EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Sales of veterinary antimicrobial agents in 31 European countries in 2017

Trends from 2010 to 2017
Ninth ESVAC report

An agency of the European Union

Mission statement

The mission of the European Medicines Agency is to foster scientific excellence in the evaluation and supervision of medicines, for the benefit of public and animal health.

Legal role

The European Medicines Agency (hereinafter 'the Agency' or EMA) is the European Union (EU) body responsible for coordinating the existing scientific resources put at its disposal by Member States for the evaluation, supervision and pharmacovigilance of medicinal products.

The Agency provides the Member States and the institutions of the EU and the European Economic Area (EEA) countries with the best-possible scientific advice on any questions relating to the evaluation of the quality, safety and efficacy of medicinal products for human or veterinary use referred to it in accordance with the provisions of EU legislation relating to medicinal products.

The founding legislation of the Agency is Regulation (EC) No 726/2004 of the European Parliament and the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency[1].

Principal activities

Working with the Member States and the European Commission (EC) as partners in a European medicines network, the Agency:

- Provides independent, science-based recommendations on the quality, safety and efficacy of medicines, and on more general issues relevant to public and animal health that involve medicines;
- Applies efficient and transparent evaluation procedures to help bring new medicines to the market by means of a single, EU-wide marketing authorisation granted by the EC;
- Implements measures for continuously supervising the quality, safety and efficacy of authorised medicines to ensure that their benefits outweigh their risks;
- Provides scientific advice and incentives to stimulate the development and improve the availability of innovative new medicines;
- Recommends safe limits for residues of veterinary medicines used in food-producing animals, for the establishment of maximum residue limits by the EC;
- Involves representatives of patients, healthcare professionals and other stakeholders in its work, to facilitate dialogue on issues of common interest;
- Publishes impartial and comprehensible information about medicines and their use;
- Develops best practice for medicines evaluation and supervision in Europe and contributes alongside the Member States and the EC to the harmonisation of regulatory standards at the international level.

Guiding principles

- We are strongly committed to public and animal health.
- We make independent recommendations based on scientific evidence, using state-of-the-art knowledge and expertise in our field.
- We support research and innovation to stimulate the development of better medicines.
- We value the contribution of our partners and stakeholders to our work.
- We assure continual improvement of our processes and procedures, in accordance with recognised quality standards.
- We adhere to high standards of professional and personal integrity.
- We communicate in an open, transparent manner with all of our partners, stakeholders and colleagues.
- We promote the well-being, motivation and ongoing professional development of every member of the Agency.

[1] OJ L 136, 30.4.2004, p. 1

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About the European Medicines Agency

The European Medicines Agency (EMA) is a decentralised body of the EU, located in Amsterdam. Its main responsibility is the protection and promotion of public and animal health, through the evaluation and supervision of medicines for human and veterinary use.

The Agency is responsible for the scientific evaluation of applications for European marketing authorisations for both human and veterinary medicines (centralised procedure). Under the centralised procedure, companies submit a single marketing authorisation application to the Agency. Once granted by the EC, a centralised marketing authorisation is valid in all EU Member States and, after implementation at national level, in the EEA-EFTA states (Iceland, Liechtenstein and Norway).

The Agency, with the help of its Committee for Medicinal Products for Veterinary Use (CVMP), and its Antimicrobials Working Party (AWP), has produced a strong body of scientific advice[2] in relation to the use of antimicrobials and the risk of antimicrobial resistance (AMR), with the intention of promoting the continued availability of effective antimicrobials for use in animals while, at the same time, acting to minimise risks to animals or humans arising from their use.

The European Surveillance of Veterinary Antimicrobial Consumption (ESVAC) project was launched by the Agency in September 2009, following a request from the EC to develop a harmonised approach to the collection and reporting of data on the use of antimicrobial agents in animals from the Member States.

About the report

The ninth ESVAC report presents data on the sales of veterinary antimicrobial agents from 31 European countries in 2017, provided at package level according to a standardised protocol and template. In addition, it includes a chapter describing changes in consumption of veterinary antimicrobials for the years 2010-2017 (Chapter 2.7).

Of note is that compared to previous editions, this report does not present changes across years by country (chapter 2.8.2 in previous reports).

The report emphasises certain classes or subclasses of antimicrobials included in Category 2 of the categorisation made by the EMA Antimicrobial Advice ad hoc Expert Group (AMEG) in 2014 (see selection criteria in Annex 5). The AMEG categories consider the World Health Organization (WHO) categorisation of antimicrobials, the consumption of those antimicrobials in veterinary medicine, the hazards of zoonotic relevance in Europe and the risk of resistance transfer to humans. The AMEG classification is published on the EMA webpage[3].

Category 2 of the AMEG categorisation includes those veterinary antimicrobials where the risk for public health is estimated to be higher than other classes of antimicrobials; fluoroquinolones, 3rd- and 4th-generation cephalosporins and polymyxins are included in this category. Macrolides are currently not included in Category 2 of the AMEG categorisation[4].

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[2] Available on the European Medicines Agency website (www.ema.europa.eu) via Home > Veterinary regulatory > Overview > Antimicrobial resistance

[3] EMA/AMEG: Answer to the second request from the EC (ranking of antibiotics) (EMA/381884/2014): https://www.ema.europa.eu/en/documents/other/answers-requests-scientific-advice-impact-public-health-animal-health-use-antibiotics-animals_en.pdf

[4] Although macrolides are not included in Category 2, the CVMP has made recommendations indicating that, amongst others, the responsible use of antimicrobials (macrolides) should be strongly promoted, and that although acknowledging that macrolides are first-line treatment against a number of animal diseases, there is a need to avoid unnecessary use.

Aminoglycosides and certain penicillins (aminopenicillins, i.e. amoxicillin, ampicillin and metampicillin) have been revised by the CVMP without suggesting a category for those groups of antimicrobials[5]. The classification of antimicrobial classes by AMEG is currently being revised and the updated scientific advice of AMEG on the categorisation of antimicrobials is expected to be finalised by the end of 2019[6].

In 2017, the European Centre for Disease Prevention and Control (ECDC), the European Food Safety Authority (EFSA) and EMA published the second joint report on the integrated analysis of the consumption of antimicrobial agents and occurrence of AMR in bacteria from humans and food-producing animals (JIACRA II report)[7]. Whilst recognising the complexity of evaluating the association between the sales of antimicrobials and occurrence of AMR in animals and humans, the report confirms that a reduction in the sales of antimicrobials is desirable objective in order to contain AMR.

ECDC, EFSA and EMA have also jointly established a list of harmonised outcome indicators[8] to assist EU Member States in assessing their progress in reducing the use of antimicrobials and occurrence of AMR in both humans and food-producing animals. For food-producing animals, the proposed indicators for antimicrobial consumption include: overall sales of veterinary antimicrobials; sales of 3rd- and 4th-generation cephalosporins; sales of quinolones (specifying the proportion of fluoroquinolones); and sales of polymyxins, measured in mg/PCU.

This ninth ESVAC report places the emphasis on food-producing animals.

The data and information included in this report has been reviewed and approved by the ESVAC National Contact Points (NCs) or their alternates.

Advice on how to read this report:

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

It should be emphasised that the data presented in this report should not be used alone as a basis for setting management priorities, additional data on the production of animals per country and animal demography, available veterinary medicinal products and other factors should also be considered.

It is also recommended not to use data presented in this report to directly compare countries, as more detailed insight and analysis may be needed.

[5] See the EMA website (www.ema.europa.eu): via Home> Veterinary regulatory> Research and development > Safety and residues: antimicrobials (https://www.ema.europa.eu/en/veterinary-regulatory/research-development/scientific-guidelines/safety-residues/safety-residues-antimicrobials)

[6] EC request for updated advice on the impact on public health and animal health of the use of antibiotics in animals: https://www.ema.europa.eu/en/documents/other/mandate-antimicrobial-advice-ad-hoc-expert-group-ameg_en.pdf

[7] Available on the EMA webpage (www.ema.europa.eu) via: Home > Veterinary regulatory > Overview > Antimicrobial resistance > Analysis of consumption and resistance (JIACRA): https://www.ema.europa.eu/en/documents/report/ecdc/efsa/ema-second-joint-report-integrated-analysis-consumption-antimicrobial-agents-occurrence_en.pdf

[8] Available on the EMA webpage (www.ema.europa.eu) via Home > Veterinary regulatory > Overview > Antimicrobial resistance > Analysis of consumption and resistance (JIACRA) > Outcome indicators (https://www.ema.europa.eu/en/documents/report/ecdc-efsa-ema-joint-scientific-opinion-list-outcome-indicators-regards-surveillance-antimicrobial_en.pdf)

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Summary

A total of 31 European countries – 30 EU/EEA countries and Switzerland – submitted data on sales or prescriptions (two countries) of antimicrobial veterinary medicinal products (VMPs) to the European Medicines Agency for 2017.

A population correction unit (PCU) is applied as a proxy for the size of the food-producing animal population (including all horses). The main indicator used in the current report to express the sales is milligrams of active ingredient sold per population correction unit – mg/PCU.

A large difference in the sales for 2017, expressed as mg/PCU, was observed between the countries with the highest and lowest sales (range 3.1 to 423.1 mg/PCU); total aggregated sales linked to aggregated PCU for all 31 countries which delivered data in 2017 was 107.0 mg/PCU, while the median was 61.9 mg/PCU.

Of the overall sales of antimicrobials in the 31 countries in 2017, the largest amounts, expressed as mg/PCU, were accounted for by tetracyclines (30.4%), penicillins (26.9%) and sulfonamides (9.2%). Overall, these three classes accounted for 66.5% of total sales in the 31 countries.

The prescribing patterns of the various antimicrobial classes, expressed as mg/PCU, varied substantially between the 31 countries. In 2017, notable variations in the proportion of antimicrobial classes included in the EMA AMEG Category 2 were observed between countries, i.e. 3rd- and 4th-generation cephalosporins, fluoroquinolones and polymyxins – with sales (mg/PCU) ranging from <0.01 to 0.8 mg/PCU, <0.01 to 14.3 mg/PCU and 0 to 14.9 mg/PCU, respectively (Table 5). For these classes, sales (mg/PCU) for food-producing animals in the 31 countries accounted for 0.2%, 2.2% and 3.4% of total sales, respectively. In addition to the antimicrobial classes belonging to AMEG Category 2, WHO has classified macrolides and other quinolones as critically important antimicrobials (CIAs) with the highest priority for human medicine. Macrolides accounted for 7.4% of the total sales of antimicrobials for food-producing animals in the 31 countries in 2017, while the corresponding figure for other quinolones was 0.4%.

When aggregated across the 31 countries, sales (mg/PCU) of pharmaceutical forms suitable for group treatment accounted for 89.4% of the total sales: premixes accounted for 28.8%; oral powders for 9.9%; and oral solutions for 50.7% (Figure 9). The proportion accounted for by pharmaceutical forms applicable for group treatment varied substantially between countries, ranging from 3% to 96% (Figure 8). Of the pharmaceutical forms intended for treatment of individual animals (10.6% of total sales across all countries), 9.7% of the sales were accounted for by injectable preparations, 0.5% by intramammary preparations and 0.4% by oral pastes, boluses and intrauterine preparations (Figure 9).

In 2017, across the 31 countries, the proportion of the total sales of antimicrobial veterinary medicinal products (VMP) suitable for group treatment (oral powder, oral solution and premix) containing one active ingredient was 87%; 13% contained two or more active ingredients.

For the 25 countries which provided sales for all years between 2011 and 2017, an overall decline in sales (mg/PCU) of 32.5% was observed. Overall sales fell from 162.0 mg/PCU in 2011 to 109.3 mg/PCU in 2017 (Figure 24). A fall in sales (mg/PCU) of more than 5% was observed in 19 of these countries (ranging from -7.7% to -57.9%), whilst there was an increase of more than 5% in three countries during the reference period (ranging from 29.8% to 42.9%) (Table 8).

Among these 25 countries, a noticeable decrease in sales (mg/PCU) was identified for some of the highest-selling countries, which has had a significant impact on the overall sales reduction by 32.5% observed during this period.

