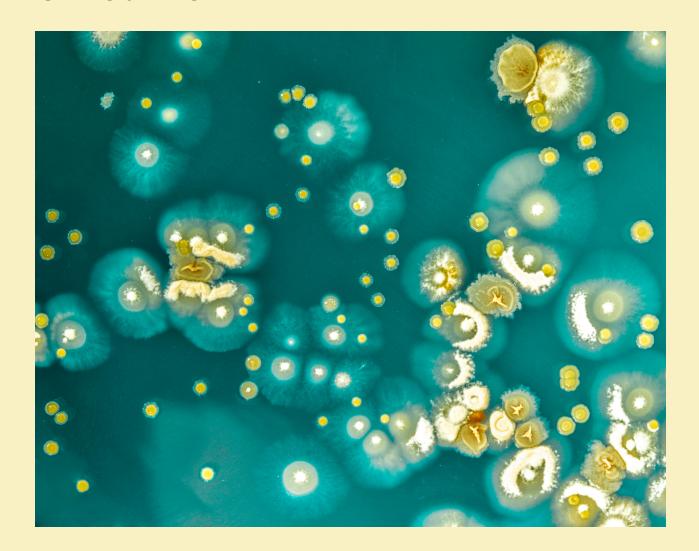
Annual Report on Antimicrobial Agents Intended for Use in Animals 6th edition





World Organisation for Animal Health Founded as OIE The World Organisation for Animal Health has launched a new brand identity, including a new acronym, in May 2022.

This document was developed before the changes took place.

Therefore, it does not reflect the new brand image of the Organisation.

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Foreword



Dr Monique Éloit OIE Director General

It is my long-held view that the One Health approach is widely recognised as the cornerstone of the strategy to stem the development of antimicrobial resistance (AMR) worldwide. With this in mind, and considering the importance of the environment in AMR, the OIE and its Tripartite partners – the Food and Agriculture Organization of the United Nations (FAO) and the World Health Organization (WHO) – have extended our long-lasting collaborative relationship on AMR to include the United Nations Environment Programme (UNEP) as a full partner in 2022. Therefore, UNEP has joined the Quadripartite Joint Secretariat on AMR and the Multi-Partner Trust Fund on AMR. The four organisations published their strategic framework, *Together for One Health*, for collaboration on AMR and a subsequent 2-year rolling

workplan on 6 April 2022. The strategic framework sets out our joint vision on curbing AMR and our united actions to preserve the effectiveness of antimicrobials.

The responsibility of the OIE to collect data on the use of antimicrobials in animals is reiterated in the global action plan (GAP) on AMR, where the OIE is requested to 'build and maintain a global database on the use of antimicrobial medicines in animals'. As a result of the tremendous efforts of its Members, the *OIE Annual Report on Antimicrobial Agents Intended for Use in Animals* (AMU) has been published every year since December 2016, and has highlighted a steady increase in participation. This report, a major milestone in the global effort to contain AMR, presents the progress achieved by 155 OIE Members, one non-contiguous territory of an OIE Member, and one non-OIE Member that participated in the data collection in the sixth round. The OIE recognises the efforts of the OIE Delegates and National Focal Points for Veterinary Products in their contribution to this extraordinary undertaking, despite the COVID-19 pandemic situation.

In 2020, the OIE began the building phase of an interactive information technology (IT) system for OIE AMU data collection. This new system is scheduled to be delivered in 2022 during the eighth round of data collection, and is expected to facilitate Members' instant access to their data, enabling guidance on decisions at the national level. The OIE is developing suitable support and training approaches that will provide all Members with the knowledge and capability to begin using this new system, while being mindful of the still ongoing pandemic.

Additionally, in 2018, the *OIE List of Antimicrobial Agents of Veterinary Importance* was discussed at the 2nd OIE Global Conference on Antimicrobial Resistance and Prudent Use of Antimicrobial Agents with the recommendation to the OIE to include in it a sub-division by animal species. This task was delegated to the OIE Working Group on Antimicrobial Resistance, with its first deliverable produced in October 2020 for the antimicrobial agents used in poultry. At the time of writing, the sub-division for swine and aquatic animals is ongoing, and it is envisaged that these evolutions will contribute to the development and updating of treatment guidelines and of tools for risk management and risk prioritisation to minimise and contain AMR at the national level.

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

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Executive summary

The OIE Annual Report on Antimicrobial Agents Intended for Use in Animals gathers data provided, on a voluntarily basis, by the Veterinary Services of OIE Members and non-OIE Members on the use of antimicrobial agents in animals. The present report has three main sections: (1) interpretation of the overall findings of the sixth annual data collection round, reporting results at global and regional levels; (2) detailed analyses for 2018, with regard to the total amount of antimicrobial agents intended for use in animals, as well as normalised using an estimated animal biomass indicator; (3) trend analyses for 2016 to 2018, after adjustment to the estimated animal biomass indicator.

Methods

Every September, the OIE invites its 182 Members and 11 non-OIE Members to participate in its annual data collection on antimicrobial agents intended for use in animals, by sending a template to complete and a series of accompanying guidance documents. The template is provided in the form of an Excel file comprising four worksheets, in which invited participants are requested to provide Baseline Information or quantitative data. This allows separating amounts to be reported by type of use ('veterinary medical use', which includes use to treat, control, or prevent disease; and 'non-veterinary medical use', which includes use for growth promotion), animal groups (terrestrial food-producing, aquatic food-producing, or companion) and routes of administration (oral, injection and others). In addition, the OIE provides a complementary tool (Excel Calculation Tool), to ease reporting of comprehensive quantitative data sets. Data come mainly from sales and import figures of antimicrobial agents, as recommended by the Terrestrial Animal Health Code ('Monitoring of the quantities and usage patterns of antimicrobial agents used in food-producing animals') [1] and of the Aquatic Animal Health Code ('Monitoring of the quantities and usage patterns of antimicrobial agents used in aquatic animals') [2], being reported at the class or subclass level. For the purpose of reporting and comparing data across participants, among different sectors and over time, antimicrobial quantities are normalised by the use of an estimated animal biomass indicator, which can vary in size and composition over time. This indicator represents the total weight of live domestic animals in a given population present during a year in a specific area, being used as a proxy to represent those likely exposed to the quantities of antimicrobial agents reported. Animal biomass was calculated for foodproducing species of participants reporting quantitative data for 2018, primarily using data from the OIE World Animal Health Information System (OIE-WAHIS) and the Food and Agriculture Organization of the United Nations Statistical Database (FAOSTAT). Normalised results are expressed in milligrams of antimicrobial quantities reported per kilogram of estimated animal biomass.

For the purpose of this report, all invited participants reporting to the OIE their antimicrobial usage, whether they are OIE or non-OIE Members, are referred throughout this document as 'Countries'.

Further details on the methodologies used for this report are available in different published references ('OIE Annual Report on Antimicrobial Agents Intended for Use in Animals: Methods Used' article published in *Frontiers in Veterinary Science* in September 2019 [3] and 'From OIE standards to responsible and prudent use of antimicrobials: supporting stewardship for the use of antimicrobial agents in animals' [4]). It is important to note that information provided belongs to participant Countries, and is made available to the OIE for the purpose of better understanding the global and regional situation. Therefore, this report does not present data at individual Country level; however, publicly available data can be found in Section 11 of this report.

Overall findings of the sixth data collection round

A total of **157 reports were submitted** during the sixth round of data collection: 155 Members (155 out of 182; 85%), one non-contiguous territory¹ of an OIE Member with its own reporting mechanism, and one non-OIE Member. One hundred and twenty-six reports (126 out of 157; 80%) included quantitative data for at least one reported year within the time frame from 2018 to 2020. Seventy reports (70 out of 126; 56%) reported antimicrobial quantities with the highest details (Reporting Option 3), which means a 5% increase from the previous annual report, in many cases, helped by the assistance given by the Excel Calculation Tool developed by the OIE. Currently 35 participant Countries (35 out of 126; 28%) have reported making their **national reports publicly available**, the vast majority (30 out of 35; 86%) being European Countries.

Among the 24 participant Countries who provided information on the **barriers faced** in reporting quantities of antimicrobials intended for use in animals, lack of a regulatory framework, human resource constraints and circumstances that prevent the data collection, such as the COVID-19 pandemic, were primarily reported. Six of these Countries (6 out of 24; 25%) confirmed that actions are being prioritised to facilitate their reporting of quantities of antimicrobials to the OIE.

In 2020, the use of antimicrobial agents in animals **for growth promotion** is no longer a practice in nearly three-quarters of the participant Countries (108 out of 157; 69%), either with or without legislation/regulation provision around their use. However, the use of growth promoters is still reported by one quarter of the participant Countries to this sixth round of data collection (40 out of 157; 26%), with 68% of those concentrating in two regions: the Americas and Asia Far East and Oceania. Twenty-seven Countries provided data on which antimicrobial agents were used as growth promoters. Flavomycin, not used in humans according to the Critically Important Antimicrobials for Human Medicine (CIA list from World Health Organization) [5] is the most frequently listed antimicrobial agent (n=18 Countries). Bacitracin and tylosin are reported to be used by 15 Countries. While the former is not classified as critically important for use in humans, the latter is. Colistin, considered as Highest Priority Critically Important Antimicrobial for use in humans, is still reported to be used by six Countries. It is noteworthy that the number of those reporting the use of colistin as a growth promoter has been reduced by half over the four years up to 2020, confirming the progressive implementation of the OIE's recommendations to prohibit its use as growth promoter.

Focused analyses for 2018

The sixth report presents analyses with a special focus on the **antimicrobial quantities reported to be used in 2018** by 109 participant Countries (7% more than in the previous reported year). According to, in most of the cases, sales and import data reported, the OIE estimates that a total of 69,455 tonnes of antimicrobial agents intended for use in animals were used in 2018. Acknowledging the different data sources, data cover was on average 91% of the total amount of antimicrobials present in the field (as estimated by each Country), the OIE estimates that the adjusted total amount could be 76,704 tonnes. Overall, tetracyclines remained the most utilised antimicrobial agent in animal health globally (40.5% of the total amount), followed by penicillins (14.1% of the total amount). Both are part of the Veterinary Critically Important Antimicrobial (VCIA) classes in the OIE's list, while they are not part of the highest priority critically important antimicrobial agents for human health according to WHO [5]. The rest of the total amount (45%) is split among 21 other reported classes of antimicrobials. It is important to note that macrolides represent less than 9% of the total amount.

The analysis of antimicrobial agents normalised by estimated animal biomass was performed on data provided by 106 participant Countries (77% higher than the initial analysis back in 2014). This is considered to represent 72% of the total animal biomass around the globe (29% higher than in 2014), encompassing terrestrial and aquatic food-producing animals, with companion animals excluded from

¹ For the purpose of the OIE AMU Data Collection, '**non-contiguous territory**' means: an insular territory separated from the mainland but affiliated to an OIE Member, with its own AMU monitoring system.

the analyses. Bovine species account for 43% of the total coverage, followed by swine (20%) and poultry (18%). Aquatic animals account for 7% of the total coverage, being almost two-thirds represented by farmed fishes. With all this taken into consideration, the OIE estimates that, in 2018 a total of 86.69 to 95.74 milligrams of antimicrobial agents were used per kilogram of animal biomass, depending on how coverage estimates were adjusted among the 106 Countries.

Trends (2016-2018)

Analysis of these data over time could be done with data from 72 participant Countries having consistently provided quantitative information since 2016 to 2018, using the normalised amount of milligrams of antimicrobials used per kilogram of estimated animal biomass. Collected data, representing 65% of the global animal biomass, show an overall decrease of 27% in the mg/kg at the global level, moving from 120 mg/kg in 2016 to 88 mg/kg, in 2018. This decreasing trend was seen across all OIE regions, and confirms the trend already reported in the fifth report, suggesting a continuous overall global reduction in the utilisation of antimicrobial agents for intended use in animals. When looking at this trend by antimicrobial class, it is worth noting that diminution is observed for tetracyclines (21%, the most used antimicrobial class in animal health and classified by the OIE list as VCIA), in macrolides (43%, VCIA within the OIE list, and high priority in the CIA WHO list), as well as in polypeptides (62%, VHIA within the OIE list and split in two categories within the CIA WHO list: bacitracin - important and colistin - high priority).

Conclusions and perspectives

Participant Countries' commitment to providing information on the use of antimicrobials, since the initial data collection round which took place in 2015, represents a remarkable achievement. The overall **participation** rate in the current sixth data collection round has barely changed with regard to previous years, despite all the difficulties associated with the management of the COVID-19 pandemic. This allows the OIE to provide a comprehensive and fair representation of the global situation in the utilisation of antimicrobial agents intended for use in animals.

Tetracyclines remain the most **utilised antimicrobial** class globally in animal health, and while some antimicrobial classes considered as critically important for use in humans are still utilised, they represent a small part of the global picture. Sixty-nine percent of the participant Countries report not using antimicrobial agents for growth promotion, and notable progress has been made in the phasing out of using some high-priority critically important antimicrobial classes such as colistin. When assessed per kilogram of estimated animal biomass, antimicrobial use in food-producing animals keeps its global reduction over time. Important progress has been made by all participant Countries and further engagement is still needed to attain a sustainable use of this common good that are antimicrobial agents.

The OIE remains committed to Members in supporting a responsible and prudent use of antimicrobials in animals. The development of a Phase 2 OIE Global Database seeks to deliver an interactive online system customised for OIE Members enabling them to complete data-entry requirements, calculate antimicrobial quantities, and have their animal biomass estimated through secure confidential access to a central database. Members will be provided with functional access to the database to review, analyse, present and use their own data, in line with the OIE's responsibility for global and regional data aggregation, analysis and reporting.

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The OIE acknowledges the continuous support provided by its Technical Officers from the OIE Regional and Sub-regional Representations during the OIE AMU Data Collection rounds and in maintaining relationships with OIE Members during the COVID-19 pandemic.

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

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

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Acronyms and abbreviations

Antimicrobial resistance
Antimicrobial use
Canadian Integrated Program for Antimicrobial Resistance Surveillance
European Surveillance of Veterinary Antimicrobial Consumption
Food and Agriculture Organization of the United Nations
United States Food and Drug Administration
Japanese Veterinary Antimicrobial Resistance Monitoring System
Livestock unit
National action plan
World Organisation for Animal Health
World Animal Health Information System
Performance of Veterinary Services
World Health Organization

OIE Glossary²

Antimicrobial agent: means a naturally occurring, semi-synthetic or synthetic substance that exhibits antimicrobial activity (kill or inhibit the growth of micro-organisms) at concentrations attainable *in vivo*. Anthelmintics and substances classed as disinfectants or antiseptics are excluded from this definition.

Growth promotion, growth promoters: means the administration of antimicrobial agents to animals only to increase the rate of weight gain or the efficiency of feed utilisation.

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

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

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

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

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

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

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

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

² For the purposes of the OIE *Terrestrial Animal Health Code* [6].

1. Introduction

1.1. Background

OIE activities on antimicrobial resistance

In May 2015, during the 83rd General Session of the World Assembly of OIE Delegates, OIE Members officially committed to combatting antimicrobial resistance (AMR) and promoting the prudent use of antimicrobials in animals, and stated their full support for the Global Action Plan on AMR, developed by the World Health Organization (WHO) in close collaboration with the OIE and the Food and Agriculture Organization of the United Nations (FAO) [7]. One year later, during the 84th General Session, the World Assembly of Delegates directed the OIE to compile and consolidate all the actions to combat AMR [8], and the resultant OIE Strategy on AMR and the Prudent Use of Antimicrobials was published in November 2016 [9].

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

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

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

As reported in the 5th annual report on antimicrobial agents intended for use in animals, almost threequarters of the 136 OIE Members assessed through an initial OIE Performance of Veterinary Services (PVS) evaluation,³ from 2007 to December 2020, could not regulate veterinary medicinal products (assessed as 'Level 1'⁴ for the Critical Competency [CC] II-8 'Veterinary medicines and biologicals'), or had only some capability of exercising regulatory and administrative control over the import, manufacture and market authorisation (registration) of these products, which would ensure their safety and quality. Consequently, these Countries were unable to ensure the responsible and prudent use of such products in the field ('Level 2' of the CC II-8). The absence or low level of control of veterinary medicinal products leads to limited control of antimicrobial agents. The latter can potentially circulate freely in the market and, like ordinary goods, they may be falsified or

³ The 'initial' PVS evaluation mission provides a careful evaluation of the current performance of national Veterinary Services, and the capacity to undertake ongoing monitoring of performance over time using consistent methods. After some years, countries may request a PVS evaluation follow-up mission, which serves to update the assessment and documents the progress made by countries.

⁴ In the OIE PVS Tool, to establish the level of performance, Critical Competencies with five possible levels of advancement are identified within each of the four Fundamental Components. A higher level of advancement assumes that the Veterinary Service are complying with the preceding levels (e.g. Level 3 assumes compliance with Level 2 criteria). CCII-8 refers to Veterinary Medicines and Biologicals from the 7th Edition of the OIE *PVS Tool* (2019); for previous editions of the *OIE PVS Tool*, the relevant Critical Competency was CCII-9.

manufactured to a sub-standard level, and/or may be sold without any previous clinical or laboratory diagnostic assessment.

As previously reported, between August 2018 and December 2021, 19 Countries were assessed through PVS evaluations on CC-9 AMR and antimicrobial use (AMU)⁵. CCII-9 was assessed for all but one of these Countries, as:

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

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

The OIE publishes international standards on AMR and AMU. Its *Terrestrial Animal Health Code* (*Terrestrial Code*), Chapter 6.8. 'Harmonisation of national antimicrobial resistance surveillance and monitoring programmes', includes examples of target animal species and animal bacterial pathogens that may be included in resistance surveillance and monitoring programmes [10]. Its *Aquatic Animal Health Code* (*Aquatic Code*) includes a corresponding chapter, Chapter 6.4. 'Development and harmonisation of national antimicrobial resistance surveillance and monitoring programmes for aquatic animals' [11]. In addition, the OIE's *Manual of Diagnostic Tests and Vaccines for Terrestrial Animals*, Chapter 2.1.1. 'Laboratory methodologies for bacterial antimicrobial susceptibility testing' provides the laboratory methods supporting surveillance and monitoring [12]. During the 87th General Session in May 2019, Members adopted updates to Chapter 2.1.1., which included guidance on the harmonisation of microbial susceptibility testing in veterinary laboratories.

OIE activities on antimicrobial use

In addition to surveillance of antimicrobial resistance, monitoring of antimicrobial use is critical to understanding possible areas of risk for the development of resistance. In 2012, the OIE developed a questionnaire with the following objectives: (1) to enhance the OIE's engagement in the initiative to prevent antimicrobial resistance; (2) to conduct a survey of the implementation by OIE Members of OIE *Terrestrial Code* chapter on 'Monitoring of the quantities and usage patterns of antimicrobial agents used in food producing animals'; (3) to improve awareness of antimicrobial use in animals by OIE Members; and (4) to determine what actions are needed to help the OIE to develop its strategy in this field. A total of 152 of 178 (85%) OIE Members completed the questionnaire. The answers received showed that, in 2012, 27% of responding Members had an official system in place for collecting quantitative data on antimicrobial agents used in animals.

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

⁵ This CC allows for a more specific understanding on AMR and AMU surveillance, One Health governance of AMR, AMRspecific drug regulation and the veterinary contribution to NAPs on AMR.

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

Following these recommendations, in 2015, the OIE World Assembly unanimously adopted Resolution No. 26 during the 83rd General Session, officially mandating the OIE to gather data on the use of antimicrobial agents in animals worldwide [13]. As a result, this global database was created in compliance with chapters of the *Terrestrial Code* [1] and of the *Aquatic Code* [2].

In the framework of the Global Action Plan on Antimicrobial Resistance [7], 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.

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

During this first round of data collection on antimicrobial agents used in animals, 130 Members (n = 180; 72%) participated. The report resulting from this impressive participation in the first annual data collection, the *OIE Annual Report on Antimicrobial Agents Intended for Use in Animals: Better Understanding of Global Situation* [14], was published in December 2016. In this sixth round of data collection, 160 Countries submitted their reports, an increase of 23% since the first round of data collection in 2015.

As part of the sixth round, the OIE requested quantitative data on antimicrobials used in animals for the 2018 calendar year, but also accepted data from 2019 and 2020. The wider timespan of quantitative data collected allowed Countries, which are at various stages of development of their antimicrobial use monitoring systems, to contribute to the OIE data collection. However, this request presents a challenge for data analysis. As the timespan of quantitative data collected from the sixth round of data collection is broad, it was decided that in this sixth report, analysis of antimicrobial quantities would focus on 2018. This single year extended analysis will enable a greater level of comparison of data as well as favouring assessments of trends for future rounds of data collection. Comparison of quantitative data also requires a denominator with which to interpret the antimicrobial quantities reported.

To address these challenges, this report provides an examination of quantitative data in the context of relevant animal populations and includes an analysis of antimicrobial quantities adjusted for animal biomass on a global and regional level by year. The focus year of this additional analysis is 2018, using quantitative data reported to the OIE by 109 Countries during all rounds of data collection.

For the seventh round of data collection currently under way, the OIE has requested quantitative data for 2019 (the target year of that round), but will also accept data for 2020 and 2021. Accepting some repeated years of quantitative data from previous rounds provides an opportunity for Countries to correct and enrich the quality of these data sets where relevant. Over time, and once the reporting of data has become more routine, the OIE will request data for one specific calendar year. This way, OIE reporting will progress in parallel with the development of data collection systems from its Members, as global monitoring on the use of antimicrobial agents becomes more systematic and reliable.

1.2. Scope

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

In addition to the descriptive analysis of the sixth round of data collection, report includes a global and regional analysis of quantitative data on antimicrobial agents intended for use in animals adjusted by animal biomass. The focus year of this quantitative analysis is 2018; additionally, 2014, 2015, 2016 and 2017 data sets are updated in this report based on Countries historical updates.

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

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

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

2. Materials and methods

Every September, the OIE invites its Members and certain non-contiguous territories and non-OIE Members to participate in its annual data collection on antimicrobial agents intended for use in animals. In order to analyse the antimicrobial quantities reported, OIE Headquarters developed a formula to calculate animal biomass. The materials and methods for reporting antimicrobial quantities and estimating animal biomass are summarised in Sections 2.1 and 2.2 of this report. More information can be found in the 'OIE Annual Report on Antimicrobial Agents Intended for Use in Animals: Methods Used' article published in *Frontiers in Veterinary Science* in September 2019 [3].

2.1. Antimicrobial quantities reported

OIE Resolution

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

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

Invitation to Countries

The OIE maintains Regional offices globally covering Africa; the Americas; Asia, Far East and Oceania; Europe and the Middle East. The OIE template (Annex 6) and accompanying guidance documents (Annexes 7 and 8) were sent to all OIE Members in all OIE regions by e-mail in September 2020. In addition, they were sent to four non-contiguous territories and five non-OIE Members that asked to be part of the survey. (The list of all OIE Members is provided in Annex 9.)

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

OIE Template

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

An annex to the guidance provides more detailed instructions on mathematical calculations to obtain quantities of active ingredients from veterinary medicinal products containing antimicrobial agents sold. All antimicrobial agents destined for use in animals and contained in the *OIE List of Antimicrobial Agents of Veterinary Importance* [15], in addition to certain antimicrobial agents used only for growth

promotion, were reportable. For this sixth round, the conversion factors for some international units (IU) and for certain derivates or compounds were updated in the annex to assist with calculations (Annex 8, Tables 2 and 3).

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

Part A (Contact Person for Antimicrobial Agents Use Data Collection) and Part B (General Information) of the 'Baseline Information' sheet can be completed by any Country, and collects information on the current situation of governance of veterinary antimicrobials, including the Competent Authority for regulation of antimicrobial use in animals, use of growth promoters, and barriers to reporting quantitative data on antimicrobial agents used in animals, if any. For Countries able to provide quantitative data on antimicrobial agents intended for use in animals, the 'Baseline Information' sheet also contains questions relevant to data collection in Part C (Data Collection of Antimicrobial Agents Intended for Use in Animals), including year covered, data sources and food-producing species included. Countries providing multiple years of quantitative data are asked to provide a single template for every year of data, with Part C modified, if necessary, to reflect the reported quantitative data.

