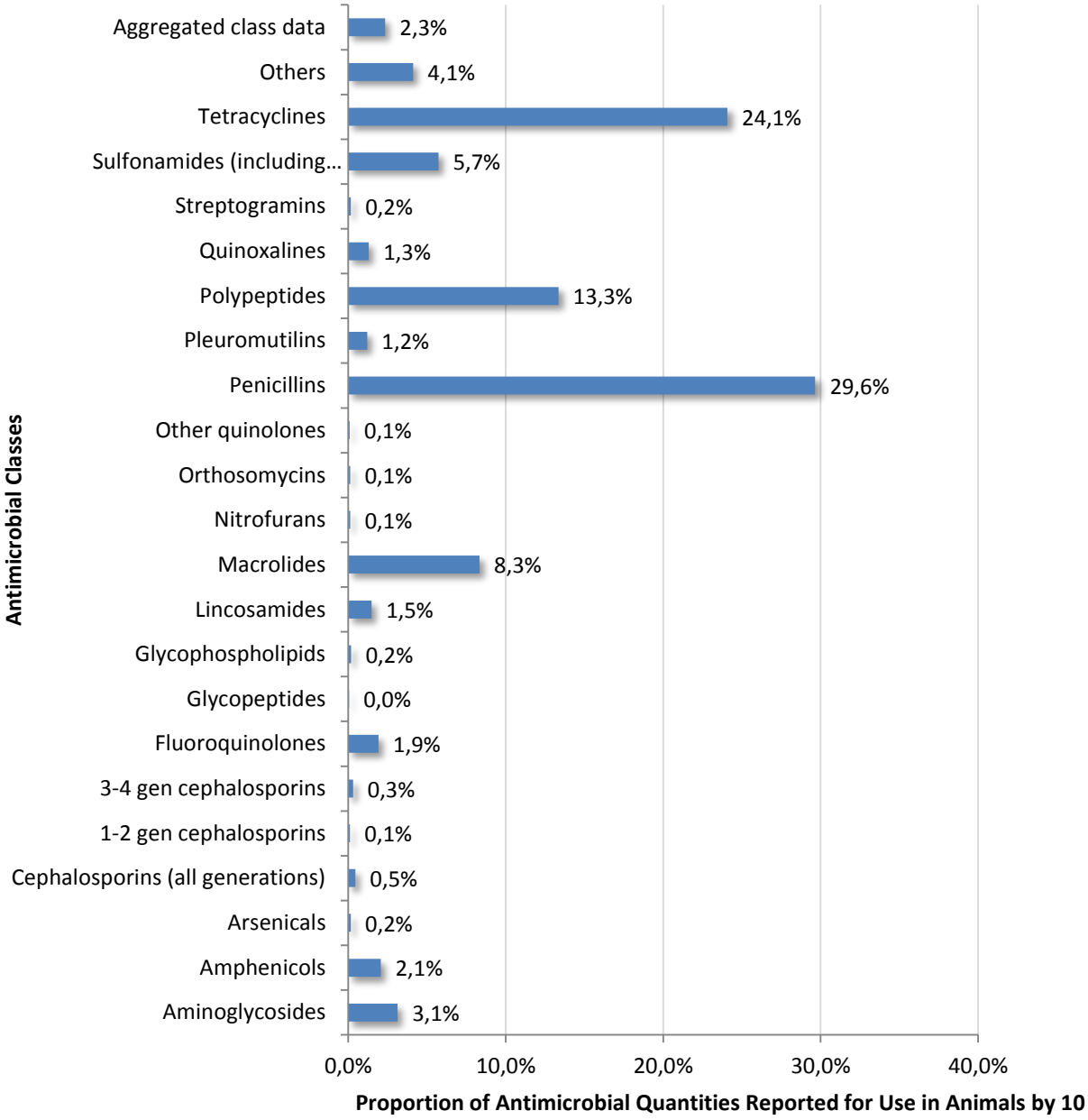
During the second phase of data collection, 40 countries chose to report their quantitative data through Reporting Option 3, the only option which allows for distinction of the data by route of administration. Among these 40 countries, a majority reported higher amounts of antimicrobial agents used via injection route.

Reporting Option 3 allows for distinction of the data by type of use (therapeutic vs growth promotion) and animal groups in addition to route of administration. However, 10 of the 40 countries 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 countries able to distinguish quantitative data by animal groups using Reporting Option 3 (30 out of 40 countries), 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.

Antimicrobial Classes Reported

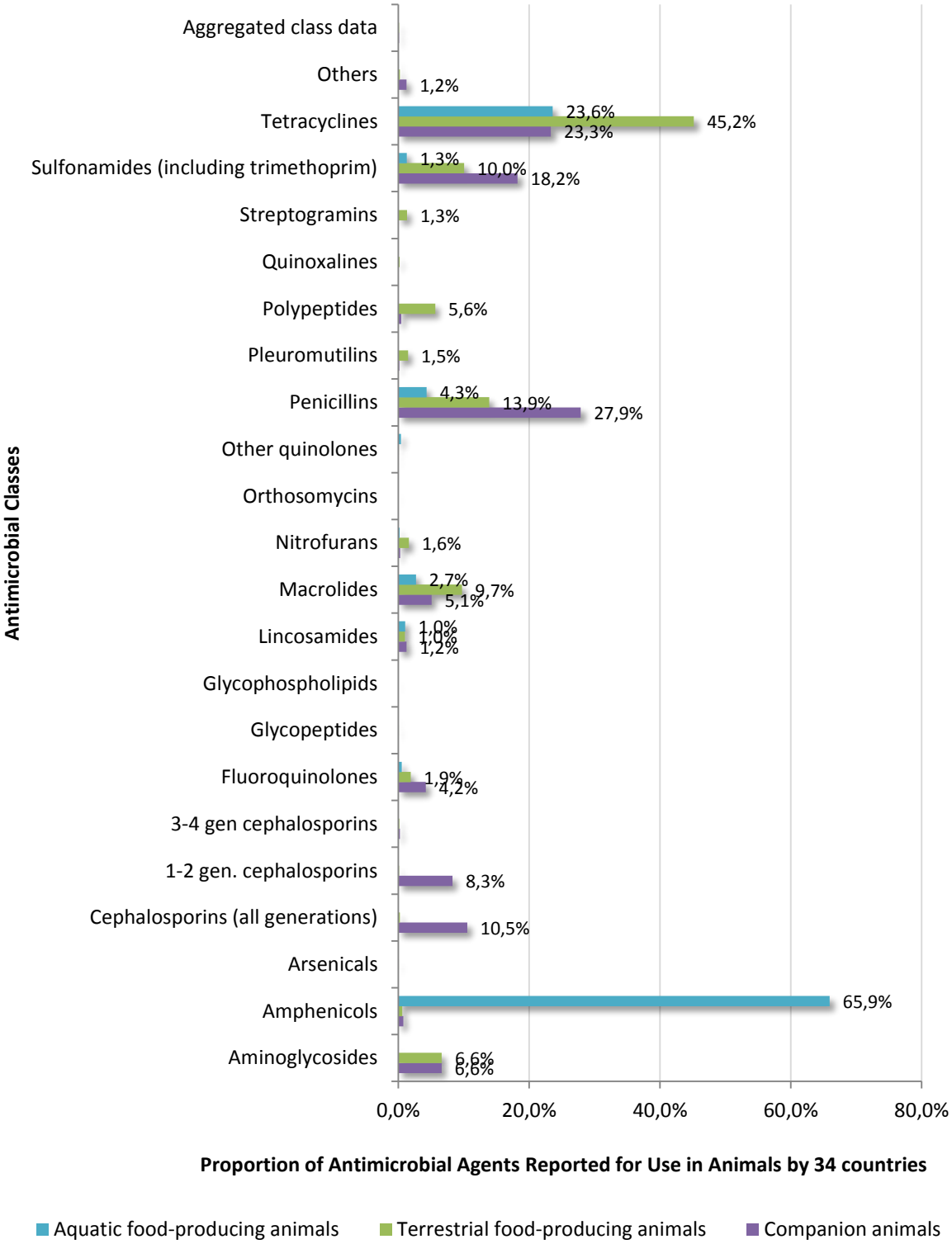
Among the 107 countries providing quantitative data on antimicrobial agents intended for use in animals during the second phase of data collection, penicillins were the most commonly reported antimicrobial class (Figure 13).

Figure 13. Proportion of Antimicrobial Quantities (by Antimicrobial Class) Reported for Use in Animals by 107 Countries from 2013-2016



Thirty-four countries of 107 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. Penicillins were more commonly reported for companion animals, and amphenicols for aquatic food-producing animals (Figure 14).

Figure 14. Proportion of Antimicrobial Classes by Groups of Animals as Reported by 34 Countries from 2013-2016



*For legibility, labels for values below 1.00% were deleted from this figure

3.3. Analysis by OIE Region

The OIE has Regional and Sub-Regional offices in Africa, the Americas, Asia and the Pacific, Europe and the Middle East. The data collection template was sent to all OIE Member Countries from all OIE Regions. In addition, new in the second phase of data collection, the data collection template was also sent to non-OIE Member Countries that asked to be part of the database. The list of all OIE Member Countries is provided in Annex 9.

In the second phase of data collection, from October 2016 to May 2017, 146 countries submitted completed templates to the OIE Headquarters: 143 from OIE Member Countries (79% of 180 Member Countries) and 3 non-OIE Member Countries (Table 4). The proportion of responses received from the different OIE Regions varies from 33% to 100% (Figure 15). Responses from non-OIE Member Countries were included in the analysis of the Americas for geographical reasons.

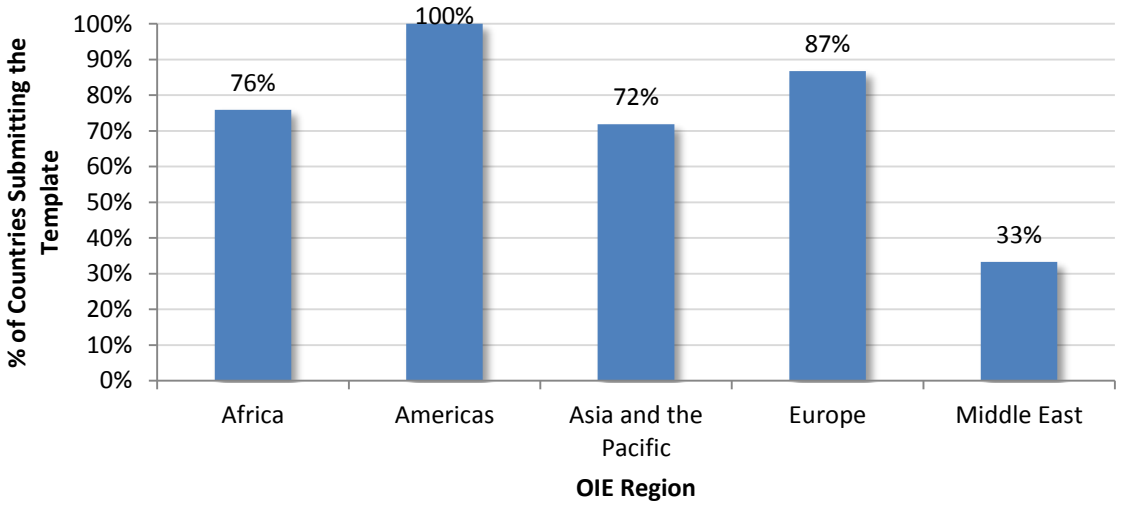
For specific information for the OIE Region, please see the Annex for each region (Annexes 1-5).

Table 4. Number of Countries that Responded to the OIE Template in the Second Phase of Data Collection, by OIE Region

OIE Region	Number of Countries that Submitted Templates by OIE Region	Number of OIE Member Countries*
Africa	41	54
Americas**		
Member Countries	29	29
Non-OIE Member Countries	3	n/a
Asia and the Pacific	23	32
Europe	46	53
Middle East	4	12

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

Figure 15. Percentage of Countries that Responded to the OIE Template in the Second Phase of Data Collection, by OIE Region



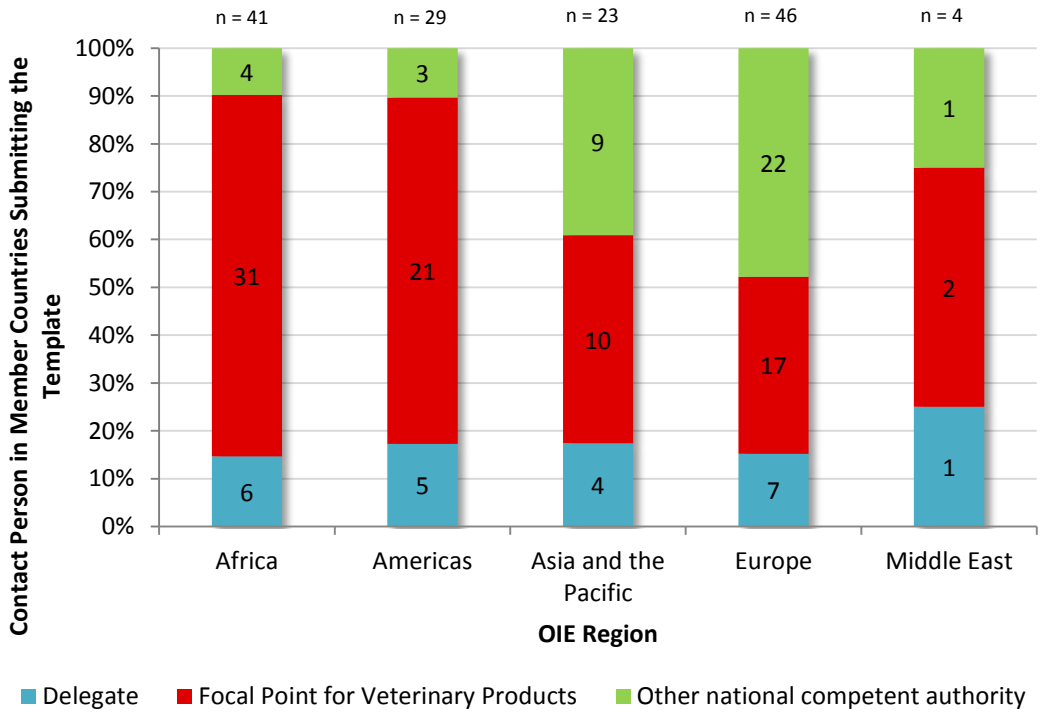
Profile of the Contact Person

Each OIE Member Country 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.

Given that OIE Delegates and National Focal Points only exist in OIE Member Countries, the following analysis on contact persons does not include non-OIE Member Countries.

The OIE recognises the efforts of National Focal Points for Veterinary Products, as in most Member Countries, the National Focal Point for Veterinary Products was responsible for completion of the template. Nevertheless, in Europe and Asia-Pacific, the Focal Points were less often responsible for responding to the template than another national competent authority. This result may be linked to differing levels of progress in development of data collection systems, where a specific person may already be dedicated to this topic (Figure 16).

Figure 16. Regional Proportion of Contact Person in 143 Member Countries that Submitted the OIE Template in the Second Phase of Data Collection



Reporting Options

When differentiated by OIE Region, more Member Countries from Europe provided quantitative data than other OIE Regions and systematically chose a more advanced Reporting Option to do so (Figures 17 and 18). Most European 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 in September 2009.

Of the European Member Countries reporting quantitative data, most did so through Reporting Option 3 (24 of 40), which allows distinction by routes of administration in addition to animal groups and type of use. However, 6 of the 24 did not distinguish quantitative data by animal group and instead reported under 'All animal species'.

Figure 17. Data Type Provided by 146 Countries Responding the OIE Template in the Second Phase of Data Collection, by OIE Region

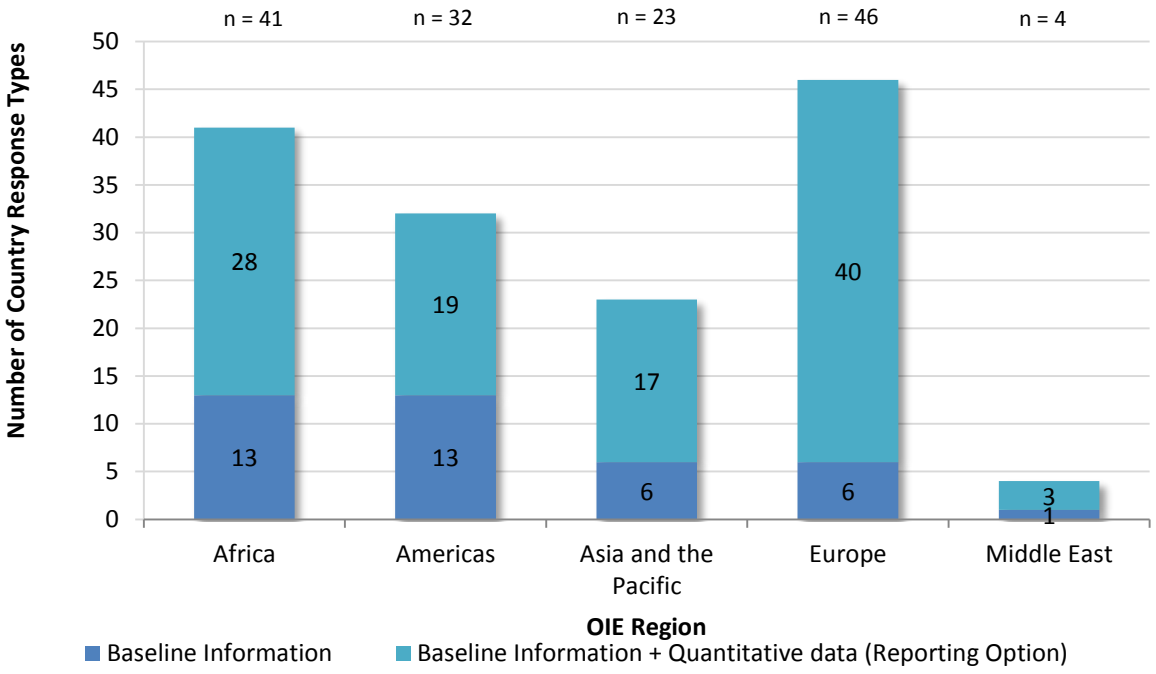
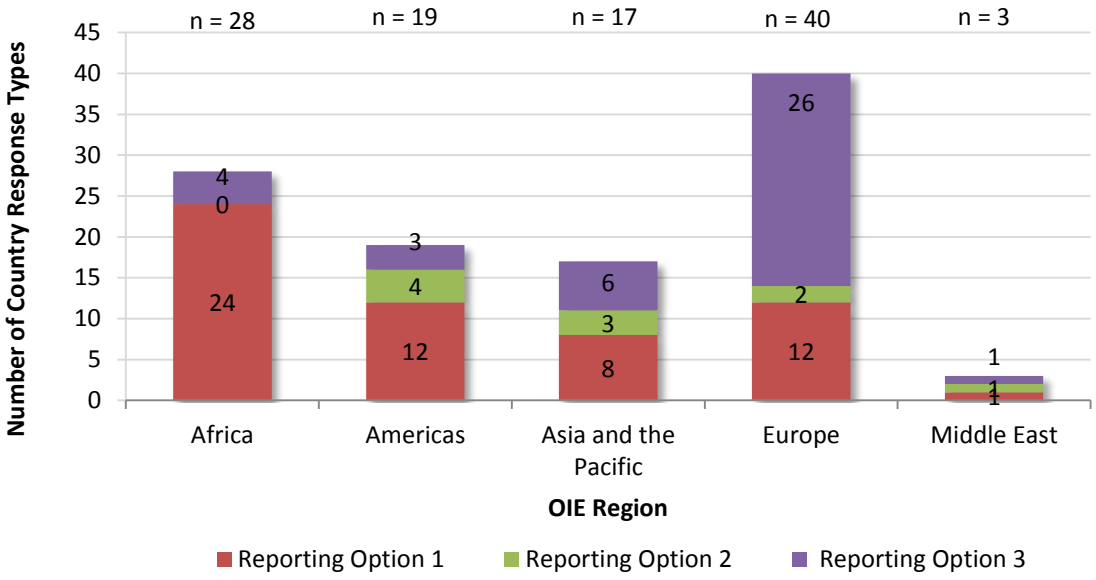


Figure 18. Reporting Option Used to Provide Quantitative Data by 107 Countries in the Second Phase of Data Collection, by OIE Region



Antimicrobial Agents Used for Growth Promotion

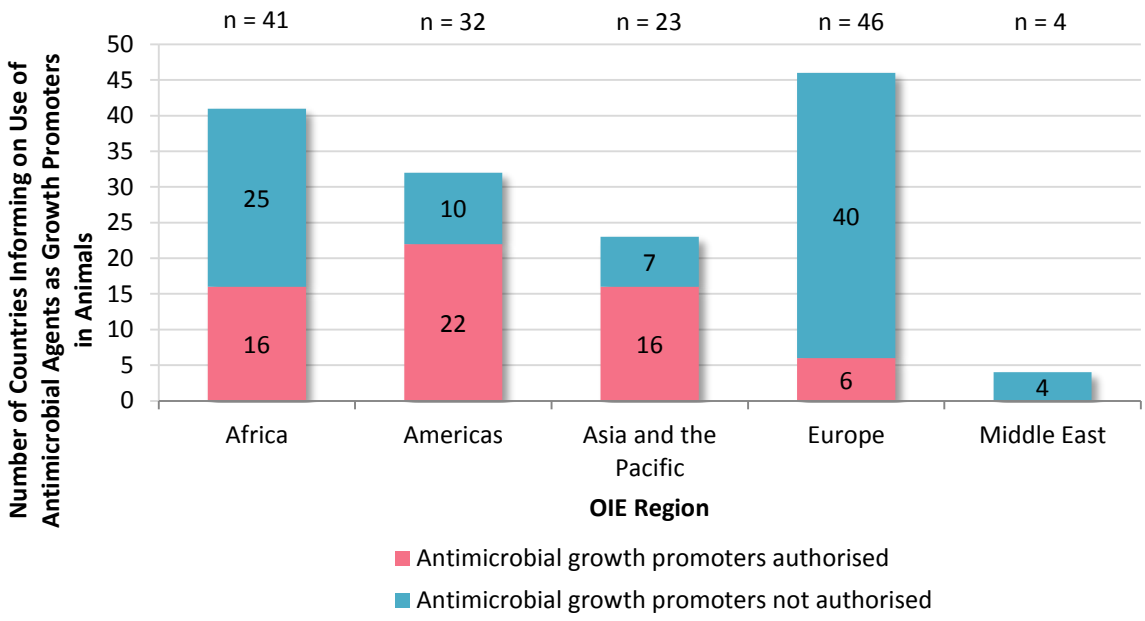
In the 2016 OIE General Session, Member Countries adopted Resolution No36, "Combating Antimicrobial Resistance through a One Health Approach: Actions and OIE Strategy", agreeing to the recommendation that:

5. 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 for use 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.

When differentiated by OIE Region, the Americas and Asia-Pacific have the highest proportions of countries using antimicrobial growth promoters (Figure 19). 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 the use or authorisation of antimicrobial growth promoters.

Figure 19. Number of Countries Authorising Use of Antimicrobial Agents for Growth Promotion in Animals in 2016, of 146 Responding Countries, by OIE Region



LACK OF REGULATORY FRAMEWORK FOR ANTIMICROBIALS USED AS GROWTH PROMOTERS

In the template and guidance sent, countries with no legislation or regulation on the use of antimicrobial growth promoters, but where the use of antimicrobial agents for growth promotion was known to occur, were asked to respond 'Yes' to the question *Are antimicrobial growth promoters authorised for use in your country?*

Sixty countries responded 'yes' to this question and were asked for further clarification on their responses. Twenty-three of these 60 countries then further described a lack of regulatory framework for use of antimicrobials as growth promoters in their countries.