The total sales of the AMEG Category 2 antimicrobials in these 25 countries showed a decreasing trend, which contributed to the overall decrease. Between 2011 and 2017, sales of 3rd- and 4th-generation cephalosporins decreased by 20.9%, polymyxins decreased by 66.4% and fluoroquinolones decreased by 10.3% in those 25 countries that provided data during this period.

Variations between the 31 countries in reported sales (mg/PCU) and in sales patterns are likely to be partly due to differences in the occurrence of bacterial diseases, in the composition of the animal population and in production systems. Furthermore, there are considerable variations in terms of the daily doses used for the various antimicrobial agents and pharmaceutical forms, as well as in the duration of treatment. However, these factors can only partly explain the differences in the sales observed between the 31 countries; therefore, other factors must also be considered. Some countries have changed their national data collection systems over the years (e.g. Slovenia in 2013, Spain in 2014 and 2017 and Romania 2015) or have identified under-reporting for some of the years (e.g. Bulgaria 2014, Spain 2014), which may also have an impact on the data. Overall, this emphasises that data presented in this report should not be used for direct comparison between countries without considering the differences between them, and that changes observed over time for certain countries should be interpreted with caution.

Introduction

Terms of reference from the European Commission

In 2008, the Council of the European Union adopted the Council Conclusions on Antimicrobial Resistance (AMR)[9], calling upon the European Commission (EC) and the Member States to strengthen surveillance systems and improve data quality on antimicrobial resistance and the consumption of antimicrobial agents within both the human and veterinary sectors. In response to the Council Conclusions, the EC requested the Agency to take the lead in the collection of data on sales of veterinary antimicrobial agents in the Member States. To guarantee an integrated approach, the EMA was requested to consult the ECDC, the EFSA and the EU Reference Laboratory for Antimicrobial Resistance (EURL-AR).

The European Surveillance of Veterinary Antimicrobial Consumption (ESVAC) project was launched in September 2009, following a request to develop an approach for the harmonised collection and reporting of data on the use of antimicrobial agents in animals in the Member States (SANCO/E2/KDS/rz D(2008) 520915). Through the EC terms of reference, the EMA was requested, among other activities:

- to identify the existing data/surveillance systems established for collection of sales and use of antibacterial drugs in the Member States;
- to develop a harmonised approach for the collection and reporting of data based on national sales figures, combined with estimations of usage in at least major groups of species;
- to collect the data from Member States and manage the database;
- to draft and publish a summary annual report presenting the data from Member States.

Regarding data collection:

- comparability with the sale/use of antimicrobials in humans should be ensured.

About ESVAC activity

Through the ESVAC exercise, data are collected on sales of antimicrobial VMPs at package level from the EU Member States, EEA countries and Switzerland. Furthermore, in 2016, ESVAC established defined daily doses for animals (DDDvet) and defined course doses for animals (DCDvet) (EMA/224954/2016[10]). To prepare for the collection of data by animal species, in 2018, ESVAC published guidance on the collection of harmonised and standardised data from Member States on the use of antimicrobials by species[11]. The ESVAC Vision and Strategy 2016-2020, published on the EMA's website, details the intended future development of ESVAC activity[12].

The organisation of the ESVAC project is illustrated in Figure 1.

The core of the ESVAC activity related to the collection of sales data is the ESVAC network of main NCs and alternates, nominated by the national competent authorities in the participating countries. Country and affiliation of the ESVAC main NCs and alternates can be found in Annex 8 of this report. The tasks of the ESVAC main NCs are: to provide sales data to the ESVAC team at the EMA in response to annual data calls; to revise the data in terms of quality and validity, following requests from the ESVAC team; to validate the data applied to calculate the PCU; and to provide comments on the annual ESVAC report.

[9] http://www.consilium.europa.eu/ueDocs/cms_Data/docs/pressData/en/lsa/101035.pdf

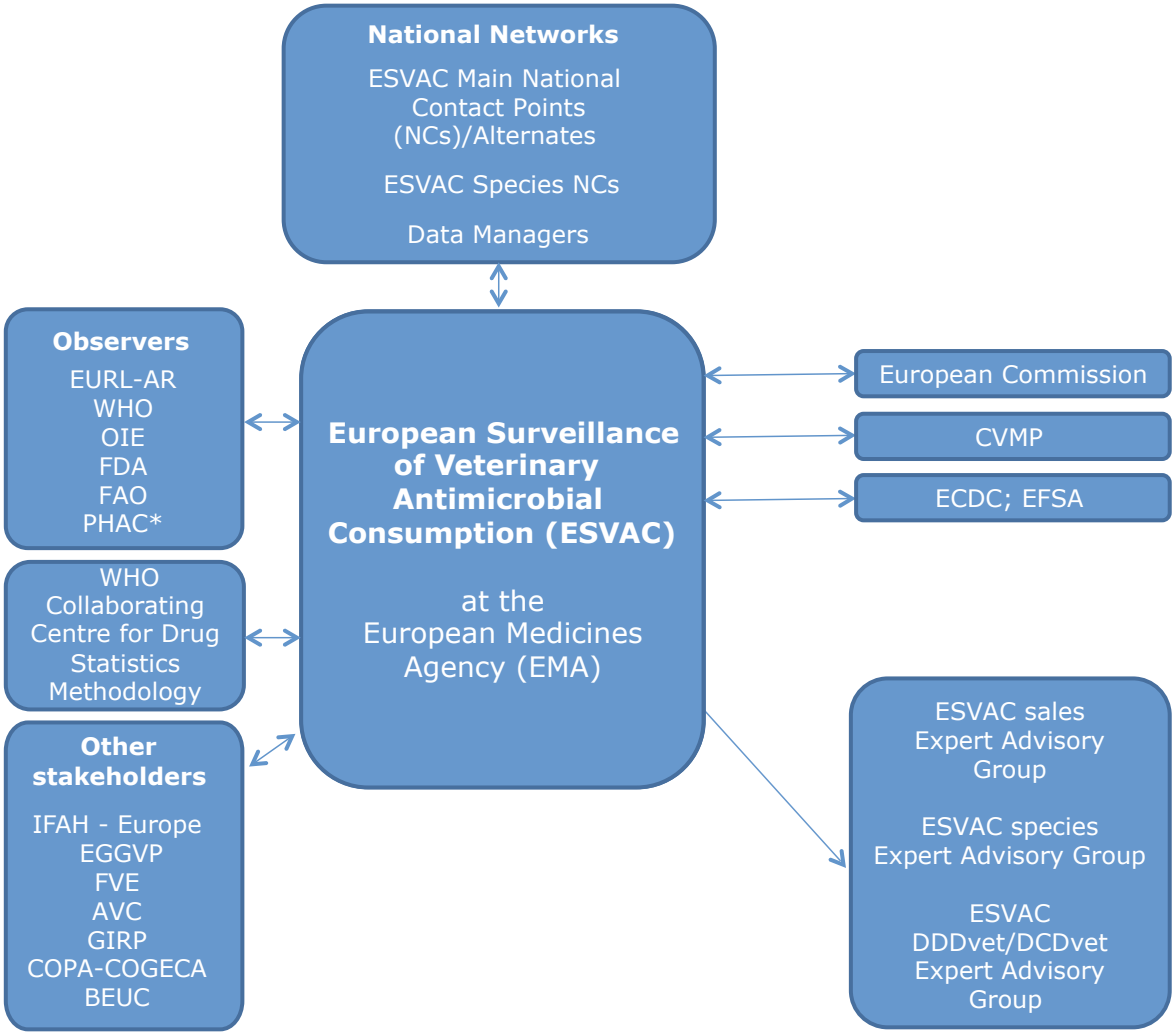
[10] Available on the EMA website (www.ema.europa.eu) via: Home > Veterinary regulatory > Antimicrobial resistance > European Surveillance of Veterinary Antimicrobial Consumption > Units of measurement

[11] Available on the EMA website (www.ema.europa.eu) via Home > Veterinary regulatory > Antimicrobial resistance > European Surveillance of Veterinary Antimicrobial Consumption (ESVAC) > Reporting data by animal species: http://www.ema.europa.eu/ema/doc_index.jsp?curl=pages/includes/document/document_detail.jsp?webContentId=WC500224492&murl=menus/document_library/document_library.jsp&mid=0b01ac058009a3dc

[12] Available on the EMA website (www.ema.europa.eu) via: Home > Veterinary regulatory > Antimicrobial resistance > European Surveillance of Veterinary Antimicrobial Consumption (http://www.ema.europa.eu/docs/en_GB/document_library/Regulatory_and_procedural_guideline/2016/04/WC500204522.pdf)

The ESVAC sales data activity is supported by an Expert Advisory Group (EAG) which comprises representatives of the ESVAC main NCs or alternate network. There are also observers from the EC, ECDC and EFSA. The task of the sales ESVAC EAG is to provide technical advice on surveillance of overall sales data of antimicrobial VMPs, including collection, analysis and reporting of data, and preparation of the annual reports. A list of the ESVAC EAG members and observers can be found in Annex 9 of this report.

Figure 1. Organisation of the ESVAC



* Public Health Agency of Canada

ESVAC deliverables also include publication of the core graphs and tables of the ESVAC sales reports available on the EMA website through ESVAC BI (Oracle Business Intelligence Enterprise Edition)[13].

[13] ESVAC interactive database accessible via the ESVAC activity web page: https://www.ema.europa.eu/en/veterinary-regulatory/overview/antimicrobial-resistance/european-surveillance-veterinary-antimicrobial-consumption-esvac

1. Technical notes

1.1. Antimicrobial veterinary medicinal products included in the data sets

To obtain harmonised data on sales of antimicrobial veterinary medicinal products from the ESVAC participating countries, the ESVAC protocol[14] has defined which antimicrobials are to be included in the data sets by using the Anatomical Therapeutic Chemical classification system for VMPs (ATCvet[15]) (Table 1). Of note is that all antimicrobials included in the dataset encompass substances with an antibacterial effect. All pharmaceutical forms[16] are included except dermatological preparations (ATCvet group QD) and preparations for sensory organs (ATCvet group QS). The contribution from these pharmaceutical forms, in tonnes of active ingredient, to the total amount of veterinary antimicrobials sold is shown to be negligible and thus the underestimation of total sales is insignificant. It should be noted that antimicrobial growth promoters are not allowed to be used in ESVAC participating countries, and therefore they are not part of the data collection. Ionophore coccidiostat feed additives and veterinary medicines containing zinc oxide are not included in the data material.

To harmonise the reporting of sales of VMPs with the data on sales of antimicrobial agents in human medicine, they are presented according to the classes/subclasses defined by the ATCvet hierarchical system, using WHO international non-proprietary names (INN), where available. If INNs have not been assigned, the ATCvet system applies either USAN (United States Adopted Names) or BAN (British Approved Names).

Table 1. Categories and ATCvet codes[15] of antimicrobial VMPs included in the data

Categories of veterinary antimicrobial agents	ATCvet codes
Antimicrobial agents for intestinal use	QA07AA; QA07AB
Antimicrobial agents for intrauterine use	QG01AA; QG01AE; QG01BA; QG01BE; QG51AA; QG51AG
Antimicrobial agents for systemic use	QJ01
Antimicrobial agents for intramammary use	QJ51
Antimicrobial agents belonging to antiparasitic products[1]	QP51AG

[1] Solely sulfonamides

1.2. Variables reported for each antimicrobial veterinary medicinal product

Detailed information on the variables to be reported for each antimicrobial veterinary medicinal product is given in Annex 2 of this report, as well as in the ESVAC protocol and ESVAC data-collection form published on the Agency's website[17]. To standardise the information, including for the purpose of data management, the following categories of pharmaceutical forms have been applied for reporting sales data to the ESVAC: boluses, injectable medicines, intramammary preparations for lactating cows, intramammary preparations for dry cow treatment, intrauterine preparations, oral solutions (includes powders for administration in drinking water), oral pastes, oral powders (powder to be administered with the feed), premixes (premix for medicated feeding stuff) and tablets (including capsules). It should be noted that when, for example, there are instructions such as "powder for solution" or "powder for administration in drinking water" in the name, on the label or in the Summary of Product Characteristics (SPC), this should be reported as an oral solution. Premixes are VMPs, usually in the form of powders or granules, which are intended to be mixed into animal feed by feed mills.

