OIE Annual report on the use of antimicrobial agents in animals

BETTER UNDERSTANDING OF THE GLOBAL SITUATION



WORLD ORGANISATION FOR ANIMAL HEALTH Protecting animals, preserving our future

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Director General's foreword



Dr Monique Eloit OIE Director General

In the framework of the Global Action Plan on Antimicrobial Resistance, adopted by WHO Member States in May 2015, the OIE, supported by FAO and WHO within the tripartite collaboration, has taken the lead to build a global database on the use of antimicrobial agents in animals.

At the 84th General Session in May 2016, the World Assembly of Delegates was informed on the outcomes of the first phase of the worldwide collection of data on the use of antimicrobial agents in animals, presented under the Technical Item 2, and adopted Resolution No. 36, 'Combating Antimicrobial Resistance through a One Health Approach: Actions and OIE Strategy'. On 21 September 2016, the United Nations General Assembly adopted a political declaration aimed at combating the global threat posed by AMR

and confirmed the 'One Health' approach in line with the Global Action Plan. The three Directors General of the tripartite partnership were present and addressed the General Assembly to support this declaration.

The structure of the OIE Strategy, published in November 2016, supports the objectives established in the Global Action Plan, and reflects the mandate of the OIE as described in its Basic Texts through four main objectives: 1) improve awareness and understanding; 2) strengthen knowledge through surveillance and research; 3) support good governance and capacity building; and 4) encourage implementation of international standards.

As a result of the tremendous efforts of its Member Countries, the OIE is pleased to present this report on the first phase of data collection at the global and regional levels.

The OIE's partners acknowledge this accomplishment as a major milestone in the global effort to contain antimicrobial resistance. Such a feat was only possible through the contributions and efforts of the 130 OIE Member Countries who responded to this first request in 2015. Nearly 90 of those Member Countries provided detailed quantitative data, and the OIE recognises the efforts of the OIE Delegates and the National Focal Points for Veterinary Products in assisting in this extraordinary effort.

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

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Executive Summary

This report provides for the first time an overview of the global use of antimicrobial agents in animals. It presents the findings of the first annual reporting of data on the use of antimicrobial agents in animals, providing a global and regional analysis based on data ranging from 2010 to 2015.

The template used to collect data was designed to allow all OIE Member Countries to participate in annual data collection, even if quantitative data on antimicrobial agents used in animals are not available. The template includes administrative information and provides three options for reporting data on antimicrobials agents used in animals with various levels of detail depending on the data available at the national level.

The template was completed by 130 Member Countries (72% of the 180 OIE Member Countries).

The National Focal Point for Veterinary Products was most often responsible for filling in the OIE template (85 of 130 Member Countries: 65%). This information supports the OIE's efforts to conduct regular training of the OIE National Focal Points for Veterinary Products to establish a regional and global network.

OIE Member Countries were asked if they authorise antimicrobials for growth promotion. A total of 96 of 130 (74%) OIE Member Countries indicated that they do not authorise antimicrobial agents for growth promotion in animals. Twenty-five Member Countries provided a list of antimicrobial agents authorised for growth promotion, in which Tylosin and Bacitracin were most frequently quoted. Colistin was mentioned by 10 of 25 Member Countries.

A total of 89 of 130 OIE Member Countries (68%) submitted to the OIE their quantities on the use of antimicrobial agents in animals for years ranging from 2010 to 2015.

Forty OIE Member Countries reported use of antimicrobial agents through Reporting Option 1, the less detailed option, while 19 Member Countries reported through Reporting Option 2, and 30 Member Countries reported through Reporting Option 3 (the most detailed reporting option).

The source of data varied among countries, the most common sources being data collected from 'Wholesalers and Retailers' and from 'Imports'.

Quantitative results allowed a first picture to be drawn on the use of antimicrobial agents worldwide and by region. The main route of administration in animals was the oral route, and Tetracyclines and Macrolides were the most commonly reported antimicrobial agents used; differences however, were observed between OIE Regions.

The information provided in this report represents a remarkable first step to better understanding the global use of antimicrobial agents in animals.

Nevertheless further efforts and support will be needed to improve the data collection system and the quality of the data collected by countries.

Detailed interpretation of the data also needs further development, in particular to define a denominator (animal biomass) that will allow better data interpretation in the future.

Acknowledgements

This report was prepared by Dr G. Moulin, Dr D. Góchez, Ms J. Lasley, and Dr E. Erlacher-Vindel. Assistance and expertise in writing the Report was provided by Dr M. Szabó and Dr F. Diaz.

The OIE is grateful to the members of the OIE *ad hoc* Group on Antimicrobial Resistance following the work on the database, Dr Carolee Carson, Dr Donald Prater, Prof. Kari Grave, Dr Masumi Sato, Dr Chris Teale, Dr Jordi Torren Edo, and Dr Gerard Moulin for all of their efforts from the initial work on this issue in 2011, to the present day. Special thanks are extended to Dr Barbara Freischem for her extensive work on this initiative from its early stages. The OIE would also like to thank all OIE Member Countries, Delegates, National Focal Points for Veterinary Products and other governmental officials who contributed to this first annual collection on data of antimicrobial agents used in animals, without which such knowledge and insight could never be gained on the global use of antimicrobial agents in animals

The OIE thanks the members of the OIE Scientific Commission on Animal Diseases who gave their encouragement and support for this initiative since the beginning.

Acronyms and Abbreviations

AMR	Antimicrobial resistance
ESVAC	European Surveillance of Veterinary Antimicrobial Consumption
FAO	Food and Agriculture Organization of the United Nations
OIE	World Organisation for Animal Health
PVS	Performance of Veterinary Services
wно	World Health Organization

OIE Glossary

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

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

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.

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

1. Introduction

1.1. Background

For two decades, the World Organisation for Animal Health (OIE) has engaged in combatting resistance to antimicrobial agents and endorsed the 'One Health' concept. The topic of antimicrobial resistance is crucial as it concerns both human and animal health.

During the 76th General Session of the World Assembly of Delegates in May 2008, OIE Delegates were requested to nominate a National Focal Point for Veterinary Products in their countries. Since then, the OIE, through its Regions, has been implementing seminars and meetings to facilitate the harmonisations of standards, records and control of veterinary medicinal products among OIE Member Countries.

In many countries today, antimicrobial agents are widely available, directly or indirectly, with virtually no restriction or control. Out of 130 OIE Member Countries assessed through the OIE PVS Pathway, more than 110 Member Countries do not yet have complete and relevant legislation to ensure appropriate conditions for the import, manufacturing, distribution and use of veterinary medicinal products, including antimicrobial agents. As a result, these products circulate freely, like ordinary goods, and are often adulterated.

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

The OIE international standards published in the *Terrestrial Animal Health Code*, Chapter 6.7. 'Harmonisation of national antimicrobial resistance surveillance and monitoring programmes'; the *Aquatic Animal Health Code*, Chapter 6.4. 'Harmonisation of national antimicrobial resistance surveillance and monitoring programmes for aquatic animals'; and the *Manual of Diagnostic Test and Vaccines for Terrestrial Animals*, Guideline 3.1 'Laboratory methodologies for bacterial antimicrobial susceptibility testing' provide a basis for such surveillance and monitoring. Future work is needed to provide indicator bacteria relevant to the most commonly raised animal species and to refine recommendations for harmonisation of susceptibility testing in veterinary laboratories.

In 2012, the OIE developed a questionnaire with the following objectives: (1) to enhance the OIE's engagement in the initiative to prevent antimicrobial resistance; (2) to conduct a survey of the implementation by OIE Member Countries of OIE *Terrestrial Animal Health Code* Chapter 6.8. 'Monitoring of the quantities and usage patterns of antimicrobial agents used in food producing animals'; (3) to improve awareness of antimicrobial use in animals by OIE Member Countries and; (4) to determine what actions are needed and to help the OIE to develop its strategy in this field. A total of 152 out of 178 (85%) OIE Member Countries completed the questionnaire. The answers received show that, in 2012, 27% of responding Member Countries had an official system in place for collecting quantitative data on antimicrobial agents used in animals.

The results were presented at the OIE Global Conference on the Responsible and Prudent Use of Antimicrobial Agents for Animals held in March 2013 in Paris, France; the conference recommended the following to its Member Countries:

• To collect harmonised quantitative data on the use of antimicrobial agents in animals with the view to establish a global database, and submit them to the OIE.

• 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), and submit it to the OIE Member Countries.

To this end, in January 2014, the OIE *ad hoc* Group on Antimicrobial Resistance developed a data collection template along with guidance for its completion, endorsed by the Scientific Commission for Animal Diseases. The documents were discussed during 2014 with the OIE National Focal Points for Veterinary Products in the Americas, Europe and Asia-Pacific regions in the framework of the third cycle of training seminars for the OIE National Focal Points for Veterinary Products. National Delegates and their OIE National Focal Points for Veterinary Products of selected countries in Africa and the Middle East were also consulted by letter in 2015.

Through the unanimous adoption of Resolution No. 26¹ during the OIE General Session in May 2015, the OIE was officially mandated to gather data on the use of antimicrobial agents in animals worldwide and to create a global database for monitoring the use of antimicrobial agents in compliance with Chapters 6.8. of the *Terrestrial Animal Health Code* (Monitoring of the quantities and usage patterns of antimicrobial agents used in food-producing animals) and 6.3. of the *Aquatic Animal Health Code* (Monitoring of the quantities and usage patterns of antimicrobial agents used in aquatic animals).

In the framework of the Global Action Plan on Antimicrobial Resistance, developed by the WHO with the active contributions of FAO and OIE in the spirit of 'One Health', the OIE is tasked with the construction and maintenance of a global database on the use of antimicrobial agents in animals. In this endeavour, the OIE is supported by the FAO and the WHO through their tripartite collaboration.

Towards this goal, in the last trimester of 2015, the OIE launched its first annual data collection on the use of antimicrobial agents in animals in OIE Member Countries. The template and guidance documents were developed by the OIE *ad hoc* Group on Antimicrobial Resistance (AMR), endorsed by the Scientific Commission for Animal Diseases, and tested by Member Countries through regional training seminars for OIE National Focal Points for Veterinary Products.

The template for the first annual collection of data on the use of antimicrobial agents was sent to all the OIE Member Countries in October 2015.

As a part of the first phase of the data collection on the use of antimicrobial agents in animals, the OIE requested data for 2013², but accepted more recent data or the most recent older data, but not before 2010. This request presents a challenge for data analysis, as the data collected spans 2010 to 2015 and as a result, the analysis presented in this report are cumulative over that time span. In the second phase of data collected in the first phase will be completed over the next phase, enriching the quality. Over time and once the reporting of data by OIE Member Countries has become more routine, the OIE will request data for one specific calendar year. As a result, reporting on the global use of antimicrobial agents will become more systematic and reliable.