Among these countries, a regulatory framework for use of antimicrobial agents as growth promoters was found to be lacking at the following rates in the OIE Regions: Africa 63% (10/16), the Americas 27% (6/22), Asia and the Pacific 38% (6/16) and Europe 17% (1/6). Based on these results, African countries frequently reported that a regulatory framework on antimicrobial growth promoters was lacking.

For more information on this question, please see the sub-section relevant to growth promoters in Section 3.1, Global Analysis.

4. Focus on 2014: Additional Analysis of Antimicrobial Quantities

This section provides for the first time an analysis of globally reported quantitative data on antimicrobial agents intended for use in animals adjusted by animal biomass, focusing on 2014.

This analysis has been done with the understanding that many countries contributing to the OIE database are in the first stages of development of their national surveillance 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

Years Covered by Quantitative Data in First and Second Phases of Data Collection

During the first and second phases of data collection on antimicrobial agents intended for use in animals, 116 countries provided at least one year of quantitative data for one or more years between 2010-2016.

As seen in Figure 20, 2014, the target year for second phase of data collection, had the highest number of submissions of quantitative data (62 Member Countries). As such, it was decided that 2014 would be the focus of the analysis of quantitative data adjusted for animal biomass, using data from the first two phases of data collection.

While there were also a high number of submissions for 2015, these were not analysed at this time as it is expected that these data will be refined with reporting countries in the coming year.

Figure 20. Number of Countries Globally Reporting Quantitative Data per Year from 2010-2016, During the First and Second Phases of Data Collection

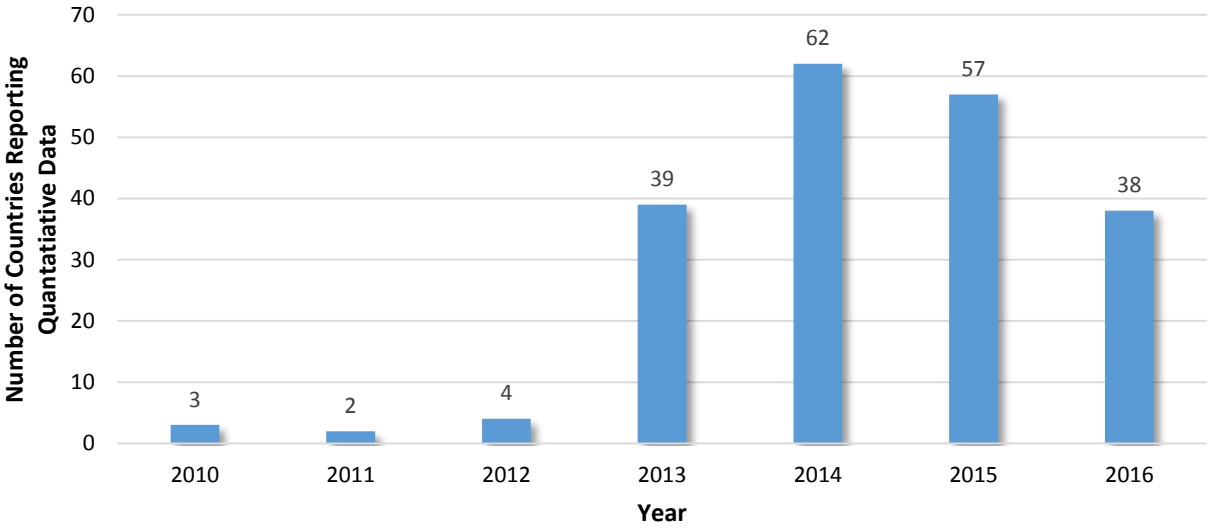
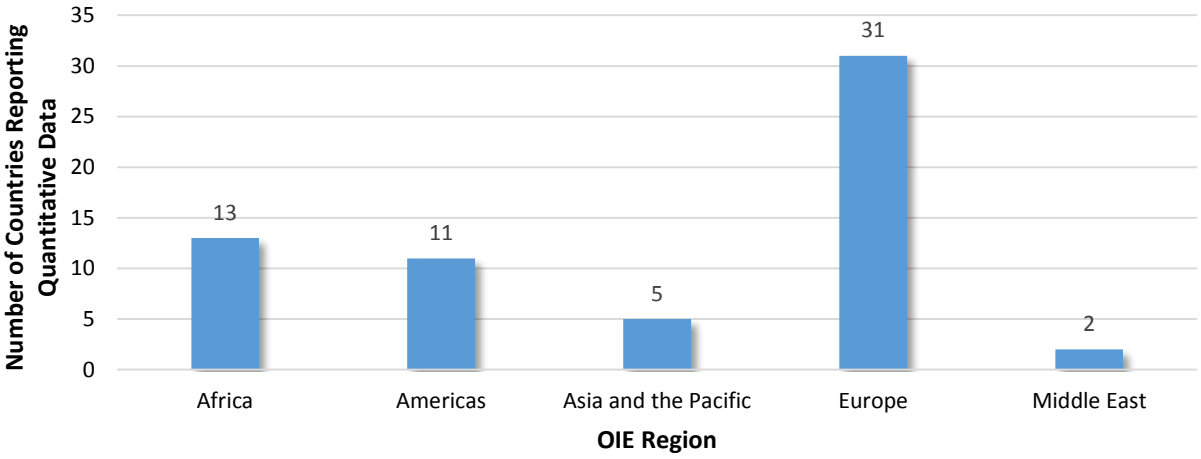


Figure 21 highlights the distribution by OIE Region of countries providing quantitative data for 2014. Due to geographic considerations, two non-OIE Member Countries providing quantitative data for 2014 were included in the Americas for the 2014 analysis.

In order to maintain the confidentiality of reporting countries, the two countries from the Middle East were excluded from the remainder of the 2014 analysis. Future data submissions from this OIE Region may permit a 2014 analysis of antimicrobial quantities adjusted by animal biomass for the Middle East in following reports.

Figure 21. Number of Countries by OIE Region Reporting Quantitative Data for 2014

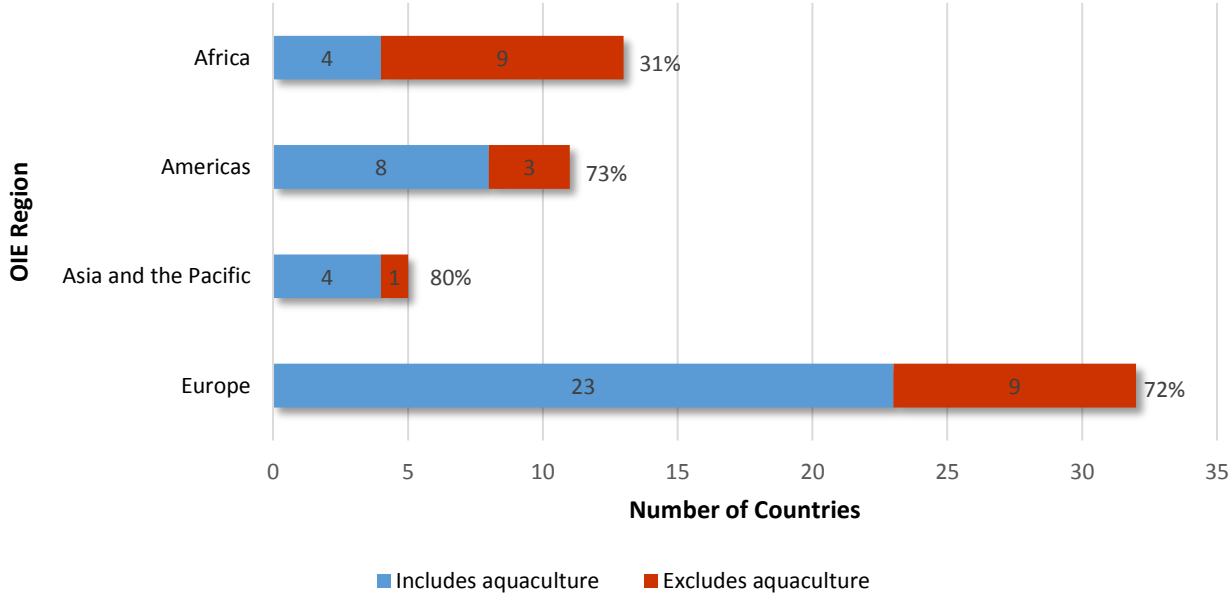


Animal Groups Covered by Data in 2014

Of the countries providing quantitative data for 2014, 39 countries (65% of 60 countries) reported that in addition to terrestrial animals, their data covered aquatic food-producing animal species.

As shown in Figure 22, the highest proportion of countries including aquatic food-producing animals in the reported quantitative data on antimicrobial agents was in Asia and the Pacific (80%, 4 of 5 countries). The Americas and Europe showed similar results with 73% (8 of 11 countries) and 72% (23 of 31 countries) respectively. 31% countries in Africa (4 of 13 countries) reporting quantitative data included aquatic food-producing animal species.

Figure 22. Countries Including Aquatic Food-Producing Animal Species in Quantitative Data for 2014



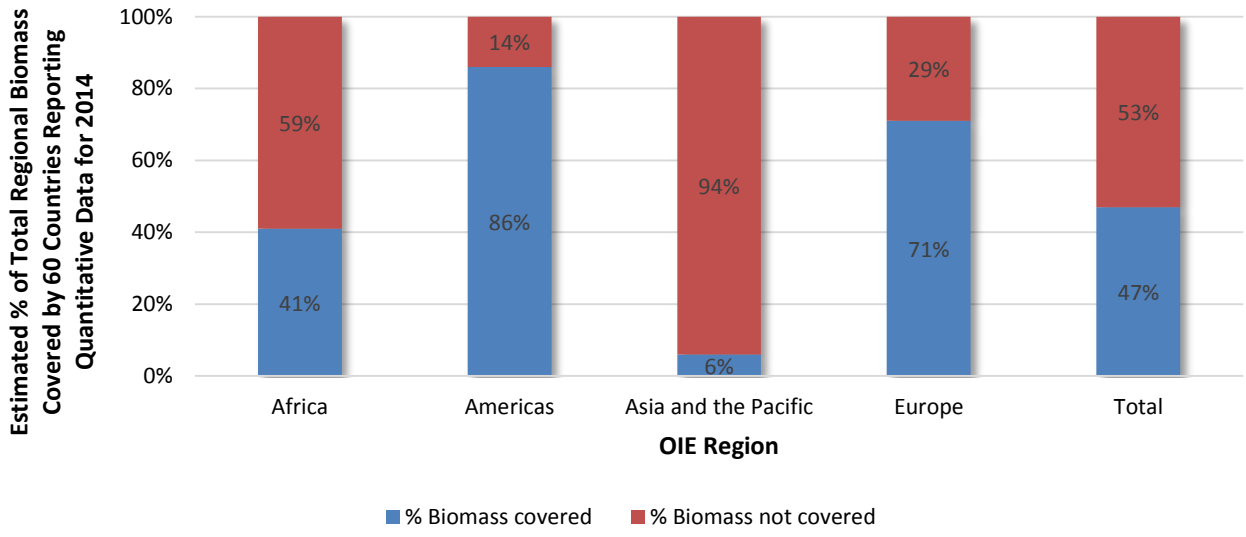
Animal Population Covered by Data in 2014

Figure 23 shows the estimated percentage of the total regional animal biomass covered by the 60 countries included in the analysis of antimicrobial quantities for 2014. These estimates were made by calculating the ratio of FAOSTAT 2014 indigenous meat production figures for the reporting countries, relative to the regional total.

The Americas and Europe had particularly high animal population coverage for 2014, with responding countries representing approximately 86% and 71% of the regions' total animal biomasses, respectively. Africa's biomass coverage was approximately 41%. Asia and the Pacific represented the lowest animal population coverage for 2014, with responding countries representing approximately 6% of the total possible animal biomass for the OIE Region. Coverage of total regional biomass for both Africa and Asia-Pacific is expected to increase for 2015, based on the number of countries that have already reported quantitative data.

From the 60 countries included in the 2014 analysis, the estimated coverage of total animal biomass from the four OIE Regions is 47%.

Figure 23. Estimated Percentage of Total Regional Biomass Covered by 60 Countries Reporting Quantitative Data for 2014



TONNAGE OF ANTIMICROBIAL QUANTITIES REPORTED IN 2014

Tables 5 and 6 show the total tonnage of antimicrobial agents intended for use in animals for 2014, as reported to the OIE in the first and second phases of data collection.

It is important to remark that 8 countries (13% of 60 Member Countries) providing quantitative data for 2014 during the first phase of data collection updated these results during the second phase. Reasons cited for these updates included errors in the original calculations of kilograms of active ingredients, changes in period of time covered or new data sources allowing for increased data coverage at a national level. The figures used for this analysis are the most up-to-date quantitative data reported to the OIE.

The number of countries providing quantitative data is significant to its interpretation, but also, the size and composition of each country's animal populations. 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 5. Reported Quantity of Antimicrobial Agents Intended for Use in Animals by OIE Region, 2014

OIE Region	Number of Countries Reporting Quantitative Data for 2014	% of Total Estimated Biomass	Quantities Reported (in tonnes)
Africa	13	41%	3,869
Americas	11	86%	26,271
Asia and the Pacific	5	6%	3,396
Europe	31	71%	8,891
Total	60	47%	42,427

In the OIE template for quantitative data collection, countries were also 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.

When the antimicrobial quantities reported were adjusted for these coverage estimates, the following quantities as shown in Table 6 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.

Table 6. Reported Quantity of Antimicrobial Agents Intended for Use in Animals by OIE Region, 2014, Adjusted by Estimated Coverage

OIE Region	Number of Countries Reporting Quantitative Data for 2014	% of Total Estimated Biomass	Quantities Reported (in tonnes)
Africa	13	41%	4,279
Americas	11	86%	40,579
Asia and the Pacific	5	6%	3,833
Europe	31	71%	9,220
Total	60	47%	57,911

4.2. Animal Biomass

As described in the methodology, animal biomass was calculated for 60 countries providing quantitative data for 2014 in the first and second phases of data collection. Farmed fish were included in the biomass for countries reporting that their data covered aquaculture, or could not be distinguished by animal group (39 countries, 65%)

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 Biomass Covered by the 2014 Additional Analysis: Global View

Table 7 shows the animal biomass (in 1,000 tonnes) of farmed animals covered by quantitative data reported to the OIE for 2014, during the first two phases 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 2014.

Table 7. Animal Biomass Covered by Quantitative Data Reported to the OIE for 2014, Results for 60 Countries

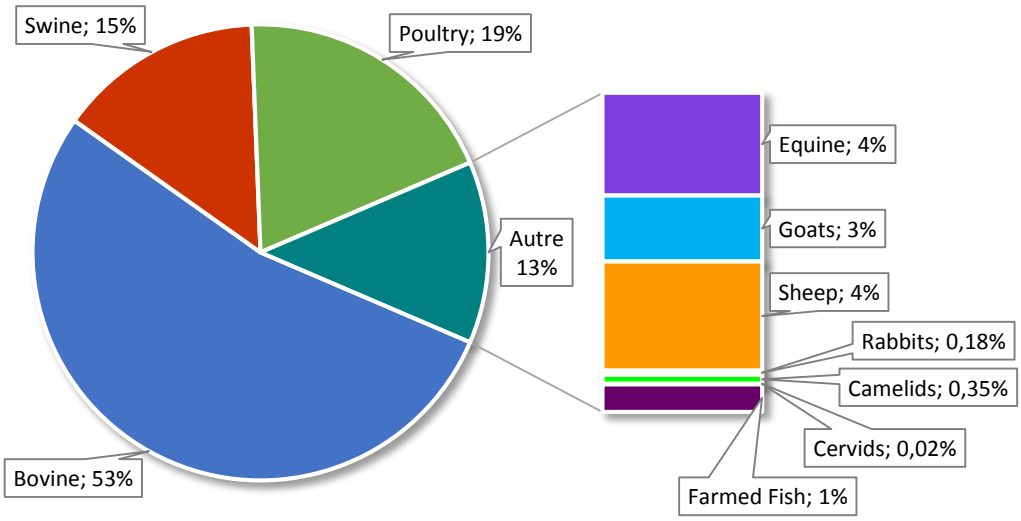
Animal species	Biomass (in 1,000 tonnes)	Percent of Results for 60 Countries
Bovine	230,060	53%
Swine	62,804	15%
Poultry	82,771	19%
Equine	17,895	4%
Goats	11,458	3%
Sheep	18,983	4%
Rabbits	756	0.18%
Camelids	1,527	0.35%
Cervids	97	0.02%
Farmed Fish	4,825	1%
All Species	431,177	100%

Figure 24 shows the global species composition of animals at risk for exposure to the antimicrobial quantities reported to the OIE for 2014. These percentages are a function of animal populations in the reporting countries, as well as their average weights.

Globally, bovines (53%) make up the largest contribution to animal biomass for the quantitative data reported. Swine (35%) and poultry (19%) also play a significant role, with equines (4%), sheep and goats (4% and 3% respectively) and farmed fish (1%) playing relatively minor roles in this analysis. The contributions of rabbits (0.18%), camelids (0.35%), and cervids (0.02%) are negligible for the covered countries.

These percentages may change significantly 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 24. Species Composition of Animal Biomass for 60 Countries Reporting Quantitative Data for 2014



Animal Biomass Covered by the 2014 Additional Analysis: Regional View

Table 8 highlights the regional species composition of biomass by OIE Region, for 60 countries submitting quantitative data for 2014 in the first two years of the data collection.

Table 8. Animal Biomass Covered by Quantitative Data Reported to the OIE for 2014, Regional Results for 60 Countries

	Africa	Americas	Asia and the Pacific	Europe
Number of Countries	13	11	5	31
Bovine Biomass (in 1,000 tonnes)	32,502	154,926	3,184	39,448
Swine Biomass (in 1,000 tonnes)	934	24,509	5,580	31,782
Poultry Biomass (in 1,000 tonnes)	3,494	54,813	4,527	19,937
Equine Biomass (in 1,000 tonnes)	3,427	11,604	1,59	2,705
Goat Biomass (in 1,000 tonnes)	9,629	1,079	236	514
Sheep Biomass (in 1,000 tonnes)	9,237	3,542	4	6,200
Rabbit Biomass (in 1,000 tonnes)	55	30	0	671
Camelid Biomass (in 1,000 tonnes)	1,485	36	0	6
Cervid Biomass (in 1,000 tonnes)	0	29	2	66
Farmed Fish Biomass (in 1,000 tonnes)	326	1,965	1,172	1,362
All Species Biomass (in 1,000 tonnes)	61,088	252,534	14,864	102,691

Regional biomass covered by the reported quantitative data (Table 8) is affected by the number and characteristics of countries providing quantitative data in each OIE Region, including the relative size and average weights of their animal populations in 2014. Therefore, the composition of animal biomass is better represented as percentage of total biomass for the Region (Figures 25-28).

Figure 25. Species Composition of Animal Biomass for the 13 Countries in Africa Reporting Quantitative Data for 2014

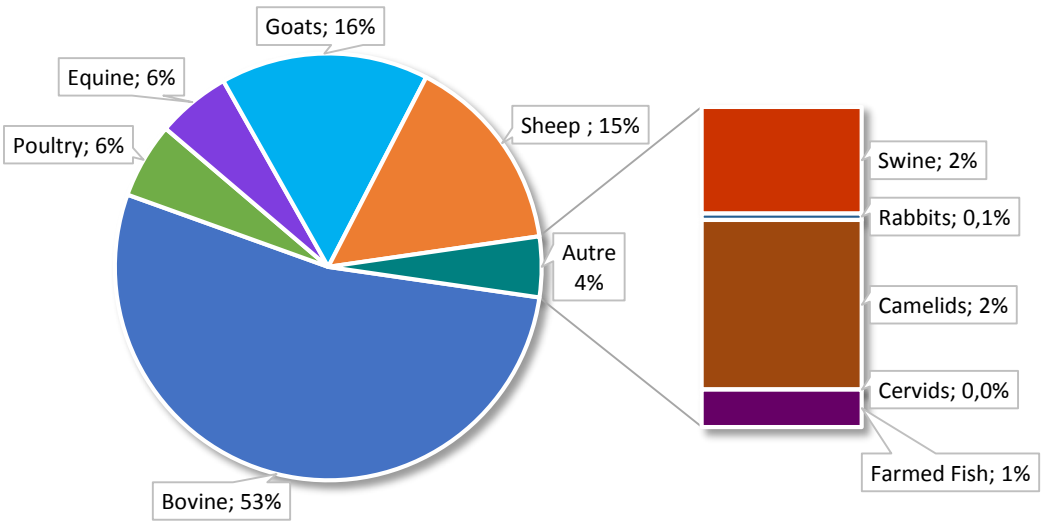


Figure 26. Species Composition of Animal Biomass for the 11 Countries in the Americas Reporting Quantitative Data for 2014

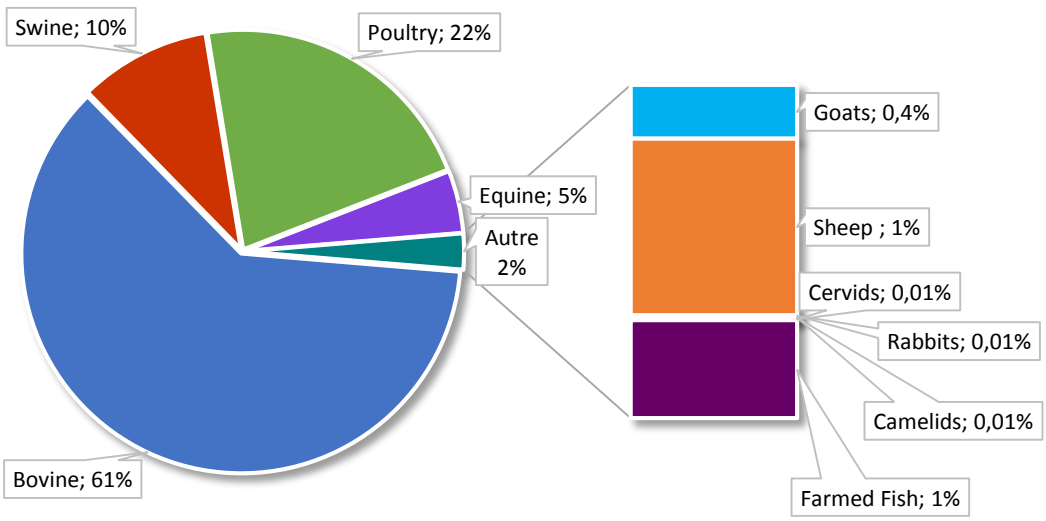


Figure 27. Species Composition of Animal Biomass for the 5 Countries in Asia and the Pacific Reporting Quantitative Data for 2014

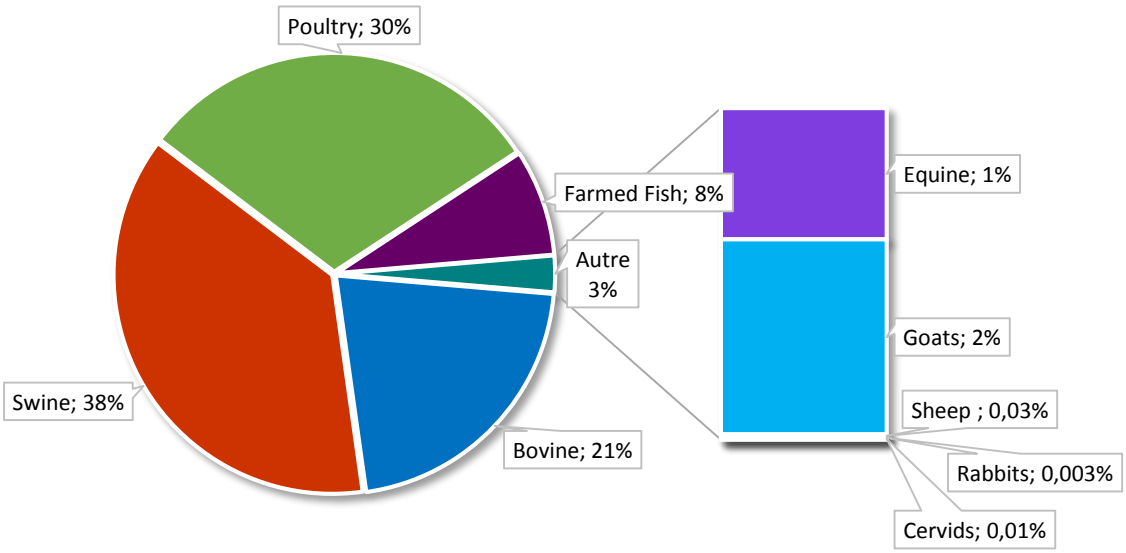
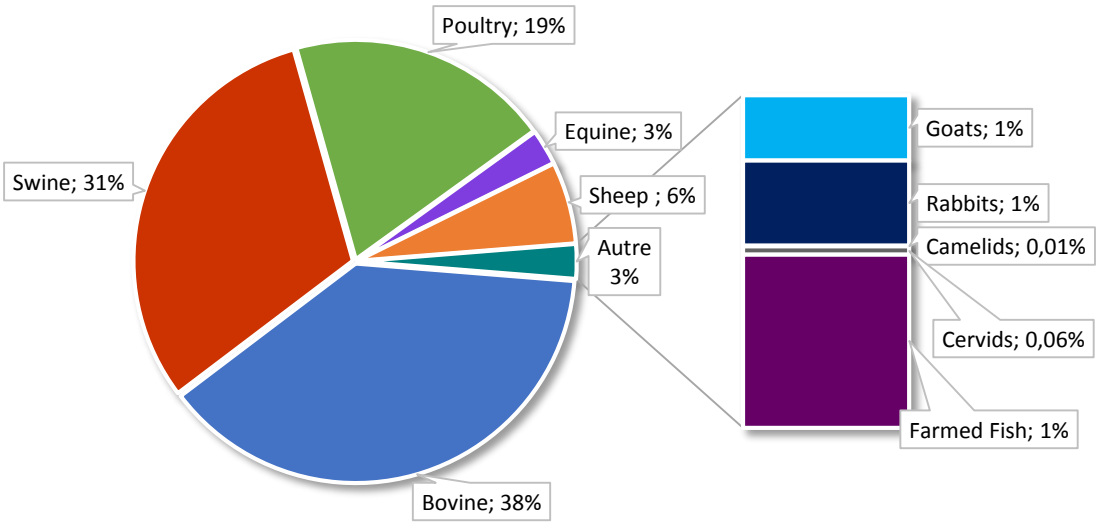


Figure 28. Species Composition of Animal Biomass for the 31 Countries in Europe Reporting Quantitative Data for 2014



TERRESTRIAL ANIMALS

In this analysis, bovines were the most significant[13] contributor to biomass in the Americas (61%), followed by Africa (53%), and Europe (38%). In Asia and the Pacific, swine (38%) surpassed bovines (21%) as the most significant contributor to biomass. Swine were also significant in Europe (31%), and relatively less so in the Americas (10%) and Africa (2%). Poultry were also a major species in Asia and the Pacific (30%), Europe (19%) and the Americas (22%), but were relatively minor in Africa (6%).