[14] Available on the EMA website (www.ema.europa.eu): http://www.ema.europa.eu/docs/en_GB/document_library/Other/2010/04/WC500089584.pdf
[15] www.whocc.no/atcvet/
[16] Includes premixes used to produce medicated feed.
[17] Available on the EMA website (www.ema.europa.eu) via: Home > Regulatory > Veterinary medicines > Overview > Antimicrobial resistance > European Surveillance of Veterinary Antimicrobial Consumption > Sales data collection form and protocol.

1.3. Collection and calculation of sales data

The ESVAC participating countries provided the number of packages sold for each product presentation – i.e. name of VMP, pharmaceutical form, strength and pack size. Data were directly uploaded into the ESVAC database by the reporting countries using a web-based application. The sales (in weight of active substance) for each product presentation were calculated by multiplying the number of packages sold by the amount of active ingredient (strength) in each package; for combination preparations, the amount sold is calculated for all ingredients. Tonnes sold for each product presentation were automatically calculated in a standardised and harmonised manner. This implies application of standard conversion factors to calculate from international units (IU) to mg when the strength was given in IU (Table A11) and when prodrug standard conversion factors are used to convert to mg active ingredient (Table A12). For combination preparations, the amount sold was calculated for each ingredient separately.

1.4. Denominator: population correction unit (PCU)

The amounts of veterinary antimicrobial agents sold in the different countries are normalised by the animal population at risk of being treated with antimicrobials in each country. The PCU has been established as a denominator for the sales data. The data sources used and the methodology for the calculation of the PCU are comprehensively described in Appendix 2 of the Agency's report 'Trends in the sales of veterinary antimicrobial agents in nine European countries: 2005-2009' (EMA/238630/2011)[18]. Animal categories included in the calculation of the PCU and the weights used to calculate the PCU are described in Annex 3 of this report. It must be emphasised that the PCU is purely a surrogate for the animal population at risk.

1.4.1. Calculation of PCU

The PCU for each animal category is calculated by multiplying numbers of livestock animals (dairy cows, sheep, sows and horses) and slaughtered animals (cattle, goats, pigs, sheep, poultry, rabbits and turkeys) by the theoretical weight at the most likely time for treatment. However, due to the limited availability of living goat data in Eurostat, this category was not included when the PCU methodology was established for the first ESVAC report[19]. For countries with a relatively high number of goats compared to other food-producing animals, this results in an underestimation of the PCU. For animals exported or imported for fattening or slaughter (cattle, goats, pigs, sheep and poultry), the PCU was calculated by multiplying the number of animals by a standardised weight.

For farmed fish, Eurostat data are given only as live-weight slaughtered rather than numbers slaughtered; thus, for fish biomass, live-weight slaughtered is used to calculate the total PCU. The PCU of the animals exported for fattening or slaughter to another Member State – i.e. cattle, pigs, poultry, goats and sheep – was added to the PCU of livestock and slaughter animals in the country of origin because young animals are typically treated more frequently than other age classes. The PCU for animals imported for fattening or slaughter from another Member State was subtracted from the total PCU of livestock and slaughter animals of the importing country, to avoid double counting (counting by both the exporting and importing country) and since it is included in the data on slaughter animals (Eurostat data).

The PCU is calculated for each species, weight class and/or production type, as follows:

PCU domestic

- Number of animals slaughtered × estimated weight at treatment
- Number of livestock × estimated weight at treatment

PCU export

- Number of animals transported to another country for fattening or slaughter × estimated weight at treatment

PCU import

- Number of animals imported from another country for fattening or slaughter × estimated weight at treatment

Total PCU is calculated as follows: PCU = total $PCU_{Domestic}$ + total PCU_{Export} – total PCU_{Import}

The total PCU by country is calculated according to the above data.

1 PCU = 1 kg of animal biomass.

[18] Available on the EMA website (www.ema.europa.eu) via: Home > Veterinary regulatory > Overview > Antimicrobial resistance > European Surveillance of Veterinary Antimicrobial Consumption

[19] Trends in the sale of veterinary antimicrobial agents in nine European countries (http://www.ema.europa.eu/docs/en_GB/document_library/Report/2011/09/WC500112309.pdf)

1.4.2. Animal species and categories included in the PCU; selection of data sources

Eurostat, the Statistical Office of the EU, covers data on numbers of food-producing animals slaughtered, as well as numbers of livestock animals. Therefore, the Eurostat database[20] was selected as the source for these data. If data were not available via Eurostat (e.g. for rabbits and fish), national statistics were applied. In addition, national statistics on animal categories were applied for non-EU countries: Iceland, Norway and Switzerland, as data for these countries are not available from Eurostat. For horses (food-producing species according to EU legislation), national statistics provided by the ESVAC NCs were used. Data on dogs and cats are not available in all participating countries. Therefore, these species were not included in the PCU in order to have comparable data. As tablets are typically approved only for companion animals, they were excluded from the data sets prior to the normalisation of sales by PCU.

The Eurostat data on numbers of cattle, pigs, poultry, sheep and goats exported or imported for fattening or slaughter might not be complete, as exports and imports are only reported above a certain amount. Therefore, data were obtained from TRACES (TRAde Control and Expert System run by the EC's DG SANTE), as these are based on health certificates, which are obligatory for all animals crossing any border, and thus the data are complete.

In cases where the deviation between the Eurostat data and/or TRACES data and national statistics was more than 5%, countries could provide national statistics for calculating the PCU.

1.5. Correction of historical data

Note that subsequent to the correction of historical data, the updated values were published in the ESVAC Interactive Database as soon as they had been validated and approved by Member States.

1.5.1. Sales data

Revisions were made to the 2016 sales data for two countries. The United Kingdom identified one Marketing Authorisation Holder had over-reported the number of packages for several VMPs reported for 2016. Other updates to the United Kingdom database have also resulted in minor changes to the calculation of total tonnes and mg/PCU for 2014 and 2015. Iceland identified inconsistencies in strength reported for a minor number of presentations for 2010-2016 datasets. The above-mentioned updates are included in the ESVAC database and in the results of this report.

1.5.2. PCU data

Updates were made to the PCU data, compared to the values used for the ESVAC 2016 report. For Croatia, the data for biomass of fish produced were revised for 2014, 2015 and 2016. For Switzerland, the data on slaughtered turkeys were updated for previous years, i.e. 2014-2016. While, the difference in mg/PCU following the updates was apparent, it was not extensive.

1.6. Quality check and validation of the sales and PCU data

The countries participating in ESVAC upload sales data directly using a web-based submission tool (ESVAC web application) designed for data collection. To ensure the consistency of variables submitted automated warning and error messages are displayed instantaneously when any of the figures uploaded do not meet standardisation requirements. When data are uploaded, various summary reports can be created using the ESVAC BI application and can be used for validation. Each country is responsible for the quality of the sales delivered to the ESVAC. The ESVAC secretariat assists with data validation, including the identification of outliers, mainly by comparison with available data from previous years. Possible outliers are cross-checked and addressed with each ESVAC NC until final agreement is reached.

Development of suitable quality control measures, including assessment of data coverage and accuracy, are defined and set up by each country individually, taking into account the distinctive aspects of each country's data collection.

Reference data for the denominator (PCU) gathered by the Agency from the Eurostat database and TRACES are uploaded into the ESVAC web application. The data are subsequently validated by ESVAC participating countries. To ensure data quality and validity, the PCU data are displayed in the ESVAC BI reports in a way that allows for comparison with values per animal category and the overall PCU approved for previous years. Possible outliers are cross-checked and addressed with each ESVAC NC until final agreement is reached.

[20] https://ec.europa.eu/eurostat/data/database

1.7. Analysis and reporting of the data

Based on the assumption that tablets are almost solely used for companion animals (boluses in food-producing animals), tablets are excluded from the dataset used to report sales for food-producing animals. All other pharmaceutical forms except tablets are reported as sold for use in food-producing animals, including horses. Of note is that some of the sales allocated to food-producing animals could be for non-food-producing animals such as fur animals. In the current report, the term 'group treatment' is used for medication given via feed or water; intramammary preparations for lactating cows and for dry cow treatment are reported aggregated.

The main indicator applied in this report to express the consumption of veterinary antimicrobials is mg of active ingredient normalised by the population correction unit (mg/PCU):

$$\frac{\text{Amount sold in tonnes} \times 10\text{^}9}{\text{PCU in kg}}$$

In this report, the term food-producing species includes horses. The data are presented according to the classes or subclasses defined in the ATCvet hierarchical system. For combination preparations, sales of each active ingredient are reported according to the ATCvet class or subclass name for each single substance in question. Maps of the spatial consumption of the various veterinary antimicrobial agents were created using Adobe Illustrator CC 2015.

It should be noted that data presented in this report are calculated using the exact sales figures for each product (five decimals), but in the tables and graphs the numbers are aggregated and rounded. Therefore, the total sales of tables, for example, may differ slightly from the more detailed data presented in this report.

All data presented in this report reflect the datasets available on 29 August 2019; any updates made to the data at a later stage are not included in the data analyses.

Data on sales, including tablets used for treatment of companion animals, are available in the ESVAC Interactive Database.

1.8. Summary of included data sources/types, by country

Information concerning the years of collecting data, legal basis for the data collection at national level, systems for distribution of antimicrobial VMPs, sources from which the data were obtained, type of data, and the data included by country are shown in Table 2.

Table 2. Summary of information on years of collecting data, legal basis for collecting data at national level, national data providers, sources for ESVAC data and characteristics of data, by country, for 2017

Country	Years collecting data	Legal basis	National data provider to ESVAC	Sources for ESVAC data (approx. number)	Sales data, prescription data or purchase data[1]	Sales between wholesalers and/or MAHs[2] excluded (Yes/No)	Products sold on special licence included (Yes/No)
Austria	>5 years	Mandatory to report	Austrian Agency for Health and Food Safety	MAHs (n=9); Wholesalers (n=10)	Sales to pharmacies	Yes	No
Belgium	>5 years	Mandatory to report	Federal Agency for Medicines and Health Products	Wholesalers (n=23); Feed mills (n=51)	Sales to veterinarians and pharmacies; Sales by feed mills to farmers	Yes	Yes
Bulgaria	>5 years	Not mandatory	Bulgarian Food Safety Agency	Wholesalers (n=36)	Sales to veterinarians, farmers and pharmacies	Yes	No
Croatia	4 years	Mandatory to report	Ministry of Agriculture, Veterinary Directorate	Wholesalers (n=16)	Sales to pharmacies and veterinarians	Yes	No
Cyprus	>5 years	Mandatory to report	Ministry of Agriculture, Natural Resources and Environment – Veterinary Services	Wholesalers (n=23); Feed mills (n=29)	Sales to veterinarians, pharmacies and farmers	Yes	Yes (15%)
Czechia	>5 years	Mandatory to report	Institute for State Control of Veterinary Biologicals and Medicines	Wholesalers (n=95); Feed mills (n=38)	Sales to veterinarians, pharmacies and farmers; Sales by feed mills to farmers	Yes	Yes (<0.1%)
Denmark	>5 years	Mandatory to report	Danish Veterinary and Food Administration	VetStat (n=1) obtaining data from pharmacies (n=523), veterinarians (n=150), feed mills (n=3)	Prescriptions data from pharmacies, veterinarians, distributors and feed mills	Yes	Yes (0.1%)
Estonia	>5 years	Mandatory to report	State Agency of Medicines	Wholesalers (n=7)	Sales to veterinarians and pharmacies	Yes	Yes
Finland	>5 years	Mandatory to report	Finnish Medicines Agency	Wholesalers (n=1); Feed mills (n=1); Importers of medicated feed (n=1)	Sales to pharmacies and veterinarians	Yes	Yes
France	>5 years	Mandatory to report	National Agency for Veterinary Medicinal Products (Anses-ANMV)	MAHs (n=52)	Sales to veterinarians, pharmacies, wholesalers and feed mills	Yes	No