Data were reported back to the OIE by 130 OIE Member Countries (out of 180 Member Countries), with 68% (89 out of 130 Member Countries) providing concrete data on the use of antimicrobial agents in animals. Given the outstanding participation of OIE Member Countries and their expressed desire to further increase transparency on the use of antimicrobial agents in animals, we expect that the annual data collected will become more and more precise with each passing year. Each year,

¹ http://www.oie.int/fileadmin/Home/eng/Our_scientific_expertise/docs/pdf/AMR/A_RESO_AMR_2015.pdf

² Calendar year.

more countries are readying themselves to put in place surveillance systems on the use of antimicrobial agents in animals.

This report gives the first ever glimpse into the global use of antimicrobial agents in animals and presents the overall findings of the first annual reporting of data on the use of antimicrobial agents in animals, providing a global and regional analysis from 2010 to 2015.

1.2. Scope

Taking into account the vast differences among OIE Member Countries to monitor antimicrobial use, this report presents the first results from the annual collection of data on the use of antimicrobial agents in animals in OIE Member Countries.

In this first stage, the OIE focused on sales of antimicrobial agents destined for use in animals and for those agents listed in the OIE 'List of antimicrobial agents of veterinary importance'.

The amounts of antimicrobial agents sold or imported for use in animals were provided to the OIE by some Member Countries in kilograms (kg) of antimicrobial agent (chemical compound as declared on the product label) that were calculated according to the information provided in Annex 3. This information was provided by each Member Country in the strictest confidence, and for the sole purposes to better understand the global and regional situation of antimicrobial agent use in animals. This report does not present individual Member Country raw data. Nevertheless, Member Countries are invited to indicate if data and information on the sale of antimicrobial agents in animals are available on the Web.

In addition, at this stage, the numerator, total kilograms of antimicrobial agent used in animals, is not yet robust enough for detailed interpretation, and the denominator (Animal biomass), is currently being optimised for interpretation of the global use of antimicrobial agents in animals. The total amount of antimicrobials agents being used in animals around the world can only be interpreted over time, in the context of a robust denominator. As Member Countries refine their surveillance systems and collect more precise and better quality data, the OIE will be able to present a more refined picture of the use of antimicrobial agents in animals.

2. Materials and Methods

Specific recommendations were given at the OIE World Assembly of Delegates in 2015 in Resolution No. 26 'Combating Antimicrobial Resistance and Promoting the Prudent Use of Antimicrobial Agents in Animals':

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

In response to these recommendations, the OIE *Ad hoc* Group on Antimicrobial Resistance developed a template for harmonised data collection (Annex 1), as well as guidance for its completion (Annex 2). This template was translated in the three official OIE languages (i.e. English, French and Spanish) and was sent to all 180 OIE Member Countries in October 2015. An Annex to the Guidance was also developed to give more detailed instructions on mathematical calculations to obtain quantities of active ingredients from antimicrobial products sold (Annex 3). All antimicrobial agents destined for use in animals and contained in the *OIE List of Antimicrobial Agents of Veterinary Importance*³, in addition to certain antimicrobial agents used only for growth promotion, were reportable.

For this first phase of the project, the data were collected through worksheets using predefined conditional formulas and analysis tools available in Microsoft Excel. The OIE template (Microsoft Excel file) contains four worksheets labelled 'Baseline Information', 'Reporting Option 1', 'Reporting Option 2', and 'Reporting Option 3'.

The sheet 'Baseline Information' was created to collect general information such as the use of growth promoters, data source and animal groups covered by the data collected.

The different 'Reporting Options' were developed to collect the overall amount of antimicrobial classes used in animals, with the possibility of separating them by type of use (Therapeutic – Growth Promotions), animal group (Terrestrial – Aquatic) and route of administration. The three reporting options represent increasing levels of detail in the data.

The responses endorsed by OIE Delegates were compiled and the results were analysed at OIE Headquarters.

For clarification and validation purposes, questions were addressed to respondents, mainly OIE National Focal Points for Veterinary Products, when relevant.

3. Global Analysis

3.1. General Information

The OIE maintains offices throughout the world, in: the African Region, the Americas Region, the Asian and Pacific Region, the European Region and the Middle Eastern Region. The data collection template was sent to all OIE Member Countries within all OIE Regions. The list of OIE Member Countries is provided in Annex 4.

From mid-December 2015 to May 2016, 130 of the 180 (72%) OIE Member Countries submitted completed templates to the OIE Headquarters (Table 1). The proportion of responses across OIE Regions varies between 42% and 81% (Figure 1).

³ <u>http://www.oie.int/fileadmin/Home/eng/Our_scientific_expertise/docs/pdf/Eng_OIE_List_antimicrobials_May2015.pdf</u>

OIE REGION	Number Member Countries who submitted templates by OIE Region	Number of OIE Member Countries*
AFRICA	44	54
AMERICAS	19	29
ASIA	26	32
EUROPE	36	53
MIDDLE EAST	5	12

Table 1. OIE Member Countries that submitted templates in 2015, by OIE Region

* Distribution of countries by OIE Region is done according to the OIE Note de Service 2010/22 – Annex 4

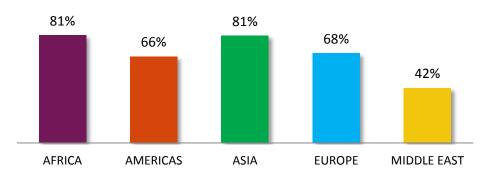


Figure 1. OIE Member Countries that submitted templates in 2015, by OIE Region

Global analysis of baseline information

Each OIE Member Country must designate a Delegate who is usually the person in charge of the official Veterinary Services of the Member Country concerned. Since the 76th General Session in May 2008, the World Assembly of Delegates decided that OIE Delegates should nominate National Focal Points to assist them in their work on specific topics.

For the 2015 data collection, the National Focal Point for Veterinary Products was most often responsible for filling in the OIE template (85 out of 130 Member Countries). This information supports the OIE's efforts to conduct regular trainings of the OIE National Focal Points for Veterinary Products to establish a regional and global network (Figure 2).

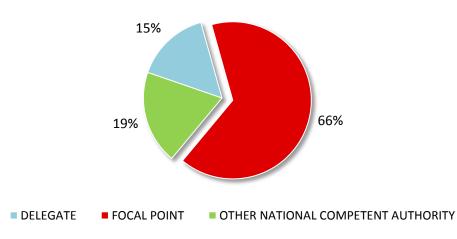


Figure 2. OIE Member Country contact person profile in 2015, for 130 Member Countries

Reporting Option

The data collection template was designed to allow all Member Countries to participate in the annual data collection, even if quantitative data on antimicrobial agents used in animals are not available. The first part of the template—aimed to collect relevant administrative information—was completed by 130 Member Countries. Quantitative data was provided by 89 of those 130 Member Countries (68%). The following sections of the template, named 'Reporting Options' 1, 2 and 3, collect the actual quantities of antimicrobial agents for use in animals. The ability of a Member Country to provide quantitative information reflects their capacity to collect detailed data on the use of antimicrobial agents in animals.

Most Member Countries reported use of antimicrobial agents through Reporting Option 1, requiring only distinction of antimicrobial agents by type of use (Figure 3); Reporting Option 2 requiring distinction by type of use and animal groups was chosen initially by three Member Countries; and Reporting Option 3, requiring distinction by type of use, groups of animals and routes of administration, was chosen by 29 Member Countries.

After analysis of the data submitted by Member Countries, it was found that 16 Member Countries chose Reporting Option 1 to declare the amounts of antimicrobial agents used in animals, while their data had a sufficient level of specificity related to the different animal groups to be reported in Reporting Option 2. For further information please see the section 'Animal groups' of this report.

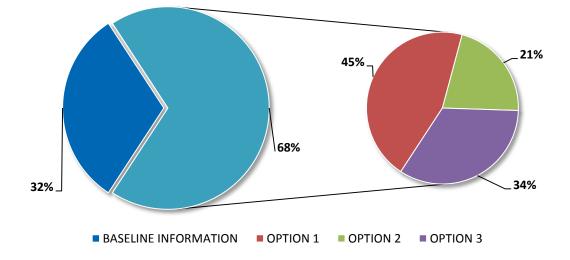


Figure 3. Reporting Option and level of specificity of data on antimicrobial agents used in animals in 2015 by 89 Member Countries

Growth Promotion

All antimicrobial agents destined for use in animals and listed in the OIE List of antimicrobial agents of veterinary importance⁴, plus certain antimicrobial agents only used for growth promotion were to be reported. The exception to the OIE's request was ionophores, which are mostly used for parasite control, have different regulatory classifications in different countries, and for the purposes of the collection of data on the use of antimicrobial agents in animals, was not to be reported as antimicrobial agents.

In 2015, a total of 96 out of 130 (74%) OIE Member Countries did not authorise antimicrobial agents for growth promotion in animals in their countries (Figure 4). This indicates an important decrease in the percentage of countries authorising use of antimicrobials as growth promoters: in 2012, 77 out of 151 (51%) Member Countries totally banned the usage of antimicrobial agents as growth promoters.

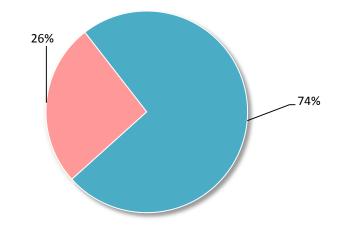


Figure 4. Authorisation of Antimicrobial Growth Promoters in 130 OIE Member Countries in 2015

Antimicrobial growth promoters authorised Antimicrobial growth promoters not authorised

For those Member Countries that reported the authorisation of antimicrobial agents as growth promoters, the OIE also requested a list of antimicrobial agents that were authorised as growth promoters (based on active ingredient). The most frequently listed antimicrobial agents for this purpose were Tylosin and Bacitracin. Colistin was mentioned by 10 countries (Figure 5). Sixty-two percent (62%) of 34 Member Countries authorising antimicrobial agents as growth promoters reported quantities of antimicrobial agents sold for use in animals.