[13] The use of the term 'significant' in this section does not denote statistical significance. Statistical analysis could not be undertaken at this stage as only one year of data was adjusted for animal biomass.

In most regions, sheep and goats were a minor contributor to biomass (6% and 1% respectively in Europe, 0.03% and 2% respectively in Asia and the Pacific, and 1% and 0.4% respectively in the Americas). In Africa, sheep and goats were far more relatively significant, contributing 15% and 16% to the total biomass respectively.

Rabbits were most significant in Europe, contributing 1% to the total biomass. Camelid species were most significant in Africa (contributing 2% to the total biomass). Cervids had a negligible impact on biomass (<1%) in all OIE Regions.

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 underestimate the significance of species that are often slaughtered outside of slaughterhouses for personal consumption. The amount of slaughter done outside slaughterhouses and the extent to which this population is captured in slaughter data is expected to vary significantly between countries and regions.

AQUATIC ANIMALS

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 regional aquaculture production.

For the purposes of the 2014 analysis of quantitative data, aquaculture was most significant in Asia and the Pacific, where farmed fish made up 8% of the covered animal biomass. In the three other OIE Regions, farmed fish made up 1% of the covered animal biomass.

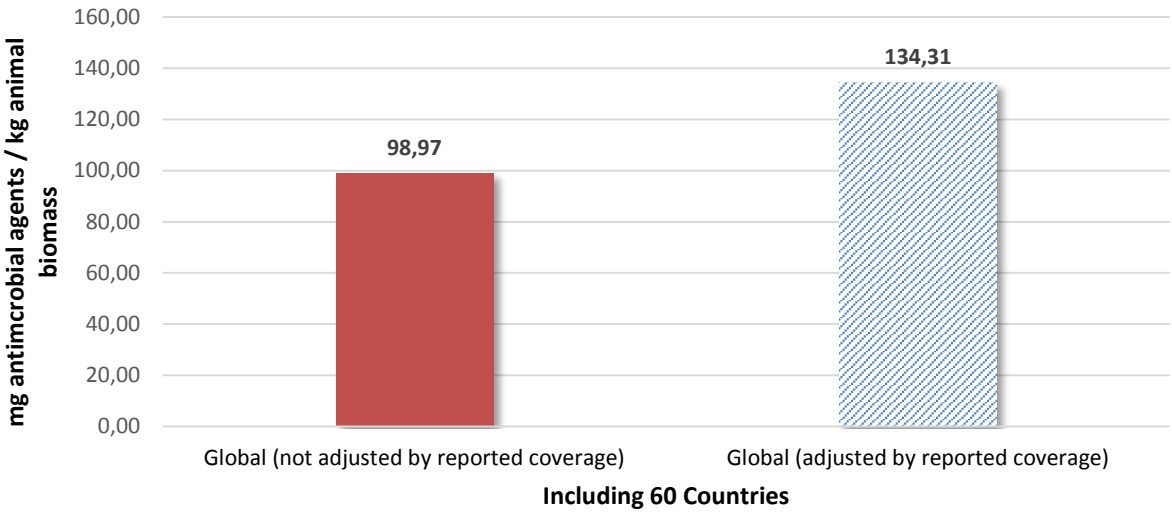
4.3. Antimicrobial Quantities Adjusted for Animal Biomass

2014 Antimicrobial Quantities Adjusted for Animal Biomass, Global View

Figure 29 provides an overview of antimicrobial agents intended for use in animals adjusted for animal biomass. The estimates incorporate the data of 60 countries providing data in both phases of data collection for 2014, from 4 OIE Regions (Africa, Americas, Asia and the Pacific and Europe).

The first estimate of 98.97 mg/kg represents a global estimate of antimicrobial agents used in animals adjusted for animal biomass, as represented by the quantitative data reported to the OIE from 60 countries during the first two phases of data collection for 2014. The second estimate of 134.31 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 2014. These coverage estimates are subjective to each reporting country, but can provide an upper level estimate of global antimicrobial use in animals.

Figure 29. Global Quantities of Antimicrobial Agents Intended for Use in Animals as Reported for 2014, Adjusted for Animal Biomass (mg/kg)



2014 Antimicrobial Quantities Adjusted for Animal Biomass, Regional View

Figure 30 provides a regional view of antimicrobial agents intended for use in animals adjusted for the animal biomass of countries within that region. Both estimates for each OIE Region incorporate the data of 60 countries providing data in both phases of data collection for 2014.

The lower estimate for each OIE Region represents the quantitative data reported to the OIE from that region during the first two phases of data collection for 2014, adjusted for 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 2014. These coverage estimates are subjective to each reporting country, but can provide an upper level estimate 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, followed by Asia and the Pacific, and then Africa. In Europe, countries were the most confident of their data coverage, with almost all reporting countries estimating 100% coverage.

Figure 30. Quantities of Antimicrobial Agents Intended for Use in Animals Adjusted for Animal Biomass, 2014 Regional Comparison (mg/kg)

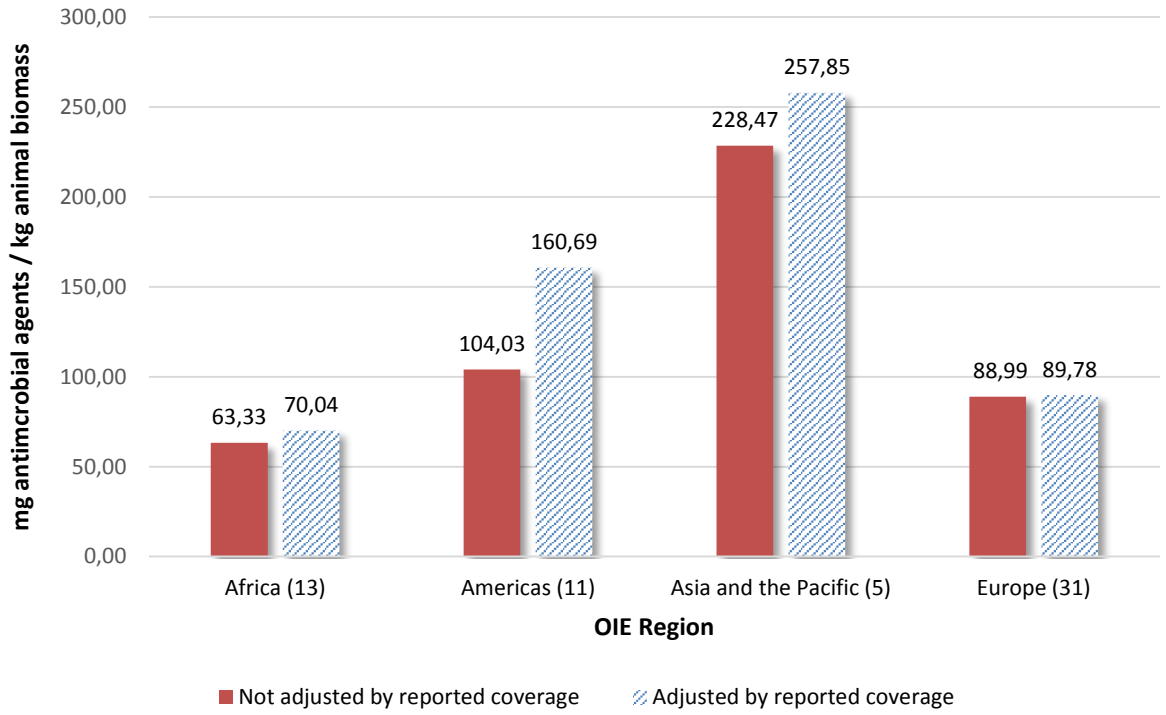


Table 9 displays the same regional figures of antimicrobial quantities adjusted for animal biomass (with the upper level estimates adjusted by country estimates of data coverage in parentheses). Additionally, some characteristics of the data distribution by OIE Region are provided, including the median, standard deviation and range.

The widest variation between antimicrobial quantities adjusted for animal biomass within an OIE Region was in the Americas, followed closely by Asia and the Pacific. The lowest variations between countries within an OIE Region were in Europe and Africa.

Table 9. Antimicrobial Quantities Adjusted for Animal Biomass by OIE Region, 2014

OIE Region	Number of Countries	% Covered of Total Regional Estimated Biomass	Antimicrobial Quantities Adjusted for Animal Biomass (and estimated data coverage) (mg/kg)	Descriptive Statistics		
				Median (mg/kg)	Standard deviation (mg/kg)	Range (mg/kg)
Africa	13	41%	63.33 (70.04)	4.42 (5.17)	75.85 (82.58)	186.59 (219.48)
Americas	11	86%	104.03 (160.69)	49.96 (105.96)	165.69 (192.24)	507.67 (635.15)
Asia and the Pacific	5	6%	228.47 (257.85)	136.87 (136.87)	149.48 (165.51)	335.23 (338.50)
Europe	31	71%	88.99 (89.78)	40.47 (40.47)	70.61 (75.19)	270.04 (276.95)

It is important to interpret the estimates of antimicrobial quantities adjusted for 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 2014 were calculated and explained in Section 4.1. For areas with lower coverage, particularly Asia and the Pacific (6%) and Africa (41%), a future increase of quantitative data reported covering a larger percent of total animal population of the region may substantially impact regional and global estimates.

5. Discussion

5.1. Progress Made by Member Countries

During the second phase of data collection, an increased number of Member Countries were engaged in data reporting than in the previous phase.

Of the 143 Member Countries that submitted templates, 104 had also participated during the first phase of data collection. Among these 104 Member Countries, the following progress was noted:

- 13 Member Countries (13% of 104) passed from reporting only Baseline Information to reporting quantitative data on antimicrobial agents used in the animals for the first time. Most of these (8 Member Countries) used Reporting Option 1, which allows for distinction of the quantitative data by antimicrobial class and by type of use (therapeutic or growth promotion). One Member Country 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. Impressively, 4 of these Member Countries reported their quantitative data using Option 3, which allows for distinction of quantitative data by type of use, animal groups and routes of administration.
- 13 Member Countries (13%) who had previously reported quantitative data increased specificity of their data when reporting the second time. Eleven Member Countries moved from reporting quantities through Reporting Option 1 to one of the two higher level options: 5 were found to have switched to Reporting Option 2, and 6 switched to Reporting Option 3. Two Member Countries that had previously reported through Option 2 now used Reporting Option 3.

It is important to note that the OIE Regions of Africa and the Americas showed the highest number of countries supplying quantitative data for the first time.

The barriers described by the 39 Member Countries unable to provide quantitative data on antimicrobials used in animals in the second phase of data collection have been described in Section 3.1 of this report. Among this group, 13 Member Countries (33% of 39) informed that actions will be undertaken in the near future to facilitate their reporting of quantities of antimicrobials to the OIE. Some of these Member Countries also described the work that has been done to implement their National Action Plans (NAP), to support development of activities or strategies aimed at monitoring the quantities of antimicrobial agents in animals.

5.2. Limits of Analysis of Antimicrobial Quantities

All the countries that reported quantities of antimicrobial agents intended for use in animals did so through 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 second phase of data collection, 22% (24 of 107 countries) reported data sources indicating a possibility for duplicated or overlapped data (see examples below). As countries select their quantitative data sources and compile the summed results by antimicrobial class without input from the OIE, it is not always possible to identify where countries have made such errors.

Data duplication was considered to be a risk when the following situations were reported in a country's data sources:

- Import data of active ingredients or manufacturing data reported without taking into account 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.

Countries where these possible errors were identified were present in all the OIE Regions, however, were most predominant in Africa (10 Member Countries), followed by the Americas (7 countries).

The OIE engages with countries where these situations are noted to highlight and clarify possible areas of data duplication. In this initial engagement, many countries informed that the information necessary to amend or minimize such errors was held by another uninvolved national authority, or private industry that had contributed to the data collection (such as pharmaceutical companies). As most of these countries are in the first 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 will work closely with these countries to understand their systems and support them to avoid the overlapping of the data.

Calculation of quantitative data:

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

During the second phase, this analysis could be conducted for 67 countries where data from previous years were available for comparison. In 30 of these 67 countries, the data varied more than 25% from one year to another, and could reach ± 100-200% variation; in a particular case a change of almost 1700% was observed.

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 were present in all OIE Regions, however, Africa presented the highest number of Member Countries having such challenges (11), followed by Asia and the Pacific (8). These regions also represent the most recent participants in such data collection, as would be expected.

The OIE will continue to work on this issue with its Member Countries through its Regional Trainings for National Focal Points for Veterinary Products, where the guidelines are reviewed and Member Countries can ask questions to the OIE and share their experiences.

Development of antimicrobial monitoring systems:

During the first phase of data collection, 89 Member Countries reported quantitative data on antimicrobial agents intended for use in animals, and 74 of these also participated during the second phase of data collection.

In the second phase of data collection, 18 of the 74 Member Countries (24%) made amendments to the quantitative data they had reported during the first phase. These amendments corresponded to errors noted in the calculations, or availability of new data, including data from more months in the year, or data from wholesalers or pharmacists newly participating in the data collection. In the template of the first phase of data collection, the question on which year the quantitative data corresponded to was a free text field, and one Member Country was noted to have made an error in the year previously reported.

Taking into account that most of 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, it is necessary to interpret the results carefully. 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*.

5.3. Limits of 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, using animal population data globally available for 2014. 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 6, Future Developments).

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), estimated average weights at time of treatment are used. [20] The Canadian Integrated Surveillance Program for Antimicrobial Resistance (CIPARS) uses the same standard weights at time of treatment, as well as Canadian standard weights. [21] The surveillance programs of Japan [22] and the United States [23] 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 the OIE Annual Report on antimicrobial agents intended for use in animals, 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 on a 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 the 2014 analysis are not directly comparable to those of ESVAC or the CIPARS estimates based on treatment weights.

Specificity of data:

As described in the methodology, the globally available data sources on animal population, FAOSTAT and WAHIS, were not reported by production class for the year 2014. However, it is necessary to stratify a 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 ideally 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. At this time, the methodology did not support incorporation of import/export data in the calculation of animal biomass on a global level. However, to minimise the effect of animals imported/exported, 'indigenous' slaughter data were used wherever slaughter data were applied, which considers only domestic animals slaughtered in a country. This use of indigenous slaughter data will minimise the effect of this limitation for countries importing or exporting animals for slaughter.

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.

Reproduction rates and weights: Data on reproduction rates were not collected at the time of reporting, nor was slaughter data for cervids, camelids, and equines in some regions. Therefore, this information was taken from literature where necessary, or extrapolated from regions where data was 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.

5.4. 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 noticed that there are countries where other national authorities, outside the veterinary services, manage veterinary antimicrobials and the relevant data in the country, most often the Ministry of Health (see section 3.1, 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 National Action Plans which should be designed 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 availability of global antimicrobial use data in animals.

6. Future Developments for the Antimicrobial Use Database

After the results of the first and second phases of the data collection, the OIE made changes to the template for the third phase regarding the use of antimicrobials as growth promoters, noting that in many countries there is lack of legislation for this topic. These changes to the questions on growth promotors will enable a more nuanced understanding of the situation in a country, separating the use and authorisation of antimicrobial agents for this purpose.

For the 5th cycle of seminars for National Focal Points for Veterinary Products, currently underway, the OIE will work more closely with Member Countries to support them in calculating kilograms of active ingredients of antimicrobials. An automated system for this calculation will be developed over time to assist Member Countries in this effort. This automated system will particularly help Member Countries with the burden of manually calculating kilograms of active ingredients, and avoid errors of these calculations.

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

An important next step in this process will be collaboration with the OIE World Animal Health Information and Analysis Department (WAHIAD). In consultation with the OIE *ad hoc* Group on Antimicrobial Resistance, new species and animal sub-categories have been added to the OIE World Animal Health Information System (WAHIS) data collection guidelines, so that future data collected will be better tailored to the calculation of animal biomass.

WAHIS+, the next generation of the WAHIS data collection interface, is currently in progress and will incorporate further updates to the collection of global animal population data. In addition to more sub-categories representing detailed production data where Member Countries are able to supply it,

the interface will also include free text boxes allowing for explanations of the reported data. WAHIS+ will also newly support the reporting of data on number of animals slaughtered in Member 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 were frequently extrapolated from European data. Particularly, better understanding carcass conversion factors (for estimating live weights) and annual multiplication rates of species living less than one year (i.e., 'cycle factor') is necessary within the current methodology to ensure its applicability on a global scale.

7. Conclusions

This report is the result of a significant commitment by OIE Member Countries to the development of data collection systems on antimicrobial agents intended for use in animals. This global initiative, the first of its kind, highlights not only reported quantitative data where countries are currently able to provide it, but also the current situation of governance of veterinary antimicrobials worldwide, and barriers to quantitative data collection. This information is critical to the international effort necessary for reducing inappropriate use of antimicrobial agents in animals, and the capacity to measure trends over time.

Contributions to the database have continued to grow, with increasing engagement by responding countries. The OIE also commends the participating non-OIE Member Countries for their invaluable efforts, and will continue to support their engagement with the data collection. Results of the second phase of data collection have demonstrated a growing capacity worldwide for collection of more quantitative data, while also increasing in quality.

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 continued support of the OIE *ad hoc* Group on Antimicrobial Resistance. 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.

8. References

1. World Organisation for Animal Health (OIE). – *Terrestrial Animal Health Code.* Available at: http://www.oie.int/en/standard-setting/terrestrial-code/access-online/ (accessed on 6 December 2017).

2. World Organisation for Animal Health (OIE). – *RESOLUTION No. 26: Combating Antimicrobial Resistance and Promoting the Prudent Use of Antimicrobial Agents in Animals.* 83 GS/FR – PARIS, May 2015. Available at: http://www.oie.int/fileadmin/Home/eng/Our_scientific_expertise/docs/pdf/AMR/A_RESO_AMR_2015.pdf (accessed on 6 December 2017).

3. World Organisation for Animal Health (OIE). – *RESOLUTION No. 36 Combating Antimicrobial Resistance through a One Health Approach: Actions and OIE Strategy.* 84 GS/FR – PARIS, May 2016. Available at: http://www.oie.int/fileadmin/Home/eng/Our_scientific_expertise/docs/pdf/AMR/A_RESO_AMR_2016.pdf (accessed on 6 December 2017).

4. World Organisation for Animal Health (OIE). – *The OIE Strategy on Antimicrobial Resistance and the Prudent Use of Antimicrobials* – PARIS, November 2016. Available at: http://www.oie.int/fileadmin/Home/eng/Media_Center/docs/pdf/PortailAMR/EN_OIE-AMRstrategy.pdf (accessed on 6 December 2017).

5. World Organisation for Animal Health (OIE). – *Terrestrial Animal Health Code.* Chapter 6.7. Harmonisation of national antimicrobial resistance surveillance and monitoring programmes. Available at: http://www.oie.int/fileadmin/Home/eng/Health_standards/tahc/current/chapitre_antibio_harmonisation.pdf (accessed on 6 December 2017).

6. World Organisation for Animal Health (OIE). – *Aquatic Animal Health Code.* Chapter 6.4. Development and harmonisation of national antimicrobial resistance surveillance and monitoring programmes for aquatic animals. Available at: http://www.oie.int/fileadmin/Home/eng/Health_standards/aahc/current/chapitre_antibio_development_harmonisation.pdf (accessed on 6 December 2017).

7. World Organisation for Animal Health (OIE). – *Manual of Diagnostic Tests and Vaccines for Terrestrial Animals.* Chapter 3.1. Laboratory methodologies for bacterial antimicrobial susceptibility testing. Available at: http://www.oie.int/fileadmin/Home/eng/Health_standards/tahm/3.1_ANTIMICROBIAL.pdf (accessed on 6 December 2017).

8. World Organisation for Animal Health (OIE). – *Terrestrial Animal Health Code.* Chapter 6.8. Monitoring of the quantities and usage patterns of antimicrobial agents used in food-producing animals. Available at: http://www.oie.int/fileadmin/Home/eng/Health_standards/tahc/current/chapitre_antibio_monitoring.pdf (accessed on 6 December 2017).

9. World Organisation for Animal Health (OIE). – *Aquatic Animal Health Code.* Chapter 6.3. Monitoring of the quantities and usage patterns of antimicrobial agents used in aquatic animals. Available at: http://www.oie.int/fileadmin/Home/eng/Health_standards/aahc/current/chapitre_antibio_quantities_usage_patterns.pdf (accessed on 6 December 2017).