The OIE template was designed to allow all Countries to participate in the annual data collection even if the quantitative data on antimicrobial agents intended for use in animals were not nationally available. Even if no quantitative data collection system exists in the Country, the template section titled 'Baseline Information' can still be completed. This section contains three parts (A, B and C), as described in Table 11.

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.

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

Table 1. OIE Template sections and how Countries respond based on available data

Following completion of the Baseline Information, the template either directs Countries to submit the questionnaire if no quantitative data were available, or to complete one of the three 'Reporting Options' if quantitative data were available. The three reporting options represent increasing levels of detail of quantitative data on antimicrobial classes used in animals, with the possibility of separating amounts reported by type of use: Veterinary medical use, which includes use to treat, control or

prevent disease; and Non-veterinary medical use, which includes use for growth promotion; animal groups (Terrestrial, Aquatic or Companion); and routes of administration.

Data validation

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

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

2.2. Animal biomass estimation methodology

Background

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

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

Animal biomass is currently employed as a denominator in the 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 United States Food and Drug Administration (FDA), the Canadian Integrated Program for Antimicrobial Resistance Surveillance (CIPARS), and the Japanese Veterinary Antimicrobial Resistance Monitoring System (JVARM).

Data sources and methodology development

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

Data collected by global animal surveillance databases (OIE-WAHIS, FAOSTAT) are point-in-time species-level census data⁶ with little-to-no detail relating to production class. Such data are difficult to interpret given that production classes within a species can have very different average weights, such as beef cattle and veal calves. Additionally, given that census data are collected at a specific time of the year, the total annual population is not known for production groups which are slaughtered and repopulated a certain number of times within one year (this multiplication factor is hereafter referred to as the 'cycle factor').

The development of the methodology for the calculation of an annual animal biomass utilised globally available census data from the OIE-WAHIS interface. OIE-WAHIS data are reported by national Veterinary Services through the OIE Delegate, with the active support of OIE Focal Points for Animal

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

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 data set. 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 imputation of a data point by its statistical team.⁷ The two data sets are therefore similar but can display variation.

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

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

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

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

The methodology for calculation of animal biomass was developed with the support and validation of the previous OIE *ad hoc* Group on Antimicrobial Resistance, shared with Members in the report of the OIE Scientific Commission for Animal Diseases meeting of September 2017 and published in *Frontiers in Veterinary Science* in September 2019 [3]. The potential for inaccuracies in the estimation of animal biomass, in particular from extrapolating data available for one region of the world to other regions, is further discussed in Section 7.3 of the report.

Year of analysis

The target year of the sixth round of data collection, 2018, is the focus of the additional analysis of antimicrobial quantities adjusted for the animal biomass denominator. Countries providing quantitative data on antimicrobial agents intended for use in animals for 2018 during all rounds of data collection were included in this additional analysis.

Calculations of live weights for all species

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

⁷ According to the OECD Glossary of Statistical Terms imputation is the process used to determine and assign replacement values for missing, invalid or inconsistent data that have failed edits' (<u>https://stats.oecd.org/glossary/detail.asp?ID=3462</u>).

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

Carcass weights were converted to live weights from the animal at time of slaughter using conversion coefficients (k) as defined by Eurostat [16]. Conversion coefficients represent the difference between a processed carcass weight and the expected live weight of that animal species before slaughter, expressed as a fraction.

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

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

Countries were grouped by sub-region as defined by the OIE, also taking into account livestock unit (LSU) classifications.⁸ Mean sub-regional live weights were then determined by calculating the average live weight of a given species for Countries within the sub-regional grouping.

Methodology for calculating species biomass by Country

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

All weights and biomass figures are measured in kilograms.

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

- From the calculated sub-regional mean live weight, the weights of the different bovine production categories [adults, young (between 1 and 2 years of age), calves (<1 year of age)] were determined by applying relevant weight proportions standards, originating from livestock unit ratios as defined by Eurostat [18].
- Consecutively, the weight of each bovine production category was then multiplied by a predicted population ratio resulting in a representative weight for bovines for the sub-region. The applied population ratios were calculated in the reference Eurostat database and consider an anticipated renewal rate of 30%.

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

census population \times [(sub – regional mean live weight \times LSU_{calves} \times P.pop_{calves})

+ $(sub - regional mean live weight \times LSU_{young 1-2yrs} \times P. pop_{young 1-2yrs})$

+ $(sub - regional mean live weight \times LSU_{adults} \times P. pop_{adults})$]

Whereby,

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

LSU_{calves}, LSU_{young 1-2yrs}, and LSU_{adults} represents the livestock unit ratios for calves, young and adults, respectively, as defined by Eurostat [18].

⁸ Livestock units (LSU) [17], 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.

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

Swine biomass was calculated according to the following formula:

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

Whereby,

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

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

- sow weight: the standard weight of a sow in Europe is 240 kg [19]. This weight was adapted by region using livestock unit ratios (Americas = 240 kg, Asia, Far East and Oceania = 240 kg, Africa = 192 kg);
- 0.09 is the expected percentage of sows in a given swine population, as calculated using Eurostat animal population data.

Poultry biomass was calculated according to the following formula:

(live weight chicken \times number of chicken slaughtered)

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

Equidae biomass was calculated according to the following formula:

(live weight horse \times horse census population)

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

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

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

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

Whereby,

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

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

- 1.5 is the average number of breeding cycles per year;
- the standard weight of a breeding sheep in Europe is 75 kg [19]. This weight was used globally based on livestock unit ratios;
- the standard weight of breeding goats was adapted regionally according to bibliographical reviews [20].

Rabbit biomass was calculated according to the following formula:

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

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:

- o five is the average number of breeding cycles per year;
- the standard weight of a breeding doe is 4.5 kg [21].

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

standard weight \times census population

According to the following considerations [22]:

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

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

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

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

Changes in the methodology for the calculation of animal biomass

The results for animal biomass from previous years analysis (2014, 2015, 2016 and 2017) shown in this report may differ from the results of published previous reports as they have been recalculated using the latest updated data sets to support comparison. More information on the impact of the updated animal biomass analysis is provided in Section 5 Updates of Historical Data.

2.3. Antimicrobial quantities adjusted for animal biomass

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

antimicrobial agents reported (mg)

animal biomass (kg)

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

3. Results of the sixth round of data collection

3.1. General information

In this sixth round of data collection, launched in September 2020, 157 Countries submitted completed reports to OIE Headquarters: 155 from OIE Members (n = 182; 85%), one from a non-contiguous territory of an OIE Member and one from a non-OIE Member. The proportion of responses received from the different OIE regions varied from 83% to 91% (Table 22). The responses from the non-contiguous territory and non-OIE Member were included in the analysis of the Americas for geographical reasons.

For simplicity when reporting results, this section refers to the 155 OIE Members, one non-contiguous territory and one non-OIE Member as the 157 'Countries' that responded to the questionnaire during the sixth round of data collection.

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

OIE region	Number of Countries that submitted reports by OIE region	Number of OIE Members*	Proportion of response (%)
Africa	43	54	80%
Americas**			
OIE Members	26	31	84%
Non-contiguous territories	1	n/a	n/a
Non-OIE Members	1	n/a	n/a
Asia, Far East and Oceania	28	32	88%
Europe	48	53	91%
Middle East	10	12	83%
Total	157	182	85%***

Table 2. Number of Countries that responded to the OIE survey in the sixth round of data collection, by OIE region

* Distribution of Countries by OIE region is in accordance with the OIE Note de Service 2010/22 (Annex 9).

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

*** Non-contiguous territories and non-OIE Members are excluded from the ratio.

n/a: Not applicable

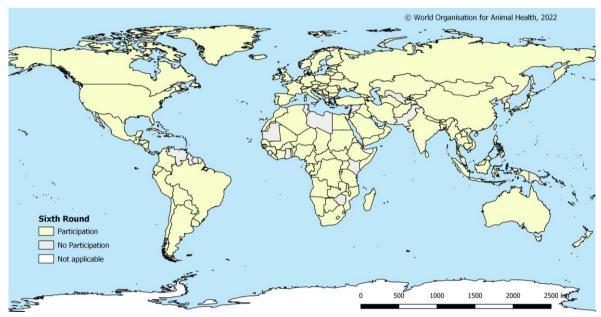


Figure 1. Geographical distribution of participants that responded to the OIE survey in the sixth round of data collection

Profile of the contact person

For the sixth round of antimicrobial use data collection, the OIE template was most frequently completed by the Member's National Focal Point for Veterinary Products (88 out of 155 Members) (Figure 2). The OIE recognises the efforts of National Focal Points for Veterinary Products. In Europe, the Focal Points were less often responsible for responding to the survey, with another national Competent Authority supplying the data. This result may be linked to differing levels of progress in the development of data collection systems, where a specific institution may already be mandated to undertake this responsibility (Figure 3).

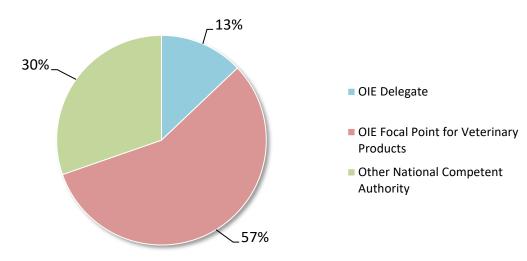


Figure 2. Contact person profile of 155 Members that submitted an OIE report in 2020

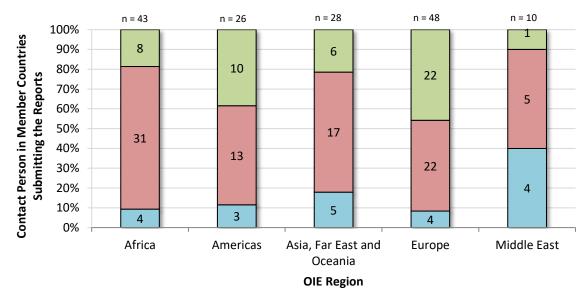


Figure 3. Regional proportion of contact persons of 155 Members that submitted a response to the OIE survey in the sixth round of data collection

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

3.2. Reporting options

Corrections made to data reported in the previous rounds of data collection

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

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

Results of the sixth round - reporting options

In the sixth round of data collection, Baseline Information (parts A and B) was completed by 157 Countries (155 Members, one non-contiguous territory and one non-OIE Member). Of these, one Country submitted data for the first time, and 13 Countries, that missed the fifth-round reporting, renewed their participation in this sixth round. Ninety-four Countries have consistently participated in all cycles since the first cycle was launched in 2015.

The ability of a Country to provide quantitative information reflects its capacity to collect detailed data on antimicrobial agents intended for use in animals. For the first round of data collection, 85 OIE Members reported quantities of antimicrobial agents intended for use in animals (n = 130; 65%). In this sixth round, 126 Countries (n = 157; 80%) reported quantitative data, demonstrating growing commitment to the development of monitoring systems for veterinary antimicrobial agents (Figure 4).

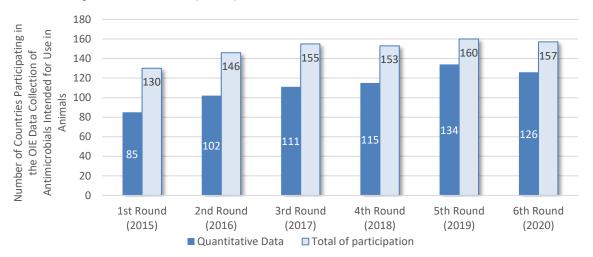


Figure 4. Number of participant Countries over different data collection rounds

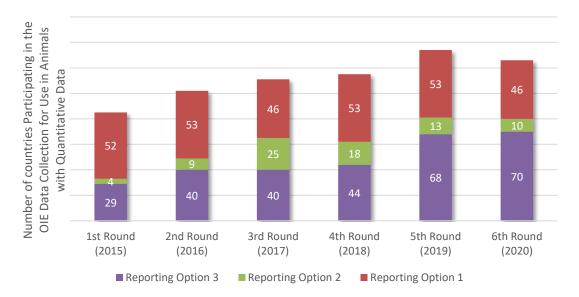
Reporting Option 3 allows Countries to distinguish antimicrobial quantities by type of use and route of administration (distinguishing by group of animals is optional) and this option was the one chosen most frequently by respondents (70 out of 126 Countries). For the second time in a row, this highest level reporting option was the predominant one; facilitated through an Excel Calculation Tool that the OIE developed and presented to OIE regions during the last two rounds. Twenty-nine percent of the Countries providing antimicrobial quantities during the sixth round used the OIE Tool. Reporting Option 1, which allows Countries to distinguish antimicrobial quantities by antimicrobial class and provides them with the possibility of separating by type of use (veterinary medical use or growth promotion [1]), was chosen by 46 Countries. Finally, Reporting Option 2, which allows Countries to distinguish quantities of antimicrobial agents by type of use and animal group (food-producing terrestrial and aquatic species and companion animals), was chosen by ten Countries (Figure 5). In previous rounds, when differentiated by OIE region, more Countries from Europe provided quantitative data than other OIE regions. Most Countries in the European Union already have a detailed system in place launched by the European Medicines Agency more than a decade ago for data collection on antimicrobial agents intended for use in animals: the European Surveillance of Veterinary Antimicrobial Consumption (ESVAC).

For the sixth round, while all OIE regions have made progress on the number of Countries reporting antimicrobial quantities and the use of Reporting Option 3, Asia, Far East and Oceania has shown significant progress in recent years and is only surpassed by Europe, in which many Countries are part of the ESVAC project that was established in 2008 (Table 3).

		First F	Round	Sixth Round	
OIE Region	Number of Countries per OIE Region	Number of Countries Reporting Antimicrobial Quantities (%)	Number of Countries Using Reporting Option 3 (%)	Number of Countries Reporting Antimicrobial Quantities (%)	Number of Countries Using Reporting Option 3 (%)
Africa	54	24 (44%)	3 (13%)	30 (55%)	22 (73%)
Americas	31	8 (26%)	1 (13%)	20 (65%)	12 (60%)
Asia, Far East and Oceania	32	16 (50%)	4 (25%)	26 (81%)	10 (38%)
Europe	53	35 (66%)	20 (57%)	45 (85%)	25 (55%)
Middle East	12	2 (17%)	1 (50%)	5 (42%)	1 (20%)
Global	182	86 (47%)	29 (34%)	126 (69%)	70 (56%)

Table 3. Countries participating with quantitative data (Reporting Options) in the first and sixthround of the data collection by OIE region

Figure 5. Number of Countries participating with quantitative data (Reporting Options) in all rounds of the data collection



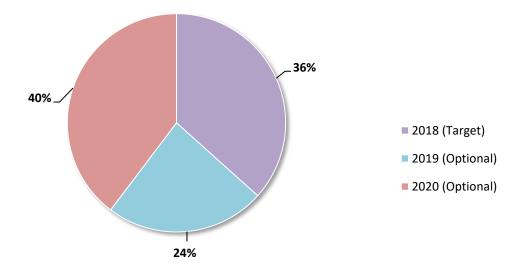
3.3. Years of quantitative data reported

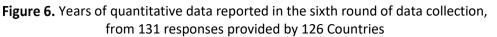
Table 4. Breakdown of Country response types in the sixth round of data collection

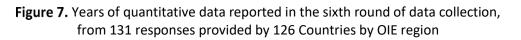
Number of Countries that <u>responded</u> to the OIE questionnaire			
Number of Countries that provided quantities of antimicrobial agents			
-	Number of Countries that provided quantitative data for <u>only one year</u> between 2018 and 2020	121	
-	Number of Countries that provided quantitative data for <u>more than one year</u> between 2018 and 2020	5	

Most Countries providing antimicrobial quantities submitted data for only one year between 2018 and 2020 (121 out of 126 Countries; 96%). Five Countries submitted quantitative data for more than one year within this time frame. Given these multiple submissions, 131 responses were provided by 126 Countries (Table 4) in the sixth round of data collection.

Fifty-two responses (n = 131; 40%) provided data for 2020 during the sixth round of data collection and 48 responses to the target year which was 2018 (Figure 6). These findings reinforce what was presented in previous OIE Reports that most Countries outside the European Union have only recently begun to collect this information and therefore only have access to current information rather than historical information (Figure 7).









3.4. National reports available online

In the OIE template, Countries were asked if a national report on the antimicrobial agents used in animals was available online. In the sixth round of data collection, 91 Countries (n = 126; 72%) did not publish online national reports, Europe is the only region where more than 50% of Countries' national reports are available online (Figure 8).

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

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

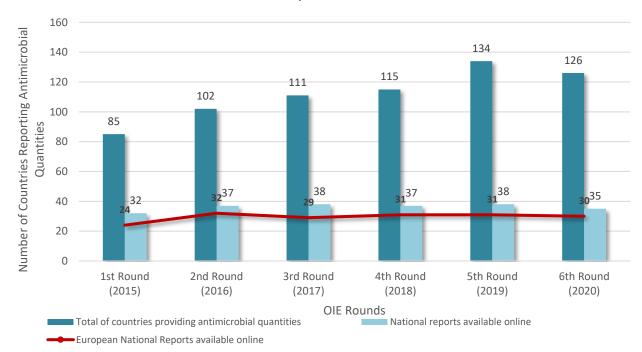


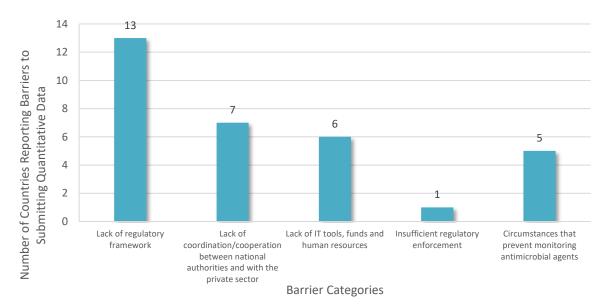
Figure 8. Number of Countries participating in all rounds of OIE data collection with national reports available online

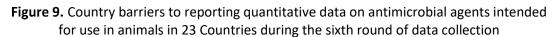
3.5. Country barriers to providing quantities of antimicrobial agents in animals

In the sixth round, some Countries that reported barriers during the fifth round were seen to have made progress. Eight of these Countries progressed from reporting Baseline Information to reporting antimicrobial quantities. Of these eight Countries, five had previously indicated that a lack of IT tools impeded their progress to report antimicrobial quantities. During the sixth round, these Countries made progress using the OIE Calculation Tool to report their quantities through Reporting Option 3.

Of the Countries responding to the fifth round, 30 (n = 157; 19%) provided Baseline Information only so did not report antimicrobial quantities. Of these, 23 Countries (n = 30; 77%) outlined their barriers to reporting antimicrobial quantities. The barriers have been grouped into five categories (Figure 9). Thirteen Countries reported one main barrier, and ten Countries reported two. The relative importance of these categories may change when analysing the results on a regional level (Annexes 1-5).

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





Lack of regulatory framework

Six Countries indicated regulatory framework limitations or absence for the manufacture, registration, distribution, commercialisation and pharmacovigilance of veterinary products. One of these Countries reported that actions were being taken to address the absence of legislation and that the Country was working with external consultants to provide data, but that COVID-19 had put these plans on hold.

Three Countries' legislation did not provide a legal basis for collecting data on antimicrobial agents intended for use in animals, and four indicated that data collection mechanisms did not exist.

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

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

Two Countries reported a lack of collaboration or coordination with relevant stakeholders, such as pharmaceutical companies and veterinarians.

Lack of IT tools, funds and human resources

Three Countries described their main problem in data collection was that records (mainly imports of veterinary products and the information related to their authorisation) were not yet digitised. For these Countries, the time burden would be too high to calculate the amounts of active ingredients for veterinary products. Two of these Countries were building software that will assist in the collection of data on the import or sale of the veterinary products.

Three Countries were unable to report antimicrobial quantities due to lack a of dedicated staff within the Veterinary Authority for the collection and analysis of the data. One Country mentioned that the OIE Calculation Tool could assist them in calculating the kilograms of active ingredients; nevertheless, the Country will need additional staff resources to cross-check the list of approved veterinary products against the import permits available in hard copy only.

Insufficient regulatory enforcement

One Country considered the situation of illegal veterinary products on the market to be an impediment to the collection of antimicrobial quantities intended for use in animals.

Circumstances that prevent the monitoring of antimicrobial agents

Three Countries reported that COVID-19 had worsened their situations; one of them had to pause a project that intended to support the creation of the necessary regulatory framework. Two Countries reported insecurity as the main reasons that prevented them from reporting antimicrobial quantities in animals.

Summary on barriers

Most respondents who communicated barriers to the OIE, faced compliance and structural barriers with the application of OIE standards and weak enforcement of regulatory frameworks for veterinary products. The development of a robust regulatory framework for importation, manufacture, registration, distribution, commercialisation and use of veterinary products – and capability for effective enforcement – within these Countries the facilitation of the monitoring of the use of antimicrobial agents in animals should be prioritised. The work of the OIE through the PVS Pathway provides essential support in helping Countries to identify their policy, regulatory and resourcing gaps. The Antimicrobial Use Team compared the responses from the Countries with available mission reports (16 reports available for 23 Countries) from the OIE PVS Pathway ⁹. In most of the cases, the mission reports had identified the same Country barriers for legislation that were reported to the Antimicrobial Use Team.

A significant barrier was the lack of cooperation with other national authorities in the Country, mainly the Ministry of Health that was described by the Countries as the institution with the legal authority on the veterinary products' registration.

Finally, it is interesting to highlight that several barriers to providing quantities of antimicrobial agents in animals corresponds with the weaknesses identified in an analysis of legislation for AMR and veterinary products, conducted in 2021 on all OIE Veterinary Legislation Identification Mission reports (i.e. an incomplete legal framework, weaknesses related to the Competent Authority/Authorities, and

⁹ Chronologically in the OIE PVS Pathway Cycle (<u>www.oie.int/en/what-we-offer/improving-veterinary-services/pvs-pathway/</u>), following a PVS Evaluation, countries can request different kinds of options, including a PVS Gap Analysis, and/or a Veterinary Legislation Identification mission:

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

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

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

inadequate resources to ensure compliance and enforcement). In addition, the OIE highlighted the need for coordination amongst the different national authorities that are part of the monitoring of antimicrobial agents process.

3.6. Antimicrobial agents used for growth promotion

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

'OIE Member Countries fulfil their commitment under the Global Action Plan to implement policies on the use of antimicrobials in terrestrial and aquatic animals, respecting OIE intergovernmental standards and guidelines on the use of critically important antimicrobial agents, and the phasing out of the use of antibiotics for growth promotion in the absence of risk analysis'. [8]

The OIE List of Antimicrobial Agents of Veterinary Importance also states that the 'responsible and prudent use of antimicrobial agents does not include the use of antimicrobial agents for growth promotion in the absence of risk analysis' [15].

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

In this sixth round of data collection, and as presented in Figure 10, a total of 108 (n = 157; 69%) responding Countries did not use antimicrobial agents for growth promotion in animals, either with or without legislation or regulations. Forty Countries (n = 157; 25%) reported use of antimicrobials for growth promotion. The nine remaining Countries indicated that they were unsure if antibiotics were being used in the field or not. All of them did not have legislation related to growth promotion.

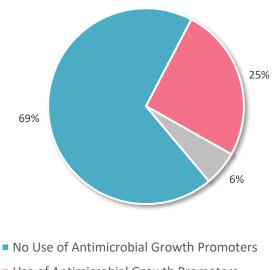
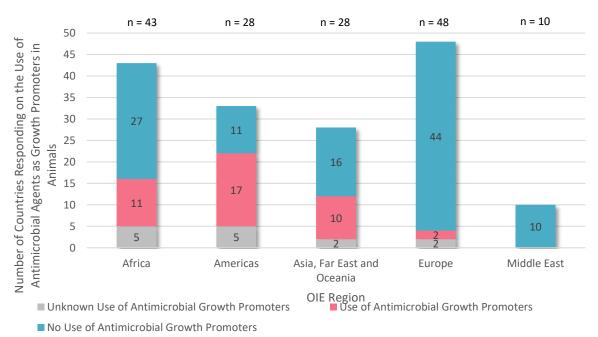


Figure 10. Use of antimicrobial growth promoters in 157 Countries in 2020

- Use of Antimicrobial Growth Promoters
- Unknown Use of Antimicrobial Growth Promoters

When differentiated by OIE region, the Americas has the highest proportion of Countries using antimicrobials as growth promoters (Figure 11). Europe has been working on this issue for many years and this is reflected in the responses provided, with Europe being one of the regions with the lowest percentage of use and authorisation of antimicrobial growth promoters.