⁴ <u>http://www.oie.int/fileadmin/Home/eng/Our_scientific_expertise/docs/pdf/Eng_OIE_List_antimicrobials_May2015.pdf</u>

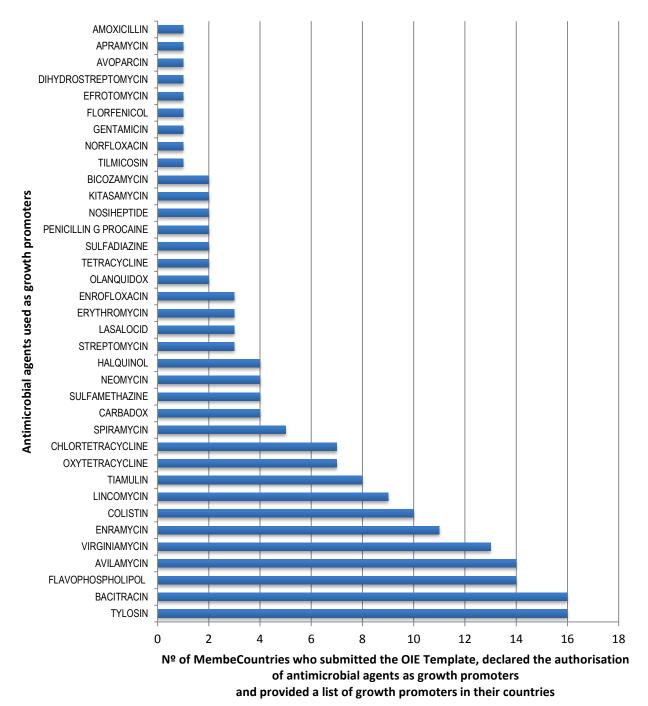


Figure 5. Antimicrobial growth promoters authorised for use in animals in 25 Member Countries, 2010-2015

3.2. Quantity of antimicrobial agents reported

The information contained in the 'Reporting Option' sections of the data collection template provides an important first glimpse of the total amount of antimicrobial agents used in animals around the world. The data reported, is difficult to interpret and is presented here as a temporary outcome of the first phase of reporting, until a more robust denominator is finalised to allow accurate data interpretation in the future. In the 2012 OIE questionnaire, only 23 Member Countries provided quantitative data, a small number of countries compared to the 89 Member Countries that provided such data in 2015.

Based on templates received by 89 Member Countries, the OIE calculated the total amount of antimicrobials agents reported in kilograms.

Year of data collection

Table 2. Breakdown of Member Countries that filled in the template, by year of reported data

Number of Member Countries that filled in the OIE template in 2015	130
Number of Member Countries that filled in quantities of antimicrobial agents in 2015	89
Number of Member Countries that filled in templates for only one year between 2010 and 2015	85
Number of Member Countries that filled in templates for more than one year between 2010 and 2015	2
Number of Member Countries that filled in templates for a range of years	2

For this first phase of data collection, the OIE aimed to collect data for 2013, but accepted data collected since 2010. The OIE accepted also submissions from any Member Country who wished to provide data for more than one year.

Most OIE Member Countries (85 out of 89; 96%) submitted data for only one year between 2010 and 2015. In this timeframe, only two Member Countries submitted templates for more than one year, and two Member Countries submitted templates for a range of years (one from 2005 to 2015 and other from 2013 to 2015). Since the latter group did not reply to queries requesting clarification of the year for which the data applied, these two submissions were removed from the analysis of the 'Year of data collection' variable. The OIE received a total of 92 templates providing data for specific years of data collection from 87 Member Countries (Table 2).

Thirty-six percent (33/92; 36%) of templates received provided data for 2013 (Figure 6).

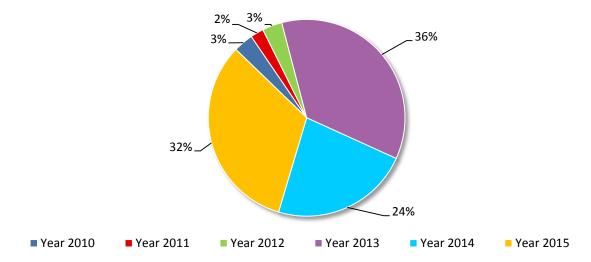


Figure 6. Years of reported data, reported in 92 templates from 87 Member Countries in 2015

The first year of data collection on the use of antimicrobial agents in animals was launched in 2015; for the purposes of this report, the analysis that follows is based on account the quantitative data from all Member Countries between 2010 and 2015.

Data coverage

Member Countries were asked to estimate the extent to which their data represented overall antimicrobial agent sales for use in animals, as a percentage of the total sales in their country. Information on data coverage was provided by 79 Member Countries that provided quantitative data on use. As a global average, data coverage achieved was 84.6%; these data are further analysed by region in later sections of this report. This data coverage shows that in a number of Member Countries, surveillance systems do not capture the totality of the antimicrobial agents used in animals.

Data sources

The OIE data collection template provided an exhaustive list of the possible sources of data, in accordance with Chapter 6.8. of the *Terrestrial Animal Health Code* (Monitoring of the quantities and usage patterns of antimicrobial agents used in food-producing animals) and with Chapter 6.3. of the *Aquatic Animal Health Code* (Monitoring of the quantities and usage patterns of antimicrobial agents used in aquatic animals). Multiple choices were possible and data sources provided were grouped as follows:

A. WHOLESALERS & RETAILERS:

- a. Sales data–Wholesalers.
- b. Sales data-Retailers.
- *c.* Purchase data–Wholesalers.
- d. Purchase data–Retailers.
- e. Purchase data–Agricultural cooperatives.

B. IMPORTS:

- *a.* Import data–Customs declarations-Veterinary products.
- b. Import data–Customs declarations-Active ingredients.

C. MARKETING AUTHORISATIONS HOLDERS:

- a. Sales data–Marketing authorisations holders.
- *b.* Sales data–Registration authorities.

D. VETERINARIANS:

- a. Sales data-Veterinarians.
- *b.* Veterinary prescriptions data–Sales.
- c. Veterinary prescriptions data–Prescriptions.
- d. Veterinary prescriptions data Dispensing.

E. PHARMACISTS:

- a. Sales data–Pharmacies.
- b. Sales data–Farm shops/Agricultural suppliers.
- c. Purchase data–Pharmacies.

F. FEED MANUFACTURERS:

- a. Sales data–Feed mills.
- b. Purchase data–Feed mills.

G. MANUFACTURERS:

- a. Sales data–Industry trade associations.
- b. Purchase data–Producer organisations.

H. FARMERS & OTHERS:

a. Antimicrobial use data–Farm records.

The OIE stated in the Guidance document that ideally, the source of information should be as close to the point of use as possible. However, among the 89 Member Countries that reported actual quantities (Figure 7), the point of use was not the main source of data; 'Farmers & Others'--the closest category to the point of actual use--was only reported by 7 Member Countries. In 2015, data collected from 'Wholesalers & Retailers' (56 out of 89 Member Countries) was most commonly reported, followed by 'Imports' (42 out of 89 Member Countries).

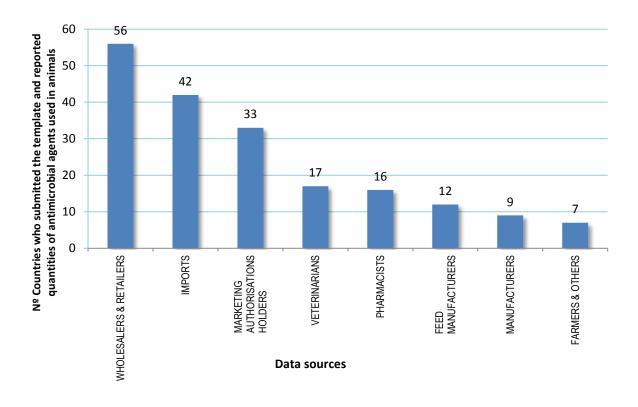


Figure 7. Data source as reported by 89 Member Countries, 2010-2015

Animal groups⁵

Most Member Countries (47 out of 89; 53%) were unable to differentiate how antimicrobial agents are being used in different groups of animals (Figure 8).

⁵ For the purposes of the OIE database, animal groups means: 'Terrestrial food-producing animals', 'Aquatic food-producing animals' or 'Companion animals'.

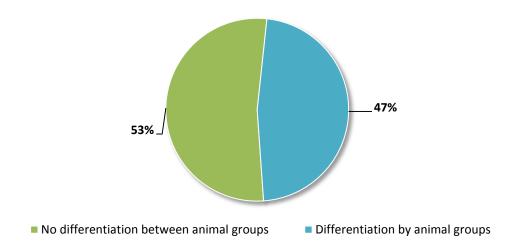


Figure 8. Differentiation of the data reported by animal groups in 89 Member Countries, 2010-2015

Different possibilities were available to report data by animal group (Figure 9). Multiple options were possible in this field.

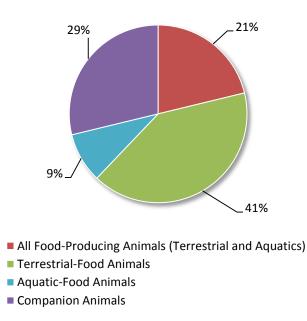


Figure 9. Animal groups reported by 42 Member Countries, 2010-2015

Most Member Countries (39 out of 47; 83%) that were unable to differentiate data by animal group reported antimicrobial quantities through Reporting Option 1. Member Countries that were able to report by animal group specifically (42 out of 89; 47%), chose Reporting Options 2 or 3 (Figure 10). From this first year of analysis, a preliminary finding shows that national monitoring systems on the use of antimicrobial agents in aquatic food-producing animals are implemented only after national monitoring systems on the use of antimicrobial agents in terrestrial food-producing animals have been implemented to the highest level of specificity, by route of administration.

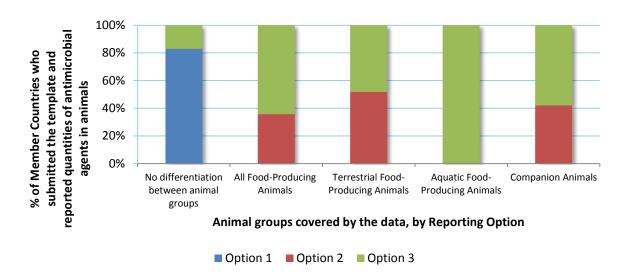


Figure 10. Animals groups covered by the data in 89 Member Countries, by Reporting Option, 2010-2015

Food-producing animal species

Animal species considered to be food-producing animals vary between countries and the OIE needed to understand how this difference could impact the data reported in the future when comparisons of antimicrobial agents used in milligrams by kilograms of live weight will be possible. The categories below have been adjusted and contain the following species declared in the template:

A. POULTRY

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

B. CATTLE

- a. Cattle
- b. Buffaloes (not Syncerus caffer)
- C. SHEEP AND GOATS
 - a. Sheep
 - b. Goats
 - c. Sheep and goats (mixed flocks)

D. PIGS

- a. Pigs commercial
- b. Pigs backyard
- E. FISH
 - a. Fish aquaculture production
 - b. Fish fish farmed in fresh water

In 2015, poultry, cattle and sheep/goats are the most frequently reported food-producing species covered by the data provided by Member Countries (Figure 11).