10. World Health Organization (WHO). – *Global Action Plan on Antimicrobial Resistance*. (2015). Available at: http://apps.who.int/iris/bitstream/10665/193736/1/9789241509763_eng.pdf?ua=1 (accessed on 6 December 2017).

11. World Organisation for Animal Health (OIE). – *Global Action to Alleviate the Threat of Antimicrobial Resistance: Progress and Opportunities for Future Activities Under the 'One Health' Initiative.* Available at: http://www.oie.int/fileadmin/home/eng/Media_Center/docs/pdf/85SG/TT1_AMR/A_85SG_9.pdf (accessed on 6 December 2017).

12. World Organisation for Animal Health (OIE). – *RESOLUTION No. 38 Global action to alleviate the threat of antimicrobial resistance: progress and opportunities for future activities under the 'One health' initiative.* 85 GS/FR – PARIS, May 2017. Available at: http://www.oie.int/fileadmin/Home/eng/Our_scientific_expertise/docs/pdf/AMR/A_AMR_RESO_2017.pdf (accessed on 6 December 2017).

13. World Organisation for Animal Health (OIE). – *OIE List of antimicrobial agents of veterinary importance*. Available at: http://www.oie.int/fileadmin/Home/eng/Our_scientific_expertise/docs/pdf/Eng_OIE_List_antimicrobials_May2015.pdf (accessed on 6 December 2017).

14. Europe Commission, Eurostat. - *Manual for the compilation of supply balance sheets for meat*. (2009) Available at: https://circabc.europa.eu/sd/a/90447c6f-5b7c-4b6f-87e9-27c5a7a5c923/ASA-TE-F-655%2520SBS%2520Manual%2520-%2520meat.doc (accessed on 6 December 2017).

15. Food and Agriculture Organization of the United Nations (FAO). – *Guidelines for the Preparation of Livestock Sector Reviews.* (2011). Available at: http://www.fao.org/docrep/014/i2294e/i2294e00.pdf (accessed on 6 December 2017).

16. European Commission, Eurostat – Statistics Explained. *Glossary*. Available at: http://ec.europa.eu/eurostat/statistics-explained/index.php/Glossary:Livestock_unit_(LSU) (accessed on 6 December 2017)

17. Food and Agriculture Organization of the United Nations (FAO). – *The Rabbit: Husbandry, Health and Production.* (1997). Available at: http://www.fao.org/docrep/014/t1690e/t1690e.pdf (accessed on 6 December 2017)

18. Porter, Valerie & Alderson, Lawrence & Hall, Stephen & Sponenberg, D. – *Mason's World Encyclopedia of Livestock Breeds and Breeding: 2 Volume Pack.* (2016).

19. World Organisation for Animal Health (OIE). – *OIE Annual report on the use of antimicrobial agents in animals.* (2016). Available at: http://www.oie.int/fileadmin/Home/eng/Our_scientific_expertise/docs/pdf/AMR/Survey_on_monitoring_antimicrobial_agents_Dec2016.pdf (accessed on 6 December 2017).

20. European Medicines Agency, European Surveillance of Veterinary Antimicrobial Consumption (ESVAC). – *Sales of veterinary antimicrobial agents in 29 European countries in 2014: Sixth ESVAC report.* (2016). Available at: http://www.ema.europa.eu/docs/en_GB/document_library/Report/2016/10/WC500214217.pdf (accessed on 6 December 2017)

21. The Canadian Integrated Program for Antimicrobial Resistance Surveillance (CIPARS). – *2015 Annual Report*. (2017). Available at: https://www.canada.ca/en/public-health/services/surveillance/canadian-integrated-program-antimicrobial-resistance-surveillance-cipars/2015-annual-report-summary.html (accessed on 6 December 2017)

22. Japan - *National Action Plan on Antimicrobial Resistance (AMR) 2016-2020*. Available at: http://www.mhlw.go.jp/file/06-Seisakujouhou-10900000-Kenkoukyoku/0000138942.pdf (accessed on 6 December 2017)

23. United States Food and Drug Administration (FDA). – *FDA's Proposed Method for Adjusting Data on Antimicrobials Sold or Distributed for Use in Food-Producing Animals, Using a Biomass Denominator.* Available at: https://www.fda.gov/downloads/AnimalVeterinary/SafetyHealth/AntimicrobialResistance/UCM571099.pdf (accessed on 6 December 2017)

9. Country Information Available on the Web

AUSTRALIA

Report on the Quantity of Antimicrobial Products Sold for Veterinary Use in Australia (2005, July to 2010, June). Retrieved from: http://archive.apvma.gov.au/publications/reports/docs/antimicrobial_sales_report_march-2014.pdf

AUSTRIA

Antibiotika-Vertriebsmengen in der Veterinärmedizin in Österreich (2010 to 2016). Retrieved from: https://www.ages.at/themen/ages-schwerpunkte/antibiotika-resistenzen/vertriebsmengen/

BELGIUM

Belgian Veterinary Surveillance of Antibacterial Consumption, National consumption report (2007 to 2015). Retrieved from: http://www.fagg-afmps.be/nl/DIERGENEESKUNDIG_gebruik/geneesmiddelen/geneesmiddelen/goed_gebruik/Antibiotica_0

CANADA

Canadian Integrated Program for Antimicrobial Resistance Surveillance (CIPARS) Annual Reports (2008 to 2014). Retrieved from: http://www.phac-aspc.gc.ca/cipars-picra/pubs-eng.php

CHILE

Declaración de venta de antimicrobianos (2014 to 2015). Retrieved from: http://www.sag.cl/ambitos-de-accion/medicamentos-de-uso-veterinario

CROATIA

Opseg prodaje VMP 2015 (2015). Retrieved from http://www.veterinarstvo.hr/default.aspx?id=1218

CYPRUS

Annual Sales Reports in Cyprus (2009 to 2013). Retrieved from: http://www.moa.gov.cy/moa/vs/vs.nsf/vs74_en/vs74_en?OpenDocument

CZECH REPUBLIC

Spotřeby Antibiotik A Antiparazitik (2003 to 2012). Retrieved from: http://www.uskvbl.cz/en/information/press-office/press-release-and-other-information

DENMARK

Danish Integrated Antimicrobial Resistance Monitoring and Research Programme (DANMAP) Reports (1996 to 2015). Retrieved from: http://www.danmap.org/Downloads/Reports.aspx

FINLAND

Consumption of Veterinary Antimicrobials (2010 to 2015) Retrieved from: http://www.fimea.fi/web/en/veterinary/consumption_of_veterinary_antimicrobials

FRANCE

Sales Survey of Veterinary Medicinal Products containing Antimicrobials in France (2014). Retrieved from: https://www.anses.fr/fr/system/files/ANMV-Ra-Antibiotiques2014.pdf

GERMANY

Antibiotikaabgabe in der Tiermedizin sinkt weiter (2014). Retrieved from: http://www.bvl.bund.de/DE/08_PresseInfothek/01_FuerJournalisten/01_Presse_und_Hintergrundinformationen/05_Tierarzneimittel/2015/2015_07_28_pi_Antibiotikaabgabemenge2014.html

IRELAND

Report on Consumption of Veterinary Antibiotics in Ireland (2009 to 2015). Retrieved from: https://www.hpra.ie/homepage/veterinary/special-topics/antibiotic-resistance

JAPAN

Annual Report of Sales Amount and Sales Volume of Veterinary drugs, Quasi-drugs and Medical Devices (therapeutic use). (2005 to 2015) Retrieved from: http://www.maff.go.jp/nval/iyakutou/hanbaidaka/index.html

Results of Official Testing of Specified Feed Additives (growth promotion) (2014) Retrieved from: http://www.famic.go.jp/ffis/feed/obj/sub2_kentei26.pdf

(THE) NETHERLANDS

Usage of Antibiotics in Agricultural Livestock in the Netherlands in 2015 (2015). Retrieved from: http://www.autoriteitdiergeneesmiddelen.nl/Userfiles/Eng%20rapport%20AB%20gebruik%202015/def-engels-rapportage-ab-gebruik-2015.pdf

NEW ZEALAND

Antibiotic sales analysis (2011 to 2014). Retrieved from: http://www.foodsafety.govt.nz/industry/acvm/reports/reviews/sales.htm

NORWAY

Usage of Antimicrobial Agents and Occurrence of Antimicrobial Resistance in Norway (1999 to 2015). Retrieved from: http://www.vetinst.no/overvaking/antibiotikaresistens-norm-vet

POLAND

Dane dotyczące sprzedaży produktów leczniczych weterynaryjnych przeciwbakteryjnych w Polsce. (2010 to 2013). Retrieved from: http://www.wetgiw.gov.pl/produkty-lecznicze-weterynaryjne

SWEDEN

SWEDRES/SVARM, Consumption of antibiotics and occurrence of antibiotic resistance in Sweden (2009 to 2016). Retrieved from: http://www.sva.se/en/antibiotics/svarm-reports

Försäljning avdjurläkemedel 2014 (2014). Retrieved from: http://www.jordbruksverket.se/download/18.7d1b731214d22cf8cd49b86/1430813848982/Rapport+djurl%C3%A4kemedel+2014.pdf

SWITZERLAND

Usage of Antibiotics and Ocurrence of Antibiotic Resistance in Bacteria from Humans and Animals in Switzerland. Swiss Antibiotic Resistance Report (2011 to 2016). Retrieved from: https://www.blv.admin.ch/blv/fr/home/tiere/publikationen-und-forschung/statistiken-berichte-tiere.html

UNITED KINGDOM

UK Veterinary Antibiotic Resistance and Sales Surveillance (2013 to 2015). Retrieved from: https://www.gov.uk/government/collections/veterinary-antimicrobial-resistance-and-sales-surveillance

UNITED STATES OF AMERICA

Animal Drug User Fee Act (UDUFA) Reports. (2009 to 2015). Retrieved from: http://www.fda.gov/ForIndustry/UserFees/AnimalDrugUserFeeActADUFA/ucm042896.htm

EUROPEAN UNION

European Surveillance of Veterinary Antimicrobial Consumption (ESVAC). (2005 to 2014). Retrieved from: http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/document_listing/document_listing_000302.jsp

ANNEXES

Annex 1. Africa, Responses from the Second Phase of Data Collection

Table A1. General Information for Africa

General Information for Africa	
Number of Member Countries	54
Number of Member Countries responding to the questionnaire	41 (76%)
Number of Member Countries providing only qualitative data	13 (32%)
Number of Member Countries providing quantitative data	28 (68%)

Barriers to Providing Quantities of Antimicrobial Agents in Animals

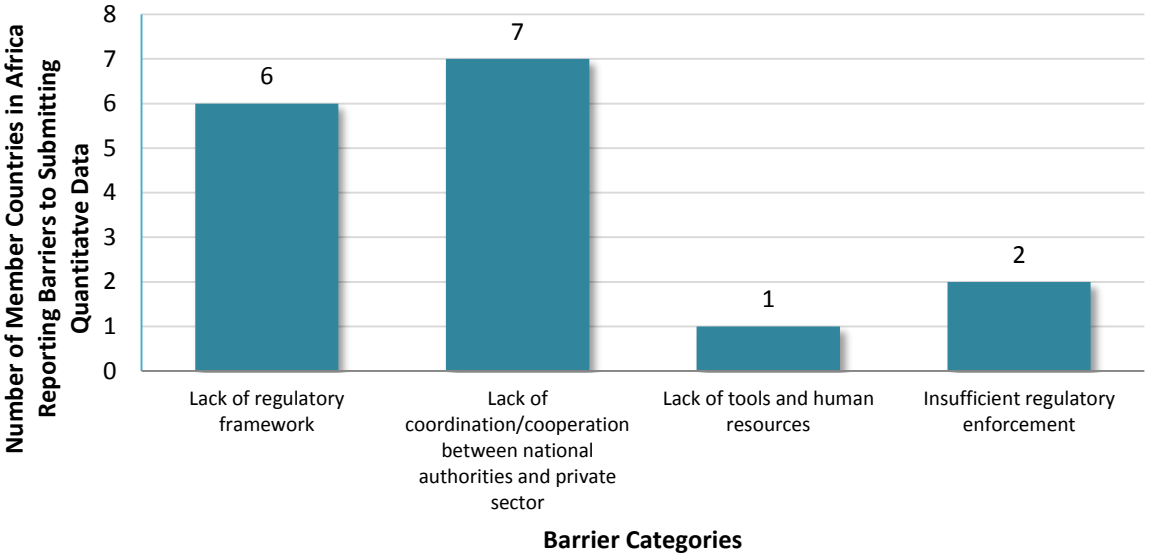
Thirteen Member Countries (13/41; 32%) responded with Baseline Information (qualitative data) and no quantitative data on antimicrobial agents used in animals (Table A1), and explained the barriers to reporting quantities of antimicrobial agents used in animals to the OIE. Member Countries could report more than one barrier relevant to their situation, and responses were grouped by category (Figure A1). For further information on the category groupings, please see the explanatory section in the global analysis for this report.

Seven countries in Africa described a 'lack of coordination/cooperation between national authorities and with private sector' as a contributing barrier to reporting amounts of antimicrobials to the OIE; 5 out of these 7 Member Countries (5/7; 71%) specified that data were available with another Governmental Authority, usually the Ministry of Health.

One Member Country described a 'lack of tools and human resources' as the reason why available data could not be processed. This Member Country also described 'insufficient regulatory enforcement' for collection of data, including black market sales and usage of antimicrobials in the field by unauthorised persons.

Three African Member Countries reported a 'lack of regulatory framework' (3/6; 50%) for the manufacture, registration, distribution, commercialization and pharmacovigilance of veterinary products.

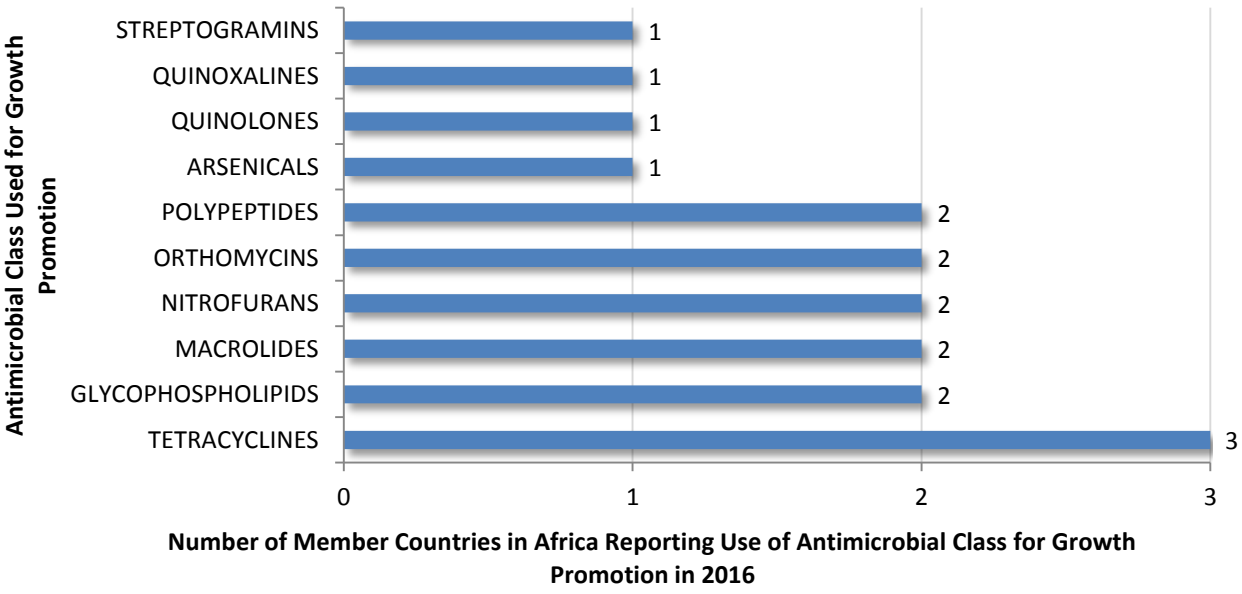
Figure A1. Country Barriers to Reporting Quantitative Data on Antimicrobial Agents Intended for Use in Animals in 13 Countries in Africa During the Second Phase of Data Collection



Antimicrobial Agents Used for Growth Promotion

Sixteen African countries use antimicrobial agents as growth promoters. Seven of these 16 Member Countries (7/16; 44%) provided a list of antimicrobials used for growth promotion, with Tetracyclines most commonly named (Figure A2). Africa is the OIE Region with the most number of Member Countries reporting a lack of legislation or regulation for antimicrobial as growth promoters (10/16; 63), and therefore, to provide a list of antimicrobials used for growth promotion purposes remains difficult for this region.

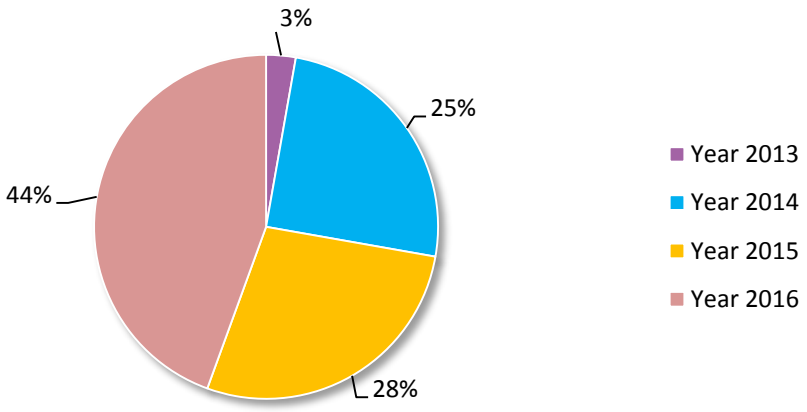
Figure A2. Antimicrobial Growth Promotors Used in Animals in 7 Member Countries in Africa in 2016



Years of Quantitative Data Reported

Based on 28 responses from African Members, the most commonly reported year for quantitative data on antimicrobial agents intended for use in animals was 2016 (Figure A3). Few countries were able to provide data for 2013, and 4 countries provided data for more than one year. These findings reinforce what was presented in the first OIE report, that most Member Countries in Africa have just begun to collect such information recently, and therefore have access only to current information.

Figure A3. Years of Quantitative Data Reported from 28 Member Countries in Africa During the Second Phase of Data Collection



Quantitative Data Sources Captured

From the list of data source options provided in the OIE Template, 'Import data for veterinary products' was most commonly chosen, with 8 Member Countries selecting this option (Figure A4). Nevertheless, 9 Member Countries described other data source not provided in OIE List, mostly relating to 'Import data' (Figure A5).

Figure A4. Data Sources Selected by 28 African Member Countries Reporting Quantitative Information from 2013-2016

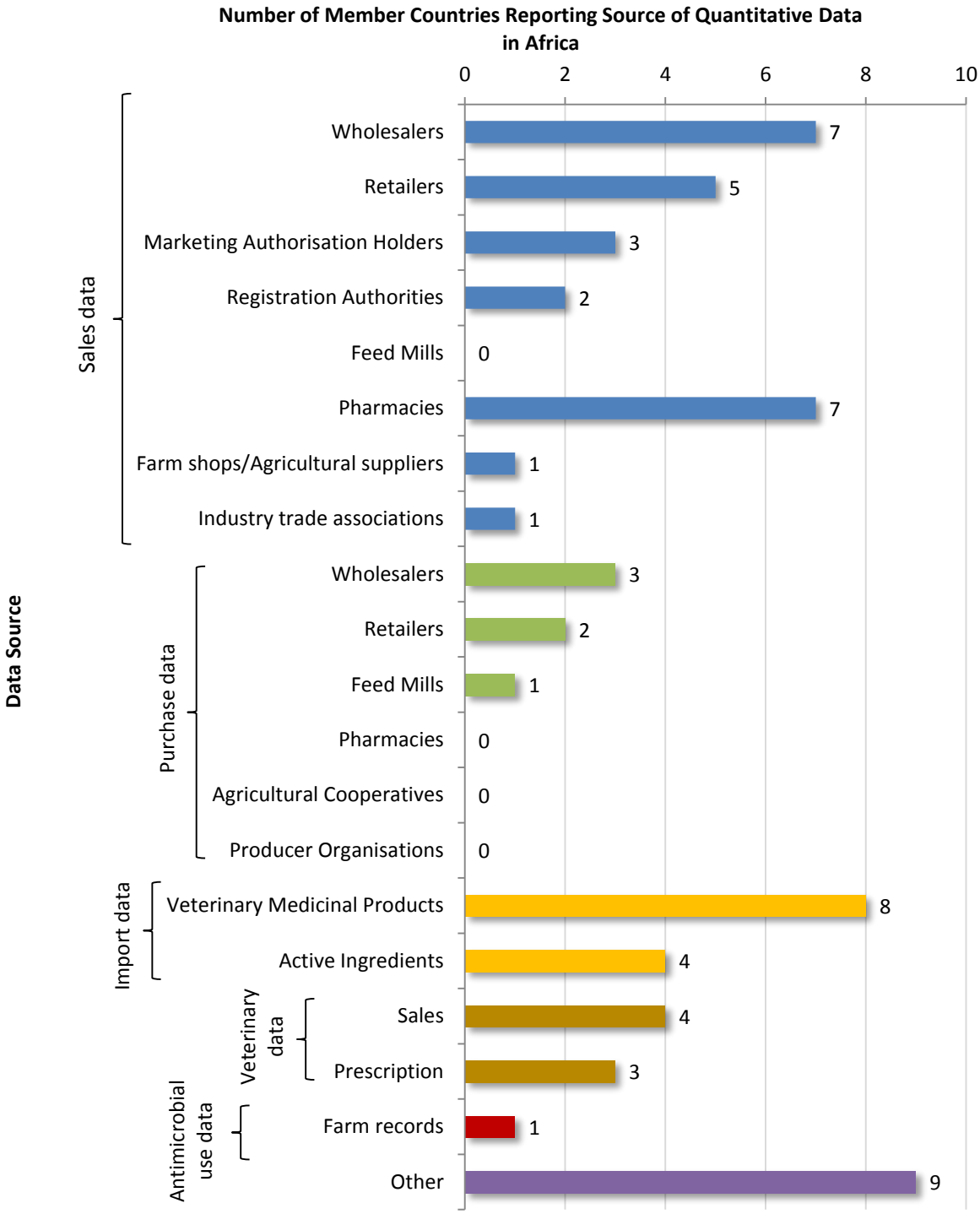
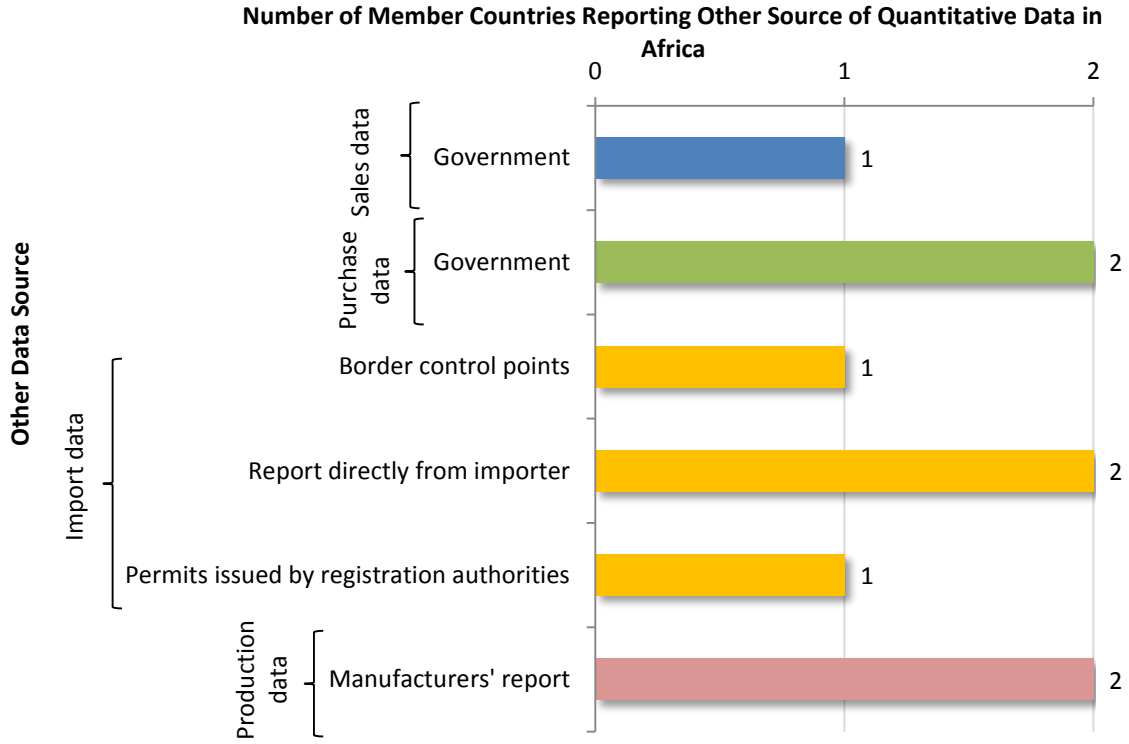


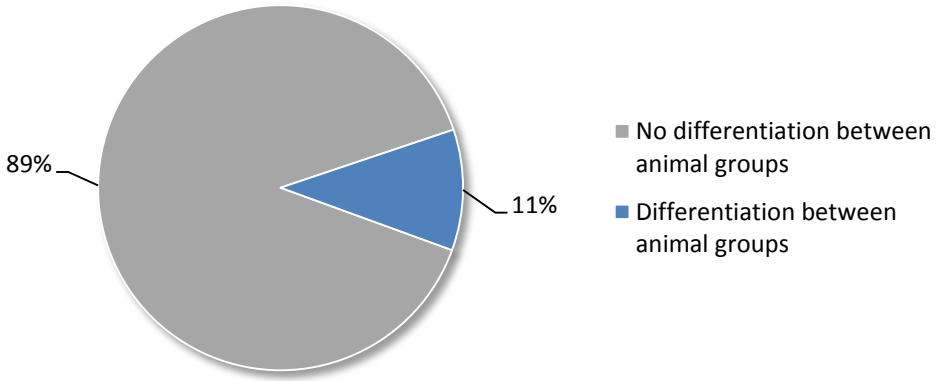
Figure A5. 'Other' Source of Data as Explained by 9 Member Countries in Africa Reporting Quantitative Information from 2013-2016



Quantitative Data Differentiation by Animal Groups

Most of the quantitative data from the African Member Countries 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 A6). For the three African countries that were able to distinguish antimicrobial quantities by animal groups, data were provided only for 'terrestrial food-producing animals'.