Figure 11. Number of Countries using antimicrobial agents for growth promotion in animals in 2020, of 157 responding Countries, by OIE region



Regulatory framework for antimicrobial agents used as growth promoters

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

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

As presented in Figure 12, 33 Countries stated that they did not use antimicrobials as growth promoters even though no regulatory framework exists. In two cases Countries stated that these molecules were banned without a regulatory framework; therefore, the OIE asked these Countries to provide further information on how antimicrobial growth promoters were banned in the absence of legislation or regulations. One Country is amending its legislation to ban growth promoters. Meanwhile, the following approaches are being taken to guarantee that these products are not available on the market: to prohibit their import; to monitor the manufacturing companies to ensure that they only produce antibiotics for veterinary medical use and; to not allow their registration.

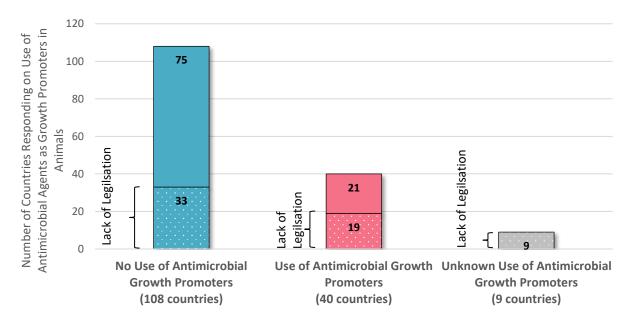


Figure 12. Use of antimicrobial growth promoters by legislation, in 157 Countries in 2020

Almost half of the Countries reporting the use of antimicrobials as growth promoters do not have a regulatory framework (19 out of 40 Countries; 48%).

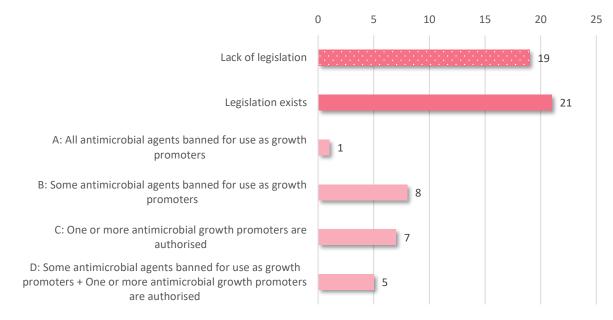
Of those 21 Countries using antimicrobials as growth promoters within a regulatory framework (n = 40; 53%), the legislation in place either provides a list of molecules that should not be used as growth promoters (n = 8) or provides a list of antimicrobials that can be used as growth promoters (n = 7), while in other cases, both types of lists have been established (n = 5). One Country with legislation that bans growth promoters reported the use of these molecules in the field (Figure 13), indicating that enforcement of the legislation is needed, with feed manufacturers continuing to illegally produce these types of products.

Among the 21 Countries using growth promoters within a regulatory framework, some stated that they had partially or completely banned all growth promoters for certain animals.

Of those 19 Countries using growth promoters without a regulatory framework, the majority were located in Africa and the Americas; nine Countries for both regions. In the Americas, two Countries mentioned their cooperative work with pharmaceutical companies for the voluntary removal of growth promotion claims from the labels of all products that are considered to be medically important antimicrobials in human medicine. Both Countries mentioned their success in this collaborative approach with the private sector.

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

Figure 13. Type of legislation for growth promotion in 40 Countries that reported the use of growth promoters in 2020



List of antimicrobial agents used for growth promotion

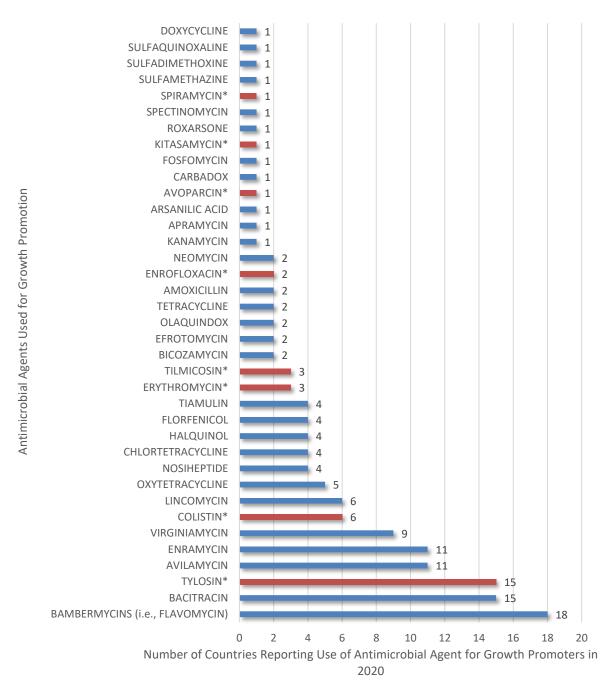
The 40 Countries reporting the use of antimicrobial agents for growth promotion were further asked for a list of antimicrobial agents (by active ingredient) either authorised as growth promoters or known to be used in cases where legislation on this issue did not exist.

Twenty-seven Countries (n = 40; 68%) responded with a list of antimicrobial agents used for growth promotion. The most frequently listed antimicrobial agent was flavomycin (currently not used in humans according to the WHO *List of Critically Important Antimicrobials for Human Medicine*), followed by bacitracin and tylosin. Colistin was mentioned by six Countries (Figure 14); based on this result and compared with the second round of data collection in 2016 where 13 Countries reported colistin, the Countries are making efforts to phase out molecules that are important for human medicine.

The OIE List of Antimicrobial Agents of Veterinary Importance recommends the urgent prohibition of the use of colistin, fluoroquinolones and third and fourth generation cephalosporins as growth promoters.

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

Figure 14. Antimicrobial agents used for growth promotion in animals in 27 Countries in 2020



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

Thirty-one Countries using antimicrobial agents as growth promoters (n = 40; 78%) provided quantitative data on antimicrobial agents intended for use in animals. Sixteen of these Countries (n = 31; 52%) could distinguish these quantities by use (i.e. for growth promotion or veterinary medical purposes). During the sixth round, most of the Countries using the OIE Calculation Tool and using growth promoters, indicated the use of veterinary products for both veterinary medical use and growth promotion purposes; those products with dual indications provided different dosage instructions according to the type of use. As Countries are still using mainly sales and imports as data sources, it would be difficult for them to distinguish the quantities by type of use for these products, unless data at the field level are collected.

4. 2018 analysis of antimicrobial quantities

This section provides an analysis of globally reported quantitative data on antimicrobial agents intended for use in animals adjusted by animal biomass, focusing on 2018.

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

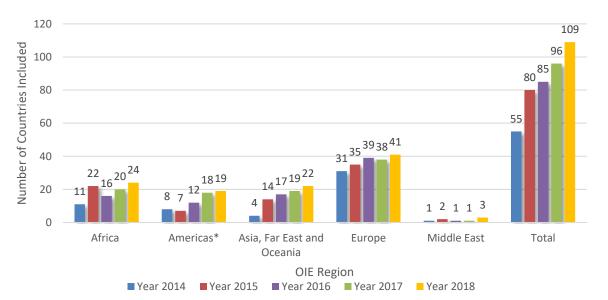
4.1. Antimicrobial quantities

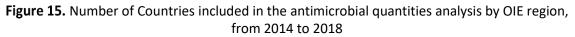
Regional representation of Countries included in the 2018 analysis

The focus of this section is covering all 2018 data provided during any round of data collection; therefore, the results presented in this section differ from those presented in Section 3 in which the data provided during the sixth round only is included.

For all rounds of data collection compiled, 109 Countries provided validated antimicrobial quantities intended for use in animals for 2018. The regional distribution of Countries included in the 2018 analysis is shown in Figure 15. Due to geographical considerations, quantitative data for 2018 of two non-Members and one non-contiguous territory were included in the Americas for this analysis.

For three out of the 109 Countries analysed in this section, animal biomass data were not available; therefore, they were not included in the analysis presented in Sections 4.2 and 4.3 of this report.





* For 2018, one Country provided quantities for companion animals only and two did not use animal biomass in their reports, therefore, these Countries will be excluded from the section related to animal biomass and analysis of mg/kg.

A lack of validated data from the Middle East did not allow for the inclusion of this OIE region in the regional 2018 analysis, but the validated data submitted by this region's Countries have been included

in the global analysis. Future data submissions from this OIE region may permit an analysis of antimicrobial quantities adjusted by animal biomass in subsequent reports.

Period of time covered

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

For the 109 Countries included in the 2018 analysis, one Country from Asia, Far East and Oceania and Africa respectively did not report the period of time covered so were excluded from this analysis. The average time period covered was 357 days for 109 Countries; this information shows that most Countries are providing quantitative data for most of a calendar year. Information by the OIE region is shown in Table 5.

OIE region*	Number of Countries	Mean (days)	Standard deviation (days)	Maximum (days)	Minimum (days)
Africa	23	354	12	389	269
Americas	19	357	17	360	299
Asia, Far East and Oceania	21	356	17	369	327
Europe	41	359	16	360	300
Global	107	357	17	389	269

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

Quantitative data sources captured

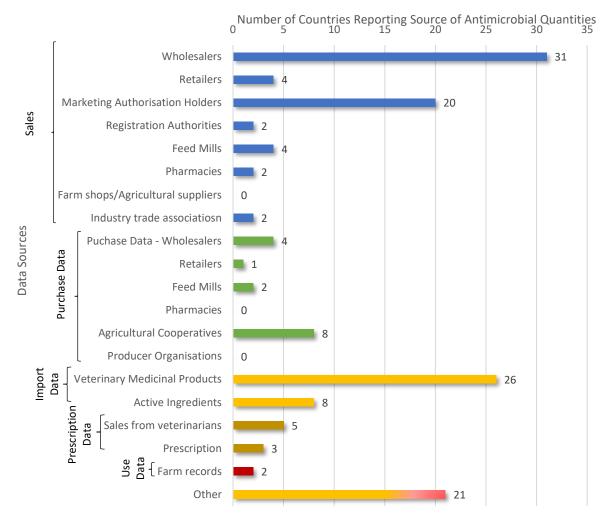
The OIE template includes an exhaustive list of possible quantitative data sources, in accordance with Chapter 6.9. of the *Terrestrial Code* (Monitoring of the quantities and usage patterns of antimicrobial agents used in food-producing animals) and with Chapter 6.3. of the *Aquatic Code* (Monitoring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

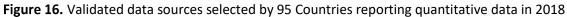
All Countries' data sources were analysed, and all Countries where the duplication was considered to be a risk were asked to provide clarification on their answers and/or data collection systems. Thirty-four Countries' data sources were considered to present a risk of duplication (n = 109; 31%). Following these clarifications, 20 Countries (n = 34; 59%) either changed their answers or demonstrated that there was no risk of duplication or overlapping data sources. The remaining Countries (14 out of 34; 41%) that did not respond with clarification and were excluded from the analysis in Figure 16.

In the Guidance for Completing the OIE Template for the Collection of Data (Annex 7), Countries were asked to provide data as close to the point of use (i.e. administration) as possible. However, among the 95 Countries that reported validated quantitative data, 'Antimicrobial use data – Farm records' – the category representing on-farm administration of antimicrobials – was only selected as a data source by two Countries that accompanied those quantities with sales and import data (Figure 16). All other data sources represent use through what was sold, imported or manufactured for intended administration to animals.

Sources of quantitative data were most commonly sales data, particularly from wholesalers, selected by 31 Countries. After sales data, import data declared by customs authorities was the next most common source of reported quantities of antimicrobial agents intended for use in animals.

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

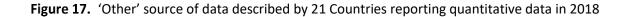


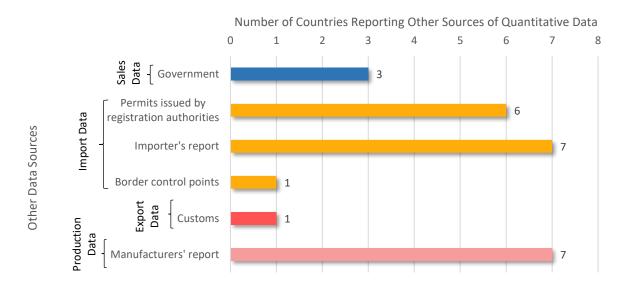


Other data sources reported

Twenty-one Countries (n = 95; 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 commonly reported were from other import control systems apart from customs declarations, particularly from importers or permits authorising the importation of antimicrobials issued by registration authorities (Figure 17). In some Countries where the importation of a product is not confirmed following issue of a permit, these quantities may not represent antimicrobial agents actually entering the Country and used in the animal population.





Data coverage

In the OIE template for quantitative data collection (Annex 6), Countries are asked to estimate the extent to which their data represented overall sales of antimicrobial agents intended for use in animals, as a percentage of the total estimated sales in their Country. For example, a hypothetical Country may report that the quantitative data reported covers only 80% of all estimated national sales of antimicrobial agents used in animals based on known sources of missing data. All 109 Countries that provided quantitative data with validated data responded to this question.

The global average for quantitative data coverage achieved was 91% (Table 6). 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 are inaccessible, and therefore the responses can vary in accuracy.

OIE region	Number of Countries	Mean (%)	Median (%)	Standard deviation (%)	Minimum (%)	Maximum (%)
Africa	24	94	98	12	65	100+20*
Americas	19	89	98	14	60	100
Asia, Far East and Oceania	22	87	94	17	40	100
Europe	41	95	100	11	50	100
Global	90	91	98	15	25	100+20*

Table 6. Reported percentage of antimicrobial quantity coverage by OIE region, 2018

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

Sources not captured by the data

Of the 95 Countries estimating the coverage of their data with validated data sources, 46 Countries stated that they covered 100% of the data source used to report the data. The 49 Countries that did

not cover 100% of available quantitative data were asked to provide further information on uncaptured data sources.

Forty-five Countries (n = 49; 92%) responded with an explanation on uncaptured data sources. Responses were grouped by category. All Countries' uncaptured data sources were analysed and, if needed, further questions were asked on their data collection systems. After the analysis, the uncaptured data sources were validated for all 45 Countries. Countries could have reported more than one uncaptured data source.

Most uncaptured data sources derive from import data not provided, particularly those of illegal or unofficial veterinary products that enter a Country, reported by ten Countries. The provision of partial responses for sales data from relevant stakeholders was also a significant contributor, reported by nine Countries.

Table 7 describes the quantitative data coverage lost due to a lack of access to data sources, as estimated by 45 Countries. This question allows Countries to self-report which type of data they were unable to access, and what percentage of total possible available data was estimated to be lost due to this inaccessibility. For Countries naming an uncaptured data source, the mean, minimum and maximum reported estimates of related coverage lost are shown. The information in Table 7 highlights which data sources Countries consider necessary in order to provide complete coverage. However, these categories may not be relevant in all Countries.

Sources estimated not captured in quantitative	Number of Countries	Estimated data coverage lost		
data	naming uncaptured data source	Mean	Minimum	Maximum
Sales data				
Partial response from relevant stakeholders	9	22%	1%	75%
Antibiotics authorised for humans that are used in companion animals	6	6%	1 %	10%
Certain veterinary products	3	4%	1%	10%
Illegal or unofficial veterinary products	1	7%	7%	7%
Purchase data				
Illegal or unofficial veterinary products	2	15%	5%	25%
Partial response from relevant stakeholders	1	40%	40%	40%
Import data				
Illegal or unofficial veterinary products	10	11%	5%	20%
Partial data, not from a whole calendar year	1	8%	8%	8%
Partial data, not for all veterinary products	3	13%	5%	25%
Data from the drug agency under the Ministry of Health	2	25%	15%	35%
Partial response from relevant stakeholders	3	22%	15%	30%
Active ingredients used to manufacture veterinary products	2	33%	15%	50%
Companion and zoo animals	1	2%	2%	2%
Veterinary data				
Partial response from relevant stakeholders	1	4%	4%	4%
Production data				
Manufacturer's report	3	20%	10%	30%

Table 7. Estimation of quantitative data not captured based on a lack of access to sources,as reported by 45 Countries in 2018

Antimicrobial quantities reported in 2018

Table 8 shows the total tonnage of antimicrobial agents intended for use in animals for 2018, as reported to the OIE during all rounds of data collection.

When the antimicrobial quantities reported adjusted for these coverage estimates (i.e. extrapolation to annual coverage from all data sources to account for partial temporal coverage or missing data sources), the quantities shown in Table 8 were obtained. *These coverage-adjusted figures should be interpreted with caution, as data coverage estimations are made subjectively by each Country.* By definition, this question aims to identify quantitative data that is inaccessible, and therefore the responses can vary in accuracy. However, these coverage-adjusted quantities can be considered an upper-level estimate of antimicrobial use in animals.

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

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

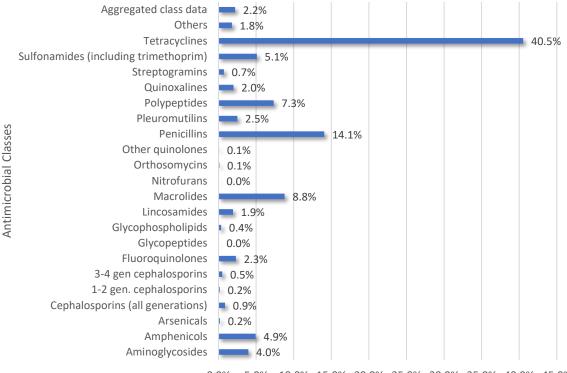
Table 8. Reported quantity of antimicrobial agents intended for use in animals by OIE region,2018

OIE region	Number of Countries included in analysis of 2018 quantitative data	Quantities reported (in tonnes)	Quantities reported adjusted by estimated coverage* (in tonnes)
Africa	24	1,410	1,477
Americas	19	19,141	22,887
Asia, Far East and Oceania	22	41,410	44,621
Europe	41	7,460	7,674
Total	109	69,455	76,704

* Estimated coverage: this refers to the subjective estimates Countries made with respect to the extent to which their data represented overall sales of antimicrobial agents intended for use in animals. In this column, the figures were adjusted to represent 100% of the total estimated amount (as further explained in the Section Data Coverage, page 40).

Among the 109 Countries that provided quantitative data on antimicrobial agents intended for use in animals, tetracyclines were the most commonly reported antimicrobial class (Figure 18).

Figure 18. Proportion of antimicrobial classes reported for use in animals by 109 Countries in 2018



0.0% 5.0% 10.0% 15.0% 20.0% 25.0% 30.0% 35.0% 40.0% 45.0%

% of Reported Quantities of Antimicrobial Agents Used in Animals by 109 countries

High use of antimicrobial classes

For 2018 data, it was noted that eight Countries (n = 109; 7%) allocated more than 70% of their total amount of antimicrobials intended for use in animals to one antimicrobial class (Table 9). Globally, it was observed that those Countries with high use of one antimicrobial class usually share the same economic status and, additionally, the high rates of the class are mainly link to economic factors.

Five of these Countries (n = 8; 63%) were from Africa and four of them were classified as least developed Countries according to the Development Assistance Committee (DAC) List of Official Development Assistance (ODA) Recipients effective for 2018 and 2019 from the Organisation for Economic Co-operation and Development (OECD).Countries reporting more than 70% of their amounts for one antimicrobial class were further asked to explain any known reason for the high levels of use for a single antimicrobial class. Four Countries provided explanations, with three Countries mentioning that tetracyclines were favoured among veterinarians because of a low financial cost or control of certain diseases. A Country with high levels of other penicillins, explained that this was mainly attributed to the medicinal policy of the national veterinary association that stated that penicillin is the first choice when selecting antimicrobials.

Antimicrobial class	Number of Countries with high levels of use in a specific antimicrobial class	Antimicrobial quantities allocated in the antimicrobial class (tonnes)	Use of the antimicrobial class compared to the total amount reported (% - mean)
Penicillins	2	0.5	74.5%
Tetracyclines	6	92	83.6%

Table 9. Antimicrobial classes with more than 70% of the total amount of antimicrobialsintended for use in animals, by eight Countries in 2018

Food-producing target species on the label of reported veterinary products

Irrespective of whether the data could be differentiated by animal groups, all 109 Countries that provided quantitative data were asked to identify the food-producing animal species covered by their data, according to the product's target species label, from a list supplied in the OIE template. One Country that provided data only for companion animals was excluded from Figure 19. The breakdown of food-producing species included in the reporting Countries' data sets is shown in Figure 19.

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

A. POULTRY

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

B. BOVINES

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

C. PIGS

- a. Pigs commercial
- b. Pigs backyard

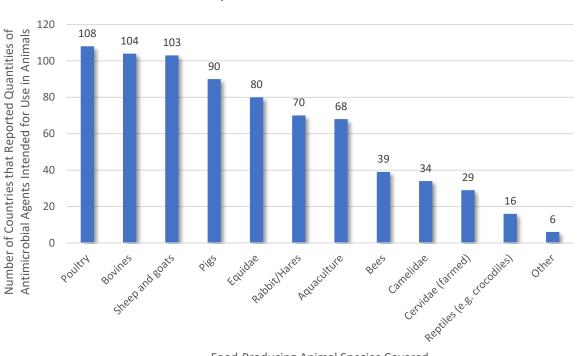
D. SHEEP AND GOATS

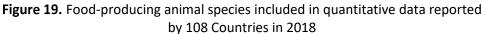
- a. Sheep
- b. Goats
- c. Sheep and goats (mixed flocks)

E. AQUACULTURE

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

In 2018, poultry was mentioned by all 108 Countries reporting quantitative data for food-producing species. Bovines, sheep and goats were also included by most Countries (Figure 19).





Food-Producing Animal Species Covered

Quantitative data differentiation by animal group

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

For 2018, 60 Countries (n = 109; 55%) provided data differentiated by animal group (Figure 20), this corresponds to the number of Countries reporting their antimicrobial quantities through Reporting Options 2 and 3. Further information on the OIE Reporting Options can be found in Section 2.1 of this report.

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

Most of the data came from sales and imports, and the attribution of antimicrobial quantities by animal group was based on the species types listed on product labels, where this was available and specified. For Countries where product labels covered a wide variety of species, it would be more difficult to report quantitative data differentiated by animal group. For 2018, 16% of the Countries started to use the OIE Calculation Tool which assisted in allocating the quantities in the different groups.