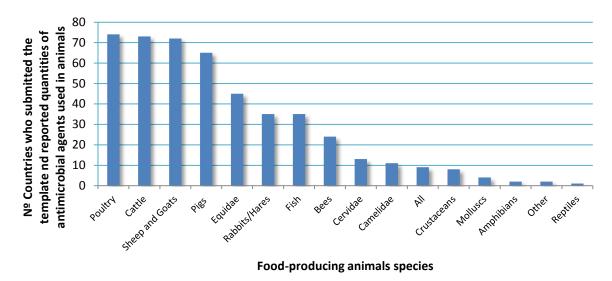
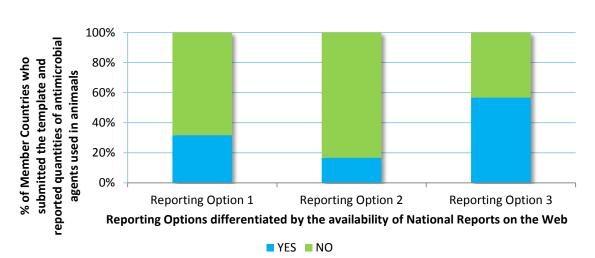
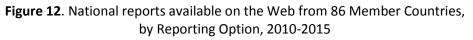


Figure 11. Food-producing animal species covered by the data, for 89 Member Countries, 2010-2015

National reports on the Web

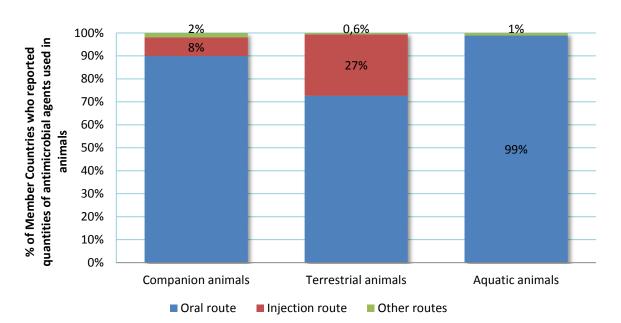
In the template, Member Countries were asked if a national report on the antimicrobial agents used in animals is available on the Web. The first year of data collection showed that 63% of national reports (54/86) on the quantities of antimicrobials used in animals are not available to the public online. Member Countries that chose Reporting Option 3 were more likely to make their reports available to the public (Figure 12).

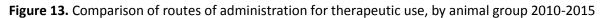




Routes of administration

Regarding the route of administration, oral administration is most commonly used across all animal groups, while in food-producing terrestrial animals, injection administration is also common (Figure 13).





Quantities of antimicrobial classes reported

Tetracyclines and Macrolides are the most commonly reported antimicrobial agents used among Member Countries that provided quantitative data on use of antimicrobial agents in animals (Figure 14).

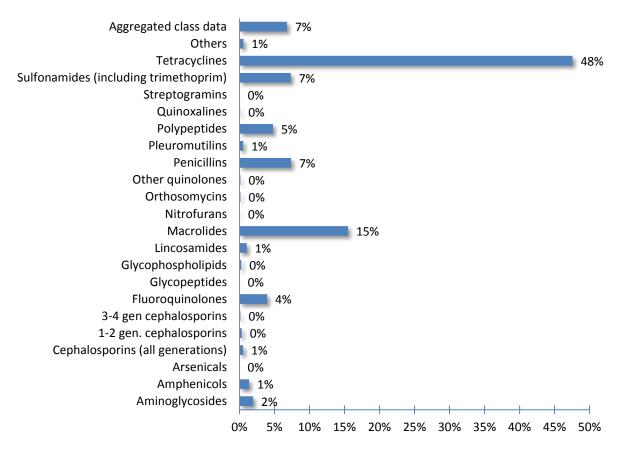


Figure 14. Proportion of reported antimicrobial classes by 89 Member Countries, 2010-2015

% of reported quantities of antimicrobial agents used in animals by 89 Member Countries

4. Analysis by OIE Region

4.1. General information by OIE Region

Profile of the contact person

The OIE recognises the efforts of the National Focal Points for Veterinary Products in the success of this first year of data collection, as in most countries, the National Focal Point for Veterinary Products was responsible for completion of the template. Nevertheless, in some regions, specifically in Europe, someone other than the OIE Delegate and the National Focal Point for Veterinary Products complete the template. This difference may be linked to differing levels of sophistication of data collection systems, which may have dedicated persons in charge of this topic (Figure 15).

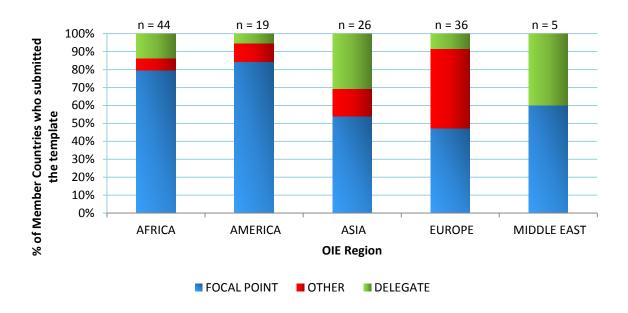


Figure 15. Regional proportion of contact person profile by 130 Member Countries

Growth promoters

When broken down by OIE Region, the Americas, followed by Asia, have the highest proportions of Member Countries that authorise the use of growth promoters (Figure 16).

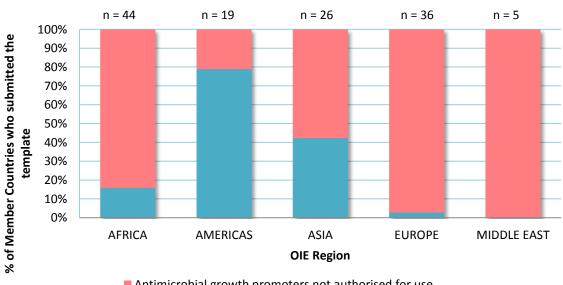


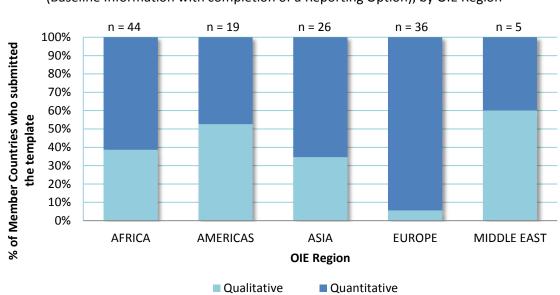
Figure 16. Proportion of 130 OIE Member Countries authorising antimicrobial growth promoters in animals, by OIE Region

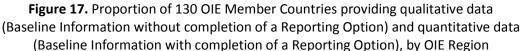
Antimicrobial growth promoters not authorised for use

Antimicrobial growth promoters authorised for use

Reporting Options

When broken down by OIE Region, Europe provided more quantitative data than other OIE Regions and systematically chose a more advanced Reporting Option (Figure 17 and Figure 18). Most European countries in the European Union already have a system in place for data collection on the use of antimicrobial agents in animals, under the European Surveillance of Veterinary Antimicrobial Consumption (ESVAC) project that was launched by the European Medicines Agency in September 2009.





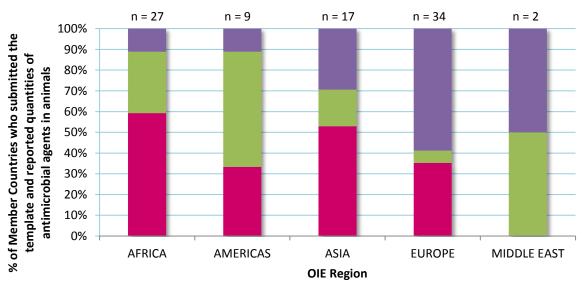


Figure 18. Comparison between choices of Reporting Options, by OIE Region

Option 1 Option 2 Option 3

Data coverage

European data was also the most comprehensive regarding data coverage representing on average 97.6% of overall antimicrobial agents sales (Table 3).

The average data coverage of the Middle Eastern countries could not be compared because countries of this region did not respond to this question on the template.

Descriptive statistics	AFRICA	AMERICAS	ASIA	EUROPE
Mean	66.9%	78.9%	85.7%	97.6%
Mode	100%	100%	100%	100%
Standard Deviation	30.4%	22.6%	19.6%	6.8%
Minimum	10%	40%	40%	70%
Maximum	100%	100%	100%	100%

Table 3. Estimation of the coverage of data provided by OIE Region

National reports on the Web

When broken down by OIE Region, most Member Countries do not publish national reports on the Web. Europe is the only region where more than 50% of Member Countries' national reports are available on the Web (Figure 19).

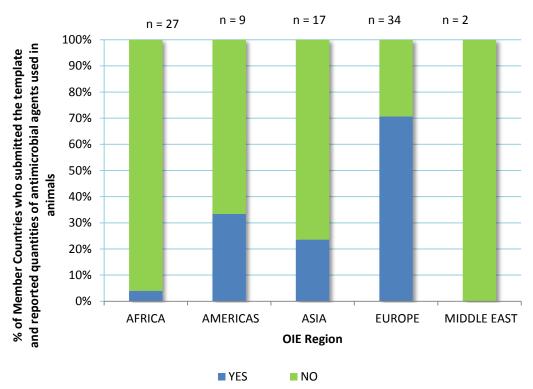


Figure 19. National reports available on the Web by OIE Region

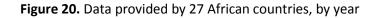
4.2. Africa

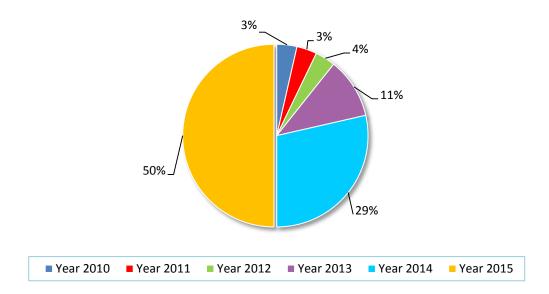
Table 4. General information for Africa

General information in Africa	
Number of Member Countries	54
Number of Member Countries responding the questionnaire	44 (81%)
Number of Member Countries providing quantitative data	27 (61%)

Year of data collection

Based on 27 responses from African Members (Table 4), the most commonly reported year for quantities of sales of antimicrobial agents in animals was 2015 (Figure 20). Few countries were able to provide data for previous years and one country provided data for two different years. These findings may indicate that most Member Countries in Africa have only begun to collect such information recently or only have access to current information.