Country	Years collecting data	Legal basis	National data provider to ESVAC	Sources for ESVAC data (approx. number)	Sales data, prescription data or purchase data[1]	Sales between wholesalers and/or MAHs[2] excluded (Yes/No)	Products sold on special licence included (Yes/No)
Germany	>5 years	Mandatory to report	Federal Office of Consumer Protection and Food Safety	MAHs (n=30); Wholesalers (n=15); PSURs[3] data for premix	Sales to veterinarians	Yes	No
Greece	3 years	Mandatory to report	Greek National Organisation for Medicines	MAHs (n=81)[4]	Sales to pharmacies and veterinarians	Yes	No
Hungary	>5 years	Not mandatory	National Food Chain Safety Office Directorate of Veterinary Medicinal Products	Wholesalers (n=34)	Sales to veterinarians, feed mills, farmers and retailers	Yes	No
Iceland	>5 years	Mandatory to report	Icelandic Medicines Agency	Wholesalers (n=2)	Sales by wholesalers to veterinarians and pharmacies	Yes	Yes
Ireland	>5 years	Mandatory to report	Health Products Regulatory Authority	MAHs (n=68)	Sales to pharmacies, veterinarians, farmers and wholesalers within the country	Yes	No
Italy	>5 years	Mandatory to report	Italian Ministry of Health	MAHs (n=47)	Sales to wholesalers, pharmacies, feed mills, and farms authorised to produce medicated feed for self-consumption	Yes	No
Latvia	>5 years	Mandatory to report	Food and Veterinary Service	Wholesalers (n=23)	Sales to pharmacies, veterinarians, veterinary clinics and farmers	Yes	No
Lithuania	>5 years	Mandatory to report	State Food and Veterinary Service	Wholesalers (n=46)	Sales to pharmacies, veterinarians and farmers	Yes	No
Luxembourg	>5 years	Mandatory to report	Ministry of Health	Wholesalers (n=3)	Sales to pharmacies, veterinarians	Yes	No
Malta	1 year	Not mandatory	Ministry for the Environment, Sustainable Development and Climate Change	Wholesalers (n=14)	Sales data to pharmacies and veterinary clinics	Yes	Yes

Country	Years collecting data	Legal basis	National data provider to ESVAC	Sources for ESVAC data (approx. number)	Sales data, prescription data or purchase data[1]	Sales between wholesalers and/or MAHs[2] excluded (Yes/No)	Products sold on special licence included (Yes/No)
Netherlands	>5 years	Not mandatory	Federation of the Dutch Veterinary Pharmaceutical Industry (FIDIN)	MAHs (n=17)	Sales to wholesalers and veterinarians	Yes	No
Norway	>5 years	Mandatory to report	Norwegian Veterinary Institute	Wholesalers (n=5) Feed mills (n=2)	Sales to pharmacies, veterinarians and prescriptions by feed mills (feed mills deliver VMPs only) to fish farmers	Yes	Yes (0.7 %)
Poland	>5 years	Mandatory to report	Ministry of Agriculture and Rural Development	Wholesalers (n=125)	Sales to veterinarians	Yes	No
Portugal	>5 years	Mandatory to report	General Directorate for Food and Veterinary Affairs	Wholesalers (n=69)[5]	Sales to retailers, veterinarians, farmers, producer organisations, veterinary clinics and feed mills	Yes	No
Romania	4 years	Mandatory to report	Institute for Control of Biological Products and Veterinary Medicines	MAHs (n=70)[6]	Sales to pharmacies, veterinarians and farmers	Yes	No
Slovakia	>5 years	Mandatory to report	Institute for State Control of Veterinary Biologicals and Medicaments	Wholesalers (n=46)	Sales to veterinarians, pharmacies, medicated feed mills and farmers	Yes	No
Slovenia	>5 years	Mandatory to report	Administration of the Republic of Slovenia for Food Safety, Veterinary Sector and Plant Protection (AFSVSPP)	Wholesalers (n=11)	Sales to pharmacies, feed mills and veterinarians	Yes	Yes (7 %)
Spain	>5 years	Not mandatory	Spanish Agency for Medicines and Health Products	Retailers (n=869)[7]	Sales to veterinarians and veterinary organisations	Yes	No

Country	Years collecting data	Legal basis	National data provider to ESVAC	Sources for ESVAC data (approx. number)	Sales data, prescription data or purchase data[1]	Sales between wholesalers and/or MAHs[2] excluded (Yes/No)	Products sold on special licence included (Yes/No)
Sweden	>5 years	Mandatory to report	National Veterinary Institute and Swedish Board of Agriculture	The Swedish eHealth Agency (n=1) obtaining data from pharmacies	Dispensed prescriptions	Yes	Yes
Switzerland	>5 years	Mandatory to report	Federal Food Safety and Veterinary Office	MAHs (n=16)	Sales to veterinarians, pharmacies, medicated feed mills	No	No
United Kingdom	>5 years	Mandatory to report	Veterinary Medicines Directorate	MAHs (n=57)	Sales to wholesalers, veterinarians, farmers and veterinary pharmacies	Yes	No

[1] Purchase/import data from e.g. pharmaceutical industry and/or from wholesalers in other countries.
[2] MAHs = marketing authorisation holders.
[3] PSURs = periodic safety update reports.
[4] Negligible sales from a few MAHs with a very small market share, and which do not have local in Greece, are not included in the dataset.
[5] Sales of premixes can represent under reporting in 2017 sales dataset submitted for Portugal.
[6] Since 2015, data have been collected from MAHs, while for 2014 the data were obtained from MAHs and wholesalers.
[7] Since 2017 data have been collected from retailers.

2. Results

2.1. Overall sales (tonnes) of antimicrobial agents for veterinary use

The overall national sales data cover sales of antimicrobial VMPs for use in food-producing animals, including horses, plus sales of tablets that are used almost solely in companion animals. Injectable veterinary antimicrobial agents are also used in companion animals. As injectable presentations are frequently marketed for both food-producing and companion animals and their use in companion animals is minor in terms of weight of active ingredient, such sales are included in the statistics for food-producing animals. Sales of tablets, and therefore use in companion animals, accounted for a minor proportion of the total sales of antimicrobial veterinary medicinal products in 2017, except in Finland, Iceland, Luxembourg, Malta, Norway, Slovenia, Sweden and the United Kingdom, where they represented 11.0%, 7.1%, 4.9%, 12.1%, 7.3%, 6.1%, 7.7% and 5.8% of the total sales, respectively (Table 3). Overall, sales of tablets in the 31 countries represented 1.0% of the total sales in tonnes.

Table 3. Overall sales, in tonnes of active ingredient, split by tablets (used mainly in companion animals) and all other pharmaceutical forms (used mainly in food-producing animals), by country, in 2017

Country	Tablets, tonnes	Tablets, %	All other forms, tonnes	% of other forms	Total tonnes
Austria	0.6	1.4%	44.6	98.6%	45.2
Belgium	1.9	0.8%	221.0	99.2%	222.8
Bulgaria	0.2	0.3%	49.6	99.7%	49.7
Croatia	0.1	0.5%	21.1	99.5%	21.2
Cyprus	0.05	0.1%	45.4	99.9%	45.5
Czechia	1.0	2.3%	44.1	97.7%	45.1
Denmark	0.8	0.9%	94.4	99.1%	95.2
Estonia	0.1	2.1%	6.3	97.9%	6.4
Finland	1.2	11.0%	9.8	89.0%	11.0
France	15.2	3.0%	482.9	97.0%	498.1
Germany	8.6	1.1%	766.6	98.9%	775.2
Greece	0.1	0.1%	116.7	99.9%	116.8
Hungary	0.3	0.2%	147.2	99.8%	147.5
Iceland	0.04	7.1%	0.6	92.9%	0,6
Ireland	1.2	1.2%	98.5	98.8%	99.7
Italy	9.9	0.9%	1,057.8	99.1%	1,067.7
Latvia	0.1	1.7%	5.9	98.3%	6.0
Lithuania	0.1	0.8%	11.6	99.2%	11.7
Luxembourg	0.1	4.9%	1.9	95.1%	2.0
Malta	0.2	12.1%	1.8	87.9%	2.0
Netherlands	2.8	1.5%	188.0	98.5%	190.9
Norway	0.5	7.3%	5.7	92.7%	6.2
Poland	1.9	0.3%	749.6	99.7%	751.6
Portugal	0.8	0,6%	135.1	99.4%	135.9
Romania	3.3	1.2%	262.9	98.8%	266.1
Slovakia	0.2	1.7%	13.9	98.3%	14.1
Slovenia	0.4	6.1%	6.7	93.9%	7.2
Spain	0.9	0.1%	1,769.5	99.9%	1,770.4
Sweden	0.8	7.7%	9.5	92.3%	10.3
Switzerland	0.7	2.2%	31.9	97.8%	32.6
United Kingdom	14.3	5.8%	233.9	94.2%	248.2
Total 31 countries	**68.6**	**1.0%**	**6,634.4**	**99.0%**	**6,703.0**

2.2. Population-adjusted sales for food-producing animals, including horses, by antimicrobial class

The sales of veterinary antimicrobial agents, expressed as mg sold per population correction unit (PCU), ranged from 3.1 mg/PCU to 423.1 mg/PCU across the 31 countries (Table 4). The sales patterns of the antimicrobial classes also varied substantially between the countries (Table 5).

Table 4. Sales, in tonnes of active ingredient, of veterinary antimicrobial agents marketed mainly for food-producing animals[1], PCU and sales in mg/PCU, by country, for 2017

Country	Sales (tonnes) for food-producing animals	PCU (1,000 Tonnes)	Sales in mg/PCU
Austria	44.6	953.9	46.8
Belgium	221.0	1,683.1	131.3
Bulgaria	49.6	374.7	132.3
Croatia	21.1	295.6	71.5
Cyprus	45.4	107.4	423.1
Czechia	44.1	693.1	63.6
Denmark	94.4	2,397.6	39.4
Estonia	6.3	110.9	56.7
Finland	9.8	507.5	19.3
France	482.9	7,038.6	68.6
Germany	766.6	8,608.8	89.0
Greece	116.7	1,242.8	93.9
Hungary	147.2	770.9	191.0
Iceland	0.6	125.1	4.6
Ireland	98.5	2,114.1	46.6
Italy	1,057.8	3,863.8	273.8
Latvia	5.9	176.3	33.3
Lithuania	11.6	333.0	34.8
Luxembourg	1.9	54.7	35.0
Malta	1.8	14.6	121.0
Netherlands	188.0	3,340.7	56.3
Norway	5.7	1,861.2	3.1
Poland	749.6	4,539.0	165.2
Portugal	135.1	1,002.1	134.8
Romania	262.9	2,916.2	90.1
Slovakia	13.9	224.7	61.9
Slovenia	6.7	183.9	36.5
Spain	1,769.5	7,684.5	230.3
Sweden	9.5	804.1	11.8
Switzerland	31.9	795.9	40.1
United Kingdom	233.9	7,202.1	32.5
Total 31 countries	**6,634.4**	**62,020.7**	**107.0***

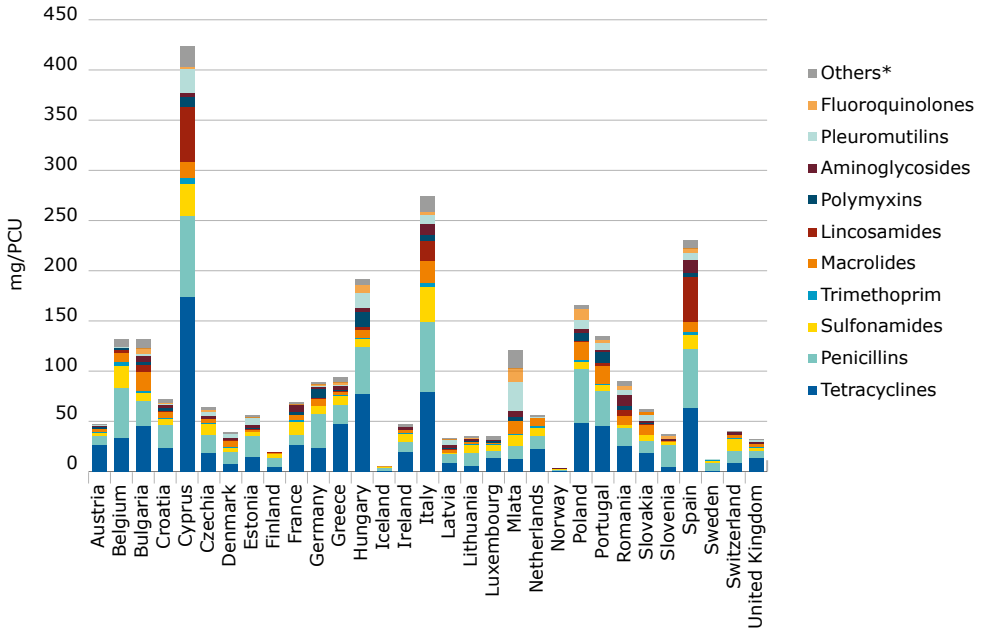
[1] Tablets excluded as used almost solely in companion animals; injectable antimicrobial VMPs can also be used in companion animals; a few other products may solely be used in companion animals, but as their proportional use is minor, these are included in the sales for food-producing animals.
* Total mg/PCU for 31 countries represents aggregated sales (tonnes) for food-producing animals normalised by the aggregated PCU (1,000 tonnes).