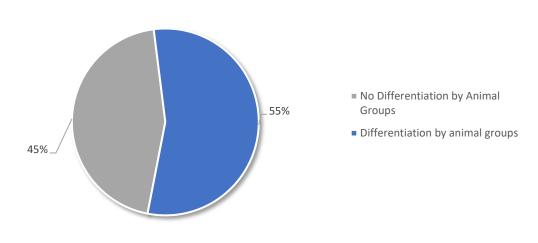
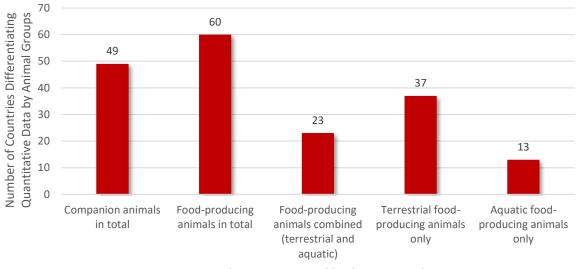


Figure 20. Differentiation by animal groups among 109 Countries reporting quantitative data in 2018

Figure 21. Representation of quantitative data from 60 Countries able to separate by animal group in 2018¹⁰



Animal Groups Proposed by the OIE Template

Forty-nine of those Countries reporting quantitative data (n = 109; 45%) were not able to distinguish the amounts of antimicrobial agents by groups of animals. Of these, the majority (38 out of 49; 78%) reported antimicrobial quantities through Reporting Option 1, which allows reporting for all animal species combined, and distinguishes quantities only by purpose of use (veterinary medical use or growth promotion [1]). Eleven of these Countries (n = 49; 22%) used Reporting Option 3, which allows

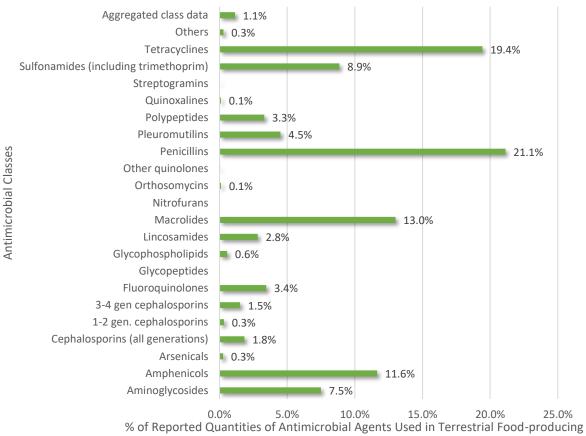
¹⁰ For OIE AMU Database purposes the animal groups proposed to allocate antimicrobial quantities for food-producing animals in Reporting Options 2 and 3 are: aquatic food-producing animals, terrestrial food-producing animals and food-producing animals combined (terrestrial and aquatic). Ideally, the data for the group of food-producing animals combined should be equal to the sum of the quantities provided for the terrestrial and the aquatic food-producing animals; however, there were cases where countries were not able to distinguish between these two animal groups due to veterinary products being labelled for use in both terrestrial and aquatic animals. As a result of this, the countries only used the group of food-producing animals combined to report quantities. The group of aquatic food-producing animals was only provided if quantities for terrestrial food-producing animals were also reported.

for distinction by type of use, animal groups and route of administration, but provided data only separated by type of use and/or route of administration. This suggests that the labelling of veterinary products in these Countries clearly separates out the route of administration but may cover a wide variety of species.

Terrestrial food-producing animals

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

Figure 22. Proportion of antimicrobial classes by terrestrial food-producing animals as reported by 37 Countries in 2018



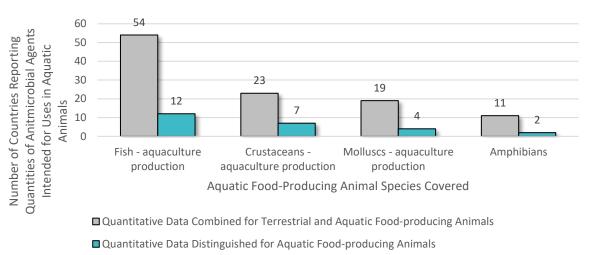


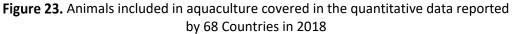
Aquatic food-producing animals

Of the 109 Countries that provided quantitative data for food-producing animals in 2018, 68 Countries stated that their labelled products also targeted aquatic food-producing animals (n= 109; 62%), nine more Countries than for 2017.

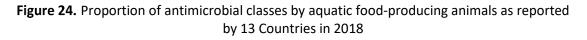
When aquatic food-producing animals were covered, in most cases, quantitative data for aquaculture represented farmed fish. Of the 68 Countries that provided amounts of antimicrobial agents under the Aquatic food-producing animals group, 'Crustaceans – aquaculture production', 'Molluscs – aquaculture production' and 'Amphibians' were reported mainly when data for 'Fish – aquaculture production' were also available. Figure 23 highlights the animals included in aquaculture covered by Countries reporting quantitative data for aquatic food-producing animals, separated by capacity to distinguish data for terrestrial and aquatic food-producing animals.

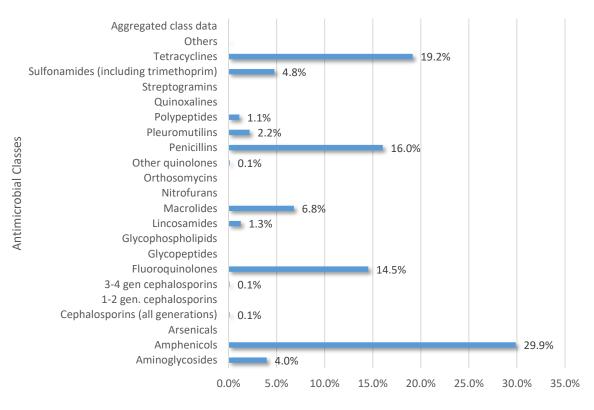
Of the 68 Countries providing antimicrobial quantities that covered aquatic animals, 13 Countries were able to report quantitative data under the Aquatic food-producing animals group separately from other animal groups using mainly Reporting Option 3 (13 out of 68; 19%).





Of the 13 Countries reporting quantitative data under the Aquatic food-producing animals group, amphenicols were most commonly reported (Figure 24).





% of Reported Quantities of Antimicrobial Agents Used in Aquatic Food-producing Animals by 13 Countries During the sixth round of the data collection, the OIE Antimicrobial Use Team observed that 18 Countries with aquaculture production communicated through OIE-WAHIS or the FAO Fisheries Division did not report antimicrobial quantities for aquatic animals to the OIE (18 out of the 43 Countries that did not include aquaculture; 42%). Consequently, some of these Countries were asked to clarify if antibiotics were not used in the Country's aquaculture sector.

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

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

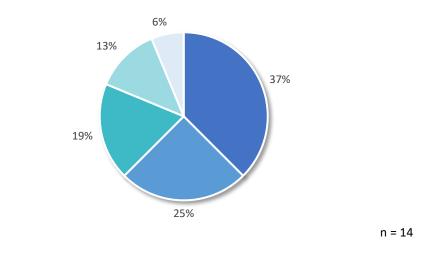


Figure 25. Explanations provided by 14 Countries for not covering aquaculture in their antimicrobial quantities' reports in 2018

- Insignificant aquaculture production or use of antimicrobials
- Lack of coordination/cooperation between national authorities and with private sector
- Absence of authorised antimicrobial products for aquaculture
- Antimicrobials banned for aquaculture

Antimicrobials are used in aquatic animals non-intended for consumption

Companion animals

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

Of the 109 Countries which provided quantitative data in 2019, 98 stated that product labels targeted companion animals (n= 109; 90%). Of these 98 Countries, 84 provided an answer related to the animals

under this group. These 84 Countries considered canines and felines as companion animals; of these, 26 Countries declared additional species; the most cited being ornamental birds and rabbits (13 and ten Countries, respectively) followed by equines (nine Countries).

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

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

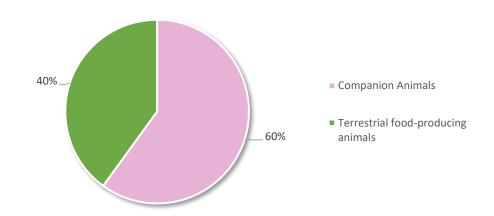
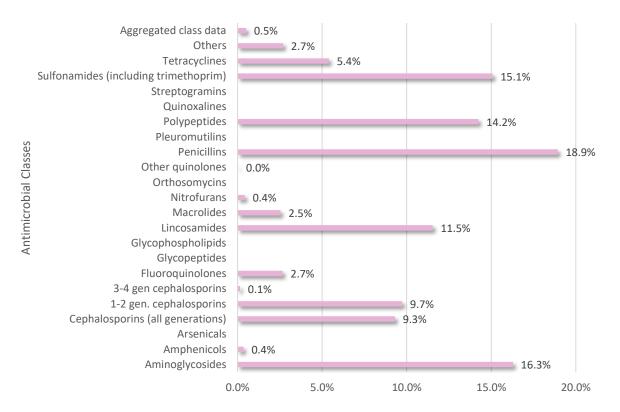


Figure 26. Differentiation of equine data by animal groups among five Countries reporting quantitative data in 2018

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

Figure 27. Proportion of antimicrobial classes in companion animals as reported by 49 Countries in 2018



% of Reported Quantities of Antimicrobial Agents Used in Companion Animals by 49 Countries

Routes of administration

For 2018, 55 Countries chose to report their quantitative data through Reporting Option 3, the only option which allows for disaggregation of data by route of administration. Among these 55 Countries, the majority reported higher amounts of antimicrobial agents used via the oral route, especially for tetracyclines (Figure 28). For the injection route (parenteral route) and other routes, penicillin was more often reported (Figures 29 and 30).

Reporting Option 3 allows for distinction of the data by type of use (veterinary medical use vs growth promotion [1]) and by animal group in addition to route of administration. However, 11 Countries (n = 55; 20%) 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 44 Countries (n = 55; 80%) able to distinguish quantitative data by animal group using Reporting Option 3, oral administration was most commonly reported for use in all animal groups.

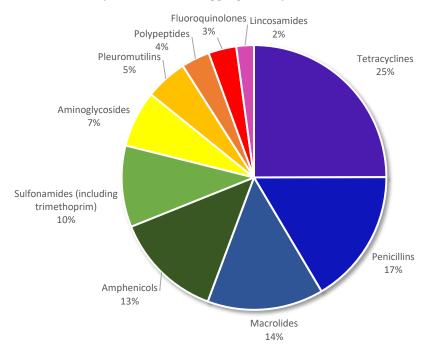
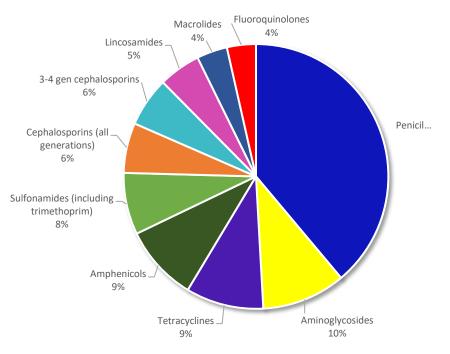


Figure 28. Proportion of antimicrobial quantities (by antimicrobial class) reported for use in animals by the oral route, aggregated by 55 Countries in 2018

Figure 29. Proportion of antimicrobial quantities (by antimicrobial class) reported for use in animals by the injection route, aggregated by 55 Countries in 2018



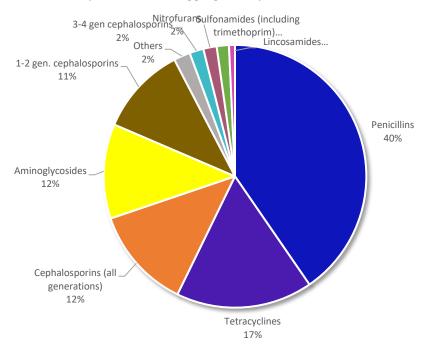


Figure 30. Proportion of antimicrobial quantities (by antimicrobial class) reported for use in animals by other routes, aggregated by 55 Countries in 2018

4.2. Animal biomass

Populations represented in the animal biomass analysis reflect the number, size and animal population dynamics of the Countries reporting data to the OIE during the given year of analysis. As described in the methodology, animal biomass was calculated for 106 Countries providing quantitative data for 2018 during all rounds of data collection. Two Countries that provided data for companion animals only were excluded from the analysis. Aquaculture was included in the biomass for Countries reporting that their data covered aquaculture, or could not be distinguished by animal group (64 out of 106; 60%).

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 of any particular OIE region.

Animal population covered by 2018 data

Figure 31 shows the estimated percentage of the total regional animal biomass covered by the 106 Countries included in the analysis of antimicrobial quantities for 2018, compared to the coverage achieved in the previous years' analysis. These estimates were made by calculating the ratio of the animal biomass for the reporting Countries relative to the estimated regional total. In previous reports, the coverage estimates were based solely on meat production. For the first time in this report, the animal biomass coverage estimates where calculated, using live animal population data following the animal biomass methodology described in section 2.2 of this report. Therefore, the estimated regional biomass covered by the Countries reporting quantitative data cannot be compared to the ones presented in previous reports. The number of Countries in each OIE region contributing to this coverage is also included (in brackets).

Globally, the estimated biomass coverage of the responding Countries has increased from 29% in 2014 to 72% in 2018. The Americas and Europe have particularly high animal population coverage for 2018, with responding Countries representing 94% and 81%, respectively, of the regions' total animal biomass.

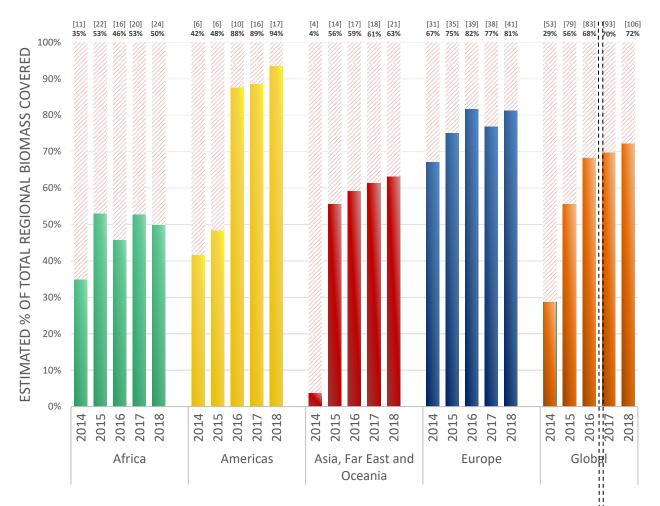


Figure 31. Estimated percentage of total regional and global biomass covered by Countries reporting quantitative data from 2014 to 2018

Figure 32 shows the regional distribution of the estimated percentages of regional biomass covered by the 106 Countries included in the analysis of antimicrobial quantities for 2018, in comparison to the global biomass estimate. The Americas and Asia, Far East and Oceania regions represent a particularly high proportion of the global biomass estimate.

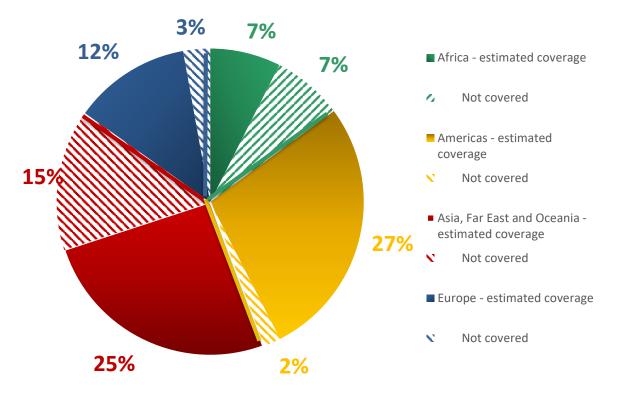


Figure 32. Regional percentages of estimated biomass covered by Countries reporting quantitative data for 2018*

* The Middle East was not included in the visual, but the region's coverage is included at the global level.

Aquaculture was included in the biomass estimation for Countries reporting that their data covered aquaculture, or could not be distinguished by animal group (64 out of 106; 60%). As shown in Figure 33, the highest proportion of Countries including aquatic food-producing animals in the reported quantitative data on antimicrobial agents was in Europe (83%; 34 of 41). Fifty-seven percent of Countries in Asia, Far East and Oceania (12/21), 59% of Countries in the Americas (10/17), and 33% of Countries in Africa (8/24) reported quantitative data that included aquatic food-producing animals.

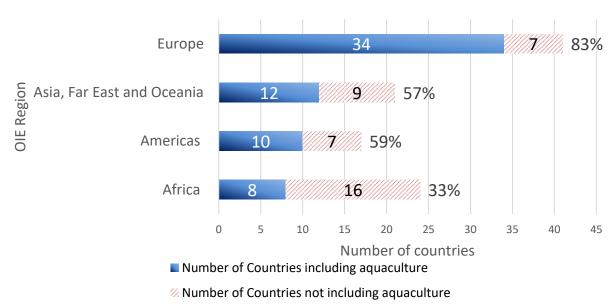


Figure 33. Countries Including aquatic food-producing animal species in quantitative data for 2018

Animal biomass covered by the 2018 additional analysis: global view

Table 10 shows the animal biomass (in million kilograms) of farmed animals covered by 2018 quantitative data.

The figures reported in this table reflect the number of Countries that provided quantitative data, and the relative size and average weights of their animal populations in 2018.

Table 10. Animal biomass covered by the quantitative data reported to the OIE for 2018obtained by the accumulation of information from all rounds of data collection, results for 106Countries

	2018	Africa	Americas	Asia, Far East and Oceania	Europe	Global
Numbe	r of Countries	24	17	21	41	106
Bovine	(in million kg)	42 265	187 656	57 888	52 925	340 734
biomass	(relative proportion)	<i>51,4%</i>	<i>61,6%</i>	<i>20,5%</i>	<i>38,8%</i>	<i>42,3%</i>
Swine	(in million kg)	1 629	31 310	93 983	36 432	163 354
biomass	(relative proportion)	<i>2,0%</i>	<i>10,3%</i>	<i>33,3%</i>	<i>26,7%</i>	<i>20,3%</i>
Poultry	(in million kg)	3 470	67 281	45 671	28 318	144 740
biomass	(relative proportion)	<i>4,2%</i>	<i>22,1%</i>	<i>16,2%</i>	<i>20,8%</i>	<i>18,0%</i>
Equine	(in million kg)	7 606	6 839	3 247	2 705	20 397
biomass	(relative proportion)	<i>9,3%</i>	<i>2,2%</i>	<i>1,1%</i>	<i>2,0%</i>	<i>2,5%</i>
Goat	(in million kg)	7 900	1 203	7 140	858	17 101
Biomass	(relative proportion)	<i>9,6%</i>	<i>0,4%</i>	<i>2,5%</i>	0,6%	<i>2,1%</i>
Sheep	(in million kg)	14 657	5 208	18 402	11 710	49 976
biomass	(relative proportion)	<i>17,8%</i>	<i>1,7%</i>	<i>6,5%</i>	<i>8,6%</i>	<i>6,2%</i>
Rabbit	(in million kg)	34	18	727	263	1 042
biomass	(relative proportion)	0,04%	<i>0,01%</i>	0,26%	<i>0,19%</i>	<i>0,13%</i>
Camelid	(in million kg)	4 216	370	364	80	5 029
biomass	(relative proportion)	<i>5,1%</i>	<i>0,1%</i>	0,1%	<i>0,1%</i>	<i>0,6%</i>
Cervid	(in million kg)	0	30	73	65	168
biomass	(relative proportion)	0,00%	<i>0,01%</i>	0,03%	<i>0,05%</i>	<i>0,02%</i>
Terrestrial	(in million kg)	81 777	299 914	227 494	133 355	742 540
animal	(relative proportion)	<i>99,5%</i>	<i>98,4%</i>	<i>80,5%</i>	<i>97,8%</i>	<i>92,2%</i>
Aquaculture	(in million kg)	394	4 743	54 969	2 948	63 054
biomass	(relative proportion)	<i>0,5%</i>	1,6%	<i>19,5%</i>	<i>2,2%</i>	<i>7,8%</i>
All species	(in million kg)	82 171	304 657	282 462	136 303	805 593
biomass	(relative proportion)	<i>100%</i>	<i>100%</i>	<i>100%</i>	<i>100%</i>	<i>100%</i>

Figure 34 shows the global species composition of animals potentially exposed to the antimicrobial quantities reported to the OIE for 2018. These percentages are a function of animal populations in the reporting Countries, as well as their average weights.

Across the four OIE regions covered by the analysis, bovines (43%) make up the largest contribution to animal biomass for the quantitative data reported. Swine (20%) and poultry (18%) also play a significant role, with aquaculture (7%), sheep (6%), equines (3%), and goats (2%) playing relatively minor roles in this analysis. The contributions of rabbits (0.1%), camelids (1.5%) and cervids (0.02%) are negligible globally for the covered Countries.

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

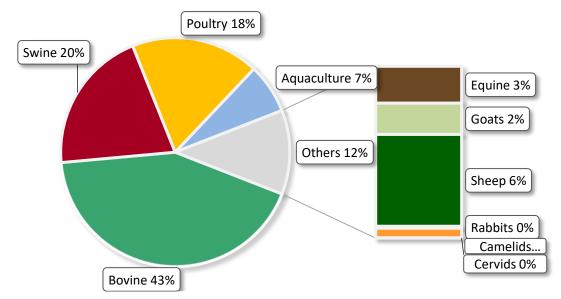


Figure 34. Species composition of animal biomass for 106 Countries included in 2018 quantitative data analysis

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

Aquaculture

Figure 345 shows the global composition of aquaculture for the 64 Countries reporting antimicrobial quantities for 2018 and in addition to terrestrial animals, their data covered aquatic food-producing animal species or could not be distinguished by animal group.

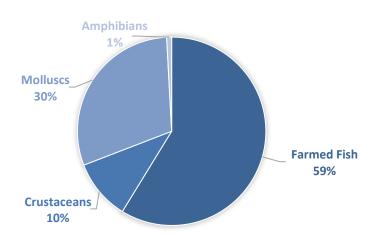


Figure 35. Composition of aquaculture animal biomass for 64 Countries included in 2018 quantitative data analysis covering aquatic food producing animals

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

For the purposes of the 2018 analysis of quantitative data, aquaculture was most significant in Asia, Far East and Oceania, where aquaculture made up 19% of the covered animal biomass. In Africa, the Americas, and Europe, aquaculture made up 0.5%, 1.6% and 2.2%, respectively, of the covered animal biomass.

4.3. Antimicrobial quantities adjusted by animal biomass

2018 Antimicrobial quantities adjusted by animal biomass, global view

Figure 36 provides an overview of antimicrobial agents intended for use in animals adjusted by animal biomass. The estimates compile the data of 106 Countries providing data for food-producing animals in all rounds of data collection for 2018, from all OIE Regions. Three Countries that did not have data on OIE-WAHIS or FAOSTAT were excluded from this section.

Using this rate (antimicrobial agents reported (mg)/animal biomass (kg)) provides an indicator that remains relevant for the purposes of comparison (e.g. over time and between regions). The first estimate of 86.69 mg/kg represents a global estimate of antimicrobial agents used in animals adjusted by animal biomass, as represented by the quantitative data reported to the OIE from 106 Countries during all rounds of data collection. The second estimate of 95.74 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 2018. These coverage estimates are subjective for each reporting Country, but can provide an upper-level estimate of global antimicrobial use in animals. For more detail of coverage estimates, see Section 4.2, Animal population covered by 2018.

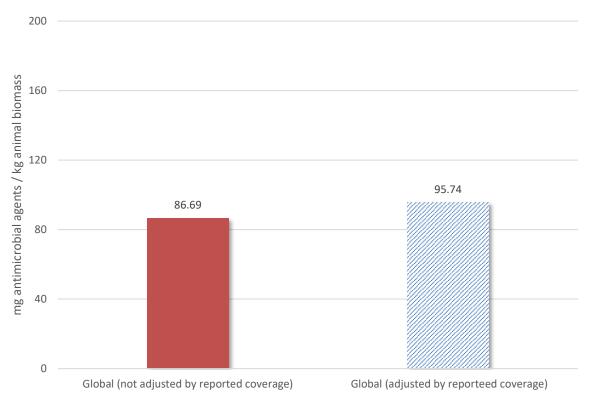


Figure 36. Global quantities of antimicrobial agents intended for use in animals based on data reported by 106 Countries for 2018, adjusted by animal biomass (mg/kg)

2018 Antimicrobial quantities adjusted by animal biomass, regional view

Figure 37 provides a regional view of antimicrobial agents intended for use in animals adjusted by animal biomass of Countries within that region. Both estimates for each OIE region incorporate the data of all Countries providing data in all rounds of data collection for 2018.

The lower estimate for each OIE region represents the quantitative data reported to the OIE from that region during all rounds of data collection for 2018, adjusted by animal biomass. The high estimate for each OIE region represents the same quantitative data, additionally adjusted by Country-level estimates of how much data on antimicrobial agents intended for use in animals they covered in 2018. These coverage estimates are subjective for each reporting Country, but can provide an upper-level approach to global antimicrobial use, including unregulated sources.