Animal groups

Most of the data from the African Member Countries cannot be differentiated by animal group. This result corresponds with the African Region's predominant use of Reporting Option 1, which does not allow for differentiation by animal group (Figure 21). Multiple options were possible.

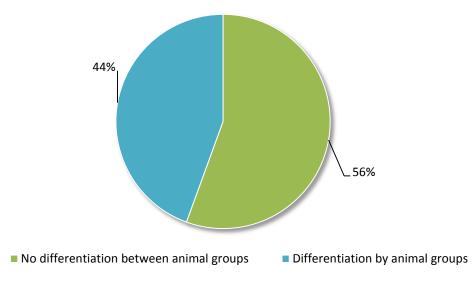


Figure 21. Animal groups covered by the data in 27 African Member Countries

Food-producing animal species

In the 27 African Member Countries that reported actual quantities of antimicrobial agents in animals, the food-producing species most frequently covered by the data are sheep, goats, poultry and cattle (Figure 22).

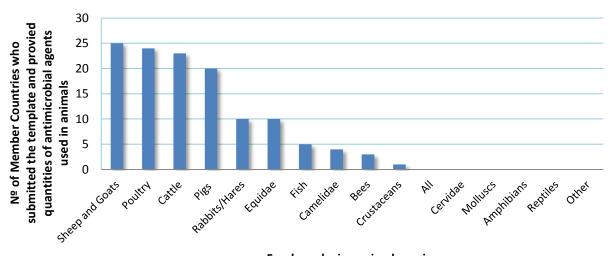


Figure 22. Food-producing animal species covered by the data in 27 African Member Countries.

Food-producing animal species

Quantities of antimicrobial classes reported

In Africa, the largest proportion of all reported antimicrobial classes were Tetracyclines and Macrolides (Figure 23).

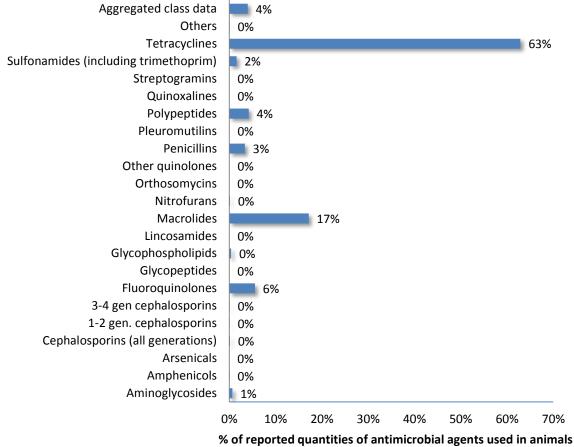


Figure 23. Proportion of reported antimicrobial classes by 27 African Member Countries, 2010-2015

by 27 African Countries

4.3. Americas

Table 5. Genera	l information	for the	Americas
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Regional facts	
Number of Member Countries	29
Number of Member Countries responding the questionnaire	19 (66%)
Number of Member Countries providing quantitative data	9 (47%)

Year of data collection

Most of the nine countries reporting from the Americas (Table 5) provided data on quantities of antimicrobial agents used in animals for 2013, the target year of data collection for the OIE (Figure 24). The OIE will work closely with Member Countries in this region to support them in reporting quantities of antimicrobial agents in animals. One country in the Americas was able to send five years' worth of data to the OIE (from 2010 to 2014), demonstrating the long-standing work of its surveillance system.

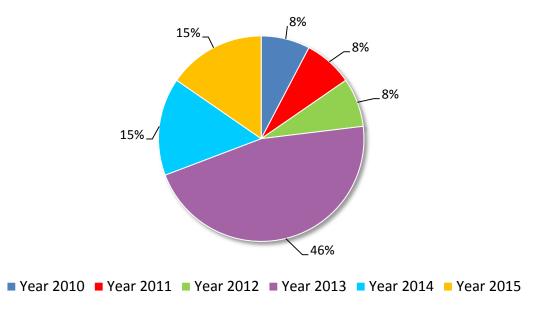


Figure 24. Data provided by 9 Member Countries in the Americas

Animal groups

Most of the data from the Americas can be differentiated by animal groups (6 out of 9; 67%). Six out of the nine Member Countries of the Americas who submitted quantitative data, can distinguished which quantities of antimicrobial classes are being reported in terrestrial food-producing animals (Figure 25). Multiple options were possible in this field.

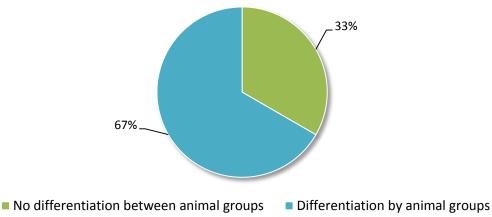


Figure 25. Animal groups covered by the data in 9 Member Countries in the Americas

Food producing animal species

The animal species most frequently reported as food-producing animals were cattle, pigs and poultry (Figure 26). For further information on the grouping of species see Section 3.2. of this report. One Member Country declared that other animals are considered food-producing as mink, lamas, alpacas and bison.

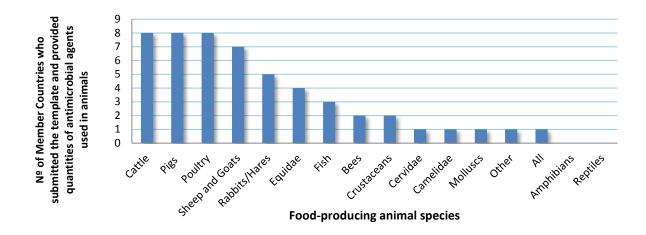
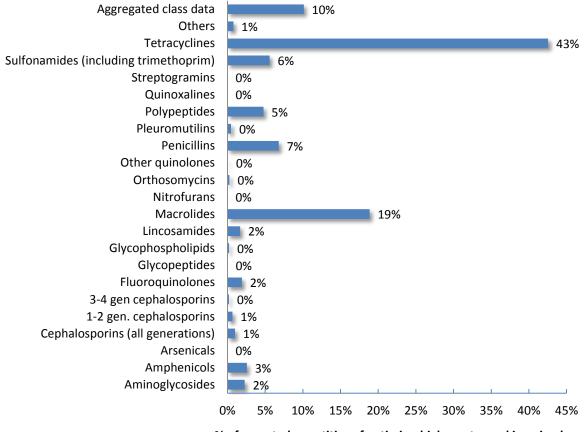


Figure 26. Food-producing animal species covered by the data for 9 Member Countries in the Americas

Quantities of antimicrobial classes reported

In the Americas, the largest proportion of all reported antimicrobial classes were Tetracyclines and Macrolides (Figure 27).

Figure 27. Proportion of reported antimicrobial classes by 9 Member Countries in the Americas, 2010-2015



% of reported quantities of antimicrobial agents used in animals by 9 Member Countries in the Americas

4.4. Asia and the Pacific

Regional facts	
Number of Member Countries	32
Number of Member Countries responding the questionnaire	26 (81%)
Number of Member Countries providing quantitative data	17 (65%)

Table 6. General information for Asia and the Pacific

Year of data collection

59% (10/17) of Asian Member Countries reported data for 2015 (Table 6). Few countries were able to provide data for previous years, and none of the countries provided data for 2011 or 2012 (Figure 28). These findings may indicate that most Member Countries in Asia have only begun to collect such information recently or only have access to current information.

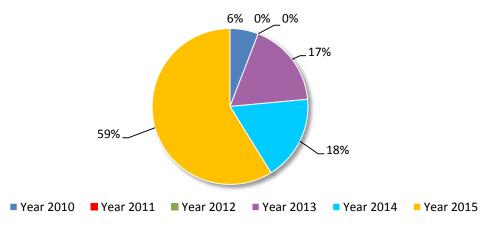
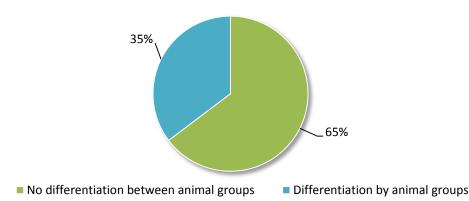


Figure 28. Data provided by 17 Asian countries, by year

Animal groups

Most of the data from the Asian Member Countries cannot be differentiated by animal groups. This result corresponds with the Asian Region's predominant use of Reporting Option 1, which does not allow for differentiation by animal group (Figure 29). Multiple options were possible.

Figure 29. Animal groups covered by the data in 17 Asian Member Countries



Food-producing animal species

In the 17 Asian Member Countries that reported actual quantities of antimicrobial agents in animals, the food-producing species most frequently covered by the data are poultry, cattle and sheep and goats (Figure 30).

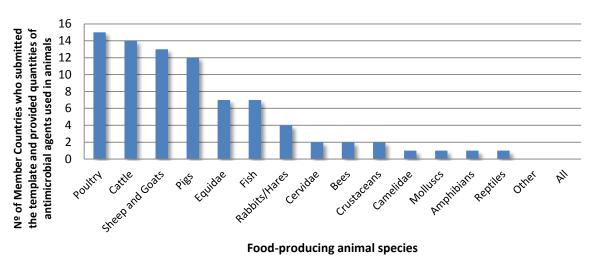
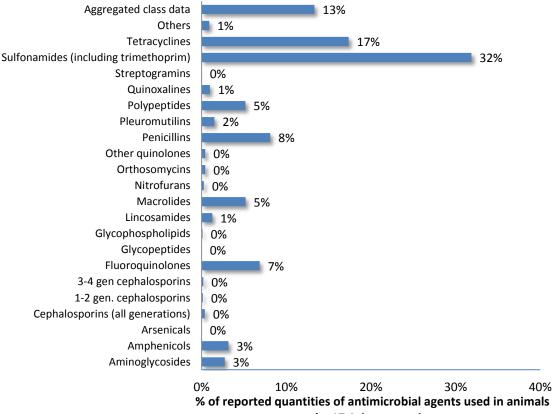


Figure 30. Food-producing animal species covered by the data for 17 Asian countries

Quantities of antimicrobial classes reported

In Asia, the largest proportion of all reported antimicrobial classes were Sulfonamides and Tetracyclines (Figure 31).