Table 5. Sales for food-producing animals, in mg per population correction unit (mg/PCU), of the various veterinary antimicrobial classes in the 31 European countries in 2017[1]

Country	Tetracyclines	Amphenicols	Penicillins	1st- and 2nd-gen. cephalosporins	3rd- and 4th-gen. cephalosporins	Sulfonamides	Trimethoprim	Macrolides	Lincosamides	Fluoroquinolones	Other quinolones	Aminoglycosides	Polymyxins	Pleuromutilins	Others*	Total, mg/PCU
Austria	26.1	0.4	8.6	0.05	0.2	3.5	0.7	3.2	0.1	0.5	0	1.3	1.7	0.3	0.2	46.8
Belgium	33.6	1.8	49.4	0.2	0.1	21.9	4.4	8.1	3.0	0.2	0.1	0.6	2.1	0.5	5.3	131.3
Bulgaria	45.6	8.1	24.7	0.02	0.1	7.9	1.1	19.1	7.1	5.7	0.5	6.1	3.0	2.2	1.1	132.3
Croatia	23.7	1.8	22.3	0.2	0.2	6.0	0.9	6.7	0.1	1.9	0.7	3.3	3.2	0.3	0.2	71.5
Cyprus	173.5	16.8	81.1	0.03	0.4	31.4	6.1	16.2	54.2	2.4	0.4	4.2	10.4	23.4	2.5	423.1
Czechia	18.8	1.4	17.3	0.3	0.5	10.9	1.2	3.5	0.1	1.9	0.01	2.6	0.6	4.3	0.4	63.6
Denmark	7.9	0.6	11.9	0.02	<0.01	3.8	0.7	5.7	0.9	<0.01	0.3	2.2	0.2	3.7	1.3	39.4
Estonia	14.0	0.5	21.7	0.2	0.8	3.0	0.6	2.1	0.5	1.3	0	3.3	1.1	6.2	1.2	56.7
Finland	4.5	0.2	8.8	0.03	<0.01	3.6	0.7	0.8	0.5	0.1	0	0.1	0	0.0	0	19.3
France	26.8	0.8	9.3	0.2	0.02	12.8	2.3	4.7	0.4	0.2	0.5	7.1	2.2	0.6	0.8	68.6
Germany	23.1	0.6	34.5	0.1	0.4	7.1	0.9	6.4	1.3	1.1	0	1.9	8.5	1.9	1.4	89.0
Greece	47.7	0.7	18.6	<0.01	0.1	8.3	1.3	3.3	0.3	2.7	3.9	4.3	1.3	0.9	0.5	93.9
Hungary	77.7	3.9	46.7	0.1	0.5	7.0	1.4	7.8	3.6	8.8	0.1	3.0	14.9	15.0	0.4	191.0
Iceland	0.3	0	3.3	0	<0.01	0.3	0.05	0	0	<0.01	0	0.6	0	0	0	4.6
Ireland[2]	19.6	1.4	9.7	0.3	0.1	7.9	0.6	3.4	0.1	0.4	0	2.5			0.5	46.6
Italy	78.9	6.0	70.3	0.2	0.4	33.9	4.1	22.0	20.8	3.0	2.8	11.1	5.2	9.2	5.8	273.8
Latvia	8.3	0.1	8.5	0.2	0.3	1.1	0.2	3.4	0.1	1.1	0.01	3.5	1.3	4.8	0.4	33.3
Lithuania	5.0	0.3	13.6	0.1	0.2	7.1	1.6	1.5	0.6	0.8	<0.01	1.6	0.7	0.8	0.9	34.8
Luxembourg	13.6	0.8	6.8	0.1	0.6	5.7	1.1	0.9	0.4	0.7	0	1.0	1.0	0.2	2.0	35.0
Malta[3]	12.5	1.4	12.1	0.1	0.2	11.5	1.5	12.0	0.4	15.3		5.7	4.6	27.9	15.6	121.0
Netherlands	22.3	1.4	12.6	0.04	<0.01	8.6	1.6	7.5	0.05	0.1	0.9	0.5	0.3	0.3	0.2	56.3
Norway	0.1	0.2	1.6	0	<0.01	0.7	0.1	<0.01	<0.01	<0.01	0.2	0.2	0	0.02	<0.01	3.1
Poland	47.9	1.8	54.1	0.1	0.2	7.1	1.4	18.1	1.5	11.1	0.01	4.7	7.5	8.4	1.2	165.2
Portugal	44.9	1.0	35.1	0.1	0.6	5.8	1.2	17.8	3.0	3.6	<0.01	2.7	10.9	6.3	1.7	134.8
Romania	25.1	3.9	18.2	<0.01	0.2	2.7	0.6	8.3	6.3	4.3	0.2	10.9	4.1	4.8	0.6	90.2
Slovakia	18.5	0.5	11.4	0.4	0.4	6.0	0.7	9.9	0.3	3.4	0.02	1.9	1.7	5.3	1.5	61.9
Slovenia	4.3	0.7	22.2	0.1	0.2	2.4	0.6	0.2	0.1	2.9	0	2.2	0.1	0.3	0.2	36.5
Spain	63.1	6.2	58.5	0.03	0.2	14.8	2.5	10.1	44.4	4.9	0.3	12.2	4.4	7.4	1.3	230.3
Sweden[4]	0.6		7.7	<0.01	<0.01	2.0	0.4	0.5	0.01	0.02	0	0.3			0.2	11.8
Switzerland[5]	8.7	0.4	11.2	0.1	0.2	12.8	0.7	2.0		0.3	0	3.1	0.4		0.2	40.1
United Kingdom	13.2	0.6	7.5	0.1	0.1	2.7	0.5	3.2	0.3	0.2	0	2.0	<0.01	1.5	0.4	32.5
Total sales[6] for 31 countries (mg/PCU)	**32.6**	**2.1**	**28.8**	**0.1**	**0.2**	**9.8**	**1.5**	**7.9**	**7.8**	**2.4**	**0.4**	**4.9**	**3.6**	**3.5**	**1.3**	**107.0**
Median[7] of 31 countries (mg/PCU)	**19.6**	**0.8**	**13.6**	**0.1**	**0.2**	**7.0**	**0.9**	**4.7**	**0.4**	**1.1**	**0.02**	**2.6**	**1.3**	**1.5**	**0.6**	**61.9**

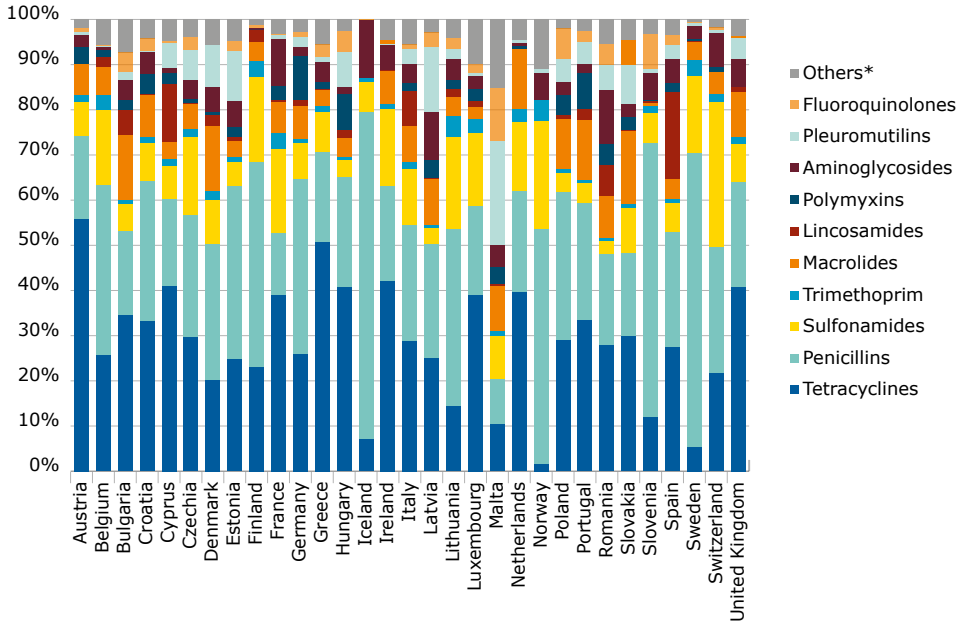
* Other antibacterials (bacitracin, fosfomycin, furaltadone, metronidazole, novobiocin, paromomycin, rifaximin and spectinomycin, classified as 'other antibacterials' in the ATCvet system).
[1] For the countries where the injectable 3rd- and 4th-gen. cephalosporins are almost solely marketed for dogs and cats, the data provides a considerable overestimate for food-producing animals.
[2] Polymyxins and pleuromutilins are aggregated with 'others' for reasons of commercial confidentiality.
[3] For confidentiality reasons, fluoroquinolones and other quinolones are aggregated.
[4] Amphenicols, polymyxins and pleuromutilins aggregated with 'others' for reasons of commercial confidentiality.
[5] For confidentiality reasons, pleuromutilins are grouped with others and lincosamides are grouped with macrolides.
[6] Total sales expressed in mg/PCU consist of total amount of antimicrobial agents sold (mg) divided by total PCU (kg) for 31 countries.
[7] Median shows the 16th value ranked from smallest to largest per each variable of 31 observations.

Figure 2. Sales for food-producing species, in mg/PCU, of the various veterinary antimicrobial classes, for 31 European countries, in 2017[1]



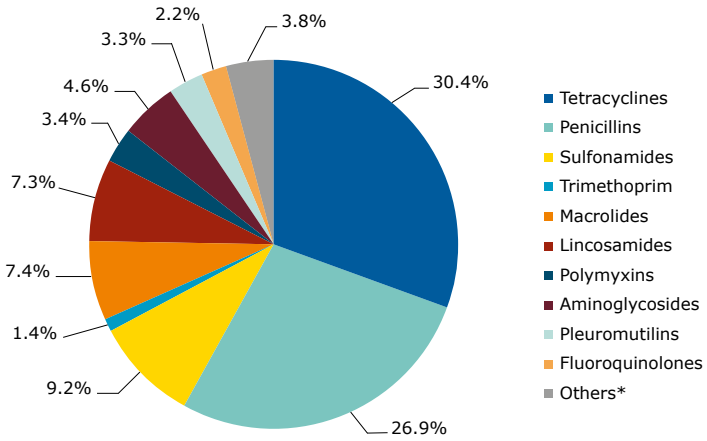
* Amphenicols, cephalosporins, other quinolones and other antibacterials (classified as such in the ATCvet system).
[1] Differences between countries can be partly explained by differences in animal demographics, in the selection of antimicrobial agents, in dosage regimes, in the type of data sources, and veterinarians' prescribing habits.

Figure 3. Proportion of the total sales of the different veterinary antimicrobial classes, in mg/PCU, in the 31 European countries, for 2017



* Amphenicols, cephalosporins, other quinolones and other antibacterials (classified as such in the ATCvet system).