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

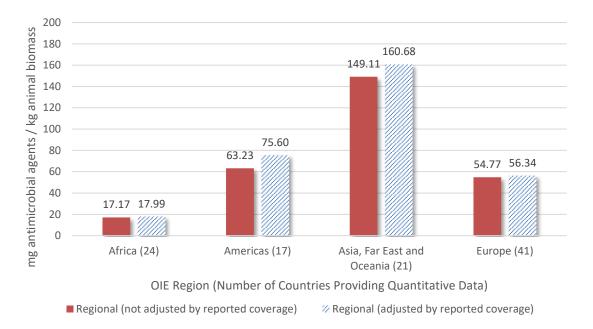


Figure 37. Quantities of antimicrobial agents intended for use in animals adjusted by animal biomass, 2018 regional comparison (mg/kg)

Table 11 displays the same regional figures of antimicrobial quantities adjusted by animal biomass (with the upper-level estimates adjusted by Country estimates of data coverage in parentheses). Additionally, some characteristics of the data distribution by OIE region are provided, including the median, standard deviation and range.

These results show that in 2018, Asia, Far East and Oceania reported the most antimicrobial agents intended for use in animals among the four regions. However, this region also displayed the most variation between individual Countries and the highest decrease in antimicrobial quantities used over the years.

	% Covered of		Antimicrobial quantities adjusted by animal	Descriptive statistics		
OIE region	Number of Countries	total regional estimated biomass	biomass (and estimated data coverage) (mg/kg)	Median (mg/kg)	Standard deviation (mg/kg)	Range (mg/kg)
Africa	24	50%	20.06 (20.78)	5.55 (5.84)	32.89 (32.71)	145.90 (145.89)
Americas	17	94%	73.47 (96.29)	37.54 (44.58)	80.12 (120.68)	235.22 (364.93)
Asia, Far East and Oceania	21	63%	106.37 (125.97)	38.12 (39.71)	159.65 (191.23)	531.93 (571.87)
Europe	41	81%	53.33 (56.88)	28.91 (31.69)	73.03 (79.84)	378.60 (377.23)

It is important to interpret the estimates of antimicrobial quantities adjusted by animal biomass (mg/kg) in the context of animal biomass coverage for the region. Estimates for the total estimated

regional animal biomass covered by the quantitative data reported for 2018 were calculated and explained in Section 4.2. Changes in reporting Countries and in regional animal biomass coverage across years of analysis may significantly change the results. The OIE is working with Countries to continue to improve and maintain data coverage in order to allow for an evaluation of trends over time.

Furthermore, since antimicrobial usage differs for different species (as a result of disease burden and husbandry practices), the species composition of regional animal biomass (Table 10) is an additional factor to be taken into account when considering the differences between regions.

Overall, while noting the need for caution in comparison of 2014 to 2018 results at global and regional levels due to the differences in the contributing Countries, the trends between regions have been maintained. Europe's reported antimicrobial quantities adjusted by animal biomass reduced from 92 mg/kg in 2014 to 53 mg/kg in 2018. These reductions are in line with the results reported by ESVAC for the same years, for those Countries that provide it with data.

2018 Antimicrobial Quantities Adjusted by Animal Biomass: Distinctions Between Terrestrial and Aquatic Animals

Of the 108 Countries that provided quantitative data for food-producing animals in 2018, 12 Countries were able to report quantitative data under the Aquatic food-producing animals group separately from other animal groups.

These 12 Countries were able to report their antimicrobial quantities for the group of terrestrial animals separately from the aquatic animals; enabling the OIE to perform a separate analysis of the mg/kg by animal groups. It was observed that in five Countries, the mg/kg ratios were higher for the aquatic animals group than the terrestrial animals group. Table 12 presents some characteristics of the data distribution by animal group, including the median, standard deviation and range (with the upper-level estimates adjusted by Country estimates of data coverage in parentheses). It is expected that these first figures will be refined over time and should therefore be interpreted with caution and should not be considered representative of global aquaculture production.

		Descriptive Statistics			
Animal Group	Number of Countries	Mean (mg/kg)	Median (mg/kg)	Standard deviation (mg/kg)	Range (mg/kg)
Terrestrial food-producing animals	12	98.38 (115.38)	51.09 (51.09)	151.95 (170.43)	236.42 (236.42)
Aquatic food-producing animals	12	123.32 (133.67)	21.61 (21.61)	146.68 (160.36)	364.36 (428.66)

Table 12. Antimicrobial quantities adjusted by animal biomass, by twelve Countries byterrestrial and aquatic animal groups, 2018

5. Updates of Historical Data

Previous data entries were updated based on new information and corrections reported by Countries in the sixth round of data collection, and therefore may differ from the results of the previous reports.

Changes in the antimicrobial quantities

Corrections to previous antimicrobial quantitative data included recalculations due to identified errors, the addition of previously inaccessible data, and corrections of the calendar year covered by the data submission. For some Countries, where errors in calculations were discovered, their data were retrospectively removed from the 2014, 2015, 2016 and 2017 analysis pending validation. Three Countries updated data for 2016 and two Countries for 2014, 2015 and 2017.

Changes in the animal biomass

For the purpose of supporting comparison, all animal biomass figures for previous years (2014 to 2017) have been recalculated using currently available slaughter and live animal data, as these may be retrospectively updated in the databases. All analyses for previous years (2014 to 2017) included in this report reflect the most current information at the time of writing.

Globally, the percentage of variation of the recalculated animal biomass for 2014, 2015, 2016 and 2017 compared to the previous report is -1.5%, -1.5%, +3.5% and -3%, respectively. These variations can be explained by the updates in the number of reporting Countries and their respective animal biomass data included in the analysis for previous years. The OIE is working with Countries to continue to improve and maintain data coverage in order to allow for an evaluation of trends over time.

6. Trends from 2016 to 2018

This section presents the changes of the mg/kg, antimicrobial classes and animal biomass in the Countries that reported data to the OIE each year from 2016 to 2018 for 72 Countries. Table 13 presents the number of Countries by each OIE Region considered for this analysis. The year 2015 was not included in the following table and figures due to insufficient representativeness of Countries from the different OIE Regions; however, and for readers interested on this year, the trends from 2015 to 2018 reported a decrease of 30% in 63 Countries. The period of 2015 to 2018 should not be compared to the trends provided from 2015 to 2017 in the previous OIE annual report, as it includes different Countries in the analysis.

OIE Region	Number of Countries that Submitted Quantities from 2016 to 2018	Number of OIE Members	Proportion of response (%)
Africa	12	54	22%
Americas			
OIE Members	9	31	29%
Non-contiguous territories	0	n/a	n/a
Asia, Far East and Oceania	15	32	47%
Europe	35	53	66%
Middle East	1	12	8%

Table 13. Number of Countries that Reported	ed Data to the OIE for Each Year from 2016 to 2018

Figure 38 presents the evolution of the calculated animal biomass by species for the 72 Countries which have reported antimicrobial quantities from 2016 to 2018. Globally, the animal biomass for these Countries was relatively stable and has increased of 2.5% from 2016 to 2018. In terms of coverage, the animal biomass for these 72 Countries is estimated to represent 65% of the global animal biomass. The OIE is continuously working with Countries to continue to improve and maintain data coverage in order to allow evaluation of trends over time for a greater number of Countries.

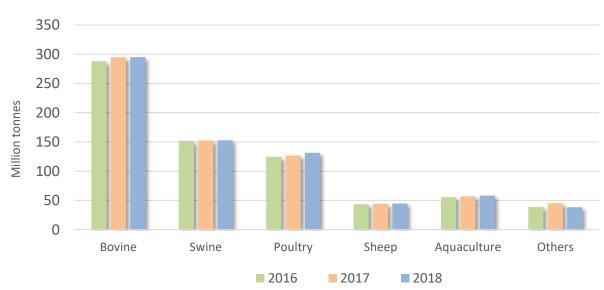


Figure 38. Trends on Time for the Animal Biomass calculated for 72 Countries by species, from 2016 to 2018

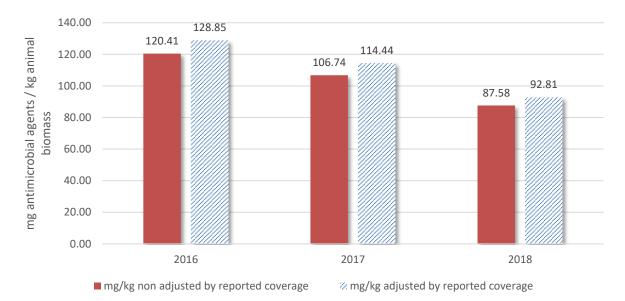
Figures 39 and 40 present the mg/kg for all OIE antimicrobial classes reported for the 72 Countries¹¹.

For the 72 Countries that reported data to the OIE each year from 2016 to 2018, an overall decrease of 27% in the mg/kg was observed. From the 72 Countries, the following situations were observed.

- A decrease in mg/kg in 46 Countries: 31 reporting a decline greater than 10% and 15 ranging between 1% and 10%.
- An increase in mg/kg in 26 Countries: 20 reporting a decrease greater than 10% and six ranging between 1% and 10%.

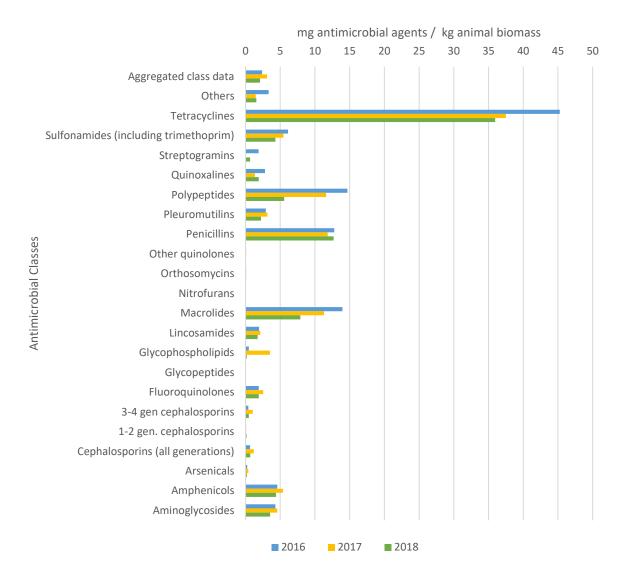
All OIE Regions presented a decrease as follows: 13% in Africa; 28% in the Americas; 30% in Asia, Far East and Oceania; and 18% in Europe.

Figure 39. Trends on Time for the Global Quantities of Antimicrobial Agents Intended for Use in Animals Based on Data Reported by 72 Countries from 2016 to 2018, Adjusted by Animal Biomass (mg/kg)



Antimicrobial quantities intended for use in animals from countries reporting data to the OIE each year from 2015 to 2018 were adjusted for animal biomass (mg/kg). For the regional analyses, country data for both the numerator and the denominator, respectively, were summed according to OIE Regions before the rate was calculated.

Figure 40. Trends over Time for the Antimicrobial Classes Reported by 72 Countries from 2016 to 2018, Adjusted by Animal Biomass (mg/kg)*

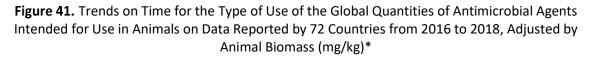


* For each antimicrobial class, the summed antimicrobial quantities reported (in mg) in all OIE Regions are divided by the total animal biomass (in kg)

Figure 41 presents the antimicrobial quantities adjusted by animal biomass (mg/kg) by type of use. For the 72 Countries, 60 had reported the antimicrobials only for veterinary medical use and 12 the use of veterinary medical use and growth promotion.

- The 60 Countries reporting antimicrobials only for veterinary medical use experienced an overall decrease of 9%. This group represents 32% of the animal biomass among the 72 Countries.
- The 12 Countries reporting antimicrobials for veterinary medical use and growth promotion experienced an overall decrease of 35%. This group represents 68% of the animal biomass among the 72 Countries.

These results may suggest that Countries are committed to the objective on the Global Action Plan on AMR that advised Countries to phase out the use of antibiotics for growth promotion in the absence of risk analysis.





2017

Years

% mg/kg adjusted by reported coverage

2018

40.00 20.00 0.00

2016

mg/kg not adjusted by reported coverage

7. Discussion

7.1. Progress Made by Member Countries

During the sixth round of data collection, a high number of Members were engaged in data reporting compared to the previous rounds.

Of the 155 Members that submitted reports in the sixth round, 142 also participated during the fifth round of data collection. Among these 142 Members, the following progress was noted:

- Eight of those Members graduated from reporting only Baseline Information in the fifth round (n = 23; 35%) to reporting quantitative data on antimicrobial agents used in the animals for the first time. Three Members used Reporting Option 1 which allows distinction by antimicrobial class and by type of use (veterinary medical use or growth promotion). Five Countries used Reporting Option 3, which allows for distinction of the quantitative data by type of use, animal groups and routes of administration.
- Eleven of those Members had previously reported quantitative data through Reporting Option 1 or 2 (n = 58; 19%) and progressed to more detailed reporting in this round. Ten Members moved from reporting quantities through Reporting Option 1 to one of the two higher-level options: one was found to have switched to Reporting Option 2, and nine switched to Reporting Option 3. One Member that had previously reported through Option 2, now used Reporting Option 3.

It is important to note that for this sixth round, all regions showed continued progress on the OIE Reporting Options; with Africa and the Americas showing the highest number of Countries progressing to more detailed reporting levels of their quantitative data. During the sixth round, 30% of the 125 Members providing quantities used the Calculation Tool that the OIE developed and introduced during Regional Webinars and Workshops to all OIE Regions between October 2019 and February 2021. This tool assisted the Countries in collecting product information and calculating amounts of active ingredients. Most of the progress demonstrated by Countries can be attributed to their use of this tool.

7.2. Limitations in the Analysis of Antimicrobial Quantities

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

Data sources

During the sixth round of data collection, 21 Countries reporting quantitative data (n = 126; 17%) reported data sources indicating the possibility of over-estimated, duplicated or overlapping data (see examples below).

Data duplication or over-estimation is considered a risk where the following situations are reported in a Country's data sources:

- Import data of active ingredients or manufacturing data reported without taking into account the potential for re-exports;
- Import data of veterinary products reported by a Country also providing data on sales of veterinary products (domestic and imported);

- Import, sales or purchase data of veterinary products reported in addition to usage data at farm level;
- Data from wholesalers or Marketing Authorisation Holders in addition to data from retailers, prescriptions, pharmacies or farm records.

Countries where these possible situations were identified were present in all the OIE Regions, however, they were predominant in Africa (n = 7), followed by the Americas (n = 6). Countries with these situations decreased from 43% in the fourth round to 17% in the sixth round.

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

Calculation of quantitative data

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

During the sixth round, this analysis could be conducted for 114 Countries where data from previous years were available for comparison. In 22 Countries (n= 114; 19%), the data varied more than 25% from one year to another, in some Countries reaching 100-200% variation, and in others, an even higher percentage of change was observed. Such changes were considered unlikely to reflect the true situation.

In Countries with high percentages of unexplained change (>25%), the OIE inquired how the calculations to obtain kg of antimicrobial agents were carried out. Through this process, errors in the calculations were discovered where Countries did not follow or misinterpreted the procedure in Annex 8. Errors in the calculations occurred in all OIE Regions. However, Africa presented the highest number of Countries experiencing challenges (n = 9); followed by Asia, Far East and Oceania (n =6), typically among Countries new to participation in data collection.

In addition to the analysis of the percentages of change, the OIE developed a tool to assist Countries in performing calculations to obtain amounts of active ingredients. The tool takes into account the different rules when reporting to the OIE: it includes different units of measurement (mg, g, ml, IU, etc.); provides conversion factors; identifies the product data (e.g. molecules names, purpose of use, target animals and routes of administration as declared on the product label); and allocates them to the different antimicrobial classes of OIE Reporting Options 1, 2 and 3. Of the 126 Countries reporting antimicrobial quantities in the sixth round, 30% used the tool for calculating amounts of active ingredients. While using the tool, most of the Countries realised that errors had occurred mainly from converting the different units of measurement to kilograms and the conversion factors for IU and derivates or compounds.

Development of antimicrobial monitoring systems

During the fifth round of data collection, 134 Countries reported quantitative data on antimicrobial agents intended for use in animals, and 114 of these also participated in the fifth round of data collection. Nineteen Countries reverted to not reporting quantitative data, due to COVID-19 pandemics situation, due to internal administrative reasons, or without any additional explanation.

In the sixth round of data collection, eight Countries (n = 114; 7%) made amendments to the quantitative data they had reported in previous rounds. These amendments corresponded to errors noted in the calculations, or availability of new data, including additional data for months in the year previously not covered, or data from wholesalers or pharmacists newly participating in the data

collection. In three specific cases, the data were found to not follow the guidelines to calculate amounts of active ingredients, and were retrospectively deleted from these Countries data sets. This error was discovered through Countries use of the OIE Calculation Tool.

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

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

7.3. Limitations in the Estimation of Animal Biomass

The animal biomass methodology was developed with the goal of best representing animal biomass in all OIE Regions, with different animal populations and data collection systems. The biomass figures obtained from this methodology reflect a margin of error, which will be reduced over time as data collection is further refined (see Section 8, Future Developments). Further information can be found in the 'OIE Annual Report on Antimicrobial Agents Intended for Use in Animals: Methods Used' article published in *Frontiers in Veterinary Medicine* in September 2019 [3].

Calculation methodology of average animal weights

Different antimicrobial use surveillance programmes have used various methodologies for the determination of average animal weights to use in the calculation of total biomass. In the ESVAC report [19], estimated average weights at time of treatment are used. The Canadian Integrated Surveillance Program for Antimicrobial Resistance (CIPARS) [23] uses the same standard weights at time of treatment, as well as Canadian standard weights. The surveillance programmes of Japan [24] and the United States of America [25] take a different approach, instead using estimates of average animal weights by production category, rather than focusing the estimates on the time of treatment.

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

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

Specificity of data

As described in the methodology, the globally available data sources on animal population, FAOSTAT and OIE-WAHIS, were not systematically reported by production class for 2018. However, it is necessary to stratify species population by production class to better assign average weights, for example, to separate veal calves from adult cattle. The methodology for calculation of biomass therefore utilises some necessary standard animal reproduction rates to extract a best estimate of the population breakdown by production class. These rates will vary between species, Countries and production systems, and therefore, are not fully representative of the animal populations of any one Country or region.

Animals imported and exported

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

Extrapolations within the methodology

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

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

Animal species not retained in denominator

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

For the Countries where cat and dog populations were available, it was seen that their contribution to overall biomass was minor (<0.5%). However, as some Countries do include antimicrobials used in companion animals in their reported quantitative data, there is expected to be a small effect on results by excluding these species. As excluding them decreases the denominator, the effect, if any, would be a minor increase in antimicrobial quantities adjusted for animal biomass.

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

7.4. Barriers to Collect Antimicrobial Quantities

For the Countries unable to report antimicrobial quantities, the main barriers reported were the structure or enforcement of their regulatory framework for veterinary products. It was also noted that there has been a decrease in the number of Countries reporting the lack of an electronic tool that can collect and analyse data. During the fourth round, seven Countries reported this obstacle, while in the sixth round this reduced to three. The three Countries are expecting to provide quantities in the upcoming round through the OIE Calculation Tool or by building a national software.

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

8. Future Developments for the Antimicrobial Use Survey

Interactive information technology (IT) system for OIE AMU Data Collection

In 2021, the OIE initiated the process of developing the OIE-AMU system and finished the two-yearsprocess of gathering Member's user requirements. In 2022, the OIE will be developing the change management procedures and materials for the future OIE-AMU IT System. Additionally, testing experiences will be launched during the first semester of 2022 for OIE Members, OIE Regional colleagues and experts in order to introduce the system and capture additional needs that could be used to refine the change management materials and orient training.

In 2022, the OIE is concluding the process of building an interactive automated system in which Members will report the use of antimicrobial agents in animals and receive support for calculating amounts of active ingredients. This AMU IT system will be accessible online and will help Members with their calculations, reduce errors and improve the quality of data. The AMU IT system will also simplify the reporting process, enable faster reporting and analysis and encourage Members to use their own data to get valuable insights and visualise important information.

During 2022, the OIE will develop training materials and user guides for the future system in order to allow Countries to embark the new system with the proper knowledge and abilities to submit data and navigate in the system. The new system will embrace the modifications to the aquatic animals that were presented in the OIE Aquatic Animal Health Strategy for 2021-2025

Animal biomass

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

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

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

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

9. Conclusions

Countries remain highly engaged in the reporting of data related to the antimicrobial use in animals. The overall **participation** has barely been impacted by difficulties associated with the management of the COVID-19 pandemics, and the number of participant Countries providing quantitative data has significantly increased when compared to pre-pandemic years. Thanks to everyone's contributions, the OIE can continue to generate accurate analyses, as well as to assess trends of antimicrobial agents use over time. The OIE would like to acknowledge and thank all the National Authorities who have participated in the collection and reporting of data. Their involvement witnesses the implementation of OIE's recommendations in its strategy for a responsible and prudent use of antimicrobials.

This report intends to provide a comprehensive and fair representation of the global situation in the utilization of antimicrobial agents intended for use in animals. Its publication aims to complete the information published by OIE Members at the national level. With 35 Members today making national data publicly available, the OIE would like to encourage all Members to publish their national reports. As stated in chapters 6.9 and 6.3 from the Terrestrial and Aquatic Animals Codes, respectively, this is an important measure to ensure **transparency**, allowing all interested parties to assess trends, to perform risk assessments, as well as for risk communication purposes. With the development of the future OIE AMU system (launch planned by the end of 2022), the OIE seeks to facilitate the understanding and utilisation of these data among all OIE Members. Secure and confidential, the system has been designed to ease data submission, and to provide instruments for data consolidation and visualisation, that could be used for decision-making at national level. We do hope to also strengthen communication with other national agencies involved in antimicrobial use data collection.

In 2020, the use of antimicrobial agents for growth promotion in animals is no longer a practise in nearly ³/₄ of the participant Countries, either with or without legislation/regulation provision for their use. The use of growth promoters is still reported by ¹/₄ of the 157 Countries to this sixth round of data collection. Under the auspices of the Global Action Plan, the OIE encourage Members to continue their efforts to implement policies on the use of antimicrobials in terrestrial and aquatic animals, respecting OIE intergovernmental standards, including recommendations for the phasing out of the use of antibiotics for growth promotion in the absence of risk analysis.

Data presented in this report estimate that, in 2018, the total amount of antimicrobial agents intended for use in animals oscillates between 69,455 and 76,704 tonnes (109 Countries to this sixth annual report). Overall, tetracyclines remained the most utilized antimicrobial agent in animal health globally (40.5% of the total amount), followed by penicillins (14.1% of the total amount). Countries providing data by antimicrobial class and per animal groups increases over time, with 60 Countries providing such level of data for 2018. When looking at terrestrial food-producing animals, penicillins and tetracyclines remain the most used (21.1% and 19.4% of the total amount respectively) among the 37 Countries providing data. When focusing on the 13 Countries providing specific data for aquaculture tetracyclines become second after amphenicols, also considered as VCIA. Ninety-eight Countries reported use of antimicrobial agents in companion animals, mainly canines and felines (n=84 Countries), followed by ornamental birds, rabbits and equines (n=13, 10 and 9 Countries respectively). Penicillins were the most reported antimicrobial class, closely followed by aminoglycosides, sulfonamides and polypeptides. All of them VCIA but the latter one, considered as Veterinary Highly Important Antimicrobial (VHIA) classes. The implementation of a calculation tool in previous years has positively contributed to the higher number of detailed returns, and the OIE would like to encourage participant Countries to continue providing such level of accurate reporting.

These absolute numbers around quantities of antimicrobial agents are also analysed in relation to the animal population concerned, by normalization with the use of the OIE animal biomass denominator, estimated to be the best indicator for global monitoring of antimicrobial sales in food-producing

animals by an independent review¹². This allows data comparison across sectors, regions and over time. In this sixth report, the OIE covers 72% of the total animal biomass for the year 2018, representing 106 Countries around the globe. This encompasses terrestrial and aquatic food-producing animals, with companion animals excluded from the analyses. Bovine species account for 43% of the total coverage, followed by swine (20%) and poultry (18%). Aquatic animals account for 7% of the total coverage, being almost 2/3 represented by farmed fishes. Taking all this into consideration, the OIE estimates that, in 2018 a total of 86,69 to 95,74 mg of antimicrobial agents were used per kg of animal biomass, depending on how coverage estimations were adjusted among the 109 Countries. Analysis of these data over time, shows that, amongst the 72 Countries that have consistently provided data since 2016 till 2018, a decrease of 27% has been observed in the normalized amount of antimicrobial agents used in animals (from 120,41 mg/Kg to 87,58 mg/Kg, respectively). This confirms trend already reported in the fifth report, suggesting the continuous global decrease in the utilization of antimicrobial agents for intended use in animals.