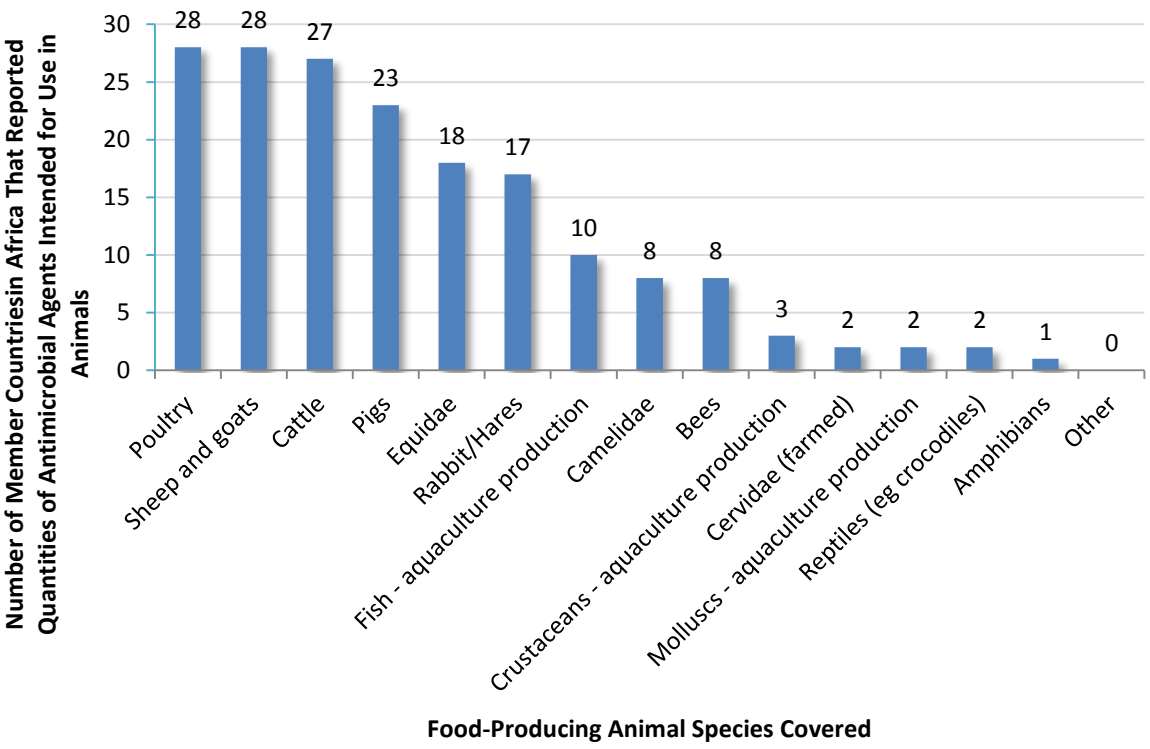
Figure A6. Differentiation by Animal Groups Among 28 Member Countries in Africa Reporting Quantitative Data from 2013-2016



Food-Producing Animal Species Covered by Quantitative Data

In the 28 African Member Countries that reported quantitative data on antimicrobial agents intended for use in animals, the food-producing species most frequently covered by the data were 'poultry', 'sheep and goats' and 'cattle' (Figure A7). Among the poultry production types, 'layers - commercial production for eggs' were named by 27 out of 28 African countries. For further information on the grouping of species see Section 3.3 of this report.

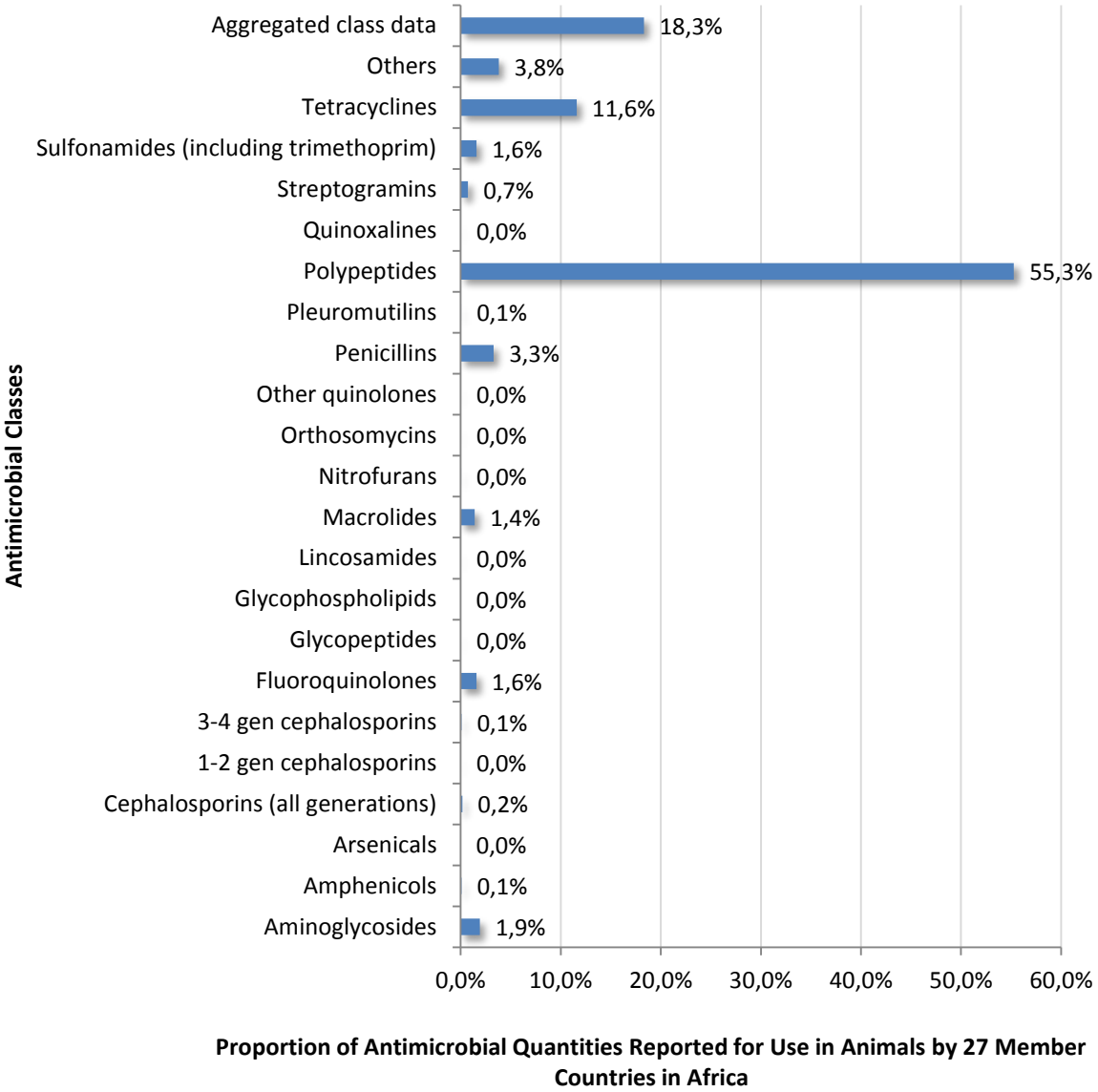
Figure A7. Food-Producing Animal Species Included in Quantitative Data Reported by 28 African Member Countries from 2013-2016



Antimicrobial Classes Reported

In Africa, the largest proportion of all reported antimicrobial classes were polypeptides, followed by tetracyclines (Figure A8). Under the group of 'others' most of the countries reported fosfomycin (5/7; 71%), followed by salinomycin (2/7; 29%).

Figure A8. Proportion of Antimicrobial Quantities (by Antimicrobial Class) Reported for Use in Animals by 27[14] African Member Countries from 2013-2016



[14] One Member Country that reported extremely high figures with known calculation errors was excluded from this analysis

Annex 2. Americas, Responses from the Second Phase of Data Collection

Table A2. General Information for the Americas

General Information for the Americas	
Number of countries*	32
Number of countries responding to the questionnaire	32 (100%)
Number of countries providing only qualitative data	13 (41%)
Number of countries providing quantitative data	19 (59%)

*29 Member Countries and 3 non-OIE Member Countries

New for the second phase of data collection, the data collection template was also sent to non-OIE Member Countries that asked to be part of the database.

In the Americas, 32 countries submitted completed templates to OIE Headquarters: 29 from OIE Member Countries (of 29 in the region; 100%) and 3 non-OIE Member Countries. The responses from non-OIE Member Countries were included in the analysis of the Americas for geographical reasons (Table A2).

Barriers to Providing Quantities of Antimicrobials Agents in Animals

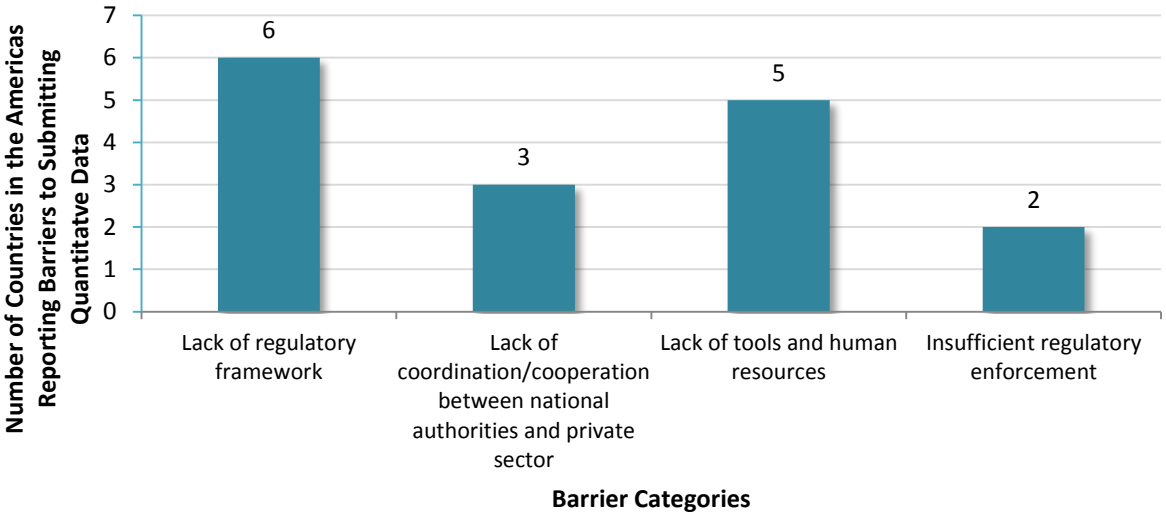
Thirteen countries (13/32; 41%) responded with Baseline Information (qualitative data) and no quantitative data on antimicrobial agents used in animals. The 13 countries explained the barriers to reporting quantities of antimicrobial agents used in animals to OIE. Countries could report more than one barrier relevant to their situation, and responses were grouped by category (Figure A9). For further information on the category groupings, please see the explanatory section in the global analysis for this report.

Almost half of the responses in the Americas (6/13; 46%) mentioned that the main impediment to reporting amounts of antimicrobials were a 'lack of regulatory framework'. Two countries in this group also reported a 'lack of tools and human resources'. Countries considered to have a 'lack of a regulatory framework' reported that data collection is not currently mandatory in their countries and that no official mechanisms to collect such data exist.

Four countries reporting a 'lack of tools and human resources' explained that the information for registration and tracking of import of veterinary medicinal products was not digitalised and therefore done by paper; a lack of human resources impeded them from collating such data, which would be labour intensive.

Three countries reporting a 'lack of coordination/cooperation between other national authorities and with private sector' indicated that data were available through another national authority, usually the Ministry of Health, and were therefore inaccessible at this time.

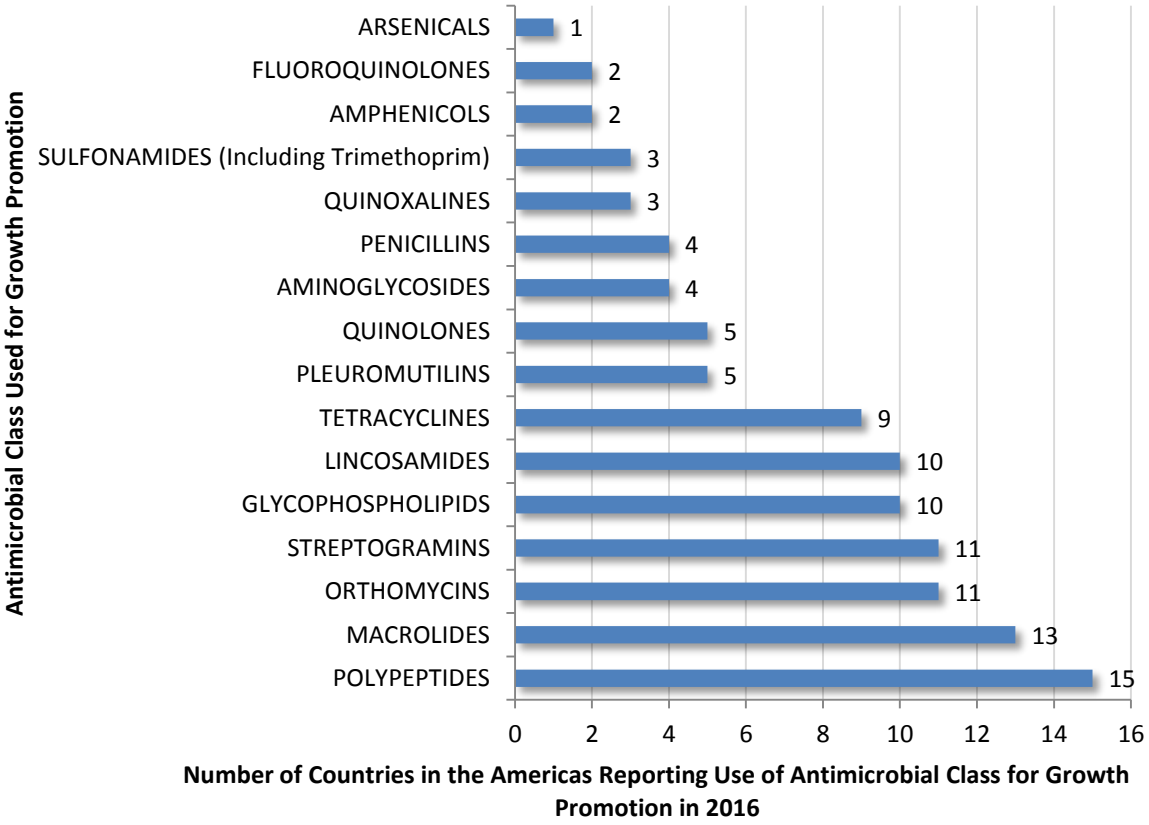
Figure A9. Country Barriers to Reporting Quantitative Data on Antimicrobial Agents Intended for Use in Animals in 13 Countries in the Americas During the Second Phase of Data Collection



Antimicrobial Agents Used for Growth Promotion

Twenty-two countries in the Americas use antimicrobial agents as growth promoters. Seventeen of these 22 countries (17/22; 77%) provided a list of antimicrobials used for growth promotion, with polypeptides most commonly named (by 15 countries), followed by macrolides (Figure A10). Two Member Countries were excluded from this variable as they were reporting only ionophores.

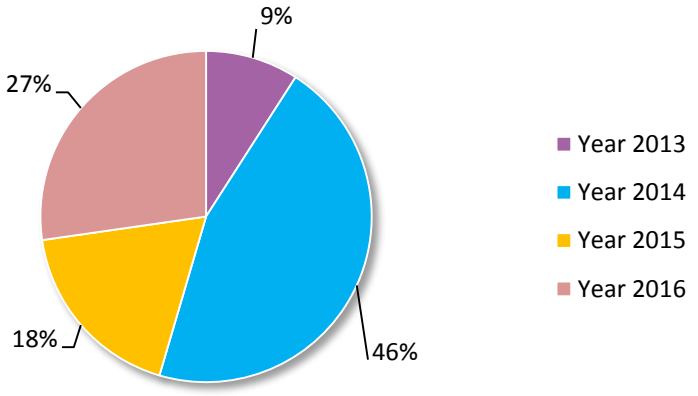
Figure A10. Antimicrobial Growth Promoters Used in 17 Countries in the Americas in 2016



Years of Quantitative Data Reported

Most of the nineteen countries reporting quantitative data from the Americas did so for 2014, the target year of data collection for the OIE (Figure A11). Countries in the Americas have shown great commitment during the second phase of the annual data collection, where 4 countries progressed from reporting only Baseline Information (qualitative data) in the first phase, to reporting quantitative data in the second phase.

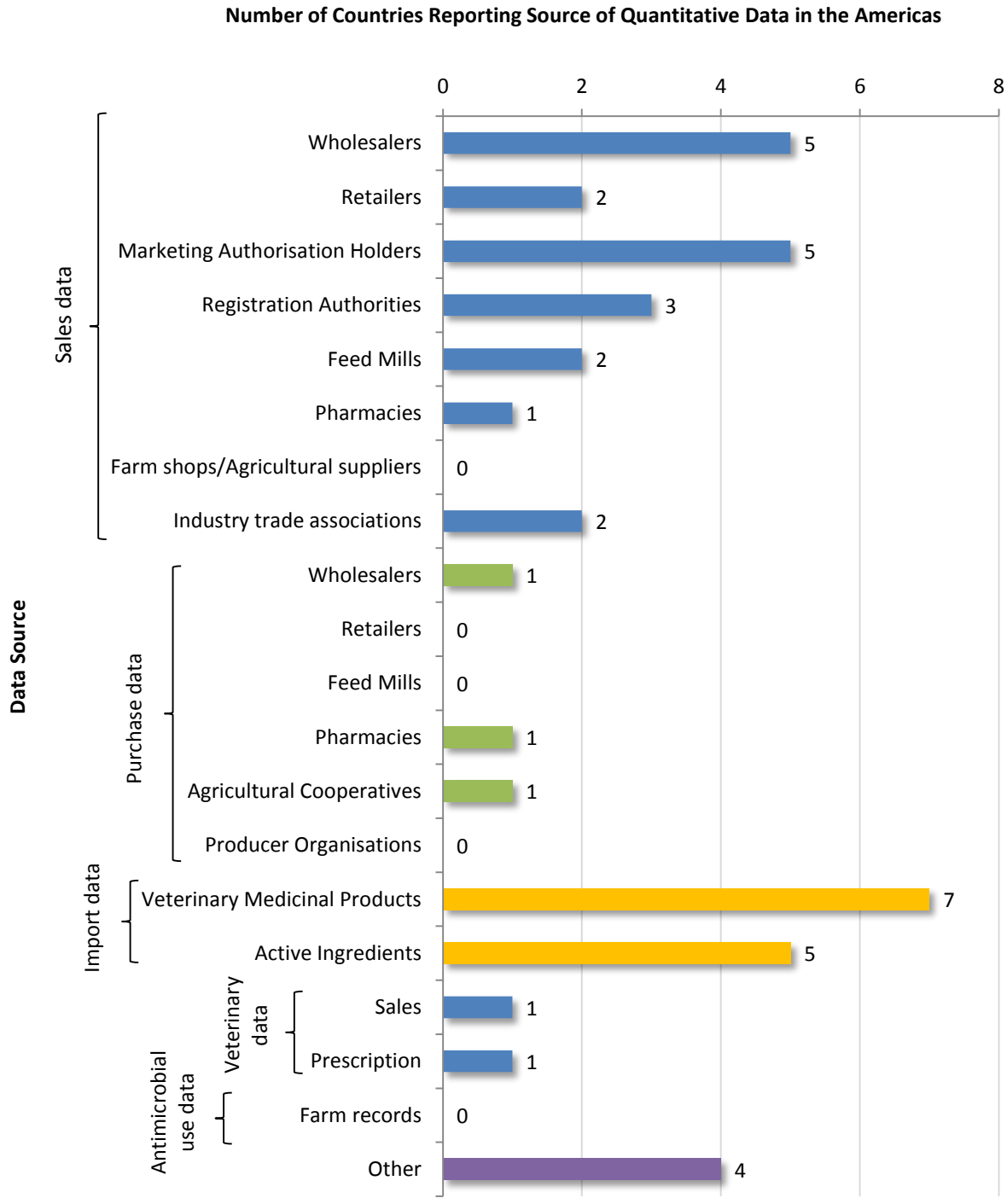
Figure A11. Years of Quantitative Data Reported from 19 Member Countries in the Americas During the Second Phase of Data Collection



Quantitative Data Sources Captured

From the list of data source options provided in the OIE Template, 'Import data – Veterinary Medicinal Products' was most commonly chosen, followed by 'Sales data – Marketing Authorisation Holders' and 'Import data – Active ingredient' (Figure A12). Four countries chose 'Other' data sources, with 3 countries describing that the data came from 'Import data – Permits issued by registration authorities'.