Figure 4. Sales of antimicrobial agents by antimicrobial class as percentage of the total sales for food-producing species, in mg/PCU, aggregated by 31 European countries, for 2017

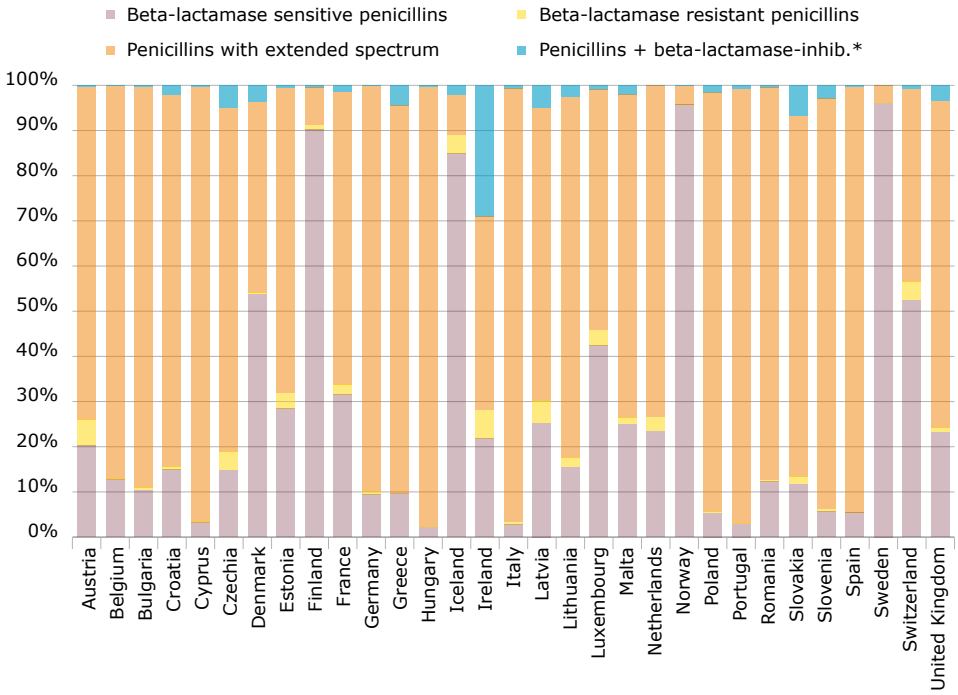


* Amphenicols, cephalosporins, other quinolones and other antibacterials (classified as such in the ATCvet system).

Across all 31 countries, the sales of tetracyclines, penicillins and sulfonamides, in mg/PCU, accounted for 66.5% of the total sales in 2017 (Figure 4). Of the overall sales in the 31 countries, 0.1% was accounted for by 1st- and 2nd-generation cephalosporins, 0.2% were for 3rd- and 4th-generation cephalosporins, 1.9% were for amphenicols, and 0.4% for other quinolones.

The percentage of sales of penicillins attributed to the various subclasses differed substantially between the 31 countries (Figure 5). In the Nordic countries, where the proportion of sales of penicillin is typically high, beta-lactamase-sensitive penicillins[21] accounted for the majority of penicillins sold (range: 54% to 96% of total penicillins sold). For countries other than the Nordics, penicillins with an extended spectrum (mainly represented by amoxicillin) accounted for the major proportion of penicillin sales.

Figure 5. Distribution of the sales, in mg/PCU, of penicillins by subclass for food-producing species, in 31 European countries, for 2017



* In the ATCvet system, they are classified as combinations of penicillins that include beta-lactamase inhibitors.

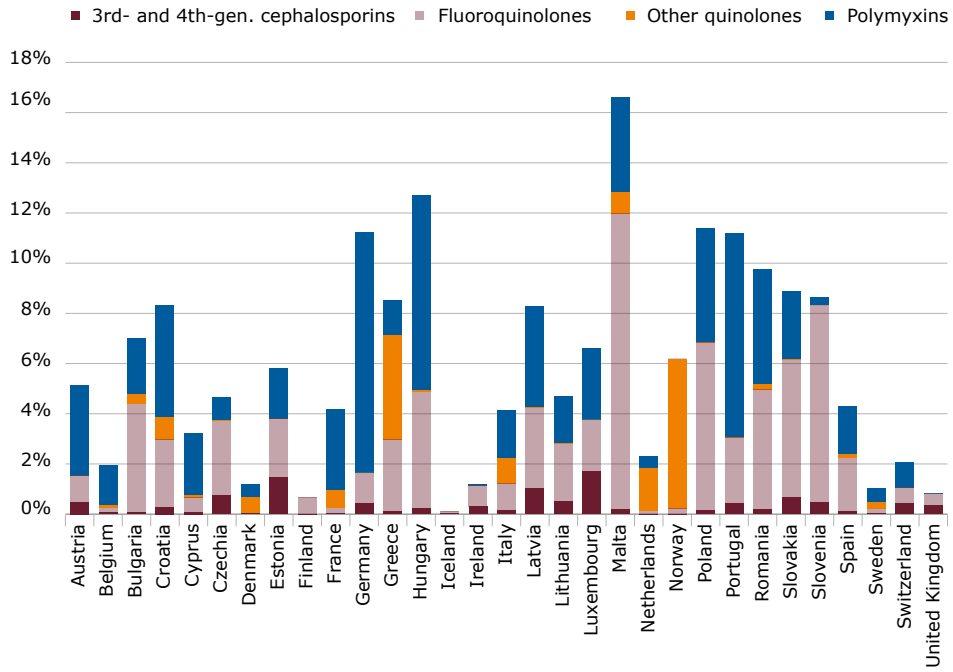
[21] Beta-lactamase-sensitive penicillins belong to ATCvet code QJ01CE. Procaine benzylpenicillin, penethamate hydriodide and phenoxymethylpenicillin accounted for the majority of sales of these penicillins.

The substances included in each of the categories in the above figure are detailed in Annex 4, Table A15. Penicillins plus beta-lactamase inhibitors refer to penicillins in combination with clavulanic acid.

The proportion of sales in 2017 of antimicrobials included in the AMEG Category 2 and classified as the highest priority critically important antimicrobials (HP CIAs) by WHO (see Annex 5, Table A16), i.e. 3rd- and 4th-generation cephalosporins, fluoroquinolones, other quinolones (included in the HP CIA list only) and polymyxins, varied substantially between the 31 countries, ranging from <0.01% to 1.7%, 0.01% to 11.8%, 0% to 6.0% and 0% to 9.6%, respectively (Figure 6). The changes in total sales, in mg/PCU, of these classes/subclasses in the 31 European countries are shown in Tables 9 to 11 and Figures 30 and 31.

Overall, in the 31 countries, the sales (mg/PCU) of 3rd- and 4th-generation cephalosporins, fluoroquinolones, and polymyxins accounted for 0.2%, 2.2% and 3.4%, respectively, of the total sales of antimicrobial VMPs in 2017.

Figure 6. Proportion of the total sales of 3rd- and 4th-generation cephalosporins, fluoroquinolones, other quinolones and polymyxins for food-producing species, in mg/PCU, for 31 European countries, in 2017[1,2,3]



[1] Variations between the countries should be interpreted with great care due to the large differences in dosing between these classes/sub-classes of antimicrobials.
[2] No sales of other quinolones in Austria, Estonia, Finland, Germany, Iceland, Ireland, Switzerland and the United Kingdom.
[3] No sales of polymyxins in Finland, Iceland and Norway.

Throughout this report, there is a special focus on certain antimicrobials that are either included in the AMEG Category 2 and/or are among the highest priority WHO CIAs. The emphasis is placed on the list of harmonised outcome indicators developed by EMA/EFSA/ECDC on request by the EC. The aim of establishing such indicators is to assist EU Member States in assessing their progress in reducing the use of antimicrobials and antimicrobial resistance in both humans and food-producing animals.

2.3. Population-adjusted sales for food-producing animals, including horses, by pharmaceutical form

The sales of veterinary antimicrobial agents for food-producing animals, including horses (hereafter designated as food-producing animals), stratified into pharmaceutical forms, by country, are shown in Figure 7. Tablets are not included in the data as they are used almost solely in companion animals.

Figure 7. Distribution of sales of veterinary antimicrobial agents for food-producing animals, in mg of active substance per population correction unit (mg/PCU), by pharmaceutical form, in 31 European countries, for 2017

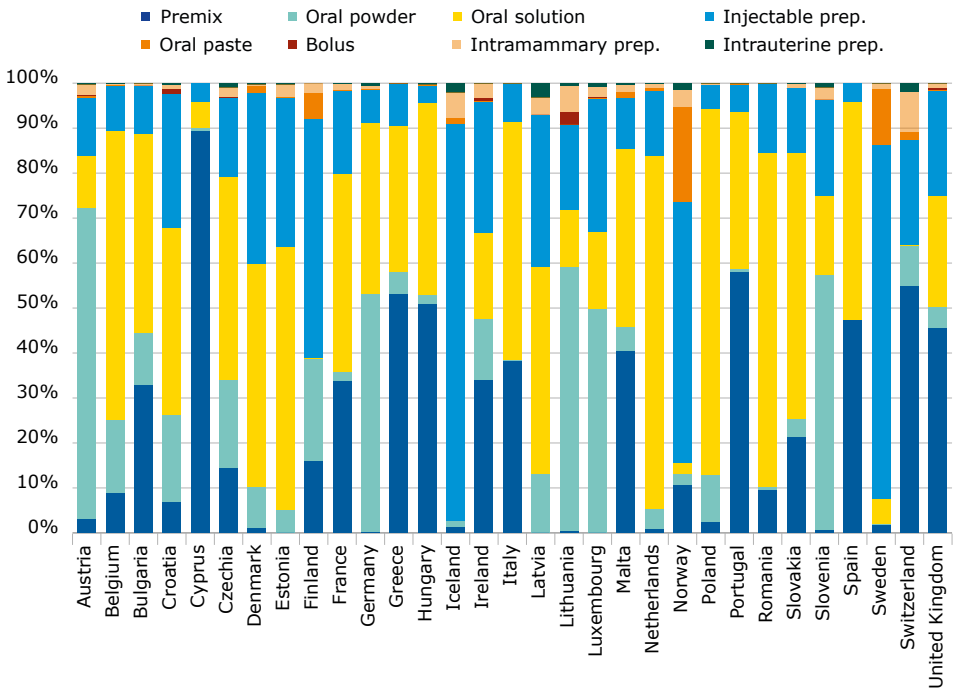
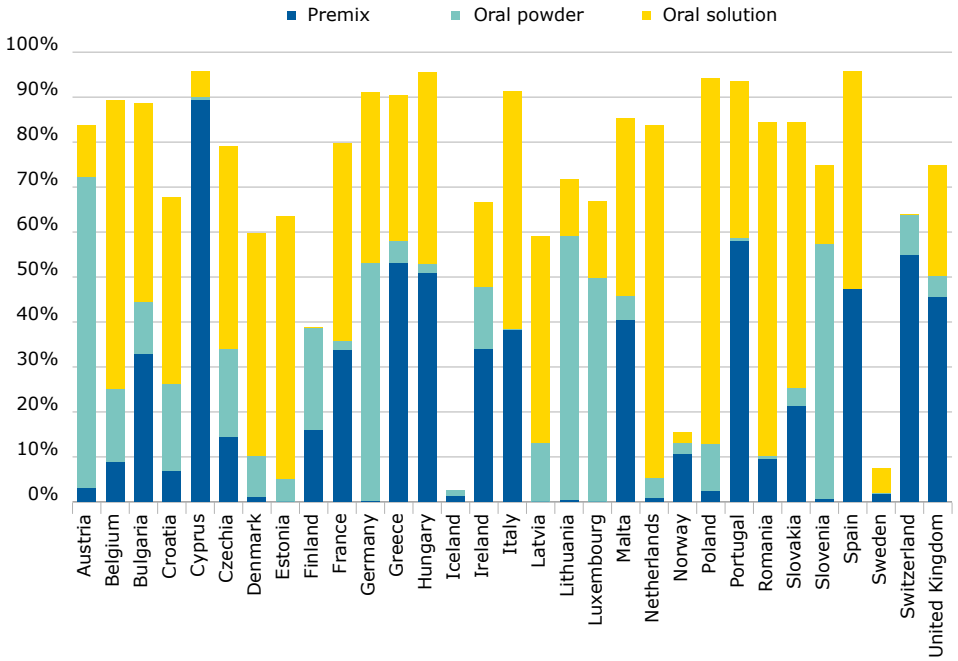


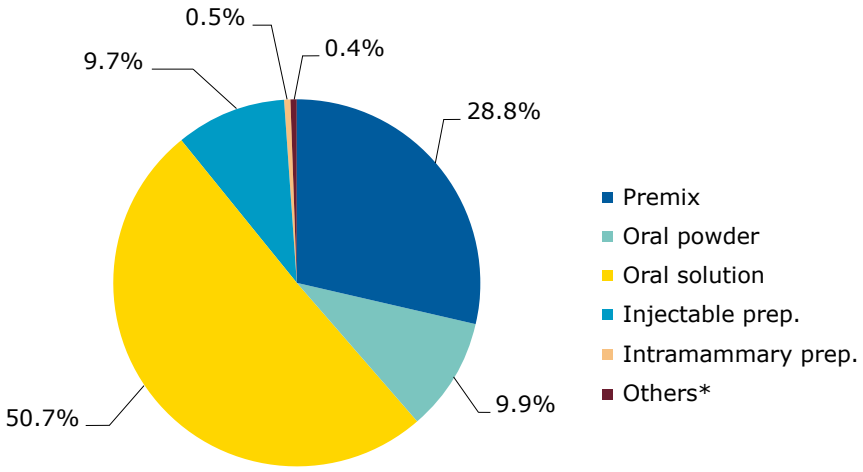
Figure 8. Oral solutions, oral powders and premixes as percentages of total sales, in mg per population correction unit (mg/PCU), of veterinary antimicrobial agents for food-producing animals, in 31 European countries, for 2017



The proportions accounted for by premixes and oral powders vary considerably between the countries, which may be attributed to whether or not the farmers in the country administer medicated feed prepared by a feed mill from premixes, or whether group treatment is carried out by the application of oral powder as, for example, top dressing on the feed at the farm. It may also be influenced by the distribution of animal species, as group medication is used mainly in poultry and pigs, and less, for example, in sheep or goats. The products available as well as national policies for in-feed medication can also influence the sales patterns in terms of pharmaceutical form.