Figure 31. Proportion of reported antimicrobials classes by 17 Member Countries in Asia, 2010-2015



by 17 Asian countries

4.5. Europe

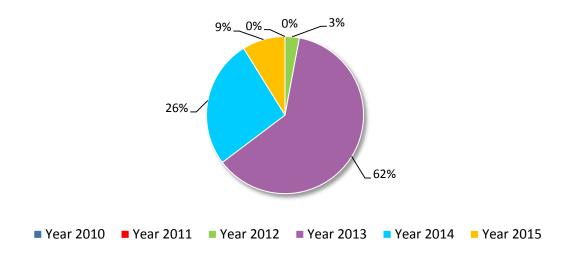
Table 7. General information for Europe

Regional facts	
Number of Member Countries	53
Number of Member Countries responding the questionnaire	36 (68%)
Number of Member Countries providing quantitative data	34 (94%)

Year of data collection

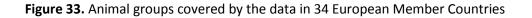
Most of the thirty-four Member Countries reporting from Europe (Table 7) provided data on quantities of antimicrobial agents used in animals for 2013, the target year of data collection for the OIE. Most of the countries of this region usually report sales of veterinary antimicrobial agents through the ESVAC project (Figure 32).

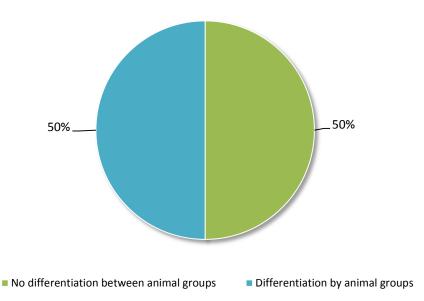




Animal groups

Half of the data reported to the OIE from European Member Countries cannot be differentiated by animals groups; however, many countries used Reporting Option 3 which allows a differentiation of the data by routes of administration and in some cases by animal groups. In Europe more Member Countries are able to report quantities of antimicrobial agents used in aquatic food-producing animals (Figure 33) than in any other region.





Food-producing animal species In the 34 European Member Countries that reported actual quantities of antimicrobial agents in animals, the food-producing species most frequently covered by the data are cattle, pigs, sheep and goats and poultry (Figure 34).

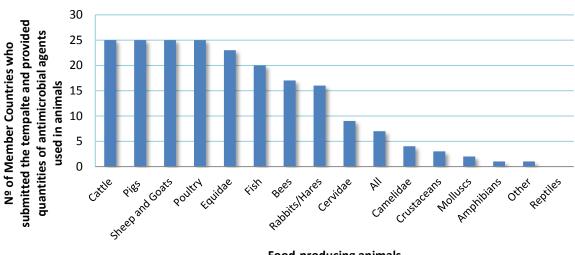


Figure 34. Food-producing animal species covered by the data for 34 European countries

Food-producing animals

Quantities of antimicrobial classes reported

In Europe, the largest proportion of all reported antimicrobial classes were Tetracyclines and Penicillins (Figure 35).

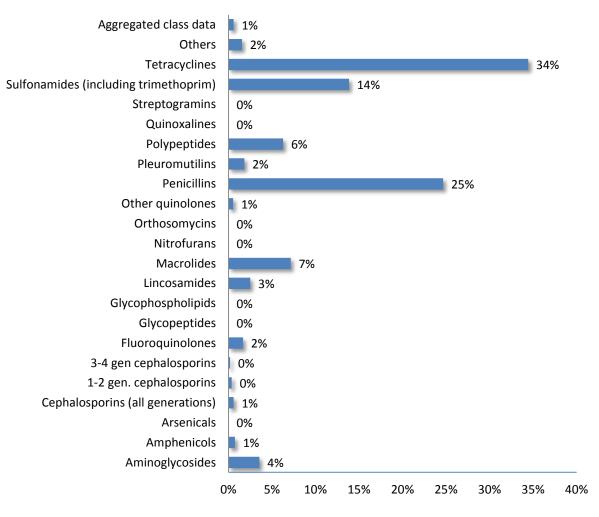


Figure 35. Proportion of reported antimicrobials classes by 34 Member Countries in Europe, 2012-2015

% of reported quantities of antimicrobial agents used in animals by 34 European countries

4.6. Middle East

Table 8. General Information for the Middle East

Regional facts	
Number of Member Countries	12
Number of Member Countries responding the questionnaire	5 (42%)
Number of Member Countries providing quantitative data	3 (60%)

Due to confidentiality concerns, most variables included in the template cannot be published in this report for the Middle East region as the data represents only a small number of Member Countries (Table 8). Higher participation by Member Countries in the Middle East Region in the future will allow a more in-depth study of the data.

5. Future developments for data collection and the database

For the second phase of this initiative, several improvements have been made to the OIE Template and Guidance documents in order to minimise misinterpretation and to simplify the burden on Member Countries.

The OIE *ad hoc* Group on Antimicrobial Resistance agreed that a provisional denominator to be used by the OIE in order to interpret antimicrobial agent usage data will need to be refined. The OIE will use additional data to explore the possibility of defining cycle factors and mean weights of main production animals by regions or sub-regions and, in parallel, precise information on additional animal sub-categories needs to be obtained from OIE Member Countries.

Further work will be conducted to refine the information on animal census data in WAHIS in order to construct the denominator for data comparison in the long-term. In particular, the total number of terrestrial animals produced in one year is critical to put into context the total amount of antimicrobial agents used in one year. Simultaneously, it is expected that Member Countries will improve the quality and details of data on their use of antimicrobial agents in animals.

A denominator based on animal population or production is currently under study, as its refinement would reduce uncertainty about the use of antimicrobial agents in animals and facilitate the detection of trends in use of antimicrobial agents in animals over time.

In the future, the OIE will work more closely with Member Countries to support them to transform national data into the reportable format through the regional seminars for National Focal Points for Veterinary Products.

6. Discussion

Several Member Countries stated that they did not provide a list antimicrobial agents used as growth promoters as no legislation exists regarding this topic in their country. In the future, the OIE will need to explore further this topic.

In this first year of data collection, the period of time covered by the data was sometimes unclear. The OIE will continue to support Member Countries to provide information covering a full year's worth of data, in order to ensure appropriate interpretation of data and trends over time.

While participation was high (72% of all OIE Member Countries) in this first year of data collection, more participation from those Member Countries who didn't participate in 2015, as well as those Member Countries who only filled in the Baseline Information section, will be sought in order to better understand trends over time.

In 2015, some Member Countries responded to two questions in the Baseline Information section that should only apply to those Member Countries who provided quantitative data. The modifications made to the 2016 version of the data collection template attempt to address difficulties in the completion and interpretation of the 'animal groups covered by the data' and 'food-producing animal species covered by the data' variables.

The information obtained in this first phase shows that national monitoring systems that collect data on antimicrobial agents used in animals rely on different sources.

In order to enable accurate comparisons between countries, it is important to take into account the animal population of the country that is susceptible to be treated. There is variability in production cycles and animal weights around the world and comprehensive data are not yet available. Further developments to define a denominator (Animal Biomass) are under development and will facilitate data interpretation in the future.

7. Conclusions

The information provided in this report represents a remarkable first step in better understanding the global use of antimicrobial agents in animals. Given the outstanding participation of OIE Member Countries and their expressed desire to further increase transparency on the use of antimicrobial agents in animals around the world, we expect that the data reported will become more and more precise with each passing year. Each year, more countries are readying themselves to put in place surveillance systems on the use of antimicrobial agents in animals, and they expressed their enthusiasm to report information to the OIE in the future.

This report shows the need to provide additional support to Member Countries to improve their national monitoring systems. Detailed interpretation of the data also needs further development and in the future, the OIE database should allow countries to provide their information through an electronic portal.

8. References

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- World Organisation for Animal Health (OIE). Aquatic Animal Health Code. Chapter 6.3. Monitoring of the quantities and usage patterns of antimicrobial agents used in aquatic animals. Available at: <u>http://www.oie.int/index.php?id=169&L=0&htmfile=chapitre_control_feed_hazard.htm</u> (accessed on 9 December 2016).
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Report on Consumption of Veterinary Antibiotics in Ireland (2009 to 2014). Retrieved from: <u>https://www.hpra.ie/homepage/veterinary/special-topics/antibiotic-resistance</u>

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ANNEXES

- Annex 1 OIE template
- Annex 2 Guidance for completing the OIE template for the collection of data on antimicrobial agents used in animals
- Annex 3 Annex to the Guidance for Completing the OIE template for the collection of data on Antimicrobial Agents used in Animals
- Annex 4 Distribution of countries by OIE region according to the OIE Note de Service 2010/2012

Annex 1. OIE Template

	This sheet of the OIE template should be complete	ed by all OIE Member Countries		ests in <i>Italics</i> and grey font are no re available they should be given.
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Macrolides						
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OIE template for the collection of data on antimicrobial agents used in animals

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Reporting option 3 - Overall amount sold for/used in animals by antimicrobial class; with the possibility to separate by type of use, species group and route of administration

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Annex 2. Guidance for completing the OIE template for the collection of data on antimicrobial agents used in animals

World Organisation for Animal Health 2015

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

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Introduction

The OIE proposes to collect data on antimicrobial agents used in animals from OIE Member Countries implementing Chapters 6.8. Monitoring of the quantities and usage patterns of antimicrobial agents used in food-producing animals of the OIE *Terrestrial Animal Health Code* and 6.3. Monitoring of the quantities and usage patterns of antimicrobial agents used in aquatic animals of the OIE *Aquatic Animal Health Code*, and to contribute to the global effort against antimicrobial resistance.

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

Through this initiative, by means of a specific template (OIE template), the OIE seeks to collect data on antimicrobial agent use in animals from all OIE Member Countries in a harmonised way. Using a phased approach, the OIE will initially focus on <u>sales</u>⁶ of antimicrobial agents destined for use in animals as an indicator of actual use. All antimicrobial agents destined for use in animals and listed in the OIE List of antimicrobial agents of veterinary importance⁷, 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 may be reported. Reporting will occur at antimicrobial class 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 kg antimicrobial agent (chemical compound as declared on the product label) that is to be calculated from the available information as explained in the annex to this guidance document), animals are grouped into 'all animal species', 'all food-producing animals', 'terrestrial food-producing animals', and 'aquatic food-producing animals'.

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

For questions on the OIE template please contact the OIE at <u>antimicrobialuse@oie.int</u>.