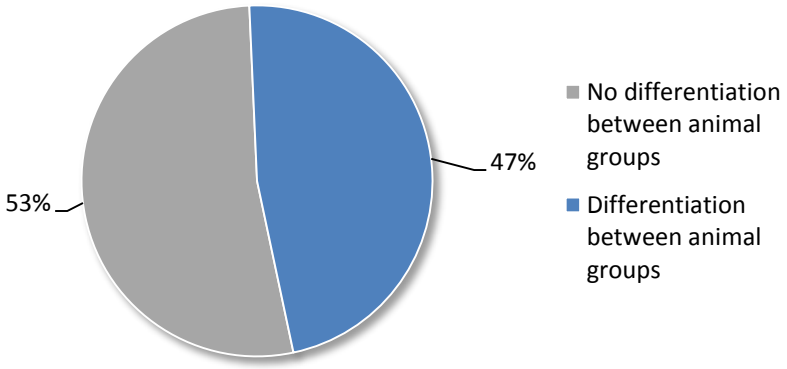
Figure A12. Data Source Selected by 19 Countries in the Americas Reporting Quantitative Information from 2013-2016



Quantitative Data Differentiation by Animal Groups

Most of the quantitative data from the Americas cannot be differentiated by animal group. This corresponds with the predominant use of Reporting Option 1 in the Americas, which does not allow for differentiation by animal group (Figure A13). Nine countries were able to distinguish antimicrobial quantities by animal groups. One country provided data only for companion animals.

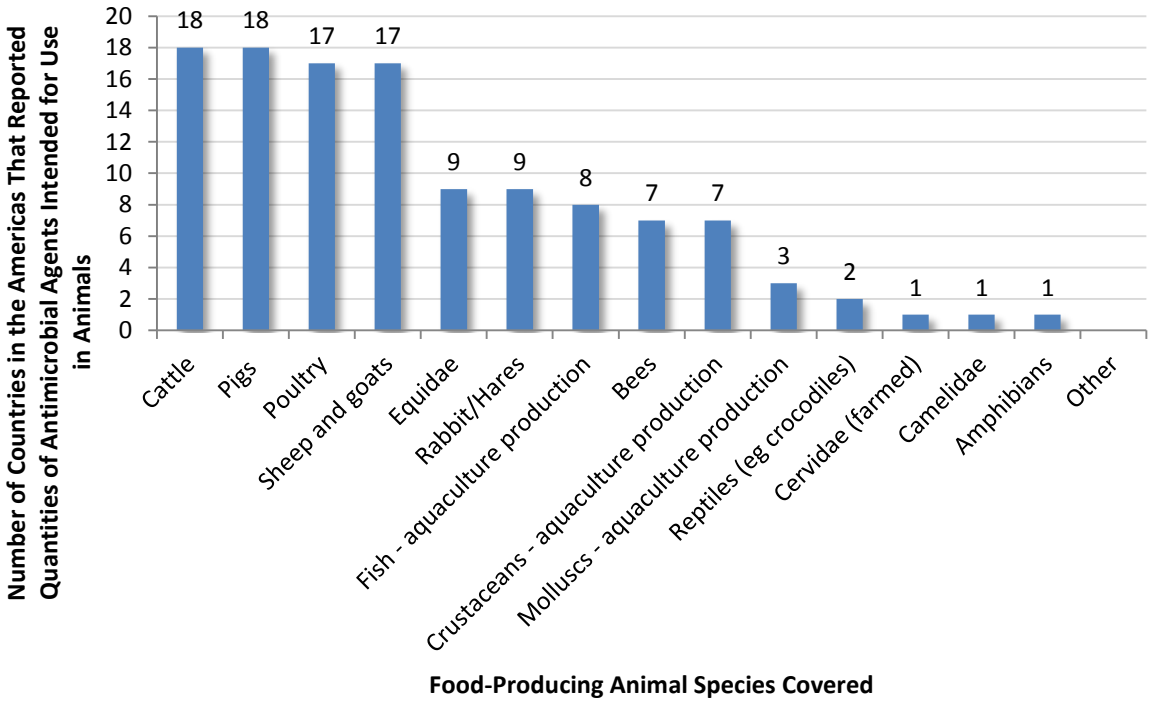
Figure A13. Differentiation by Animal Groups Among 19 Countries in the Americas Reporting Quantitative Data from 2013-2016



Food-Producing Animal Species Covered by Quantitative Data

Of the 18 countries providing quantitative data for food-producing animals in the Americas, the covered species most frequently reported were 'cattle' and 'pigs' (Figure A14). Among the swine production types, 'pigs – commercial' were named by all 18 countries, while 'pigs – backyard' was named by 14 countries. For further information on the grouping of species see Section 3.3 of this report.

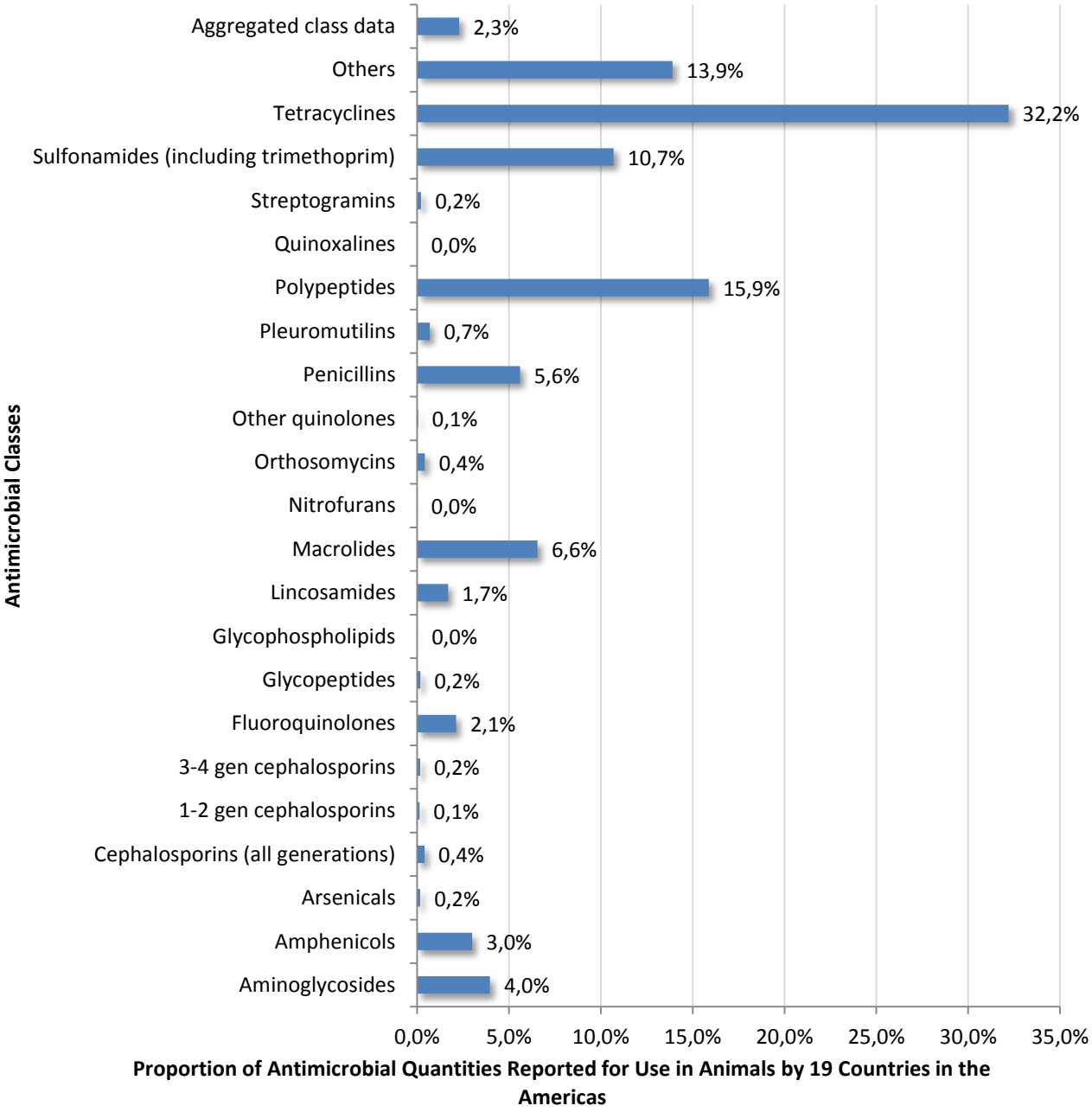
Figure A14. Food-Producing Animal Species Included in Quantitative Data Reported by 18 Countries in the Americas from 2013-2016



Antimicrobial Classes Reported

In the Americas, the largest proportion of all reported antimicrobial classes were tetracyclines and polypeptides (Figure A15). Ten countries provided data under the group of 'others' but only eight provided the list of antimicrobials included; most of these countries reported use of fosfomycin (7/8; 88%), followed by salinomycin (3/8; 38%).

Figure A15. Proportion of Antimicrobial Quantities (by Antimicrobial Class) Reported for Use in Animals by 19 Countries in the Americas from 2013-2016



Annex 3. Asia and the Pacific, Responses from the Second Phase of Data Collection

Table A3. General Information for Asia and the Pacific

General Information for Asia and the Pacific	
Number of Member Countries	32
Number of Member Countries responding to the questionnaire	23 (72%)
Number of Member Countries providing only qualitative data	6 (26%)
Number of Member Countries providing quantitative data	17 (74%)

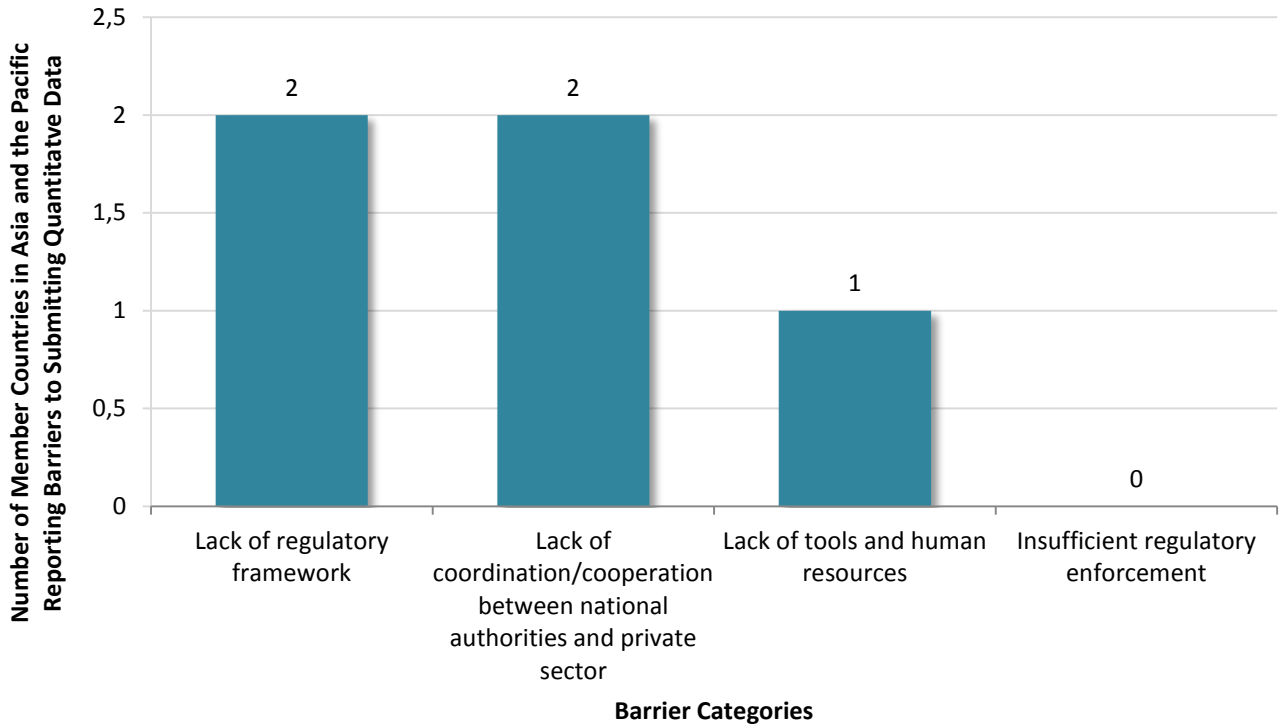
Barriers to Providing Quantities of Antimicrobial Agents in Animals

Six Member Countries (6/23; 26%) responded with Baseline Information (qualitative data) and no quantitative data on antimicrobials agents used in animals (Table A3). Five of these Member Countries explained the barriers to reporting quantities of antimicrobial agents used in animals. Member Countries could report more than one barrier relevant to their situation and responses were grouped by category (Figure A16). For further information please see the explanatory section for each category in the global analysis for this report.

Two Member Countries described the reason they were unable report quantitative data was due to a 'lack of regulatory framework'; both of these Member Countries specified that there was no regulatory framework for registration, authorisation, manufacture or importation of veterinary products, and one also described a general lack of regulatory framework for animal health.

Of the Member Countries describing a 'lack of coordination/cooperation between national authorities and with private sector', one Member Country indicated that import data were held by the Ministry of Health and another Member Country described a lack of cooperation from relevant industry stakeholders.

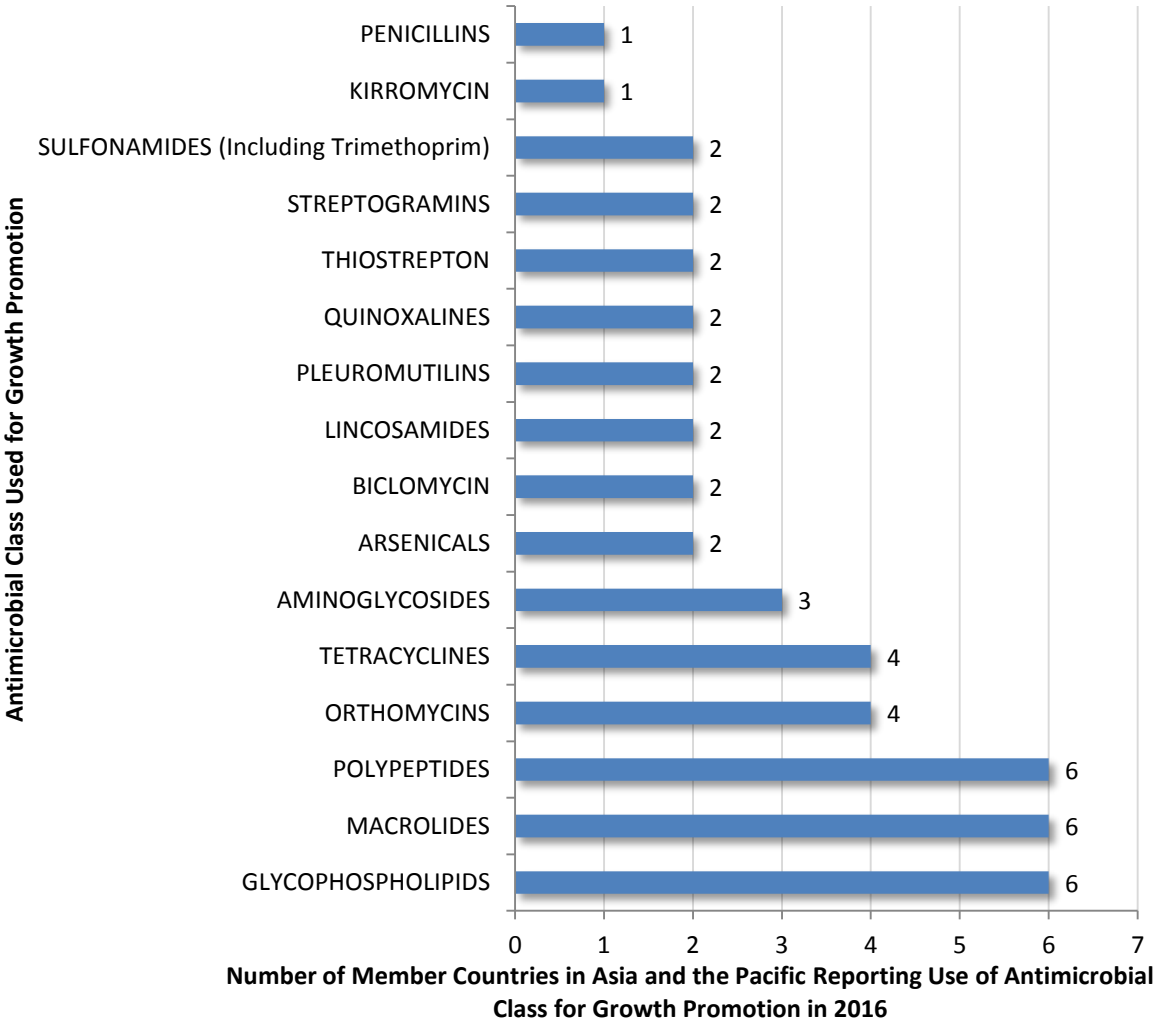
Figure A16. Country Barriers to Reporting Quantitative Data on Antimicrobial Agents Intended for Use in Animals in 5 Member Countries in Asia and the Pacific During the Second Phase of Data Collection



Antimicrobial Agents Used for Growth Promotion

Sixteen Member Countries reported use of antimicrobials as growth promoters. Of these, ten Member Countries (10/16; 63%) provided a list of utilised agents, with glycophospholipids, macrolides and polypeptides each named by six Member Countries respectively (Figure A17). Six Member Countries were unable to provide a list of antimicrobial agents used for growth promotion due to a lack of a regulatory framework on this topic.

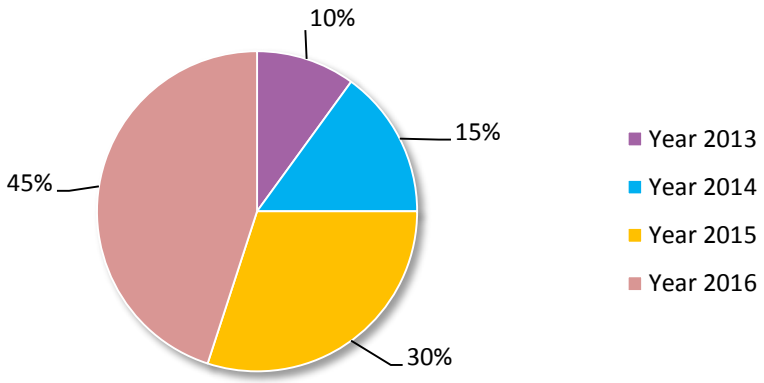
Figure A17. Antimicrobial Growth Promotors Used in Animals in 10 Member Countries in Asia and the Pacific in 2016



Years of Quantitative Data Reported

Based on 17 responses from Member Countries in Asia and the Pacific, the most commonly reported year of quantitative data on antimicrobials agents intended for use animals was 2016 (Figure A18). Few countries were able to provide data for 2013 and 2014. These findings reinforce those presented first OIE Annual Report that many Member Countries in Asia and the Pacific have recently began collecting such information, and therefore only have access to current information.

Figure A18. Years of Quantitative Data Reported from 17 Member Countries in Asia During the Second Phase of Data Collection



Quantitative Data Sources Captured

From the list of data sources provided in the OIE Template, 'Sales data – Marketing Authorisation Holders' and 'Import data – Veterinary Medicinal Products' was chosen by 4 Member Countries in Asia and the Pacific (Figure A19). Additionally, 6 Member Countries reported other data sources not provided in the OIE list, mostly relating to the category of 'Production data – Manufacturer's report' (Figure A20).

Figure A19. Data Sources Selected by 17 Member Countries in Asia-Pacific Reporting Quantitative Information from 2013-2016

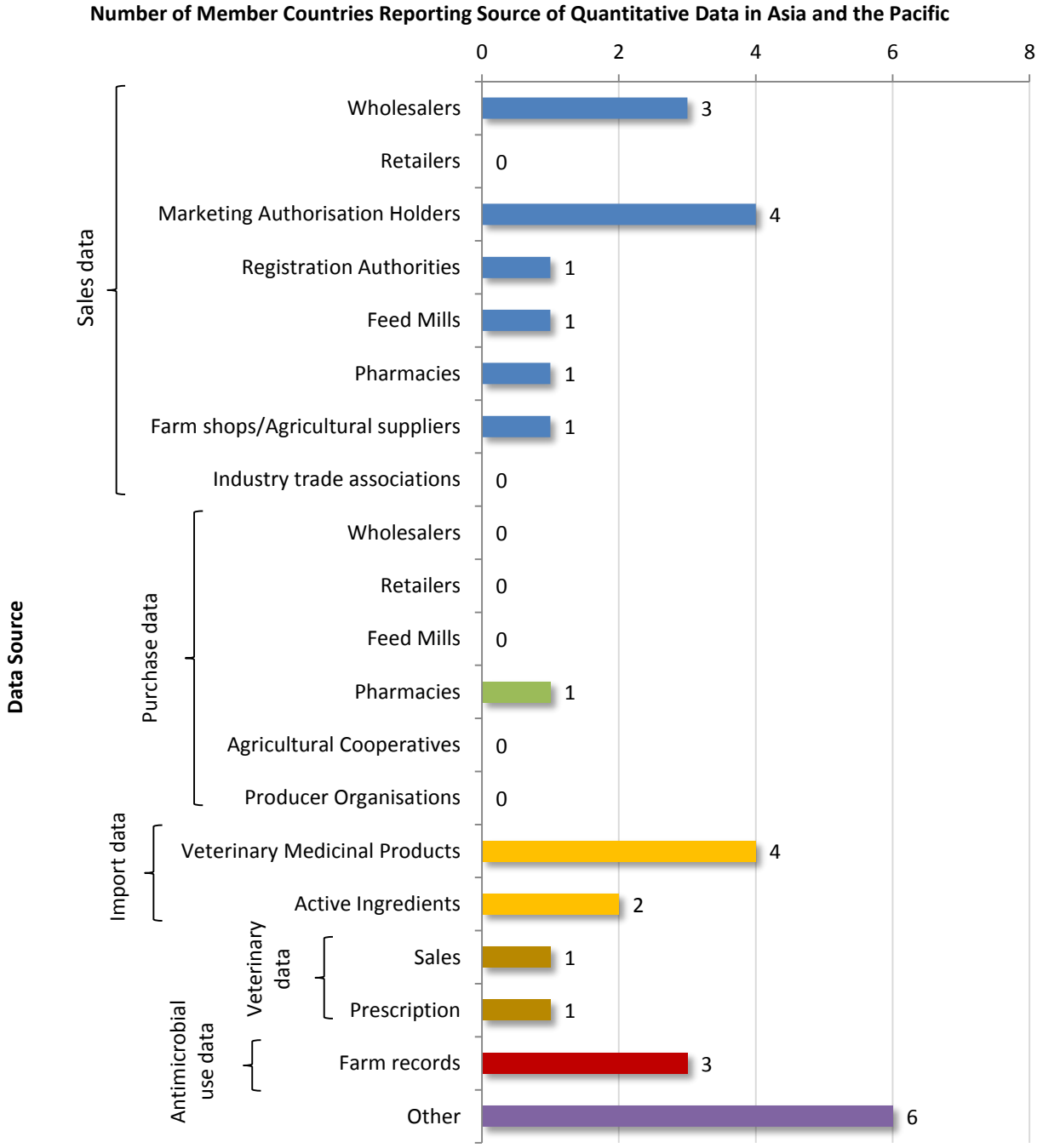
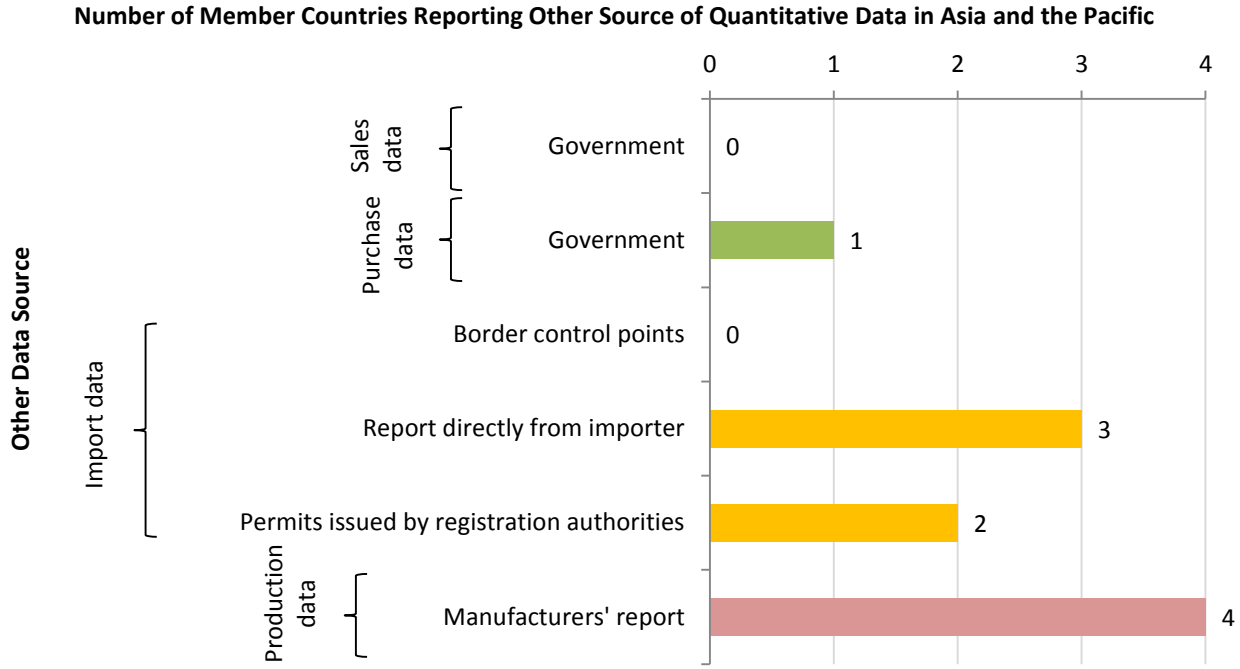