As shown in Figure 9, aggregated by the 31 countries, sales (mg/PCU) of premixes accounted for 28.8% of the overall sales, 9.9% were oral powders and 50.7% were oral solutions, i.e. 89.4% were for group treatment; 9.7% were injectable preparations, 0.5% were intramammary preparations and 0.4% were oral pastes, boluses and intrauterine preparations.

Figure 9. Distribution of sales, in mg/PCU, of the various pharmaceutical forms of veterinary antimicrobial agents for food-producing animals, aggregated by the 31 European countries, for 2017



* Oral pastes, boluses and intrauterine preparations.

Although a small proportion of oral powders and oral solutions are suitable for treatment of single animals or a very limited number of animals, the overall sales figures for these pharmaceutical forms provide a reasonable estimate of sales for group treatment, including groups in one pen/farm.

Additional graphs showing the distribution of sales for the most-selling antimicrobial classes and the highest priority CIAs by pharmaceutical form, aggregated by the 31 European countries, can be found in Annex 1, Figures A4-A7.

2.4. Distribution of sales for food-producing animals – overall and by antimicrobial class and pharmaceutical form

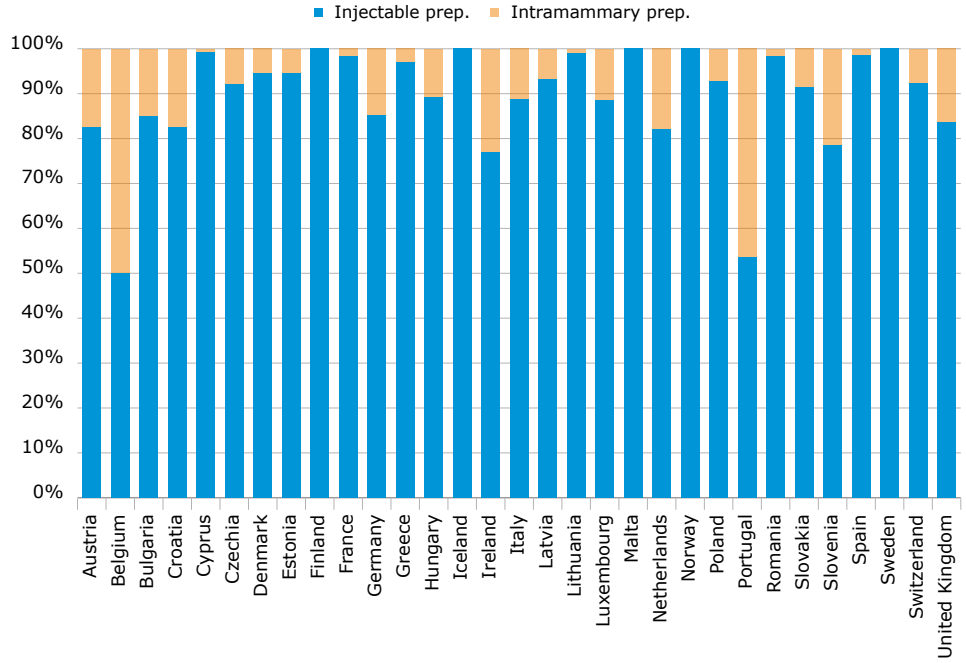
2.4.1. Distribution of sales of antimicrobials for food-producing animals, by country

Figure 10. Spatial distribution of overall sales of all antimicrobials for food-producing animals, in mg/PCU, for 31 countries, for 2017

2.4.1.1. 3rd- and 4th-generation cephalosporins

Figure 11. Spatial distribution of sales of 3rd- and 4th-generation cephalosporins for veterinary use, in mg/PCU, by country, for 2017

Figure 12. Distribution of sales of 3rd- and 4th-generation cephalosporins for veterinary use by pharmaceutical form, in mg/PCU, by country, for 2017[1,2]

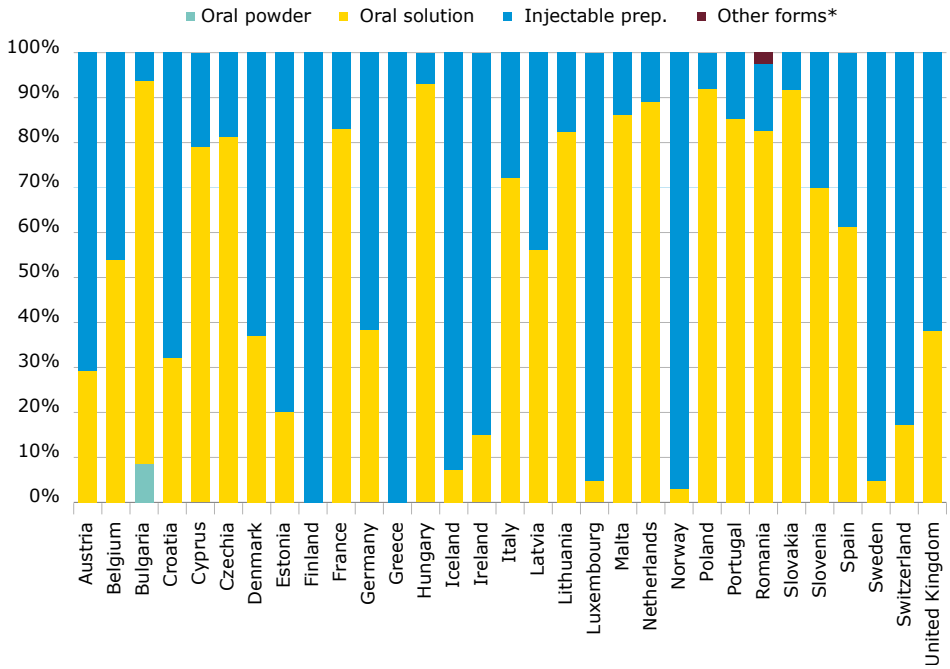


[1] Sales <1 kg in Finland, Iceland, Netherlands and Norway.
[2] For countries where the injectable 3rd- and 4th-generation cephalosporins are almost solely marketed for dogs and cats, the data provide a considerable overestimate for food-producing animals.

2.4.1.2. Fluoroquinolones

Figure 13. Spatial distribution of sales of fluoroquinolones for veterinary use, in mg/PCU, by country, for 2017

Figure 14. Distribution of sales of fluoroquinolones for veterinary use by pharmaceutical form, in mg/PCU, by country, for 2017[1]



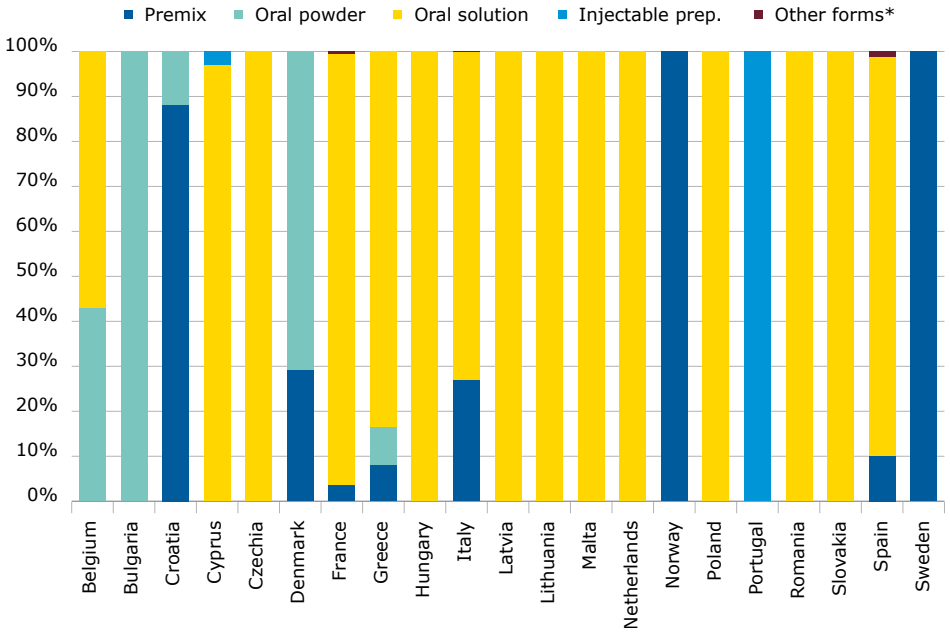
[1] In Iceland, sales of fluoroquinolones were <1kg.
* Other forms include negligible amounts sold as boluses, premixes and/or intrauterine preparations in some countries.

2.4.1.3. Other quinolones

Figure 15. Spatial distribution of sales of other quinolones for veterinary use, in mg/PCU, by country, for 2017[1]

[1] No sales in Austria, Estonia, Finland, Germany, Iceland, Ireland, Luxembourg, Slovenia, Sweden, Switzerland and the United Kingdom.

Figure 16. Distribution of sales of other quinolones for veterinary use by pharmaceutical form, in mg/PCU, by country, for 2017[1]



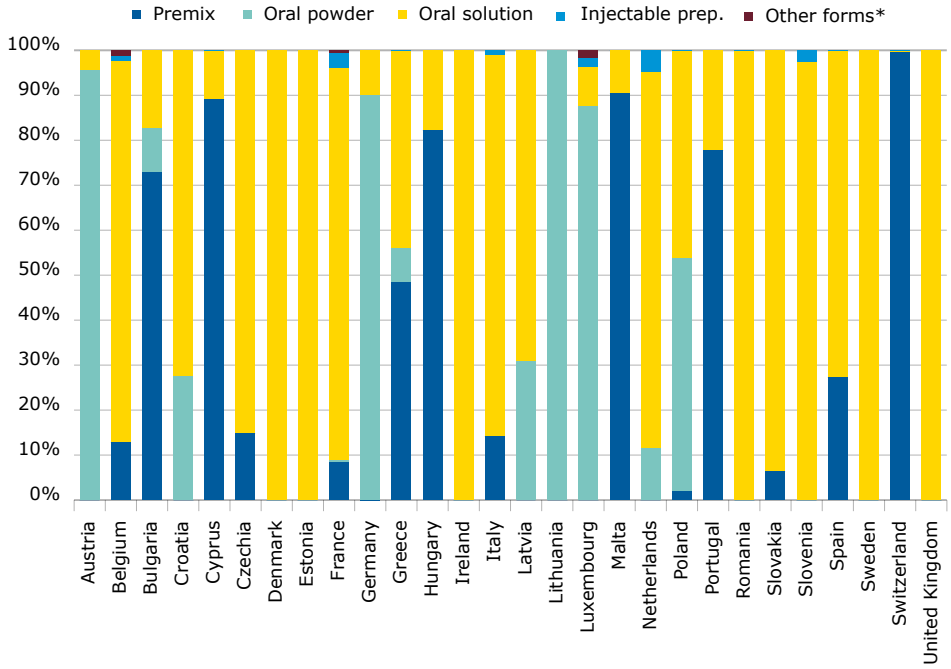
[1] No sales of other quinolones in Austria, Estonia, Finland, Germany, Iceland, Ireland, Luxembourg, Slovenia, Sweden, Switzerland and the United Kingdom; and sales of other quinolones <1kg were observed in Portugal.
* Other forms include negligible amounts sold as boluses and/or oral pastes in some countries.