Since the beginning of the OIE data collection, Countries have demonstrated their commitment to engage in this global activity. The report transparently describes collected data and reasons for a certain level of uncertainty associated with both the complex and simple estimates presented. As a result of multiple challenges participant Countries face in their way towards the collection of quantitative data, OIE continues to advise caution in the interpretation and use of the quantitative data presented in this report. The limitations of this analysis include quantitative data source errors, which may lead to overcounting of antimicrobial amounts by some Countries new to the process of data collection.

On an annual basis, the OIE highlights not only the reported quantitative data for participant Countries currently able to provide it, but also reflects the current situation of governance of veterinary antimicrobials worldwide, and barriers to quantitative data collection. The OIE will continue analysing the barriers related to the lack of regulatory framework to seek for solutions to the Countries that reported these barriers (Veterinary Legislation Support Program within the Performance Veterinary Services tool provided by OIE). Moreover, the OIE remains strongly committed to supporting its Members in developing robust and transparent measurement reporting mechanisms for antimicrobial use. Concurrent to engagement with Countries to improve these data, the methodology for calculating animal biomass will continue to be refined. As data collection systems develop further (i.e. soon available customized interactive online system, exploration of tools enabling data collection at the farm level, etc.), this annual report will continue to provide an essential global and regional analysis of antibiotic use in animals, and changes over time.

¹² Ece Bulut, Renata Ivanek, Comparison of different biomass methodologies to adjust sales data on veterinary antimicrobials in the USA, Journal of Antimicrobial Chemotherapy, 2021; <u>https://doi.org/10.1093/jac/dkab441</u>

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ANNEXES

- Annex 1 Africa, Regional Focus
- Annex 2 Americas, Regional Focus
- Annex 3 Asia, Far East and Oceania, Regional Focus
- Annex 4 Europe, Regional Focus
- Annex 5 Middle East, Regional Focus
- Annex 6 OIE Template
- Annex 7 Guidance for Completing the OIE Template for the Collection of Data on Antimicrobial Agents Used in Animals
- Annex 8 Annex to the Guidance for Completing the OIE Template for the Collection of Data on Antimicrobial Agents Used in Animals
- Annex 9 Distribution of Members by OIE Region

Annex 1 Africa, Regional Focus

General Information for Africa	
Number of OIE Members	54
Number of OIE Members responding to the questionnaire	43 (80%)
Number of OIE Members providing qualitative data only	13 (30%)
Number of OIE Members providing quantitative data	30 (70%)

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

Barriers to Providing Quantities of Antimicrobial Agents in Animals

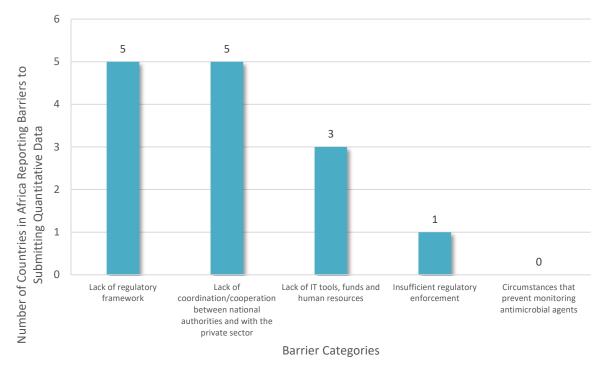
Thirteen OIE Members (n= 43; 30%) responded with Baseline Information (qualitative data) and did not provide quantitative data on antimicrobial agents used in animals (Table A1). Ten out of 13 explained their barriers to reporting quantities of antimicrobial agents used in animals. Countries can report more than one barrier relevant to their situation, and responses for this reporting year were grouped by category (Fig. A1). For further information on the category groupings, please refer to Section 3.5 of this report.

Five Countries cited the main impediment to reporting antimicrobial quantities as the lack of a regulatory framework. Of these, two Countries describe the absence of a regulatory framework for the manufacture, registration, distribution, commercialization and use of veterinary products. Two Members mentioned that the Country did not have an official procedure to collect these data; one of them reported their intention to develop a procedure.

Three Members described a lack of coordination/cooperation with the Ministry of Health. Two Country cited difficulties in coordinating with the private sector and veterinarians; one of these Countries also raised the situation on illegal veterinary products made the challenging this task.

Three Countries mentioned that the lack of staff impact on their ability to collate and analyse the data. One of these Countries had reported data in previous rounds, but the person responsible for this task left the government and the position was not made available again.





Antimicrobial Agents Used for Growth Promotion

During 2020, 11 African Countries (n = 43; 26%) used antimicrobial agents as growth promoters. Of these, six Members (n = 11; 55%) provided a list of antimicrobials used for growth promotion, with tylosin being the most frequently named (Figure A2). It was noted that of these six Countries only two had legislation regulating for these molecules. It was also observed that of the 27 Countries stating they did not use antimicrobials as growth promoters, 19 did not have any legislation or regulation banning the use of these molecules (n = 27; 70%). Five Countries reported that the use of growth promoters in the field was unknown and also experienced a lack of legislation or regulation for this type of use. For the sixth round, Africa is the OIE Region with most Countries reporting a lack of legislation or regulation for antimicrobials used as growth promoters (nine out of 11 Countries, 82%).

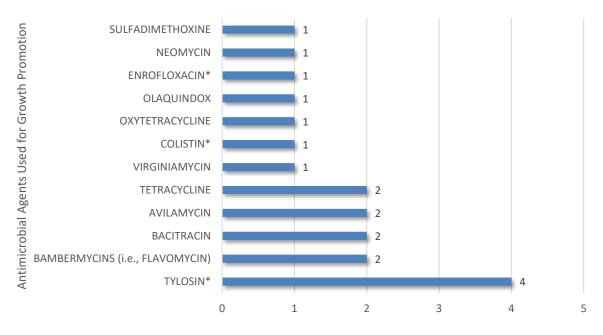


Figure A2. Antimicrobial Growth Promoters Used in Animals in Six Countries in Africa in 2020

Number of Members in Africa Reporting Use of Antimicrobial Agents for Growth Promotion in 2020

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

2018 Analysis of Antimicrobial Quantities

This section provides additional analysis of reported quantitative data on antimicrobial agents intended for use in animals adjusted by animal biomass, focusing on 2018. This analysis represents the antimicrobial quantities reported to the OIE from 24 Countries in Africa during all rounds of data collection.

QUANTITATIVE DATA SOURCES CAPTURED

All African Countries' data sources were analysed, and all Countries where data duplication was considered to be a risk were asked for clarification of their answers and/or data collection systems. Twelve Countries' data sources were considered to present a risk of duplication (n = 24; 50%); after clarifications, seven Countries (n = 12; 58%) changed their answers or proved there was no duplication or overlapping of data sources. Only the remaining Countries (five out of 12; 42%) that did not provide clarifications were excluded from the analysis in Figure A3. For a full explanation of quantitative data sources, see the Guidance for Completing the OIE Template for the Collection of Data (Annex 7).

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

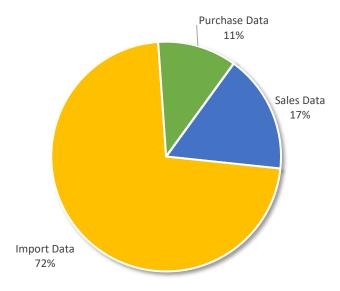
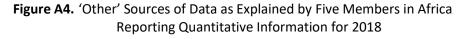
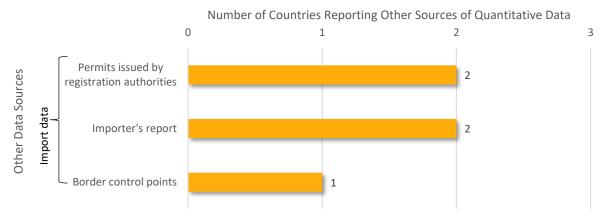


Figure A3. Data Sources Selected by 20 African OIE Members Reporting Quantitative Information for 2018





ANTIMICROBIAL QUANTITIES REPORTED IN 2018

For 2018, 24 African Countries provided validated antimicrobial quantities intended for use in animals. Of the 24 Countries, ten stated a 100% coverage of the data source used to report the data and one Country estimated 120% coverage as all import data were covered, but 20% of their total imports were planned for re-exportation to neighbouring Countries. The 13 Countries that did not cover 100% of available antimicrobial quantity data sources were asked to provide further information on uncaptured data sources. For the 24 Countries, the estimated data coverage was 94%. More information on the data coverage for Africa is available in Table 5 of this report.

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

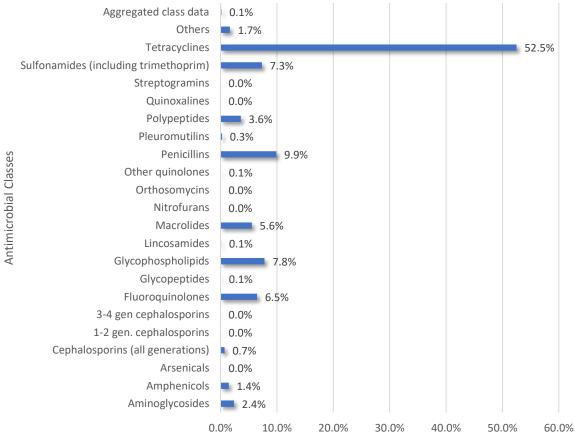


Figure A5. Proportion of Antimicrobial Classes Reported for Use in Animals by 24 African Members in 2018

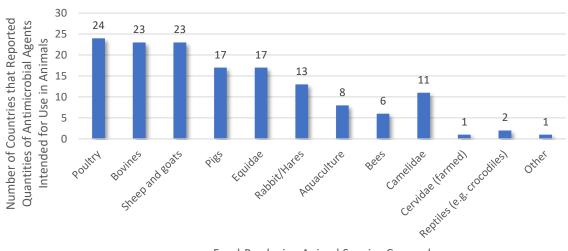
% of Reported Quantities of Antimicrobial Agents Used in Animals by 24 Countries

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

Irrespective of whether the data could be differentiated by animal groups, all 24 Countries were asked to select the food producing animal species covered by their data from a list supplied in the OIE template and according to the products target species label. For descriptive purposes, some animals were grouped in categories, for more information on the grouping of animals see page 44 of this report.

In the 24 African Members that reported quantitative data on antimicrobial agents intended for use in animals for 2018, the food-producing species most frequently covered by the data were poultry, followed by bovines, sheep and goats (Figure A6). Within the four regions analysed, Africa is one of the regions where Camelidae were more commonly named by Members.

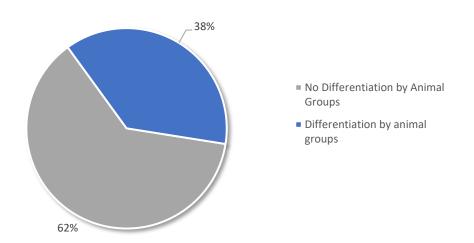
Figure A6. Food-Producing Animal Species Included in Quantitative Data Reported by 24 African Members in 2018

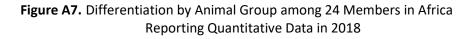


Food-Producing Animal Species Covered

QUANTITATIVE DATA DIFFERENTIATION BY ANIMAL GROUP

Most of the quantitative data from the African Members cannot be differentiated by animal group. This result corresponds with the African Region's predominant use of Reporting Option 1, which does not allow for differentiation by animal group (Fig. A7). For the nine African Countries (n = 24; 38%) that were able to distinguish antimicrobial quantities by animal groups, data were mainly provided for terrestrial food-producing animals and companion animals.





ANIMAL BIOMASS

In Africa, sheep, goat and equine biomass are relatively more significant, compared to the other regions, contributing 18%, 10% and 9%, respectively, to the total biomass. In contrast, the proportions of swine and poultry, 2% and 4%, respectively, are the lowest among all regions. It can be underlined that camelids, totalling 5%, are also proportionally more significant in Africa than in other regions.

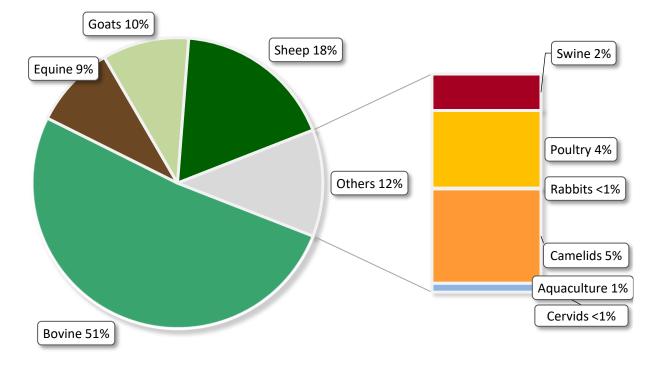


Figure A8. Species Composition of Animal Biomass for the 24 Countries in Africa Included in 2018 Quantitative Data Analysis

ANTIMICROBIAL QUANTITIES ADJUSTED BY ANIMAL BIOMASS

In Africa, the mg/kg estimate for 2018 for 24 Countries is 17.17 mg/kg, with an upper-level estimate of 17.99 mg/kg when adjusted by estimated coverage. From all OIE Regions, Africa has the lowest mg/kg estimate.

Changes in mg/kg results from 2014 to 2017

The updated mg/kg estimate for 2014 for 11 African Countries is 36.63 mg/kg, with an upper-level estimate of 41.62 mg/kg when adjusted by estimate coverage.

The updated mg/kg estimate for 2015 for 22 African Countries is 31.91 mg/kg, with an upper-level estimate of 37.27 mg/kg when adjusted by estimate coverage.

The updated mg/kg estimate for 2016 for 16 African Countries is 34.00 mg/kg, with an upper-level estimate of 40.41 mg/kg when adjusted by estimate coverage.

The updated mg/kg estimate for 2017 for 20 African Countries is 24.74 mg/kg, with an upper-level estimate of 28.73 mg/kg when adjusted by estimate coverage

Annex 2 Americas, Regional Focus

General Information for the Americas	
Number of Countries*	33
Number of Countries responding to the questionnaire	28 (85%)
Number of Countries providing qualitative data only	8 (29%)
Number of Countries providing quantitative data	20 (71%)

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

*31 OIE Members, one non-contiguous territory and one non-OIE Member

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

In the Americas, 28 Countries (n = 33; 85%) submitted completed reports to OIE Headquarters: 26 from OIE Members, one non-contiguous territory and one non-OIE Member. The response from the non-contiguous territory was included in the analysis of the Americas for geographical reasons (Table A2).

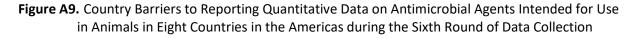
Barriers to Providing Quantities of Antimicrobial Agents in Animals

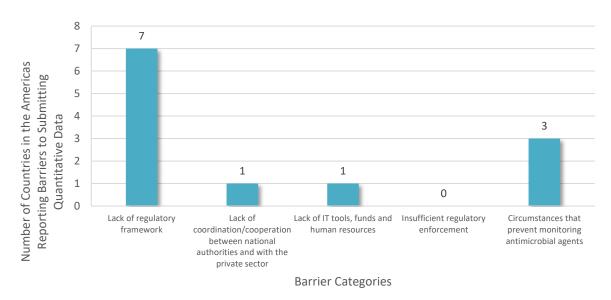
Eight Countries (n = 28; 29%) responded with Baseline Information (qualitative data) with no quantitative data on antimicrobial agents used in animals. All eight Countries explained their barriers to reporting antimicrobial quantities. Countries can report more than one barrier relevant to their situation, and responses were grouped by category (Figure A9). For further information on the category groupings, please refer to Section 3.5 of this report.

Almost all the responses in the Americas (seven out of eight Countries; 88%) mentioned that the main impediment to reporting antimicrobial quantities was the lack of regulatory frameworks. Four Countries explained that the main barrier was that their legislations/regulations did not require the monitoring of antimicrobial use, so there were no regulations or guidelines on data collection procedure or stakeholder obligations. Three Countries explained that no legislation existed for veterinary medicinal products.

Three Countries reported that COVID-19 had worsened its situation; one of them had to pause a project that intended to support the creation of the necessary regulatory framework and one noted that the COVID-19 situation had further impacted staff availability and activities for the drug agency.

In previous round, the lack of IT Tools to collect and calculate data was cited as an important barrier in the Americas. During the sixth round more Countries started to use the OIE Calculation Tool and reported antimicrobial quantities through Reporting Option 3.





Antimicrobial Agents Used for Growth Promotion

Seventeen Countries (n = 28; 61%) in the Americas used antimicrobial agents as growth promoters in 2020. Of these, 14 Countries (n = 17; 82%) provided a list of antimicrobials used for growth promotion, with bacitracin and bambermycin (i.e. flavomycin) most commonly named (Figure A10).

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

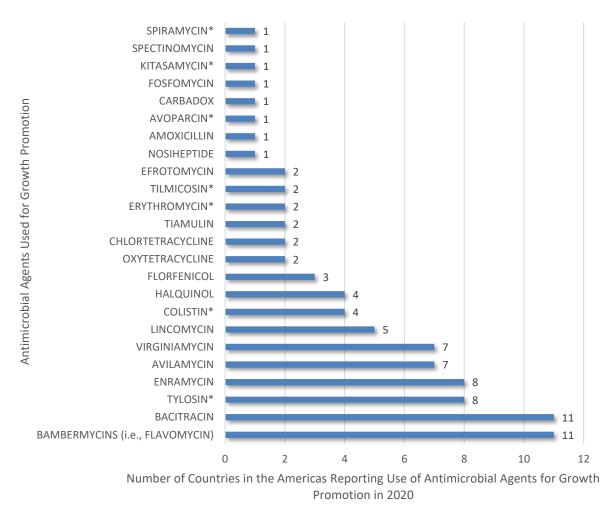


Figure A10. Antimicrobial Growth Promoters Used in 14 Countries in the Americas in 2020

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

After Africa, the Americas is the second OIE Region with most Countries reporting a lack of legislation or regulation for antimicrobials used as growth promoters (nine out of 17 Countries, 53%).

2018 Analysis of Antimicrobial Quantities

This section provides additional analysis of reported quantitative data on antimicrobial agents intended for use in animals adjusted by animal biomass, focusing on 2018. This analysis represents the antimicrobial quantities reported to the OIE from 19 Countries in the Americas during all rounds of data collection.

QUANTITATIVE DATA SOURCES CAPTURED

All Countries' data sources in the Americas were analysed, and Countries where data duplication was considered to be a risk were asked for clarification of their answers and/or data collection systems. Eight Countries' data sources (n = 19, 42%) were considered to present a risk of duplication; after the clarifications, four Countries (n = 8; 50%) changed their original data sources. The four remaining Countries that did not provide clarification were excluded from the analysis in Figure A11. For a full explanation of quantitative data sources, see the Guidance for Completing the OIE Template for the Collection of Data (Annex 7).

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

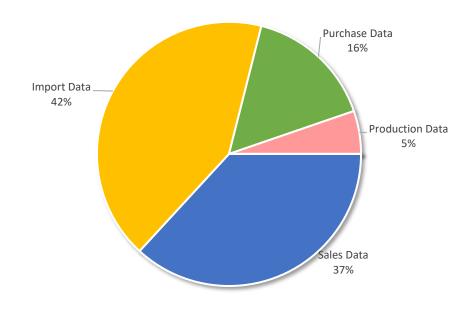


Figure A11. Data Sources Selected by 15 Countries in the Americas Reporting Quantitative Information for 2018

ANTIMICROBIAL QUANTITIES REPORTED IN 2018

For 2018, 19 Countries in the Americas provided validated antimicrobial quantities intended for use in animals. Of the 19 Countries, five stated 100% coverage of the data source used to report the data. The 12 Countries that did not cover 100% of available antimicrobial quantity data sources were asked to provide further information on uncaptured data sources. For the 19 Countries, the estimated data coverage was 89%. More information on the data coverage for the Americas is available in Table 6 of this report.

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

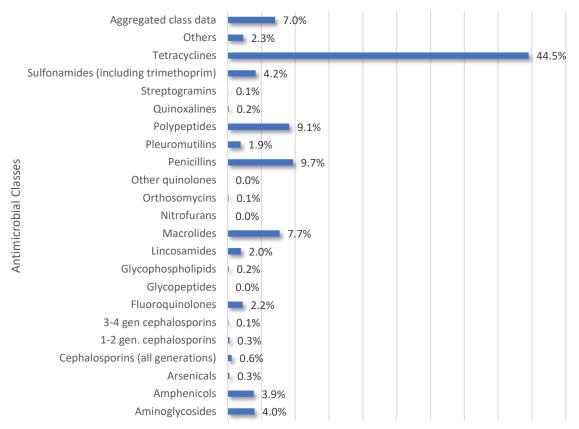


Figure A12. Proportion of Antimicrobial Classes Reported for Use in Animals by 19 Countries in the Americas 2018

 $0.0\% \quad 5.0\% \quad 10.0\% \ 15.0\% \ 20.0\% \ 25.0\% \ 30.0\% \ 35.0\% \ 40.0\% \ 45.0\% \ 50.0\%$

% of Reported Quantities of Antimicrobial Agents Used in Animals by 19 Countries

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

Irrespective of whether the data could be differentiated by animal groups, all 19 Countries were asked to select the food-producing animal species covered by their data from a list supplied in the OIE template and according to the products target species label. For descriptive purposes, some animals were grouped in categories, for more information on the grouping of animals see page 44 of this report.

In the 19 Countries from the Americas that reported antimicrobial quantities for 2018, the foodproducing species most frequently covered by the data were poultry, bovines, pigs, and sheep and goats (Figure A13).

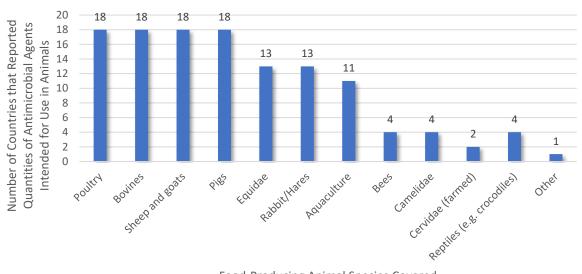
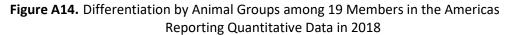


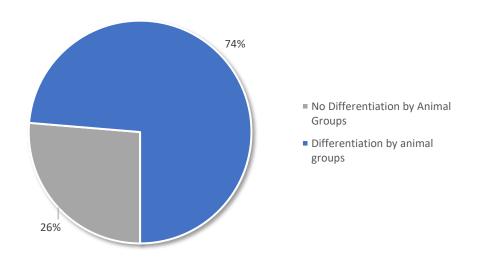
Figure A13. Food-Producing Animal Species Included in Quantitative Data Reported by 19 Countries in the Americas in 2018

Food-Producing Animal Species Covered

QUANTITATIVE DATA DIFFERENTIATION BY ANIMAL GROUP

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





ANIMAL BIOMASS

The bovine species make an important contribution (62%) to the total biomass of the Americas. In comparison to other regions, small ruminants (sheep and goats), have a relatively low impact on the region's biomass.

For two Countries of this region, animal population data was unavailable in the public databases; therefore, animal biomass was not calculated and these Countries were not included in the mg/kg analysis.

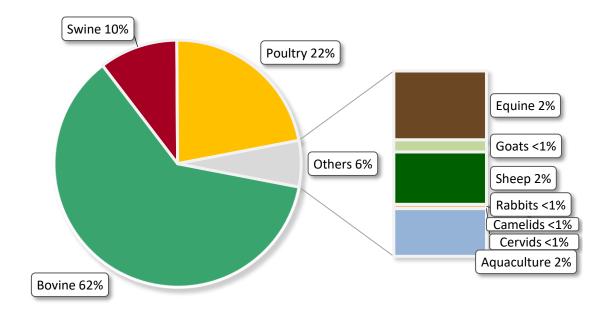


Figure A15. Species Composition of Animal Biomass for the 17 Countries in Americas Included in 2018 Quantitative Data Analysis

ANTIMICROBIAL QUANTITIES ADJUSTED BY ANIMAL BIOMASS

In the Americas, the mg/kg estimate for 2018 for 17 Countries is 63.23 mg/kg, with an upper-level estimate of 75.60 mg/kg when adjusted by estimated coverage.