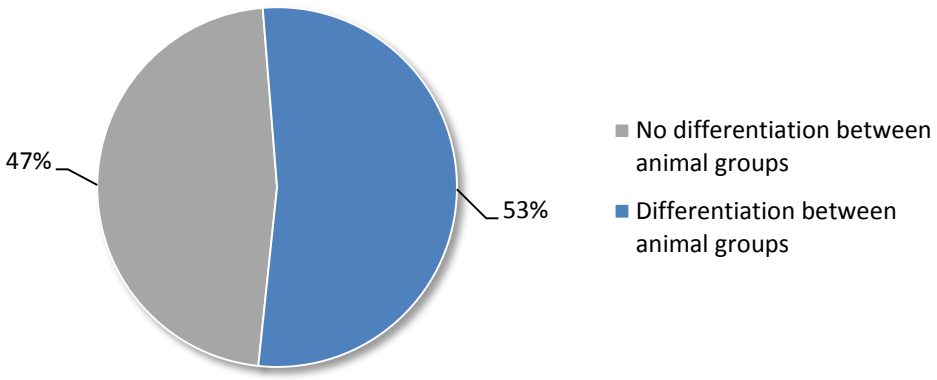
Figure A20. 'Other' Source of Data as Explained by 6 Member Countries in Asia Reporting Quantitative Data from 2013-2016



Quantitative Data Differentiation by Animal Groups

Most of the data from Member Countries in Asia and the Pacific can be differentiated by animal groups. This result corresponds with the region's predominant use of Reporting Option 2 and 3, which allows for differentiation by animal group (Figure A21).

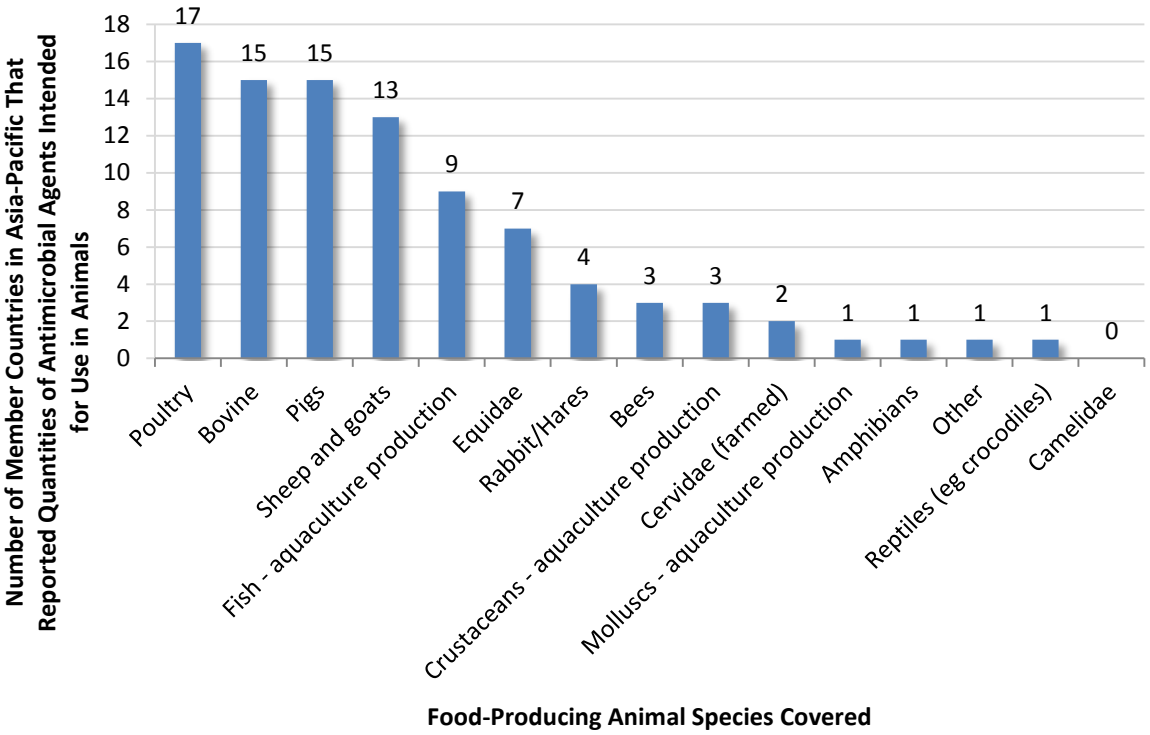
Figure A21. Differentiation by Animal Groups Among 17 Member Countries in Asia and the Pacific Reporting Quantitative Data from 2013-2016



Food-Producing Animal Species Covered by Quantitative Data

In the 17 Member Countries in Asia and the Pacific that reported quantitative data on antimicrobial agents intended for use in animals, the food-producing species most frequently covered by these data were 'poultry', 'cattle' and 'pigs' (Figure A22).

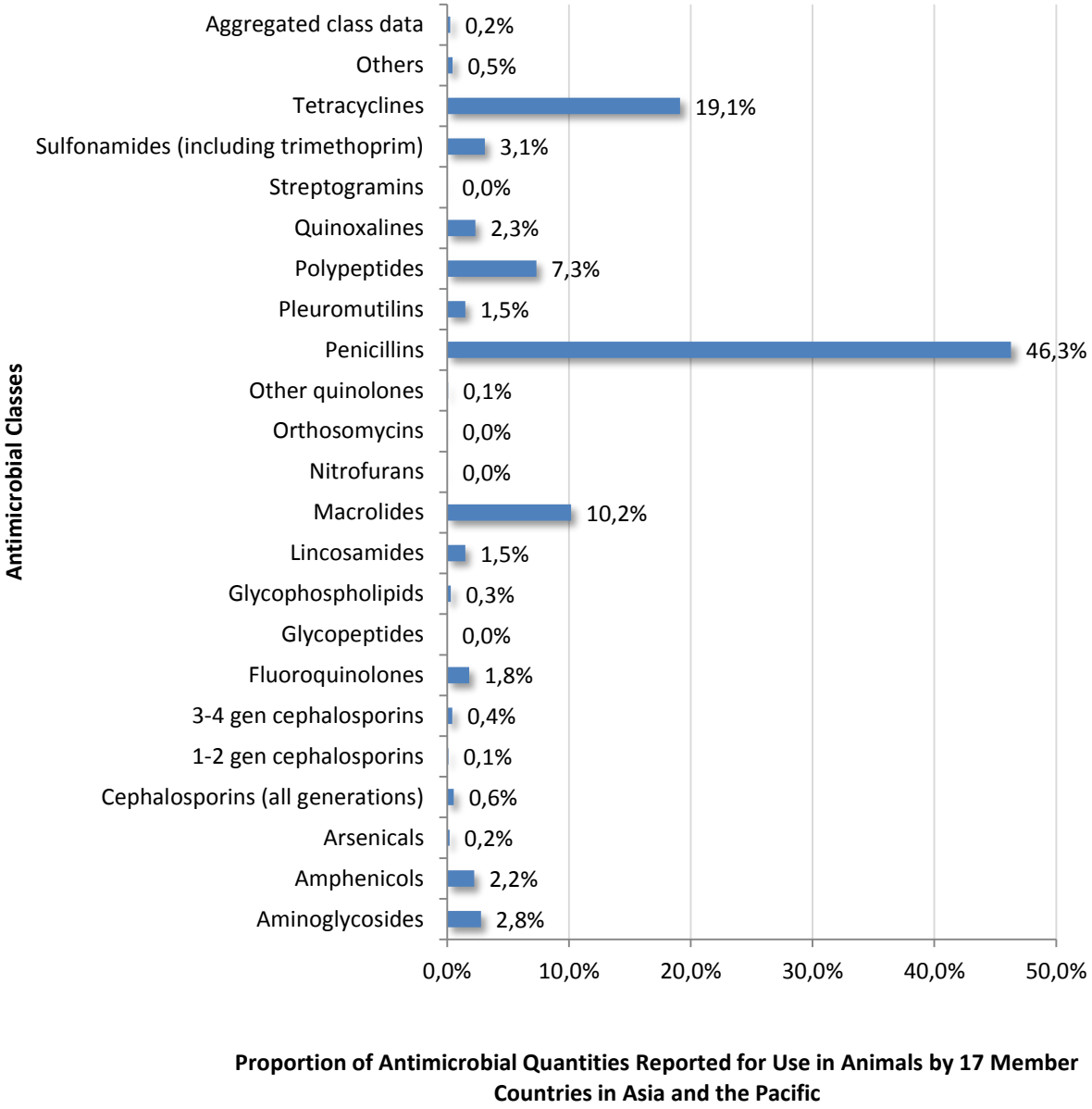
Figure A22. Food-Producing Animal Species Included in Quantitative Data Reported by 17 Member Countries in Asia and the Pacific from 2013-2016



Antimicrobial Classes Reported

In Asia and the Pacific, the largest proportion of all antimicrobial classes for which quantities were reported were penicillins and tetracyclines, followed by macrolides (Figure A23).

Figure A23. Proportion of Antimicrobial Quantities (by Antimicrobial Class) Reported for Use in Animals by 17 Member Countries in Asia and the Pacific from 2013-2016



Annex 4. Europe, Responses from the Second Phase of Data Collection

Table A4. General Information for Europe

General Information for Europe	
Number of Member Countries	53
Number of Member Countries responding to the questionnaire	46 (87%)
Number of Member Countries providing only qualitative data	6 (13%)
Number of Member Countries providing quantitative data	40 (87%)

Barriers to Providing Quantities of Antimicrobial Agents in Animals

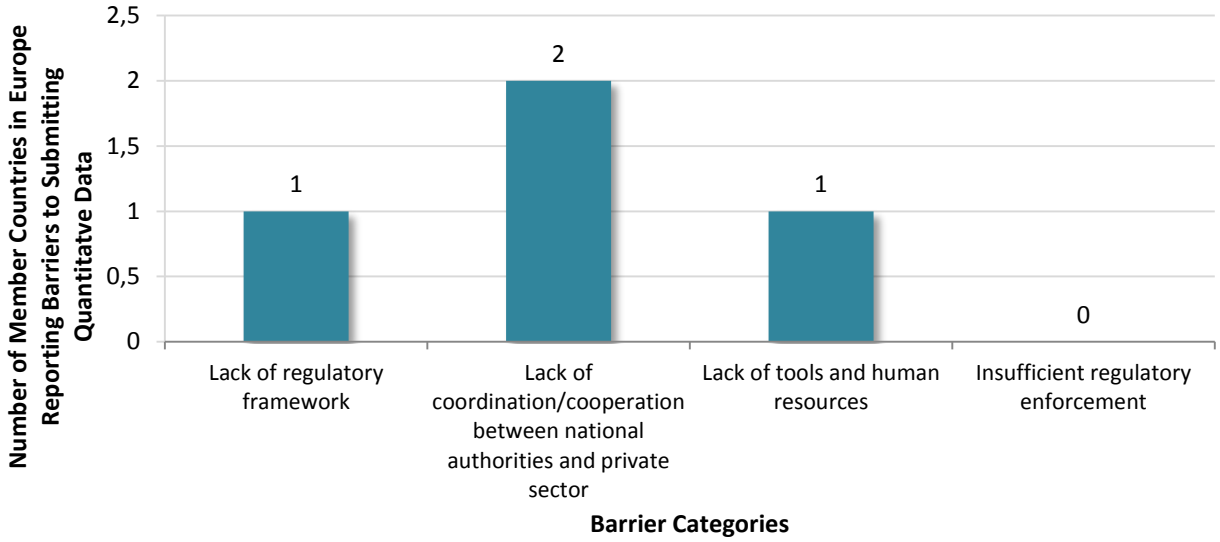
Six Member Countries (6/46; 13%) provided only Baseline Information (qualitative data) and no quantitative data on antimicrobial agents used in animals (Table A4). Two of these Member Countries explained that their data collection process was still under development and that data would be provided in the third phase of data collection. The four remaining Member Countries explained the barriers to reporting quantities of antimicrobial agents in animals to OIE, and these responses were grouped by category (Figure A25). For further information, please see the explanatory section in the global analysis for this report.

Two Member Countries in Europe described impediments to reporting amounts of antimicrobials to related to a 'lack of coordination/cooperation between other national authorities and with private sector'; one explained that the data were held under the authority of the Ministry of Health, while the other described a lack of collaboration with relevant industry stakeholders.

One Member Country describing a 'lack of regulatory framework' explained that due to absence of a National Action Plan on AMR, the country does not conduct monitoring of antimicrobial use in animals.

The Member Country describing a 'lack of tools and human resources' explained that significant progress has been made related to legislation for veterinary medicinal products, however, the data were not reported because a software for data collection was still under development. The country estimated that the software would soon be ready for reporting of quantitative data.

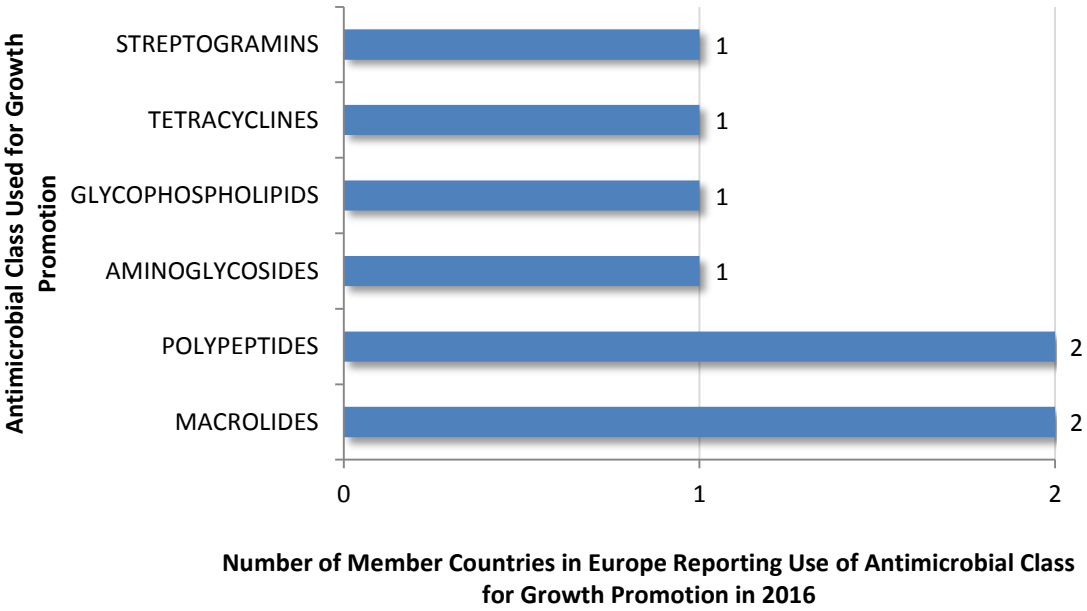
Figure A25. Country Barriers to Reporting Quantitative Data on Antimicrobial Agents Intended for Use in Animals in 4 Member Countries in Europe During the Second Phase of Data Collection



Antimicrobial Agents Used for Growth Promotion

Six European Member Countries reported using antimicrobial growth promoters in animals. Of these, 2 Member Countries (2/6; 33%) provided a list of antimicrobials used for this purpose, with macrolides and polypeptides named by both (Figure A26). The four remaining Member Countries did not report the agents used. When the four were asked to clarify why this information could not be reported, one Member Country responded that no legislation existed for antimicrobial growth promotors despite their known use, and the other three did not reply.

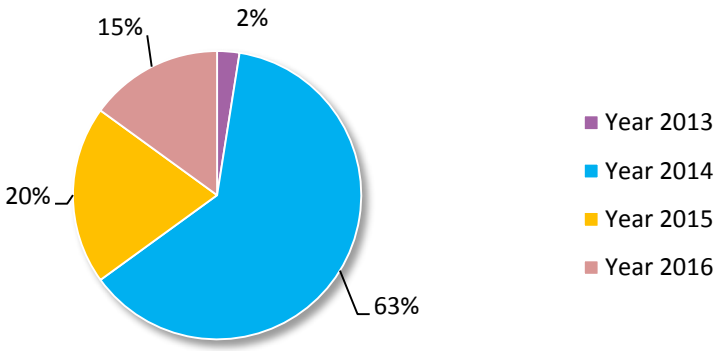
Figure A26. Antimicrobial Growth Promoters Used in Animals in 2 Member Countries in Europe in 2016



Years of Quantitative Data Reported

Most of the 40 Member Countries reporting from Europe provided quantitative data on antimicrobial agents intended for use in animals for 2014, the target year of data collection for the OIE (Figure A27). Most of the countries of this OIE Region are accustomed to reporting sales of veterinary antimicrobial agents through the ESVAC protocol, for which the 2014 data had already been collected.

Figure A27. Years of Quantitative Data Reported from 40 Member Countries in Europe During the Second Phase of Data Collection

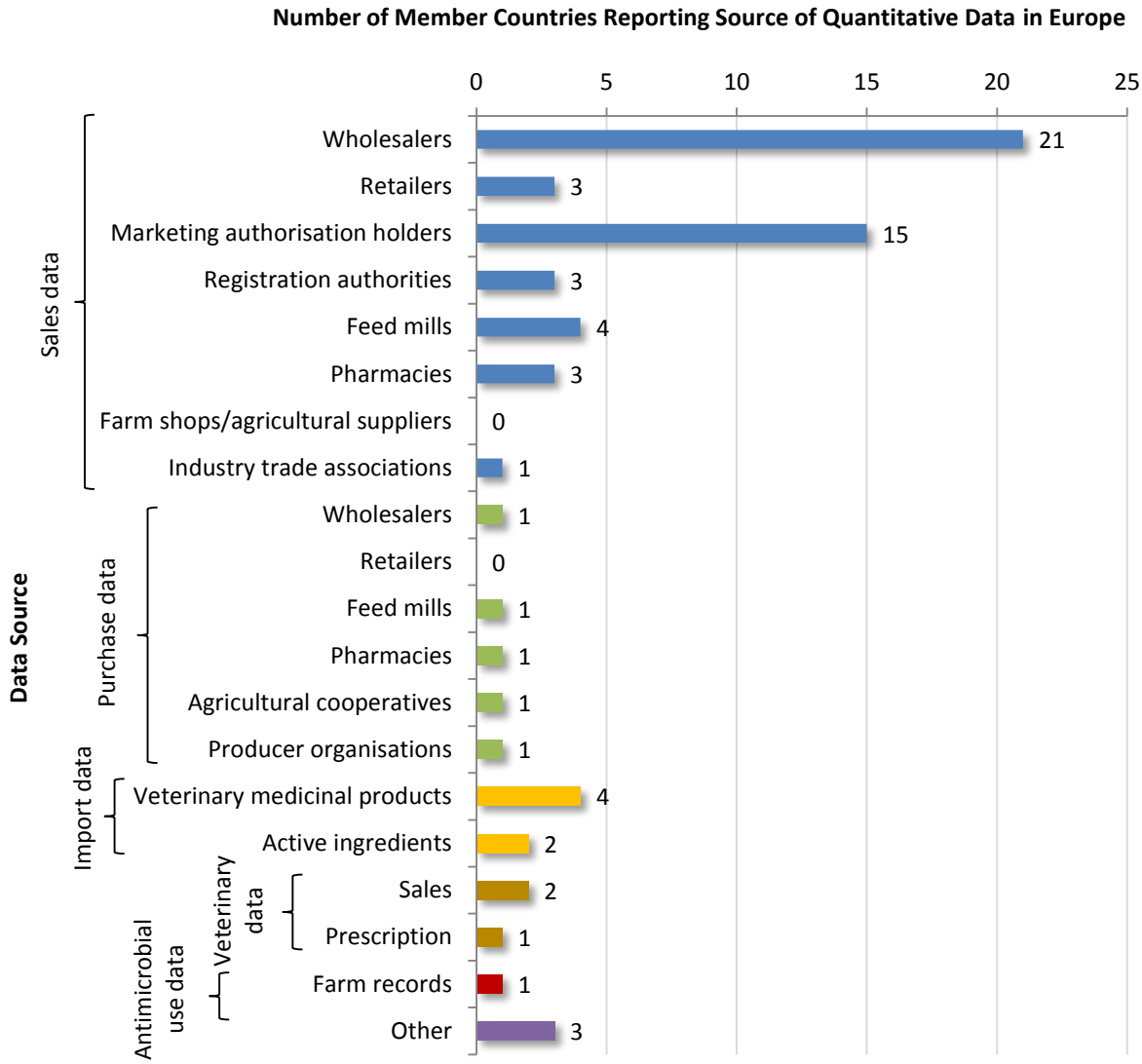


Quantitative Data Sources Captured

From the list of data source options provided in the OIE Template, sales data from wholesalers was chosen by 21 Member Countries in Europe, followed by sales from Marketing Authorisation Holders chosen by 15 Member Countries (Figure A28).

The 4 Member Countries reporting 'other' sources identified data from import permits issued by registration authorities, and data reported directly from importers. One country, in addition to data from importers, also reported production data from in-country manufacturers.