Introducing the individual sheets of the OIE template for the collection of data on antimicrobial agents used in animals

Required information and choices for reporting

As noted before, OIE Member Countries differ in the degree to which data on antimicrobial sales for use in animals is accessible and in the degree to which the quantities of antimicrobial agents used in animals can be further differentiated, for example by species. Therefore, three different reporting options are proposed.

There are four worksheets in the OIE template (four tabs at the bottom of the Microsoft excel file) labelled 'Baseline information', 'Reporting option 1', 'Reporting option 2', and 'Reporting option 3'.

All OIE Member Countries should complete the sheet **Baseline information**. On this sheet, some fields are formatted in *italics and grey;* these fields are optional, but Member Countries are encouraged to provide information to the greatest extent possible. Subsequently, and in accordance with the level of detail for 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.

⁶ **'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.

⁷ http://www.oie.int/fileadmin/Home/eng/Our_scientific_expertise/docs/pdf/Eng_OIE_List_antimicrobials_May2015.pdf

Baseline information

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

At the bottom of this sheet a matrix is provided to help OIE Member Countries decide which Reporting option to complete next.

Reporting option 1 (overall amount sold for / used in animals by antimicrobial class, with the possibility to separate by type of use)

The form **Reporting option 1** is designed for the reporting of data on amount or type of antimicrobial agents used in all animals and accommodates reporting with only limited additional differentiation. Data may be reported overall for all animal species, but can be separated by antimicrobial class and possibly by type of use (therapeutic use, including prevention of clinical signs, or growth promotion use; see definitions below). If you know which classes of antimicrobial agents are used in animals in your country, but not how much is sold, you can still use this sheet. Instead of a number, please enter three dots, <...>, in the table.

Reporting option 2 (overall amount sold for / used in use animals by antimicrobial class, with the possibility to separate by type of use and species group).

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

Reporting option 3 (overall amount sold for / used in animals by antimicrobial class, with the possibility to separate by type of use, species group and route of administration).

If the data can be differentiated by route of administration, **Reporting option 3** is the appropriate choice. Further differentiation by antimicrobial class, use in food-producing species and, where possible, by use in terrestrial and aquatic food-producing species as well as therapeutic use, including prevention of clinical signs, or growth promotion use is possible.

Guidance notes on the data to be provided in the OIE template

Explanation of terms used in the context of the OIE template and related documents

A number of terms require definition of their use in the context of the OIE template, in order to ensure a harmonised approach to data collection.

Active entity: Antimicrobial agents (see definition below) 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 entity** is the part of the chemical compound responsible for the antimicrobial agents of veterinary importance is generally identical to the **active entity** 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 entity, an antimicrobial agent may exist in the form of various chemical compounds. For example, benzylpenicillin (the active entity) 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 entity (e.g. benzylpenicillin) or the complete chemical compound (e.g. sodium benzylpenicillin).

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

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

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.

Quantitative data versus **qualitative** 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'. In the context of this template, **qualitative data** means that the classes of antimicrobial agents used in animals can be described, without knowing the amounts used.

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, manufactured 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 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.

Baseline information

Field name	Information to be provided
Contact Point for data collection	Please provide the contact details of the person entering the information, also indicating the role of the person entering the data with respect to the OIE. The information is needed in case there are queries on the data provided.
Name:	Please complete the fields as follows:
	Salutation (e.g. Dr, Ms, Mr), first or given name, surname or family name From the provided drop down list please choose either 'Delegate', 'National Focal Point for Veterinary Products' or 'Other' to describe your relation to the OIE.
Organisation:	Name of the organisation you work for, administrative subunit, and position – if necessary
Address:	Full mailing address of your organisation
Phone number:	Please provide your full telephone number including the international dialling code.
Email address:	Please provide the email address where you can best be reached.
Year of data collection	Calendar year for which you are providing data. We aim for 2013 data, but will accept more recent data or the most recent older data (but not before 2010). For each year a separate form needs to be filled in, indicating the calendar year to which the data relate.
Country	Please enter your country's name in full text.
Are antimicrobial	Please respond by ticking either 'Yes' or 'No'.
growth promoters authorised for use in your country?	Choose 'Yes' if your country's legislation / regulations has no provisions for antimicrobial growth promotion, but use of antimicrobial agents for growth promotion is known to occur.
List of allowed antimicrobial growth promoters, if the answer to the previous question is 'yes'	If antimicrobial growth promoters are used (meaning the response to the question above is 'Yes'), please list the antimicrobial agents (active ingredient name, not product name) used for growth promotion. Please report using either the simplified terminology of the tables on Reporting option 1, 2 or 3 , or by using the terminology of the OIE List of antimicrobial agents of veterinary importance.
Data source	Please describe the origin of the data on antimicrobial sales for use in animals, the preferred data at this stage. The template provides options for data sources, and you are asked to report all data sources that apply. Chapter 6.8 of the <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 sold to / bought from wholesalers. Purchase data - data based on sampling of a limited number of wholesalers and requiring extrapolation to estimate the full amount of antimicrobials purchased, but should be used with care. Import data - complete import data from customs. Manufacturing data - complete production numbers reported by manufacturers. Prescription data - complete or representative sample information obtained from veterinarians; if representative sample information is obtained extrapolation to the estimated full use may be possible.

Field name	Information to be provided
	 Antimicrobial use data - complete or representative sample information obtained from farm records; if representative sample information is obtained extrapolation to the estimated full use may be possible Other data - all other ways of delivering antimicrobial agents to the animals, including distribution through state veterinary services. It is suggested to develop an overview to the drug distribution system in your country. Mapping out the distribution pathways in your country will help you identify the most appropriate source of information on import or sales of antimicrobial agents for use in or animals. Great care is necessary to avoid duplicate or multiple reporting of quantities; mapping out the distribution will also help you devise measures aimed at avoiding multiple reporting. Ideally, the source of information should be as close to the point of use as possible. Experience has shown that whenever possible sales data at the package level should be collected, keeping in mind that the data will be measured in kg of antimicrobial agent (please refer to the annex of this document for details on the necessary conversions). Good communication between all parties involved in the data collection is critical to obtain good data sets.
Data source clarification	If under Data source the option 'Other (further specified in 'Data source clarification')' is selected, please explain here which source of information was used.
Are quantitative data on sales available?	Please indicate whether quantitative data (i.e. data on the amount) on antimicrobial agents used in animals are available, by choosing 'Yes' or 'No'. If quantitative data is available for part of your country, choose 'Yes'. In the subsequent field ' Estimated coverage of accessible data on total sales' , indicate the extent to which the available data cover total sales of antimicrobial agents for use in animals as a percentage (in relation to the overall use). In the field ' Explanation of estimated coverage and extrapolations carried out ' please provide a description of the sales not covered by the data, if there is less than 100% coverage. If the data available in your country is qualitative (the types of antimicrobial agents used in animals are known but not how much is sold), choose 'No'. If you know which substances or classes of antimicrobials are used in your country, please report this in the sheet Reporting option 1 by entering three dots, '', in the cells that would normally hold the numbers for quantities sold. If you do not know which substances or classes of substances are used in animals in your country, the completion of the OIE template is terminated after completing the Baseline information form.
Estimated coverage of accessible data on total amount (in %)	Please provide an estimate of the extent to which the quantitative data you report is representative of the overall antimicrobial sales for use in animals, as a percentage of the total sales in your country. If less than 100% are reported, please describe the data not covered.
<i>Is the information extrapolated from representative samples?</i>	Please indicate here, whether the data provided in your report have been extrapolated from representative samples.
Explanation of estimated coverage and extrapolations carried out	Please explain in this field which sales are not captured by the data on antimicrobial agents used in animals reported for your country, or the nature of any extrapolations that were carried out in order to provide the data recorded in the OIE template.

Field name	Information to be provided
	Data coverage may vary by geographical aspects; examples include but are not limited to situations that use may be well known for urban but not rural areas, or that use in certain representative regions is well known but not actually measured throughout the whole country. Incomplete data coverage may include situations where importation is not covered or statistical sampling of relevant establishments (farms, veterinary practices, etc.) is carried out. Another source of incomplete data may lie in market segment coverage, where incomplete data is available from certain market segment (e.g. some production systems are not covered such as extensive versus intensive farming systems or certain wholesalers do not report their data).
Animal groups covered by the data	Please indicate here to which broad category of animals the data provided apply, by selecting the appropriate category or categories from the list. The choices are: 'All animal species', 'All food-producing species (terrestrial and aquatic)', 'Terrestrial food-producing species', 'Aquatic food-producing species', "Companion animals" and 'Other'. Multiple selections are possible.
Animals raised in your country and considered 'food producing species'	Animal species considered to be food-producing animals vary between countries. The OIE needs to gain an understanding how this difference impacts the data reported to the OIE and future reporting of summary data by the OIE. Please indicate here which animals are considered as food-producing animals in your country. Multiple selections are possible.
Clarification of species considered as food-producing	Please provide any explanations you may feel necessary to explain which animal species are raised in your country for the purpose of providing food for humans.
<i>National report available on the web?</i>	If a national report on antimicrobial sales and/or use in animals is available in your country please insert the link to the site where the report is available on the internet.

Classes of antimicrobial agents for reporting

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

Antimicrobial class	Guidance
Aminoglycosides	Includes aminocyclitols (e.g. streptomycin, dihydrostreptomycin and spectinomycin) and all other aminoglycosides (e.g. gentamicin, kanamycin, neomycin, apramycin).
Amphenicols	Includes florfenicol and thiamphenicol.
Arsenicals	Includes nitarsone, roxarsone and others.
Cephalosporins	May be reported as Cephalosporins (all generations) or in relevant category groupings (1-2 generation cephalosporins as one category and 3-4 generation cephalosporins as a second category).
Fluoroquinolones	Includes danofloxacin, difloxacin, enrofloxacin, marbofloxacin and other fluoroquinolones, but not other quinolones (flumequine, oxolinic acid, nalidixic acid) that are reported separately.
Glycopeptides	Includes avoparcin and others.