Changes in mg/kg results from 2014 to 2017

The updated mg/kg estimate for 2014 for six Countries in the Americas is 86.64 mg/kg, with an upperlevel estimate of 90.31 mg/kg when adjusted by estimate coverage.

The updated mg/kg estimate for 2015 for six Countries in the Americas is 94.97 mg/kg, with an upperlevel estimate of 97.85 mg/kg when adjusted by estimate coverage.

The updated mg/kg estimate for 2016 for 11 Countries in the Americas is 87.48 mg/kg, with an upperlevel estimate of 106.84 mg/kg when adjusted by estimate coverage.

The updated mg/kg estimate for 2017 for 16 Countries in the Americas is 69.24 mg/kg, with an upper-level estimate of 87.17 mg/kg when adjusted by estimate coverage.

Annex 3 Asia, Far East and Oceania, Regional Focus

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

General Information for Asia, Far East and Oceania	
Number of OIE Members	32
Number of OIE Members responding to the questionnaire	28 (88%)
Number of OIE Members providing qualitative data only	2 (7%)
Number of OIE Members providing quantitative data	26 (93%)

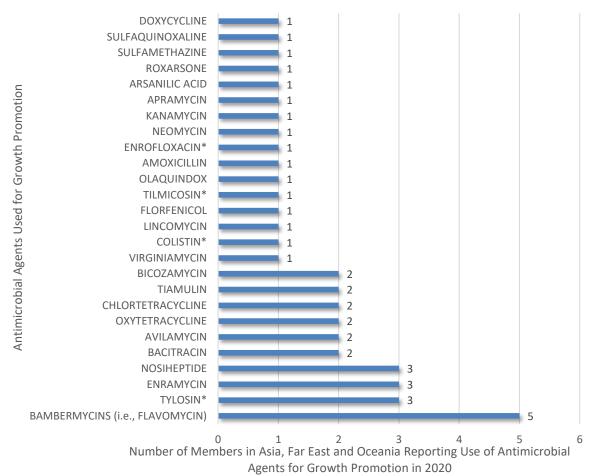
Barriers to Providing Quantities of Antimicrobial Agents in Animals

For the sixth round, two Countries responded with Baseline Information (qualitative data) with no quantitative data on antimicrobial agents used in animals. None of these Countries outlined their barriers to reporting antimicrobial quantities.

Antimicrobial Agents Used for Growth Promotion

Ten Members (n = 28; 36%) reported the use of antimicrobials as growth promoters. Of these, seven Members (n = 10; 70%) provided a list of utilised agents, the most frequently listed antimicrobial agents for this purpose were bambermycin (i.e. flavomycin), followed by tylosin, enramycin and nosiheptide (Figure A16).

Figure A16. Antimicrobial Growth Promotors Used in Animals in Asia, Far East and Oceania in 2020 as reported by Seven Members



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

2018 Analysis of Antimicrobial Quantities

This section provides additional analysis of reported quantitative data on antimicrobial agents intended for use in animals adjusted by animal biomass, focusing on 2018. This analysis represents the antimicrobial quantities reported to the OIE from 22 Countries in Asia, Far East and Oceania during all four rounds of data collection.

QUANTITATIVE DATA SOURCES CAPTURED

All Countries' data sources in Asia, Far East and Oceania were analysed, and all Countries where data duplication was considered a risk were asked for clarification on their answers and/or data collection systems. Six Countries' data sources (n = 22; 27%) were considered to present a risk of duplication; after clarifications, four Countries (n = 6; 67%) changed their answers or proved there was no duplication or overlapping of data sources. The two remaining Countries (two out of six; 33%) that did not provide clarifications were excluded from the analysis of data sources in Figure A17. For a full explanation of quantitative data sources, see the Guidance for Completing the OIE Template for the Collection of Data (Annex 7).

From the list of data source options provided in the OIE template, import and sales data were most commonly chosen (Figure A17). In addition, four Members described other data source not included in the OIE List, relating mainly to import and production data (Figure A18).

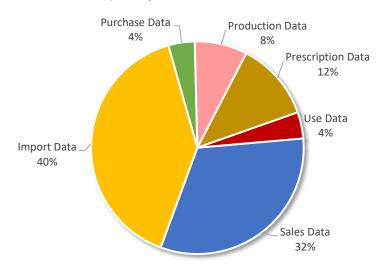
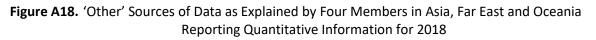
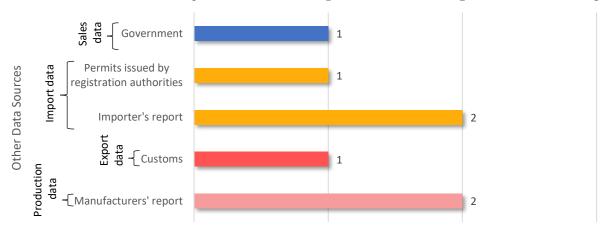


Figure A17. Data Sources Selected by 20 Countries in Asia, Far East and Oceania Reporting Quantitative Information for 2018



 $_{0}$ Number of Countries Reporting Other Sources of Quantitative Data $_{3}$

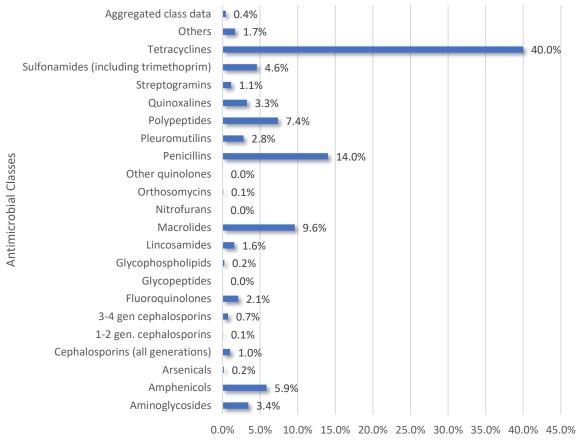


ANTIMICROBIAL QUANTITIES REPORTED IN 2018

For 2018, 22 Countries in Asia, Far East and Oceania provided validated antimicrobial quantities intended for use in animals. Of these 22 Countries, five stated 100% coverage of the data sources used to report the data. The 17 Countries that did not cover 100% of available antimicrobial quantities data sources were asked to provide further information on uncaptured data sources. For the 22 Countries, the estimated data coverage was 87%. More information on the data coverage for Asia, Far East and Oceania, is available in Table 6 of this report.

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

Figure A19. Proportion of Antimicrobial Classes Reported for Use in Animals by 22 Members in Asia, Far East and Oceania in 2018

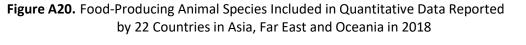


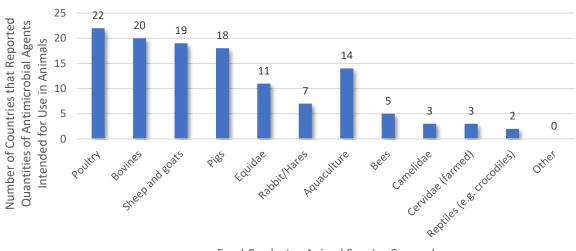
% of Reported Quantities of Antimicrobial Agents Used in Animals by 22 Countries

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

Irrespective of whether the data could be differentiated by animal groups, all 22 Countries were asked to select the food-producing animal species covered by their data from a supplied list in the OIE template and according to the products target species label. For descriptive purposes, some animals were grouped into categories, for more information on the grouping of animals see page 44 of this report.

Of the 22 Countries from Asia, Far East and Oceania that reported antimicrobial quantities for 2018, the food-producing species most frequently covered by the data were poultry, followed by bovines, sheep and goats, and swine (Figure A20). Asia, Far East and Oceania is the second OIE region that has more Countries whose data cover aquaculture.





Food-Producing Animal Species Covered

QUANTITATIVE DATA DIFFERENTIATION BY ANIMAL GROUP

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

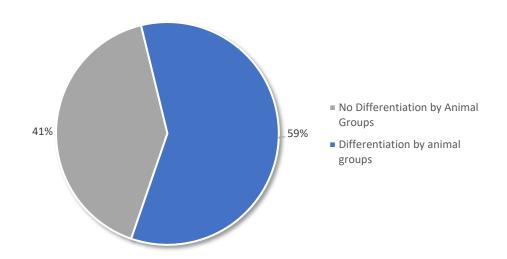
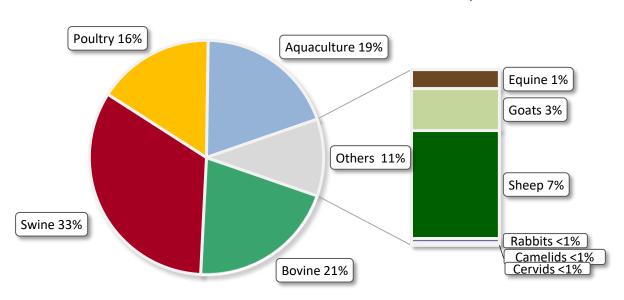


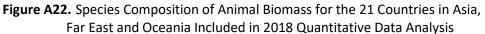
Figure A21. Differentiation by Animal Groups among 22 Members in Asia, Far East an Oceania Reporting Quantitative Data in 2018

ANIMAL BIOMASS

In contrast to the three other regions, the species contributing the most to the total biomass in Asia is swine, totalling 33% of the biomass followed by 21% for bovines. Moreover, the relative importance of aquaculture, reaching 19% of the animal biomass, exceeds the other regions. However, as detailed previously, *percentages of aquaculture should be interpreted with caution as the aquaculture biomass was only included for those Countries reporting that their data on antimicrobial agents covered aquaculture.* Therefore, the effect of aquaculture on biomass is skewed by the number of Countries in that OIE Region for which antimicrobials used in aquaculture were included.

For one Country the, animal population data was unavailable in the public databases; therefore, animal biomass was not calculated for this Country and it was not included in the mg/kg analysis.





ANTIMICROBIAL QUANTITIES ADJUSTED BY ANIMAL BIOMASS

In Asia, Far East and Oceania, the mg/kg estimate for 2018 of 21 Countries is 149.11 mg/kg, with an upper level estimate of 160.68 mg/kg when adjusted by estimated coverage.

Changes in mg/kg results from 2014 to 2017

The updated mg/kg estimate for 2014 for four Asian Countries is 58.88 mg/kg, with an upper-level estimate of 58.88 mg/kg when adjusted by estimate coverage.

The updated mg/kg estimate for 2015 for 14 Asian Countries is 364.00 mg/kg, with an upper-level estimate of 365.87 mg/kg when adjusted by estimate coverage.

The updated mg/kg estimate for 2016 for 17 Asian Countries is 227.55 mg/kg, with an upper-level estimate of 229.42 mg/kg when adjusted by estimate coverage.

The updated mg/kg estimate for 2017 for 18 Asian Countries is 195.92 mg/kg, with an upper-level estimate of 202.29 mg/kg when adjusted by estimate coverage.

Annex 4 Europe, Regional Focus

General Information for Europe	
Number of OIE Members	53
Number of OIE Members responding to the questionnaire	48 (91%)
Number of OIE Members providing qualitative data only	3 (6%)
Number of OIE Members providing quantitative data	45 (94%)

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

Barriers to Providing Quantities of Antimicrobial Agents in Animals

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

Antimicrobial Agents Used for Growth Promotion

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

2018 Analysis of Antimicrobial Quantities

This section provides additional analysis of reported quantitative data on antimicrobial agents intended for use in animals adjusted by animal biomass, focusing on 2018. This analysis represents the antimicrobial quantities reported to the OIE from 41 Countries in Europe during all four rounds of data collection.

QUANTITATIVE DATA SOURCES CAPTURED

All Countries' data sources in Europe were analysed, and all Countries where data duplication was considered a risk were asked for clarification of their answers and/or data collection systems. Six Countries' data sources (n = 41; 15%) were considered to present a risk of duplication; after clarifications, four Countries (n = 6; 67%) changed their answers or proved there was no duplication or overlapping of data sources. The two remaining Countries (two out of six; 33%) that did not provide a clarification to the OIE were excluded from the analysis in Figure A23. For a full explanation of quantitative data sources, see the Guidance for Completing the OIE Template for the Collection of Data (Annex 7).

From the list of data source options provided in the OIE template, sales data for veterinary products as declared by wholesalers was most commonly chosen, with 23 Members (n= 38; 61%) selecting this option (Figure A23).

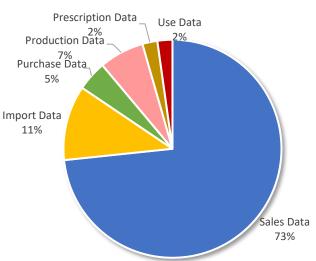


Figure A23. Data Sources Selected by 38 Countries in Europe Reporting Quantitative Information for 2018

ANTIMICROBIAL QUANTITIES REPORTED IN 2018

For 2018, 41 Countries in Europe provided validated antimicrobial quantities intended for use in animals. Of the 41 Countries, 25 stated 100% coverage of the data source used to report the data. The 16 Countries that did not cover 100% of available antimicrobial quantities were asked to provide further information on uncaptured data sources. For the 41 Countries, the estimated data coverage was 95%. For more information on the data coverage for Europe, please refer to Table 6 of this report.

In Europe, the largest proportion of all reported antimicrobial classes were tetracyclines, followed by penicillins and sulfonamides (Figure A24).

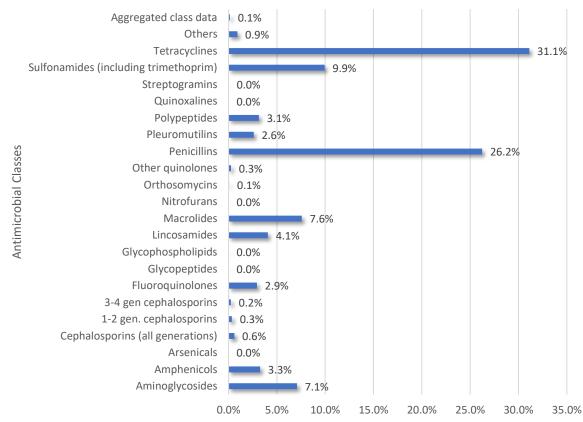


Figure A24. Proportion of Antimicrobial Classes Reported for Use in Animals by 41 European Members in 2018

% of Reported Quantities of Antimicrobial Agents Used in Animals by 41 Countries

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

Irrespective of whether the data could be differentiated by animal group, all 41 Countries were asked to identify the food producing animal species covered by their data from a list supplied in the OIE template and according to the products target species label. For descriptive purposes some animals were grouped into categories, for more information on the grouping of animals see page 44 of this report.

In the 41 Countries from Europe that reported antimicrobial quantities for 2018, the food-producing species most frequently covered by the data were poultry followed by bovines, sheep and goats (Figure A25). Europe is the OIE region with the greatest number of Countries covering aquaculture.

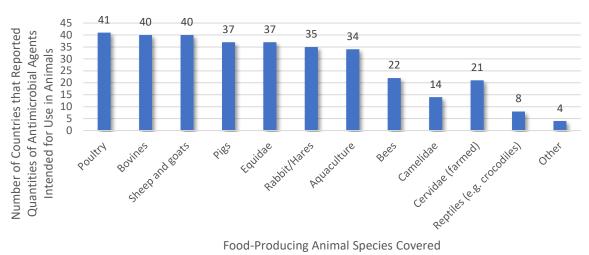
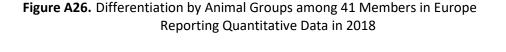
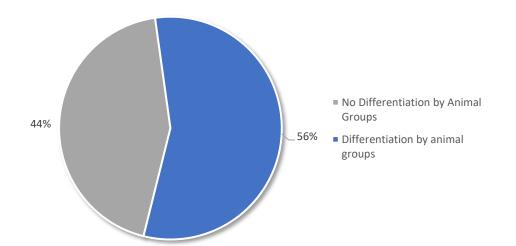


Figure A25. Food-Producing Animal Species Included in Quantitative Data Reported by 41 Countries in Europe in 2018

QUANTITATIVE DATA DIFFERENTIATION BY ANIMAL GROUPS

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





ANIMAL BIOMASS

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

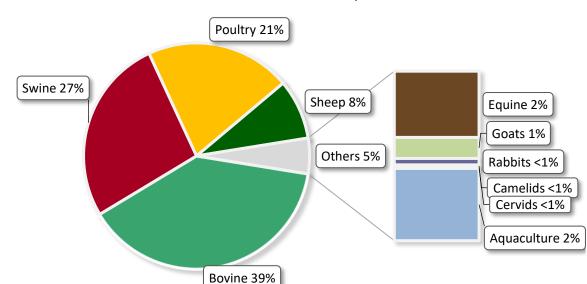


Figure A27. Species Composition of Animal Biomass for the 41 Countries in Europe Included in 2017 Quantitative Data Analysis

ANTIMICROBIAL QUANTITIES ADJUSTED BY ANIMAL BIOMASS

In Europe, the mg/kg estimate for 2018 for 41 Countries is 54.57 mg/kg, with an upper-level estimate of 56.34 mg/kg when adjusted by estimated coverage.

Changes in mg/kg results from 2014 to 2017

The updated mg/kg estimate for 2014 for 31 European Countries is 91.86 mg/kg, with an upper-level estimate of 93.52 mg/kg when adjusted by estimate coverage.

The updated mg/kg estimate for 2015 for 35 European Countries is 76.39 mg/kg, with an upper-level estimate of 80.10 mg/kg when adjusted by estimate coverage.

The updated mg/kg estimate for 2016 for 39 European Countries is 66.94 mg/kg, with an upper-level estimate of 68.48 mg/kg when adjusted by estimate coverage.

The updated mg/kg estimate for 2017 for 38 European Countries is 56.55 mg/kg, with an upper-level estimate of 58.51 mg/kg when adjusted by estimate coverage.

Annex 5 Middle East, Regional Focus

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

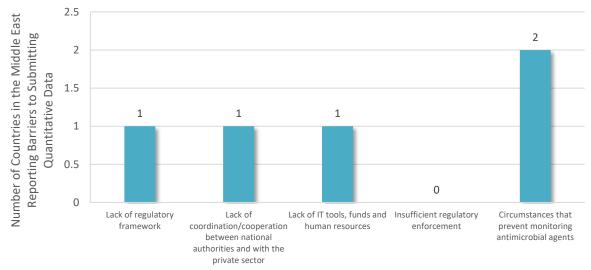
General Information for the Middle East	
Number of OIE Members	12
Number of OIE Members responding to the questionnaire	10 (88%)
Number of OIE Members providing qualitative data only	5 (50%)
Number of OIE Members providing quantitative data	5 (50%)

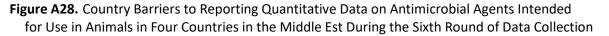
Barriers to Providing Quantities of Antimicrobial Agents in Animals

During the sixth round, five Members (n = 10; 50%) responded with Baseline Information (qualitative data) with no quantitative data on antimicrobial agents intended for use in animals (Table A5). Four out of five explained their barrier to reporting quantities of antimicrobial agents used in animals. Countries can report more than one barrier relevant to their situation, and responses were grouped by category (Figure A28). For further information on the category groupings, please refer to Section 3.5 of this report.

Two Countries explained that the Country security situation affected their ability to obtain sales data for veterinary medicinal products; one of them also mentioned that different authorities controlled the land and seaports which made the control of the products difficult, and facilitate the smuggling of large quantities of antibiotics into the Country.

One Country mentioned the lack of a regulatory framework to collect the data. Another outlined that an IT system was being developed. Both Countries mentioned that are working to address their barriers and are expect to provide antimicrobial quantities to the OIE in the upcoming rounds of data collection.





Barrier Categories

Antimicrobial Agents Used for Growth Promotion

From the Middle East, all the ten Countries reported that there is no use of antimicrobial growth promoters in animals. From these Countries, two did not have legislation or regulation for growth promoters, while eight Countries have completely banned them.

2018 Analysis of Antimicrobial Quantities

Due to confidentiality concerns, most variables included in the analysis of 2018 cannot be published in this report for the Middle East as the data represents only a small number of Countries. Higher participation in the Middle East Region in the future would allow a more in-depth study of the data.

Annex 6 OIE Template

Q		plate should be completed by all countries *** idance document for further instructions.		
	A. Contact Person for Anti	microbial Agents Use Data Collection		
1	Title	<free field="" text=""></free>		
2	Name (First name, SURNAME)	<free field="" text=""></free>		
3	Role with respect to the OIE	OIE Delegate OIE Focal Point for Veterinary Products Other		
4	Organisation	<free field="" text=""></free>		
5	Organisation's Address	<free field="" text=""></free>		
6	Country	<free field="" text=""></free>		
7	Phone Number	<free field="" text=""></free>		
8				
	B. General Information Questions 9 to 14 are related to the current situation in your country. Responses should not be linked to the year of			
Q				
		al quantities reported. 		
9	Are data on the amount of antimicrobial agents	Amounts available - Yes		
	intended for use in animals available?	Amounts available - No		
10	Please indicate why the data are not available at this time in your country, if the answer to Question 9 is 'No'			
11	Are antimicrobial agents used for growth promotion purposes in animals in your country?	Yes No Unknown		
	Does your country have legislation/regulations	Legislation/regulation exists - Yes		
12	on antimicrobial agents as growth promoters in animals?	Legislation/regulation does not exist - No		
	If your country has legislation/regulation on	All antimicrobial agents banned for use as growth promoters		
13	antimicrobial agents as growth promoters in animals, could you please indicate the	Some antimicrobial agents banned for use as growth promoters		
	appropriate case that applies in your country?	One or more antimicrobial growth promoters are authorised for use		
14	Please provide a list of antimicrobial agents used or authorised as growth promoters, if any	<free field="" text=""></free>		
If yo		d this template, once validated by the OIE Delegate and with your		
		the OIE Antimicrobial Use Team at:		
		robialuse@oie.int		
	If your response to Question 9 is 'Yes ', p	lease kindly complete Section C " <u>Data Collection</u> ".		