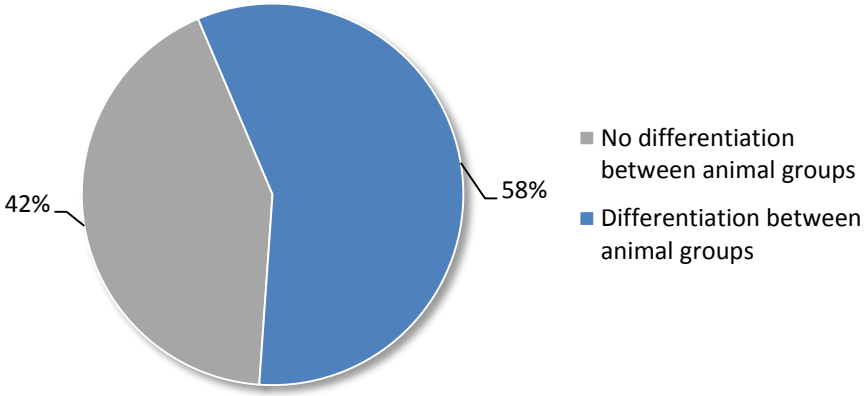
Figure A28. Data Sources Selected by 40 European Member Countries Reporting Quantitative Information from 2013-2016



Quantitative Data Differentiation by Animal Groups

More than half of the quantitative data reported to the OIE from European Member Countries were differentiated by animal groups (Figure A29). These results correspond with the European Region's predominant use of Reporting Option 2 and 3. Globally, 7 Member Countries were able to distinguish quantitative data specifically for 'Aquatic food-producing animals', and 3 of these 7 Member Countries were from Europe.

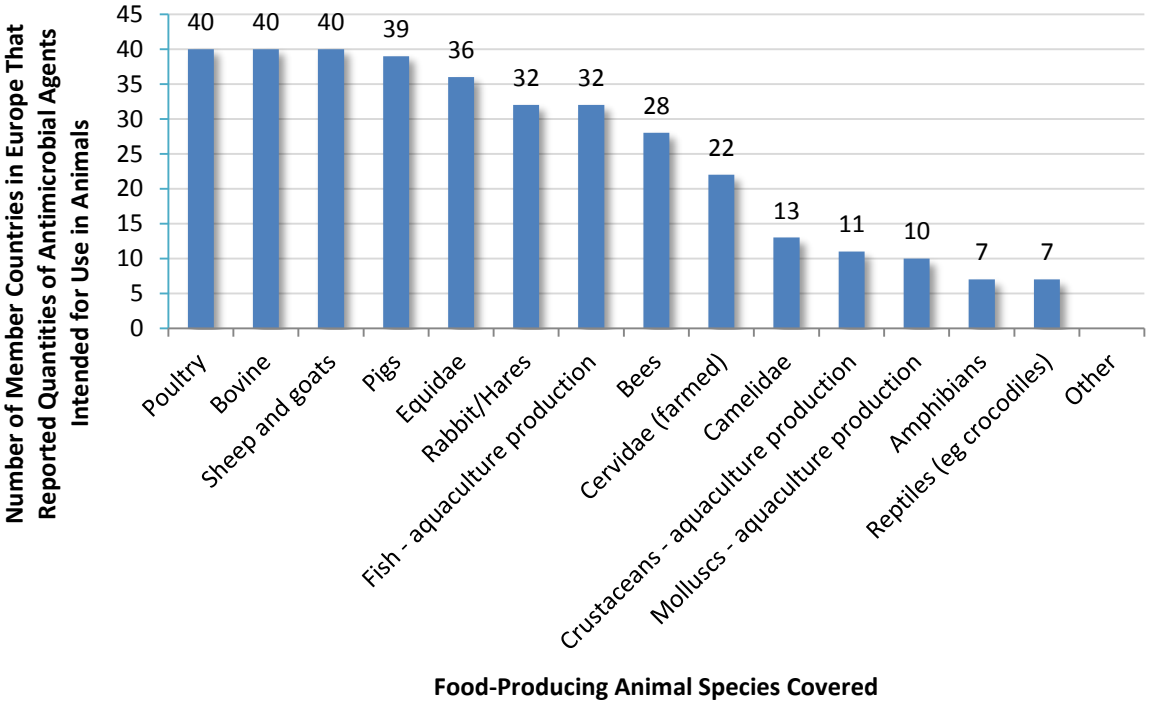
Figure A29. Differentiation by Animal Groups Among 40 Member Countries in Europe Reporting Quantitative Data from 2013-2016



Food-Producing Animal Species Covered by Quantitative Data

In the 40 European Member Countries that reported quantitative data on antimicrobial agents intended for use in animals, the food-producing species most frequently covered by the reported data were 'poultry', 'cattle', 'sheep and goats' and 'pigs' (Figure A30). Of the poultry production types, all Member Countries named reported coverage of broiler chickens.

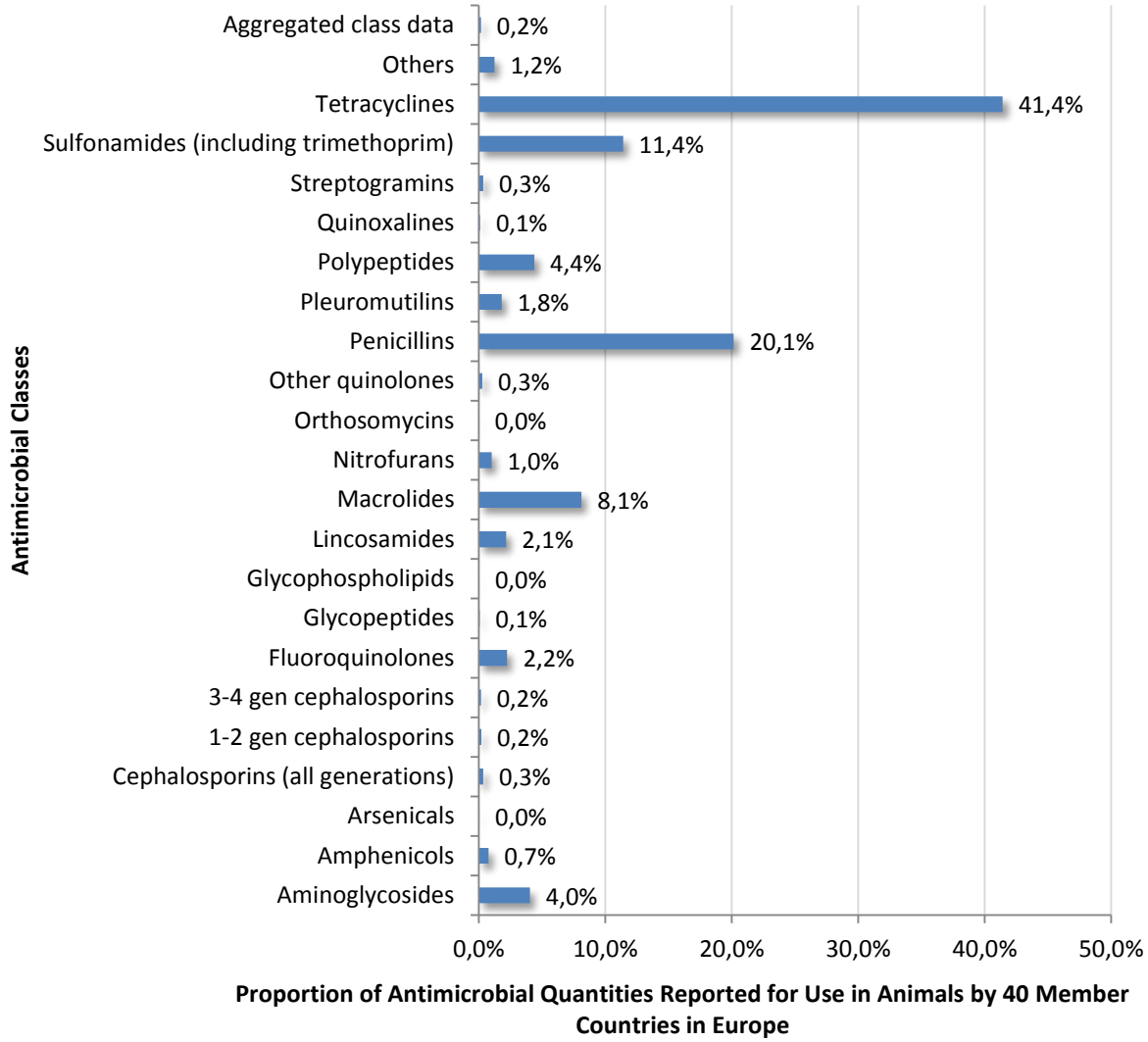
Figure A30. Food-Producing Animal Species Included in Quantitative Data Reported by 40 European Member Countries from 2013-2016



Antimicrobial Classes Reported

In Europe, the largest proportion of all antimicrobial classes reported for use in animals were tetracyclines and penicillins (Figure A31). Under the category of 'others' most of the countries reported use of spectinomycin (12/27; 44%), followed by rifaximin (11/27; 41%).

Figure A31. Proportion of Antimicrobial Quantities (by Antimicrobial Class) Reported for Use in Animals by 40 Member Countries in Europe from 2013-2016



Annex 5. Middle East, Responses from the Second Phase of Data Collection

Table A5. General Information for the Middle East

General Information for the Middle East	
Number of Member Countries	12
Number of Member Countries responding to the questionnaire	4 (33%)
Number of Member Countries providing only qualitative data	1 (25%)
Number of Member Countries providing quantitative data	3 (75%)

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

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.		Questions in **bold** are mandatory. Please provide this information as requested. Questions in *grey italics* are optional.
	A. Contact Person for Antimicrobial Agents Use Data Collection		
1	**Title**	<free text field>	Please provide details of the person completing this template, in case there are queries on the information provided. Please select the appropriate 'Role with respect to the OIE' from the list.
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>	Please provide the telephone number in the format " (country code) phone number ".
8	**Email Address**	<free text field>	
	B. General Information		
9	**Are data on the amount of antimicrobial agents for use in animals available?**	☐ Amounts available - Yes ☐ Amounts available - No	
10	*Please indicate why the data is not available at this time in your country, if the answer to Question 9 is 'No'*	*<free text field>*	
11	**Are antimicrobial growth promoters authorised for use in your country?**	☐ Yes ☐ No	Growth Promotion refers to the use of antimicrobial substances to increase the rate of weight gain and/or the efficiency of feed utilization in animals by other than purely nutritional means. **In case your country has no legislation / regulations for antimicrobial growth promotion, but use of antimicrobial agents for growth promotion is known to occur, choose 'Yes'.**
12	*List of **allowed antimicrobial growth promoters**, should be provided if you answered 'Yes' to Question 11 and legal provision exists*	*<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 on the Use of Antimicrobial Agents in Animals		
	*** Please provide data for **2014**. If you have data for another year, please select the year from the list below ***		Please provide data for **2014**. If you have data for another year, please select the year from the list. We will accept data for other years , **but not before 2014**). If you would like to provide data for additional years, please fill out one template per year of data.
13	**Year for which data apply** (Please select only one year per template)	☐ **2014** ☐ 2015 ☐ 2016	
14	**Time period for which data are provided** (e.g., 1 January to 31 December)	<free text field>	
15	**Data source**	☐ Sales - Wholesalers ☐ Sales - Retailers ☐ Sales - Marketing Authorisation Holders ☐ Sales - Registration Authorities ☐ Sales - Feed Mills ☐ Sales - Pharmacies ☐ Sales - Farms Shops/Agricultural Suppliers ☐ Sales - Industry Trade Associations ☐ Purchase data - Wholesalers ☐ Purchase data - Retailers ☐ Purchase data - Feed Mills ☐ Purchase data - Pharmacies ☐ Purchase data - Agricultural Cooperatives ☐ Purchase data - Producer Organisations ☐ Import data - Customs declarations - Veterinary Medicinal Product ☐ Import data - Customs declarations - Active Ingredient ☐ Veterinary data - Sales ☐ Veterinary data - Prescriptions ☐ Antimicrobial use data - Farm Records ☐ Other	From the list of options, indicate the data sources from which the information on the amount of antimicrobial agents for use in animals was obtained. Multiple selections are possible.
16	*Clarification of the data source, if your response to Question 15 is 'Other'*	*<free text field>*	
17	**Estimated coverage of accessible data of total amount (in %)**	**0%**	Please provide an estimate of the extent to which the quantitative data you report is representative of the overall antimicrobial sales for use in animals (percentage of the total sales in your country in relation to overall use).
18	**Explanation of estimated coverage**	<free text field>	

19	**Is the information extrapolated from representative samples?**	☐ Data extrapolated from representatives samples - Yes ☐ Data extrapolated from representatives samples - No	Please indicate whether the data provided have been extrapolated from representative samples (e.g., at farm or veterinary level).
20	*Explanation of extrapolations carried out, if your response to Question 19 is 'Yes'*	*<free text field>*	
21	**Can data be differentiated by animal group?**	☐ Data differentiated by animal group - Yes ☐ Data differentiated by animal group - 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'.
22	**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 ☐ Data for aquatic food-producing animals ☐ Data for companion animals	Please indicate which animal groups are covered by your data. Multiple selections are possible.
23	**Food-producing animal species <u>covered by the data</u>**	☐ 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/Hares ☐ Bees - Honey ☐ Fish - aquaculture production ☐ Crustaceans - aquaculture production ☐ Molluscs - aquaculture production ☐ Amphibians ☐ Reptiles (e.g., crocodiles) ☐ Other ☐ All	Please indicate which food-producing animals are covered by the data. Multiple selections are possible. For the purpose of this database, the following terms are defined: **Pigs – commercial:** pigs including piglets, fattening pigs and breeding pigs . **Sheep/goats (mixed flocks):** use this option only if there are mixed flocks and you cannot differentiate between sheep and goats in your country. **Other commercial poultry:** it includes turkey, duck, geese, quail, guinea fowl, pheasant, pigeon, ostrich, etc. in commercial production . **Poultry – backyard:** poultry including chickens and hens in backyard or village flocks . **Equidae:** domestic horses, donkeys and their crosses .
24	*Clarification of species considered to be food-producing, if your response to Question 23 is 'Other'*	*<free text field>*	When 'Other' is selected in Question 23, please clarify the other animal species that are raised for food production that are covered by the data.
25	**Can data be differentiated by route of administration?**	☐ Data differentiated by route of administration - Yes ☐ Data differentiated by route of administration - No	
26	**National report(s) on sales of antimicrobials for use in animals available on the web?**	☐ Report available on the web - Yes ☐ Report available on the web - No	
27	*Please provide the link to the report, if the answer to Question 26 is 'Yes'*	*<free text field>*	

According to your respon ses 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 21, 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 21, 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 21 and Question 25, 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 used in animals
Reporting option 1 - Overall amount sold for/used in animals by antimicrobial class; with the possibility to separate by type of use

Antimicrobial Class	Overall Amount: Growth Promotion + Therapeutic Use All animal species (kg)	Amount: Therapeutic Use (including prevention of clinical signs) All animal species (kg)	Amount: Growth Promotion 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 used in animals
Reporting option 1 - Overall amount sold for/used in animals by antimicrobial class; with the possibility to separate by type of use

Antimicrobial Class	Overall Amount: Growth Promotion + Therapeutic Use All animal species (kg)	Amount: Therapeutic Use (including prevention of clinical signs) All animal species (kg)	Amount: Growth Promotion 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 used 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: Growth Promotion + Therapeutic Use	Amount for: Therapeutic 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 used in animals

Reporting option 3 - Overall amount sold for/used in animals by antimicrobial class; with the possibility to

	Overall Amount: Growth Promotion + Therapeutic Use	Amount: Therapeutic 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

WORLD ORGANISATION FOR ANIMAL HEALTH
Protecting animals, preserving our future

Guidance for completing the OIE template for the collection of data on antimicrobial agents used in animals

Contents

Introduction

The OIE proposes to collect data on antimicrobial agents used 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 used in animals or used 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 use in animals from all OIE Member Countries in a harmonised way. Using a phased approach, the OIE will initially focus on **sales**[15] of antimicrobial agents destined for use in animals as an indicator of actual use. All antimicrobial agents destined for use in animals and listed in the OIE List of antimicrobial agents of veterinary

[15] '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.

importance[16], 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 the 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 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.

16 http://www.oie.int/fileadmin/Home/eng/Our_scientific_expertise/docs/pdf/Eng_OIE_List_antimicrobials_May2015.pdf

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	
9	**Are data on the amount of antimicrobial agents used in animals available?**	Please indicate whether quantitative data (i.e., data on the amount) on antimicrobial agents used 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 is not available at this time in your country, if the answer to Question 9 is 'No'*	Please indicate the reason why the data is not available in this moment in your country. If the answer to the previous question is 'No'.
11	**Are antimicrobial growth promoters authorised for use in your country?**	Please respond by ticking either 'Yes' or 'No'. In case your country has no legislation / regulations for antimicrobial growth promotion, but use of antimicrobial agents for growth promotion is known to occur, choose 'Yes'.
12	*List of allowed antimicrobial growth promoters, should be provided if you answered 'Yes' to Question 11 and legal provision exists*	If antimicrobial growth promoters are used (meaning the response to Question 11 is 'Yes'), please list the antimicrobial agents (active ingredient name, not product name) used for growth promotion. Please use the terminology of the OIE List of antimicrobial agents of veterinary importance[17].
	If you do not know which substances or classes of substances are used in animals in your country, the completion of the OIE template is terminated after completing Question 12 of the Baseline Information sheet.	
	C. Data Collection (Reserved to the Countries where data are available)	
13	**Year for which data apply** (Please select only one year per template)	Please provide data for 2014. If you have data for another year, please select the year from the list. We will accept data for other years, but not before 2014. If you would like to provide data for additional years, please fill out one template per year of data.
14	**Time period for which data are provided** (e.g., 1 January to 31 December)	Please provide further information regarding the reporting year, especially if the data only covers a portion of the calendar year.
15	**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.

[17] http://www.oie.int/fileadmin/Home/eng/Our_scientific_expertise/docs/pdf/Eng_OIE_List_antimicrobials_May2015.pdf

		• 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 to 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.
16	*Clarification of the data source, if your response to Question 15 is 'Other'*	If under Data source the option 'Other' is selected, please explain here which source of information was used.
17	**Estimated coverage of accessible data on total amount (in %)**	Please provide an estimate of the extent to which the quantitative data you report is representative of the overall antimicrobial sales for use in animals (percentage of the total sales in your country in relation to overall use).
18	**Explanation of estimated coverage**	Please explain in this field which sales are not captured by the data on antimicrobial agents used in animals reported for your country, or the nature of any extrapolations that were carried out in order to provide the data recorded 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 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).
19	**Is the information extrapolated from representative samples?**	Please indicate whether the data provided in your report have been extrapolated from representative samples.
20	*Explanation of extrapolations carried out, if your response to Question 19 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.

21	**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'.
22	**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 species', 'Aquatic food-producing animals', 'Data for aquatic food-producing animals' and 'Data for companion animals'. Multiple selections are possible.
23	**Food-producing animal species covered by the data**	Animal species considered to be food-producing animals vary between countries. The OIE needs to gain an understanding of how this difference impacts the data reported to the OIE and future reporting of summary data by the OIE. Please indicate which animals are considered to be food-producing animals covered by the data. Multiple selections are possible.
24	*Clarification of species considered to be food-producing, if your response to Question 23 is '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.
25	**Can data be differentiated per route of administration?**	Please respond by ticking either 'Yes' or 'No'.
26	**National report(s) on sales/use of antimicrobial agents in animals available on the web?**	Please respond by ticking either 'Yes' or 'No'.
27	*Please provide the link to the report, if your response to Question 26 is 'Yes'*	If answer is 'Yes' to Question 26, 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 therapeutic use 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.
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.

Antimicrobial class	Guidance
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*. 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*.

Field name	Information to be provided
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 used in animals in kilograms (kg) should be reported. Where data is 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 (therapeutic use including prevention of clinical signs, or growth promotion; see definitions below).

For this Reporting Option 1, complete the columns "Therapeutic Use" (including prevention of clinical signs) and "Growth Promotion". The sum of sales for "Therapeutic Use" and "Growth Promotion" should equal the amount entered in the column "Overall Amount (Growth Promotion + Therapeutic Use)" 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, therapeutic use, 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 "Therapeutic Use (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 + Therapeutic Use)" 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 therapeutic use, including prevention of clinical signs, or growth promotion, is possible.

In the category of "Therapeutic Use (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 therapeutic use 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**
  In line with the definition developed by *Codex Alimentarius* in *CAC/RCP 61-2005*, Growth Promotion refers to the use of antimicrobial substances to increase the rate of weight gain and/or the efficiency of feed utilization in animals by other than purely nutritional means. The term does NOT apply to the use of antimicrobial agents for the specific purpose of treating, controlling, or preventing infectious diseases, even when an incidental growth response may be obtained. **Growth promoters** in the context of this template are antimicrobial agents used for the purpose of growth promotion.

- **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.

- **Therapeutic use**
  Administration of an antimicrobial agent to animals to prevent, control or treat infection or disease. Acknowledging that the OIE template may be completed without consulting this guidance document, it was agreed that for reasons of clarity the OIE template would use 'Therapeutic use (including prevention of clinical signs)' in the table headings of all Reporting Options.

- **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 x 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 x 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[18]

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.

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

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.

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

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

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[19]

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

Antimicrobial agent (prodrug)	Active entity	Prodrug conversion factor for multiplication
Benethamine benzylpenicillin	Benzylpenicillin	0.65
Benzathine benzylpenicillin	Benzylpenicillin	0.39
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.

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

Annex 9. Distribution of Member Countries by Region according to the OIE Note de Service 2010/2012

Invitation of Members in all OIE meetings (except to the Conferences of the OIE Regional Commissions)

AFRICA (54)

1. ALGERIA
2. ANGOLA
3. BENIN
4. BOTSWANA
5. BURKINA FASO
6. BURUNDI
7. CAMEROON
8. CAPE 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. ETHIOPIA
20. GABON
21. GAMBIA
22. GHANA
23. GUINEA
24. GUINEA BISSAU
25. KENYA
26. LESOTHO
27. LIBERIA
28. LIBYA
29. MADAGASCAR
30. MALAWI
31. MALI
32. MAURITANIA
33. MAURITIUS
34. MOROCCO
35. MOZAMBIQUE
36. NAMIBIA
37. NIGER
38. NIGERIA
39. RWANDA
40. SAO TOME AND PRINCIPE
41. SENEGAL
42. SEYCHELLES
43. SIERRA LEONE
44. SOMALIA
45. SOUTH AFRICA
46. SOUTH SUDAN (REP. OF)
47. SUDAN
48. SWAZILAND
49. TANZANIA
50. TOGO
51. TUNISIA
52. UGANDA
53. ZAMBIA
54. ZIMBABWE

AMERICAS (29)

1. ARGENTINA
2. BAHAMAS
3. BARBADOS
4. BELIZE
5. BOLIVIA
6. BRAZIL
7. CANADA
8. CHILE
9. COLOMBIA
10. COSTA RICA
11. CUBA
12. DOMINICAN REP.
13. ECUADOR
14. EL SALVADOR
15. GUATEMALA
16. GUYANA
17. HAITI
18. HONDURAS
19. JAMAICA
20. MEXICO
21. NICARAGUA
22. PANAMA
23. PARAGUAY
24. PERU
25. SURINAME
26. TRINIDAD AND TOBAGO
27. UNITED STATES OF AMERICA
28. URUGUAY
29. 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 (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. MICRONESIA (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. ANDORRA
3. ARMENIA
4. AUSTRIA
5. AZERBAIJAN
6. BELARUS
7. BELGIUM
8. BOSNIA AND HERZEGOVINA
9. BULGARIA
10. CROATIA
11. CYPRUS
12. CZECH REP.
13. DENMARK
14. ESTONIA
15. FINLAND
16. FORMER YUG. REP. OF MACEDONIA
17. FRANCE
18. GEORGIA
19. GERMANY
20. GREECE
21. HUNGARY
22. ICELAND
23. IRELAND
24. ISRAEL
25. ITALY
26. KAZAKHSTAN
27. KYRGYZSTAN
28. LATVIA
29. LIECHTENSTEIN
30. LITHUANIA
31. LUXEMBOURG
32. MALTA
33. MOLDAVIA
34. MONTENEGRO
35. NETHERLANDS
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

Note regarding Turkey: - For WAHIS workshops Turkey will be invited to the Middle East meetings.
- For Communication seminars Turkey will be invited to both the Europe and Middle East meetings.