Antimicrobial class	Guidance
Glycophospholipids	Includes bambermycin (synonym flavomycin).
Lincosamides	Includes lincomycin, pirlimycin and others.
Macrolides	Includes substances with all macrolide structures, such as erythromycin, spiramycin, tylosin, tylvalosin, gamithromycin, tildipirosin, tulathromycin and others.
Nitrofurans	Includes furazolidone, nitrofurantoin, nitrofurazone and others.
Orthosomycins	Includes avilamycin and others.
Other quinolones	Includes flumequine, nalidixic acid, oxolinic acid and others.
Penicillins	Includes all penicillins (e.g. natural penicillins, aminopenicillins and others), but excludes other beta lactam antimicrobials like cephalosporins.
Pleuromutilins	Includes tiamulin, valnemulin and others.
Polypeptides	Includes bacitracin, colistin, polymyxin B and others.
Quinoxalines	Includes carbadox, olaquindox and others.
Streptogramins	Includes virginiamycin, pristinamycin, and others.
Sulfonamides (incl. trimethoprim)	Includes all sulfonamides, as well as trimethoprim and similar compounds.
Tetracyclines	Includes for example chlortetracycline, doxycycline, tetracycline, and oxytetracycline.
Others	All others not covered, including for example coumarin antimicrobials like novobiocin, fusidic acid, kirromycins, phosphonic acids like fosfo- or tobramycin, 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, for example to protect confidential (proprietary) information or as required by legislation. Such amounts may be reported in this line.
	Report here the individual or cumulative amounts of antimicrobial classes used in animals that cannot be reported independently for confidentiality / proprietary reasons. If more than one data aggregation exists in your country, please sum them up for the OIE template.
	In cases where the amounts sold for more than one class are reported as aggregated data, please enter <agg> in the table for those substances for which sales quantities have been included in the aggregated amount, and list the names of the classes of antimicrobial agents that cannot be reported individually in the free-text field called '<i>If 'Aggregated class data' are reported, 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 for reporting quantities.

Field name	Information to be provided
<i>If 'Aggregated class data' are reported, please list here the classes combined</i>	If for your country, there are Aggregated class data , please list here 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> , <u>http://www.oie.int/fileadmin/Home/eng/Our scientific expertise/docs/pdf/Eng OIE_List_antimicrobials_May2015.pdf</u>
	Aggregated data may include substances that are not mentioned in the definition of 'Antimicrobial classes for use in animals'. In such cases, please specify here any additional classes of antimicrobials which are included in the reported amount for <i>Aggregated class data</i> that are not listed in the table.
<i>If 'Others' are reported under 'Antimicrobial class', list here the classes reported</i>	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 here any additional calculations applied	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 guidance for completing the OIE template.

Reporting options 1, 2 and 3: Reporting quantities of antimicrobial agents

The amount of the antimicrobial agents used in animals in kilograms (kg) should be reported. Where data is available in the form of number of packages of a given pharmaceutical preparation sold or in cases or stated in international units or % weight per volume (% w/v), mathematical conversion will be necessary, which is explained in the annex to this document. In cases where the amount sold for the listed class is part of a data aggregation reported under 'Aggregated class data', please enter the three letters <AGG> in the table for all classes, for which quantities sold have been summarised.

Ideally, the OIE is interested in the amount of active entity (moiety), that is, the substance as listed in the OIE list of antimicrobial agents of veterinary importance (for example: 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 entity, 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 entities will also be accepted, but the additional calculations carried out should be described in the corresponding free-text field in the OIE template (on the sheet for reporting option 1, 2 or 3, see section above for explanation).

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 to kg from different weight units.

For veterinary medicinal products the content of the antimicrobial agent(s) may be stated in one of several ways, including (i) 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, (ii) strength in International Units (IU) per weight, volume or other unit, or (iii) strength in per cent (%) weight per weight (w/w) or weight per volume (w/v). The annex provides details on the necessary conversions.

For veterinary 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.

Reporting option 1, 2 and 3: Differentiation by type of use

For **Reporting option 1**, complete the columns **Therapeutic use (including prevention of clinical signs)** and **Growth promotion**. The sum of sales for **Therapeutic use** and **Growth promotion** should equal the amount entered in the column **Total amount (Growth promotion and Therapeutic indications)** for each class.

For **Reporting options 2** and **3**, **Growth promotion** can be reported jointly for terrestrial and aquatic foodproducing animals.

Reporting option 2 and/or 3: Differentiation by animal species group

If sales for use in animals can be differentiated into sales for therapeutic purposes and for growth promotion and additionally by animal species category, please complete under the heading **Therapeutic use (including prevention of clinical signs)** the columns for **All animal species**, **All food-producing animals (terrestrial and aquatic)**, **Terrestrial food-producing animals**, **Aquatic food-producing animals**. These animal categories include all age groups and life stages of the relevant species. The first column of the table for both Reporting option 2 and Reporting option 3, **Total amount (Growth promotion and Therapeutic use)**, allows reporting of the total amount for all uses and animal categories per antimicrobial class. The last column labelled **Growth promotion** captures the amounts sold for growth promotion purposes in terrestrial and aquatic food-producing animals.

Reporting option 3: Differentiation by routes of administration

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

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.

Calculating the quantities to report in Reporting options 1, 2 and 3

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, for pragmatic reasons in most cases the amount of the chemical compound as declared on the product label can be reported, though OIE Member Countries wishing to provide more refined data on amounts of active entities are welcome to do so.

Annex 3. 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
I	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

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

Table 1: Converting weight units into kg

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 = 2gx	5 =	10 g
(b) Pack content = 2000 mg	X	20 = 2gx	20 =	40 g
(c) Pack content = 2000 mg	X	100 = 2gx	100 = 100	200 g

Example C:

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

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

- (a) Container content = 300 mg/ml Х 100 ml = 30000 mg = 30 gPack content: (a) 6 x 30 g= 180 g, (b) $10 \times 30 \ g =$ 300 g (c) $12 \times 30 \ g =$ 360 g (b) Container content = 300 mg/ml x 250 ml = 75000 mg = 75 gPack content: $6 \times 75 g =$ 450 g, (a) (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 $\ensuremath{\mathsf{kg}}$

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)

Table 2: Conversion of International Units (IUs) of certain antimicrobial agents into mg and relevant active entities, based on the ESVAC conversion factors⁸

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

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

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

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

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

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

⁸ http://www.ema.europa.eu/ema/pages/includes/document/open_document.jsp?webContentId=WC500189269

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

Continue with Steps 1-3 of (i)

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

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

Example: Product Z containing 30% w/v benzylpenicillin will contain (30 x 10 x mg)/1ml, equal to 300 mg/ml benzylpencicillin.

Continue with Steps 1-3 of (i)

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

For pragmatic reasons the OIE accepts the reporting of antimicrobial agents in amounts of chemical compound as declared on the product label of the veterinary medicinal product. However, OIE Member Countries may wish to carry out further calculations to report amounts of active entity. If such further calculations are carried out, please describe them in the OIE template.

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

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

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

Salt (including base): Tiamulin hydrogen fumarate MW 609.8 Base: Tiamulin MW 493.7 Conversion factor = MW base/MW salt (including base) = 0.81

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

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

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

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

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

<u>Table 3</u>: Conversion of content stated in mg, g or kg of long-acting salts and prodrugs of antimicrobial agents in the veterinary product into corresponding mg, g or kg antimicrobial active entity for reporting to the OIE, based on the ESVAC conversion factors⁹

Antimicrobial agent (prodrug)	Active entity	Prodrug conversion factor for multiplication
Benethamine benzylpenicillin	Benzylpenicillin	0.65
Benzathine benzylpenicillin	Benzylpenicillin	0.39
Cefapirin benzathine	Cefapirin	0.41
Cefalexin benzathine	Cefalexin	0.36
Cloxacillin benzathine	Cloxacillin	0.43
Oxacillin benzathine	Oxacillin	0.69
Penethamate hydroiodide	Benzylpenicillin	0.63
Procaine benzylpenicillin	Benzylpenicillin	0.61

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

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

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

x prodrug conversion factor

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

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

Antimicrobial agent (active entity)(kg)

= Step 1 antimicrobial agent (chemical compound as declared on the product label) kg

x prodrug conversion factor

⁹ <u>http://www.ema.europa.eu/ema/pages/includes/document/open_document.jsp?webContentId=WC500189269</u>

Annex 4. Distribution of countries by region according to the OIE Note de Service 2010/2012

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

AFRICA (54)	AMERICAS (29)	ASIA (32)	EUROPE (53)
 ALGERIA ANGOLA BENIN BOTSWANA BURKINA FASO BURKINA FASO BURUNDI CAMEROON CAPE VERDE CENTRAL AFRICAN REP. CHAD CONGO (REP. OF THE ~) CONGO (DEM. REP. OF THE A) EGYPT EQUATORIAL GUINEA ERITREA ETHIOPIA GABON MAUINEA BUINEA EUINEA ESOTHO LIBYA MAURITANIA MAURITANIA MAURITIUS MOROCCO MOZAMBIQUE NAGERIA RWANDA SAO TOME AND 	 ARGENTINA BAHAMAS BARBADOS BELIZE BOLIVIA BRAZIL CANADA CHILE COLOMBIA COSTA RICA COSTA RICA CUBA ECUADOR ECUADOR EUADOR GUATEMALA GUYANA HAITI HONDURAS JAMAICA MEXICO NICARAGUA PARAGUAY PARAGUAY PERU SURINAME TRINIDAD AND TOBAGO UNITED STATES OF AMERICA 	1. AUSTRALIA 2. BANGLADESH 3. BHUTAN	 ALBANIA ANDORRA ARMENIA AUSTRIA AZERBAIJAN BELARUS BELGIUM BOSNIA AND HERZEGOVINA BULGARIA CROATIA CROATIA CYPUS CZECH REP. DENMARK ESTONIA FINLAND FORMER YUG. REP. OF MACEDONIA GERMANY GREECE HUNGARY ICELAND RELAND ISRAEL ITALY KAZAKHSTAN KAZAKHSTAN
22 MALIDITULO	1. AFGHANISTAN 2. BAHRAIN 3. IRAQ		 33. MOLDAVIA 34. MONTENEGRO 35. NETHERLANDS 36. NORMAN
40. SAO TOME AND	 JORDAN KUWAIT LEBANON OMAN QATAR 		36. NORWAY 37. POLAND 38. PORTUGAL 39. ROMANIA 40. RUSSIA
PRINCIPE 41. SENEGAL 42. SEYCHELLES 43. SIERRA LEONE 44. SOMALIA 45. SOUTH AFRICA 46. SOUTH SUDAN (REP. OF) 47. SUDAN 48. SWAZILAND 49. TANZANIA 50. TOGO 51. TUNISIA	9. SAUDI ARABIA 10. SYRIA 11. UNITED ARAB EMIRATES 12. YEMEN		 SAN MARINO SERBIA SLOVAKIA SLOVAKIA SLOVENIA SPAIN SWEDEN SWITZERLAND TAJIKISTAN TURKEY TURKMENISTAN UKRAINE UNITED KINGDOM UZBEKISTAN
52. UGANDA 53. ZAMBIA 54. ZIMBABWE			

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