	C. Data collection of Antimicro	bial Agents Intended for Use in Animals
;	*** Please provide data for 2018 If you have data fo	or another year, please select the year from the list below ***
15	Year for which data apply (Please select only one year per template)	2018 (target year) 2019 (optional) 2020 (optional)
16	Time period for which data are provided	<free field="" text=""></free>
17	(e.g., 1 January to 31 December 2018) Data source	Sales data Sales data - Wholesalers Sales data - Retailers Sales data - Registration Authorities Sales data - Feed Mills Purchase data Purchase data - Molesalers Purchase data - Retailers Purchase data - Feed Mills Purchase data - Pharmacies Purchase data - Pharmacies Purchase data - Producer Organisations Import data Import data - Customs declarations - Veterinary Medicinal Product Import data - Customs declarations - Active Ingredient Veterinary data - Sales Veterinary data - Sales Veterinary data - Prescriptions Antimicrobial use data - Farm Records Other data source(
18	Clarification of the data source, if your response to Question 17 is 'Other'	<free field="" text=""></free>
19	Estimated coverage of accessible data out of total amount (in %)	0%
20	Explanation of estimated coverage	<free field="" text=""></free>
21	Is the information extrapolated from representative samples?	 Data extrapolated from representatives samples - Yes Data extrapolated from representatives samples - No
22	Explanation of extrapolations carried out, if your response to Question 21 is 'Yes'	<free field="" text=""></free>
23	Can data be differentiated by animal group?	Data differentiated by animal group - Yes Data differentiated by animal group - No
24	Animal groups <u>covered by the data</u>	 Data with no differentiation (all animals combined) Data for terrestrial and aquatic food animals (all food-producing animals combined) Data for terrestrial food-producing animals and companion animals (combined) Data for terrestrial food-producing animals Data for aquatic food-producing animals Data for companion animals

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

According to your respon ses to the questions ab	ove, you are invited to fill in the following Reporting Option:
REPORTING OPTION	Appropiate for your Country
Option 1	NO
Option 2	NO
Option 3	NO

Reporting option 1 - Overall	amount sold for/used in animals by a	- Overall amount sold for/used in animals by antimicrobial class; with the possibility to separate by type of use	o separate by type of use
	Overall Amount:		
	Votorinary Modical Hea	Amount:	Amount:
		Waterinsen, Medical Hea	
	+	verenniary ivieurar use	Growth Promotion
Antimicrobial Class	Growth Promotion	(including <u>prevention</u> of clinical signs)	
	All animal species رایجا	All animal species رايما	All animal species
-		(NB)	(NG)
Aminoglycosides	0		
Amphenicols	0		
Arsenicals	0		
Cephalosporins (all generations)		0	0
1-2 gen. cephalosporins	0		
3-4 gen cephalosporins			
Fluoroquinolones			
Glycopeptides			
Glycophospholipids			
Lincosamides			
Macrolidae			
	2		
	0		
Orthosomycins	0		
Other quinolones	0		
Penicillins	0		
Pleuromutilins	0		
Polypeptides	0		
Quinoxalines	0		
Streptogramins	0		
Sulfonamides (including			
teimathaneim) Tatracvelinae			
Others	0		
Aggregated class data	0		
Total kg	0	0	0
<i>f</i> [†] 'Aggregated class data' are reported, please list the classes combined	dree text field>	List all classes for which the amounts were combined, using whenever possible the 'Antimicrobial acts' terms or the whenever possible the '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 .	ere combined, using sial agents of veterinary data aggregation that are gy should arso be listed. If main confidential , please
<i>f</i> i 'Others' are reported under Antimicrobial class', please list the classes reported	gfree 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.	s 'Others', using whenever of antimicrobial agents of
Please report any additional calculations applied	sfree 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.	out in addition to the ones ind 2 of the annex to the IE template.
	_		

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	OIE template for the collection of data on antimicrobial agents intended for use in animals	tion of data on	antimicrobia	l agents intended f	or use in anima	lls	
Reporting opti	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	in animals by antin	nicrobial class; v	vith the possibility to se	parate by type of u	ise and species gro	dn
Antimicrobial Class	Overall Amount: Veterinary Medical Use + Growth Promotion		(includi	Amount: Veterinary Medical Use (including <u>prevention</u> of clinical signs)	Jse iical signs)		Amount: Growth Promotion
	All animal species (kg)	All animal species (kg)	Companinon animals (kg)	All Food-producing animals (terrestrial & aquatic) (ke)	Terrestrial Food- producing animals (kg)	Aquatic Food- producing animals (kg)	All Food-producing animals (terrestrial & aquatic) (ker)
Aminogly cosides	0	•		0			0
Amphenicols	0			0			
Arsenicals	0			0			
Cephalosporins (all generations)	0	0	0	0	0	0	0
1-2 gen. cephalosporins	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			
Nitrofurans	0			0			
Orthosomycins	0			0			
Other quinolones	0			0			
Penicillins	0	0		0			
Pleuromutilins	0			0			
Polypeptides	0			0			
Quinoxalines	0			0			
Streptogramins	0	0		0			
Sulfonamides (including trimethoprim)	0			0			
Tetracyclines	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, Afree text field> please list the classes combined	<free field="" text=""></free>	List all classes for v terms or the termi included in the dat listed. If one class v	which the amount inology of the OIE ca aggregation thai was reported that	List all classes for which the amounts were combined, using wheneverpossible 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 '.	enever possible the ' <i>f</i> of veterinary importa nended terminology s ial , please enter ' Conf	Antimicrobial class' ance . Substances hould al so be idential '.	
lf 'Others' are reported under 'Antimicrobial class', please list the classes reported	<free field="" text=""></free>	Describe the class list of antimicrobia	or classes reporte al agents of veterir	Describe the class or classes reported as 'Others', using whenever possible the terminology of the OIE list of antimicrobial agents of veterinary importance.	ver possible the termir	nology of the OIE	
Please report any additional calculations applied	<free field="" text=""></free>	Please describe the 1 and 2 of the anne	e calculations carri ex to the instructio	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.	ies recommended by 1 e OIE template.	the OIE in sections	

	Overall Amount: Veterinary Medical Use + Growth Promotion							Veter (including	Amount: Veterinary Medical Use (including <u>prevention</u> of dinical signs)	al Use hical signs)							Amount: Growth Promotion
Antimicrobial Class	All Animal Species		All animal species		S	Companion animals		All fo (ten	All food-producing animals (terrestrial and aquatic)	mals ic)	Terrestria	Terrestrial food-producing animals	animals	Aquatic	Aquatic food-producing animals		All food-producing animals (terrestrial and aquatic)
	All routes (kg)	Oral route (kg)	Injection route (kg)	Other routes (kg)	Oral route I (kg)	Injection route (kg)	Other routes (kg)	Oral route (kg)	Injection route (kg)	Other routes (kg)	Oral route In (kg)	Injection route (kg)	Other routes (kg)	Oral route (kg)	Injection route (kg)	Other routes (kg)	All routes (kg)
Aminoglycosides			0	•		Γ	ſ	0	0	0							
Amphenicols				0				0	0	0							
Arsenicals			0	0				0	0	0							
Cephalosporins (all generations)	0		0	0	0	0	0	0	0	0	0	0	0	0	0	0	
1-2 gen. cephalosporins			0	•				0	0	0	1						
3-4 gen cephalosporins	0		0 0	0				0	0	0							
Fluoroquinolones	0		0	0				0	0	0							
Gly cope ptide s			0	0				0	0	0							
Gly cophospholipids	0		0	0				0	0	0							
Lincosamides	0		0	0				0	0	0							
Macrolides	0		0	0				0	0	0							
Nitrofurans	0		0	0				0	0	0							
Orthosomycins	0		0	0				0	0	0							
Other quinolones	0		0	0				0	0	0							
Penicillins	0		0	0				0	0	0							
Pleuromutilins	0		0	0				0	0	0							
Polypeptides	0		0	0				0	0	0							
Quinoxalines	0		0	•				0	0	0							
Streptogramins	0		0	0				0	0	0							
Sulfonamides (including trimethonrim)	0		0	•				0	0	0							
Tetracyclines	0		0	0				0	0	0							
Others	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	
	cfree text field>	List all class	List all classes for which the amounts were combined, using whenever possible, the "Anti microbial class' terms or the terminology of the OIE List of antivircinal a Janant of Gonzerianomic metazones. Gundance in the dara anternation that a zon or nart of the recommended terminology of the OIE List of	ounts were comb	ined, using whe	ineverpossible t	he 'Antimicrobia	ilclass' terms o	r the terminology	of the OIE List of	f uid alcobe						
reported , preuse is the classes combined		listed. If on	e class was reported	that needs to ren	nain confidenti	al, please enter '	sonfidential'.				2020						
If 'Others' are reported under 'Antimicrobial class', please list the classes reported	dree text field>	Describe th	Describe the class or dasses reported as Others', using whe never possible the termi nology of the OIE list of antimicrobial agents of veterinary importance	orted as 'Others'	, using whe nev	er possible the te	:rminology of th	e OIE list of anti	microbial agents o	of veterinary i mp	bortan ce.						
Please report any additional calculations applied	<free field="" text=""></free>	Ple ase desc compilation	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.	s carried out in ac	ld it ion to the or	ies recommende	d by the OIE in se	ections 1 and 2	of the annex to th	e instruct ions fc	or the						

OIE template for the collection of data on antimicrobial agents intended for use in animals

Annex 7 Guidance for Completing the OIETemplate for the Collection of Data onAntimicrobial Agents Used in Animals

Antroduction

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

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

Through this initiative, by means of a specific template (hereafter "OIE template"), the OIE seeks to collect data on antimicrobial agent intended for use in animals from all OIE Members in a harmonised way. Using a phased approach, the OIE will initially focus on <u>sales¹³</u> of antimicrobial agents intended for use in animals as an indicator of actual use. All antimicrobial agents intended for use in animals and listed in the OIE List of antimicrobial agents of veterinary importance¹⁴, plus certain antimicrobial agents only used for growth promotion should be reported. The exceptions are ionophores, which are mostly used for parasite control and therefore need not be reported as antimicrobial agents. The OIE places highest priority on food-producing animals; however, data on all animals, *including companion animals*, may be reported. Reporting will occur at antimicrobial class level and, on one occasion, at sub-class level.

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

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

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

Required information and choices for reporting

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

¹³ **'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.

¹⁴ <u>https://www.oie.int/fileadmin/Home/eng/Our_scientific_expertise/docs/pdf/AMR/A_OIE_List_antimicrobials_July2019.pdf</u>

<u>The Baseline Information sheet allows participation of all Countries: and should be completed by all.</u> On this sheet, some fields are formatted in *italics and grey;* these fields are optional, but Countries are encouraged to provide information to the greatest extent possible. Subsequently, and in accordance with the level of detail of data on antimicrobial agents used in animals available in the reporting Country, either the sheet labelled Reporting Option 1, 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.</u>

A. Baseline Information

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

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

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

		B. General Information
Qu	estions 9 to 14 are rel	ated to the current situation in your Country. Responses should not be linked to the year of antimicrobial quantities reported.
9	Are data on the amount of antimicrobial agents intended for use in animals available?	Please indicate whether quantitative data (i.e., data on the amount) on antimicrobial agents intended for use in animals are available, by choosing 'Yes' or 'No'. If quantitative data is available for part of your Country, choose 'Yes'.
10	Please indicate why the data are not available at this time in your Country, if the answer to Question 9 is 'No'	Please indicate the reason why the data are not available in this moment in your Country. If the answer to the previous question is 'No'.
11	Are antimicrobial agents used for growth promotion purposes in animals in your Country?	Please indicate if antimicrobial agents as growth promoters are being used in your Country, by choosing 'Yes', 'No' or 'Unknown'.
12	Does your Country have legislation/regulatio ns on antimicrobial agents as growth	Please respond by ticking either 'Legislation/regulation exists - Yes' or 'Legislation/regulation does not exist - No'.

	promoters in animals?	
13	If your Country has legislation/regulatio n on antimicrobial agents as growth promoters in animals, could you please indicate the appropriate case that applies in your Country?	Please respond by ticking either 'All antimicrobial agents banned for use as growth promoters', 'Some antimicrobial agents banned for use as growth promoters' or 'One or more antimicrobial growth promoters are authorised'.
14	Please provide a list of antimicrobial agents used or authorised as growth promoters, if any	If any antimicrobial growth promoters are authorised for use in animals, please list the antimicrobial agents (active ingredient name, not product name) authorised for use as growth promoters in animals.
		of antimicrobial agents intended for use in animals are not available in your pletion of the OIE template is terminated after completing Question 14 of the Baseline Information sheet.
	C. Dat	a Collection of Antimicrobial Agents Intended for Use in Animals (Reserved to the Countries where data are available)
15	Year for which data apply (Please select only one year per template)	Please provide data for 2018 . If you have data for another year, please select the year from the list. We will accept data for other years (2019 or 2020), but not from before 2018. If you would like to provide data for additional years, please fill out one template per year of data. If you have found calculation errors in data already submitted to the OIE for previous years, we ask that you please send an updated data template to the Antimicrobial Use Team.
16	Time period for which data are provided (e.g., 1 January to 31 December 2018)	Please provide further information regarding the reporting year, especially if the data only covers a portion of the calendar year.
17	Data source	 Please describe the origin of the data on antimicrobial sales for use in animals, the preferred data at this stage. The template provides options for data sources, and you are asked to report all data sources that apply. Chapter 6.9 of the <i>OIE Terrestrial Code</i> and Chapter 6.3 of the <i>OIE Aquatic Code</i> provide more detail on potential sources of such information. Possible data sources include: Sales data - complete data on antimicrobials agents sold to / bought from wholesalers. Purchase data - data based on sampling of a limited number of wholesalers and requiring <u>extrapolation</u> to estimate the full amount of antimicrobials purchased, but should be used with care. Import data - complete or representative sample information obtained from veterinarians; if representative sample information is obtained extrapolation to the estimated full use may be possible. Antimicrobial use data - complete or representative sample information is obtained extrapolation to the estimated full use may be possible. Other data - all other ways of delivering antimicrobial agents to the animals, including distribution through state veterinary services. It is suggested to develop an overview of the drug distribution system in your Country. Mapping out the distribution pathways in your Country will help you identify the most appropriate source of information on antimicrobial agents for use in animals. Great care is necessary to avoid duplicate or multiple reporting

18	data source, if your response to Question	of quantities; mapping out the distribution will also help you devise measures aimed at avoiding multiple reporting. <u>Ideally, the source of information should</u> <u>be as close to the point of use as possible.</u> Experience has shown that whenever possible, sales data at the package level should be collected, keeping in mind that the data will be measured in kg of antimicrobial agent (please refer to the annex of this document for details on the necessary conversions). Good communication between all parties involved in the data collection is critical to obtain good data sets. If under Data source the option 'Other' is selected, please explain here which source of information was used.
19	17 is 'Other' Estimated coverage of accessible data on total amount (in %)	Please provide an estimate of the extent to which the quantitative data you report are representative of the overall antimicrobial agents intended for use in animals.
20	Explanation of estimated coverage	Please explain in this field which data were not captured on the antimicrobial agents used in animals reported for your Country in the OIE template. Data coverage may vary by geographical aspects; examples include but are not limited to situations that use may be well known for urban but not rural areas, or that use in certain representative regions is well known but not actually measured throughout the whole Country. Incomplete data coverage may include situations where importation is not covered, or partial statistical sampling of relevant establishments (farms, veterinary practices, etc.) is carried out. Another source of incomplete data may lie in market segment coverage, where incomplete data is available from certain market segments (e.g., some production systems are not covered, such as extensive versus intensive farming systems or certain wholesalers who do not report their data).
21	Is the information extrapolated from representative samples?	Please indicate whether the data provided in your report have been extrapolated from representative samples.
22	Explanation of extrapolations carried out, if your response to Question 21 is 'Yes'	Please explain in this field the nature of any extrapolations that were carried out in order to provide the data recorded in the OIE template.
23	Can data be differentiated by animal group?	Please respond by ticking 'Yes' or 'No'. For the purposes of the database, animal group means: 'Terrestrial food- producing animals', 'Aquatic food-producing animals' or 'Companion animals'. If your data is differentiated by any of these groups, please select 'Yes'.
24	Animal groups covered by the data	Please indicate here which animal groups are covered by the data provided, by selecting the appropriate category or categories from the list. The choices are: 'Data with no differentiation (all animals combined)', 'Data with no differentiation between terrestrial and aquatic animals excluding companion animals', 'Data for terrestrial food-producing animals and companion animals (combined)', 'Data for terrestrial food-producing species', 'Aquatic food-producing animals', 'Data for aquatic food-producing animals' and 'Data for companion animals'. Multiple selections are possible.
25	Food-producing animal species <u>covered by the</u> <u>information on</u> <u>antimicrobial</u> <u>quantities</u>	Animal species considered to be food-producing animals vary between Countries. The OIE needs to gain an understanding of how this difference impacts the antimicrobial quantities reported to the OIE and future reporting of summary quantities by the OIE. Please indicate which animals are considered to be food-producing animals covered by the quantities. Multiple selections are possible.
26	Clarification of other species considered to be food-producing, if your response to	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.

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

B. Classes of antimicrobial agents for reporting

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

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	rephalosporinsMay be reported as Cephalosporins (all generations) or in relevant category groupi (1-2 generation cephalosporins and 3-4 generation cephalosporins).	
Fluoroquinolones Includes danofloxacin, difloxacin, enrofloxacin, marbofloxacin and fluoroquinolones, but not other quinolones (e.g., flumequine, oxolinic acid, na acid), which are reported separately.		
Glycopeptides	Includes avoparcin and others.	
Glycophospholipids	Includes bambermycin (i.e., flavomycin).	
Lincosamides Includes lincomycin, pirlimycin and others.		
Macrolides	Includes substances with all macrolide structures, such as erythromycin, spiramycin, tylosin, tylvalosin, gamithromycin, tildipirosin, tulathromycin and others.	
Nitrofurans	Includes furazolidone, nitrofurantoin, nitrofurazone and others.	
Orthosomycins	Includes avilamycin and others.	
Other quinolones	Includes flumequine, nalidixic acid, oxolinic acid and others.	
Penicillins	Includes all penicillins (e.g., natural penicillins, aminopenicillins and others), but excludes other beta lactam antimicrobials like cephalosporins.	
Pleuromutilins Includes tiamulin, valnemulin and others.		
Polypeptides	Includes bacitracin, colistin, polymyxin B and others.	
Quinoxalines	Includes carbadox, olaquindox and others.	

Antimicrobial class	Guidance	
Streptogramins	Includes virginiamycin, pristinamycin, and others.	
Sulfonamides (includ- ing trimethoprim)	Includes all sulfonamides, as well as trimethoprim and similar compounds.	
Tetracyclines	acyclines 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, <i>please list here the classes combined</i>' located underneath the table collecting the antimicrobial quantities.</agg>	

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

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

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

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

mathematical conversion will be necessary, which is explained in the Annex to this document. In cases where the amount sold for the listed class is part of a data aggregation reported under 'Aggregated class data', please enter the three letters <AGG> in the table for all classes, for which quantities sold have been summarised.

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

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

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

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

• in percentage (%) weight per weight (w/w) or weight per volume (w/v).

The <u>Annex</u> 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 Members wishing to provide more refined data on amounts of active ingredients are welcome to do so, on the condition that they describe the calculations used.

C. Reporting Option 1

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

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

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

D. Reporting Option 2

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

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

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

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

E. Reporting Option 3

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

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

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

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

Column label	Guidance	
Oral route	Includes all orally administered pharmaceutical forms, including "in water" or	
	"in feed" administration, but also oral bolus administration.	
Injection route	Includes all forms of parenteral administration that readily 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

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

• Quantitative data

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

imported, or number of packages of specific antimicrobial products used in animals, and is reportable in the metric 'kg antimicrobial agent'.

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

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

• Veterinary Medical use

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

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

• Veterinary medicinal product containing antimicrobial agent(s)

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

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

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

Calculating the quantities to report in kilogram (kg)

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

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

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

The following abbreviations and symbols will be used:

Symbol/abbreviation	Explanation
Strength	amount of antimicrobial agent per unit of veterinary product
% w/v	per cent weight per volume
mg	milligram
g	gram
kg	kilogram
t	ton (metric)
ml	millilitre
	litre
Ι	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 <u>antimicrobialuse@oie.int</u>.

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

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

Table 1: Converting weight units into kg

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

2. For data on veterinary medicinal products

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

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

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

Each situation requires a different kind of mathematical conversion.

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

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

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

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

Example A:

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

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

(a) Pack content = 100 g/kg x 1 kg = 100 g

- (b) Pack content = 100 g/kg x 5 kg = 500 g
- (c) Pack content = 100 g/kg 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 = $300 \text{ mg/ml} \times 100 \text{ ml} =$ 30000 mg = 30 g(a) $6 \times 30 g =$ Pack content: 180 g, (b) $10 \times 30 g =$ 300 g (c) $12 \times 30 g =$ 360 g (b) Container content = $300 \text{ mg/ml} \times 250 \text{ ml} =$ 75000 mg = 75 gPack content: (a) 6 x 75 g = 450 g, (b) $10 \times 75 g =$ 750 g (c) $12 \times 75 g =$ 900 g
- Step 2: Sum up the antimicrobial agent contained in all presentations and packages sold Convert all contents of antimicrobial agent calculated under step 1 to the same weight unit and add up the total
- Step 3: If necessary: convert the total sum of antimicrobial agent contained in all packages of all presentations sold to kg

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

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

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

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

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

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

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

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

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

Content of antimicrobial agent per package in mg = Content of antimicrobial agent in IU x conversion factor

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

<u>Table 2</u>: Conversion of International Units (IUs) of certain antimicrobial agents into mg and relevant active entities, based on the ESVAC conversion factors¹⁵

Antimicrobial agent in the veterinary medicine	Antimicrobial active entity for reporting to OIE	International Units per mg	Conversion factor to mg for multiplication
Apramycin	Apramycin	556	0.0018
Bacitracin	Bacitracin	74	0.013514
Benzylpenicillin (penicillin G) ¹⁶	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
Tetracycline	Tetracycline	982	0.00102
Tobramycin	Tobramycin	875	0.001143
Tylosin	Tylosin	1000	0.001

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

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

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

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

¹⁵ <u>http://www.ema.europa.eu/ema/pages/includes/document/open_document.jsp?webContentId=WC500189269</u>

¹⁶ Applies to all derivatives/compounds of benzylpenicillin

- Example 1: Product X containing 100% w/w tylosin will contain 100/100 x g = 1 g tylosin per g finished product.
- Example 2: Product Y containing 22.2% w/w amoxicillin will contain 22.2/100 = 0.222 g amoxicillin per g finished product.

Continue with Steps 1-3 of (i)

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

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

Example: Product Z containing 30% w/v benzylpenicillin will contain (30 x 10 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.

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, ester or prodrug 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

Taking the conversion factors of certain derivates or compounds 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 derivates or compounds in order to obtain the corresponding amount of the active entity.

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

<u>Table 3</u>: Conversion of content stated in mg, g or kg of derivates/compounds 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 factors¹⁷

Derivate or compound	Active entity	Conversion factor for multiplication
Benethamine benzylpenicillin ¹⁸	Benzylpenicillin	0.61
Benzathine benzylpenicillin	Benzylpenicillin	0.74
Cefapirin benzathine ¹⁹	Cefapirin	0.78
Cefalexin benzathine ²⁰	Cefalexin	0.74
Cloxacillin benzathine ²¹	Cloxacillin	0.78
Oxacillin benzathine ²²	Oxacillin	0.77
Penethamate hydriodide ²³	Benzylpenicillin	0.60
Procaine benzylpenicillin ²⁴	Benzylpenicillin	0.57

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 derivate or compound conversion factor

¹⁷ http://www.ema.europa.eu/ema/pages/includes/document/open_document.jsp?webContentId=WC500189269

 $^{^{18}}$ Conversion factor for benethamine benzylpenicillin is updated from 0.65 to 0.61

¹⁹ Conversion factor for cefapirin benzathine is updated from 0.41 to 0.78

 $^{^{\}rm 20}$ Conversion factor for cefalexin benzathine is updated from 0.36 to 0.74

 $^{^{\}rm 21}$ Conversion factor for cloxacillin benzathine is updated from 0.43 to 0.78

 $^{^{\}rm 22}$ Conversion factor for oxacillin benzathine is updated from 0.69 to 0.77

 $^{^{\}rm 23}$ Conversion factor for penethamate hydriodide is updated from 0.63 to 0.60

 $^{^{\}rm 24}$ Conversion factor for procaine benzylpenicillin is updated from 0.61 to 0.57

Region

Annex 9 Distribution of Members by OIE

AFRICA (54)

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

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

AMERICAS (31)

MIDDLE EAST (12)

31. VENEZUELA

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

52. UGANDA

53. ZAMBIA

54. ZIMBABWE

1. AUSTRALIA 2. BANGLADESH 3. BHUTAN 4. BRUNEI 5. CAMBODIA 6. CHINA (PEOPLE'S REP. OF) 7. FIJI 8. INDIA 9. INDONESIA 10. IRAN 11. JAPAN 12. KOREA (REP. OF) 13. KOREA (DEM. PEOPLE'S REP. OF) 14. LAOS 15. MALAYSIA 16. MALDIVES 17. MICRONEISA (FED. STATES OF) 18. MONGOLIA) 19. MYANMAR 20. NEPAL 21. NEW CALEDONIA 22. NEW ZEALAND 23. PAKISTAN 24. PAPUA NEW GUINEA 25. PHILIPPINES 26. SINGAPORE 27. SRI LANKA 28. TAIPEI (CHINESE) 29. THAILAND **30. TIMOR LESTE** 31. VANUATU 32. VIETNAM

ASIA, FAR EAST AND OCEANIA (32) **EUROPE (53)**

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

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