2.4.1.4. Polymyxins

Figure 17. Spatial distribution of sales of polymyxins for veterinary use, in mg/PCU, by country, for 2017[1]

[1] No sales in Finland, Iceland and Norway.

Figure 18. Distribution of sales of polymyxins for veterinary use by pharmaceutical form, in mg/PCU, by country, for 2017[1]



[1] No sales in Finland, Iceland and Norway.
* Other forms include negligible amounts sold as boluses, oral pastes and/or intramammary preparations in some countries.

2.5. Distribution of the population correction unit (PCU) by species and country

The value of the denominator (PCU) for the various species and countries is shown in Table 6. The EU countries included in the ESVAC 2017 data cover almost 100 % of the food-producing animal population in the EU measured as PCU.

Distribution of the various food-producing species by country, expressed by PCU, is shown in Table 6, Figures 19 and 20.

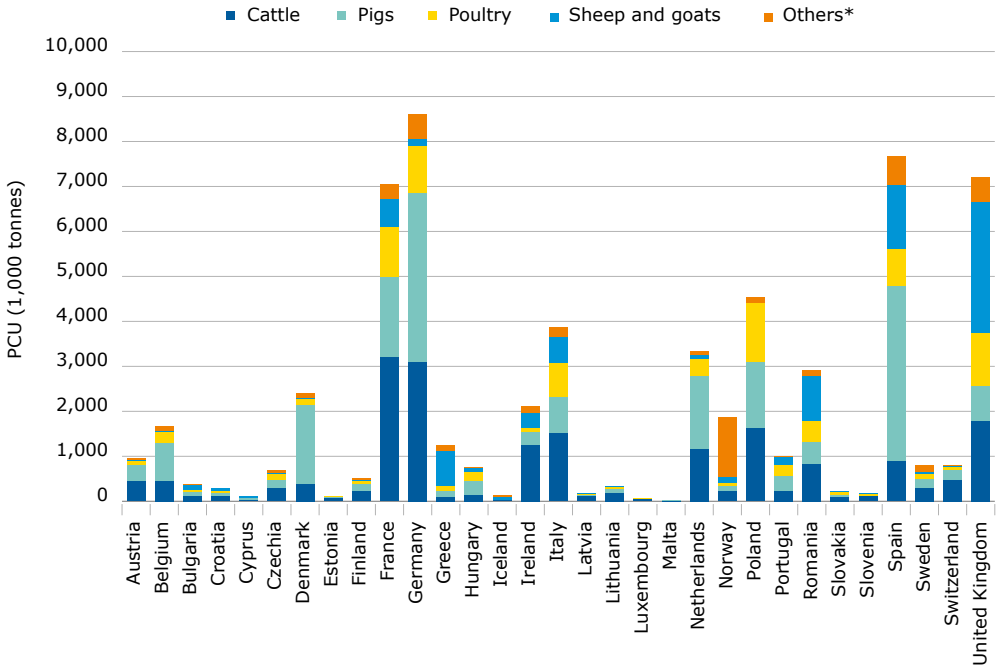
Overall, pigs, cattle, poultry and sheep plus goats accounted for 32 %, 31 %, 14 % and 14 %, respectively, of the PCU in the 31 countries.

Table 6. Estimated PCU (in 1,000 tonnes) of the population of food-producing species[1,2], by country, for 2017

Country	Cattle	Pigs	Poultry	Sheep/ goats	Fish	Rabbits	Horses	Total
Austria	440	364	80	38	0	0	32	954
Belgium	449	842	248	14	0	4	126	1,683
Bulgaria	120	84	46	98	0	0.1	27	375
Croatia	104	88	39	48	17	<0.01	0.1	296
Cyprus	18	45	13	29	0	0.1	2	107
Czechia	283	198	129	18	22	7	36	693
Denmark	387	1,752	132	13	43	0	70	2,398
Estonia	60	37	3	6	1	0	4	111
Finland	219	154	77	13	15	0	30	507
France	3,197	1,782	1,125	620	45	45	225	7,039
Germany	3,102	3,749	1,052	137	19	29	520	8,609
Greece	96	112	129	768	126	0	11	1,243
Hungary	140	307	190	90	21	2	21	771
Iceland	20	6	6	47	21	<0.01	26	125
Ireland	1,247	281	96	345	46	0	100	2,114
Italy	1,509	813	734	589	59	27	133	3,864
Latvia	102	40	21	9	0	0.1	4	176
Lithuania	187	70	57	13	0	0.1	6	333
Luxembourg	41	11	0.1	1	0	0	2	55
Malta	4	4	2	1	0	2	0.4	15
Netherlands	1,160	1,616	377	92	60	0.5	34	3,341
Norway	218	129	66	113	1,287	0	50	1,861
Poland	1,617	1,472	1,309	18	0	2	121	4,539
Portugal	223	344	224	185	11	1	15	1,002
Romania	827	477	481	983	8	0.01	138	2,916
Slovakia	91	46	51	30	1	0.4	6	225
Slovenia	103	18	42	9	2	0.02	10	184
Spain	882	3,902	820	1,414	351	64	251	7,684
Sweden	294	201	103	51	13	0	142	804
Switzerland	475	200	69	29	0	1	22	796
United Kingdom	1,785	766	1,185	2,910	177	0	378	7,202
Total 31 countries	**19,399**	**19,914**	**8,905**	**8,732**	**2,345**	**184**	**2,542**	**62,021**

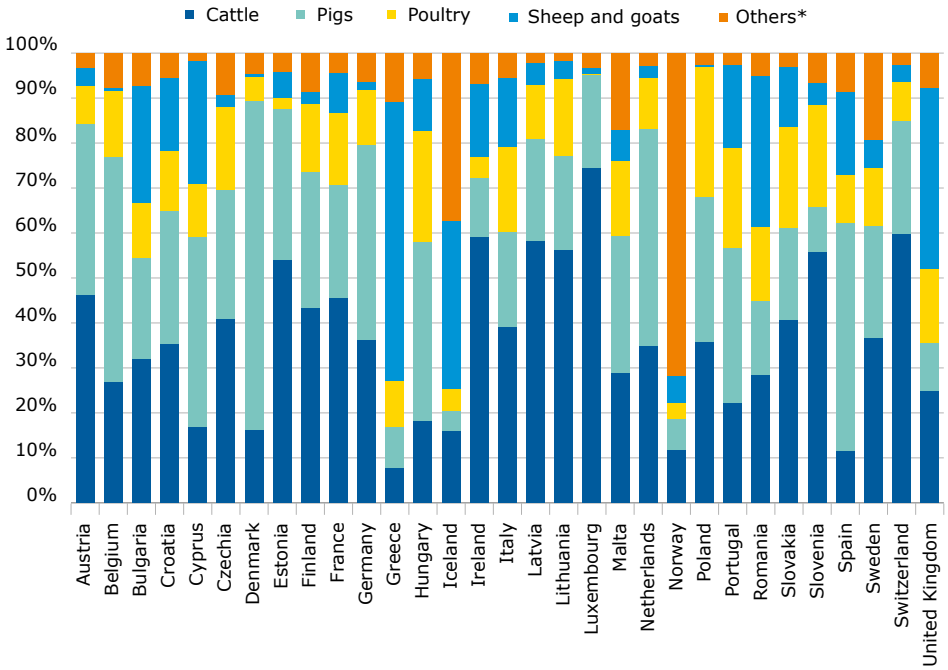
[1] See Annex 3 for animal categories included in the calculation of the PCU.
[2] When PCU is given as zero it indicates insignificant or no production of animals of specific species.

Figure 19. The denominator (PCU) and its distribution by the food-producing animal species (1 PCU = 1 kg), by country, in 2017



* Others include horses and, for some countries, fish and/or rabbits.

Figure 20. Distribution of the denominator (PCU) in weight by food-producing animal species, including horses, by country, in 2017



* Includes horses and, for some countries, fish and/or rabbits.

In 2017, of the 31 countries, 14 had a net export of animals for slaughter or fattening to other Member States which accounted for ≥5% of the total denominator (PCU), whilst 11 countries had a net import accounting for ≥5% of the total denominator.

Table 7. PCU domestic, net export and net import (1000 tonnes) of animals for fattening or slaughter, respectively, to or from another Member State and PCU (net balance) in 2017

Country	PCU Domestic	PCU Export	Proportion, export	PCU Import	Proportion, import	PCU
Austria	1,031	15	2%	92	10%	954
Belgium	1,761	159	9%	237	14%	1,683
Bulgaria	376	0.4	0.1%	2	1%	375
Croatia	313	18	6%	35	12%	296
Cyprus	108	0	0%	0,1	0.1%	107
Czechia	626	77	11%	10	1%	693
Denmark	2,003	395	16%	0	0%	2,398
Estonia	103	11	10%	3	2%	111
Finland	505	3	1%	0	0%	507
France	6,737	325	5%	23	0.3%	7,039
Germany	8,802	444	5%	637	7%	8,609
Greece	1,254	0.03	<0.01%	11	1%	1,243
Hungary	817	35	5%	81	11%	771
Iceland	125	0	0%	0	0%	125
Ireland	2,079	52	2%	17	1%	2,114
Italy	4,106	3	0.1%	245	6%	3,864
Latvia	160	22	12%	5	3%	176
Lithuania	313	31	9%	11	3%	333
Luxembourg	46	13	24%	4	8%	55
Malta	15	0.08	1%	0,01	0.1%	15
Netherlands	3,240	543	16%	443	13%	3,341
Norway	1,861	0	0%	0	0%	1,861
Poland	4,777	20	0.4%	259	6%	4,539
Portugal	1,058	28	3%	84	8%	1,002
Romania	2,900	45	2%	29	1%	2,916
Slovakia	178	66	29%	19	8%	225
Slovenia	171	20	11%	7	4%	184
Spain	7,728	104	1%	147	2%	7,684
Sweden	804	<0.001	<0.01%	0.01	<0.01%	804
Switzerland	796	2	0.2%	1	0.2%	796
United Kingdom	7,223	14	0.2%	34	0.5%	7,202

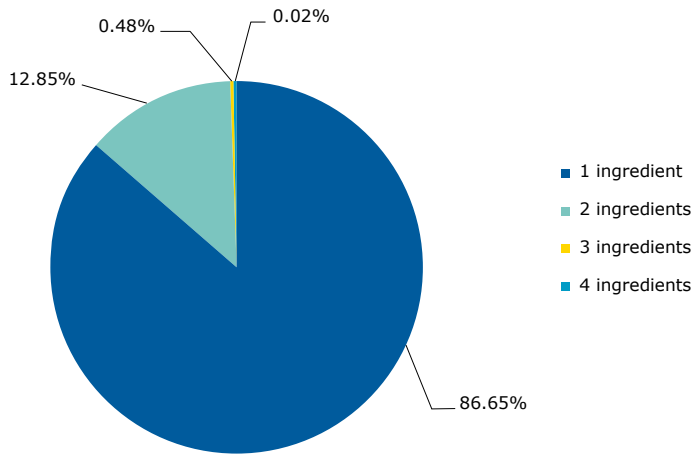
2.6. Distribution of single- and multiple-ingredient products of veterinary antimicrobial agents

Of the 9,387 product presentations (tablets excluded) for which sales were reported, 82.7% (n=7,759) contained only one active ingredient, 14.9% (n=1,401) contained two active ingredients, and 2.2% (n=203) contained three active ingredients (Annex 1, Table A7). In addition, 0.3% (n=24) of the product presentations contained four active ingredients. Sales of products with three active ingredients were accounted for almost exclusively by products for individual treatment (injections, intramammary and intrauterine preparations).

For all 31 countries, 44.2% of the product presentations of antimicrobial VMPs were for group treatment, i.e. premixes, oral powders and oral solutions. Of these, 86.4% contained one active ingredient, 12.4% two active ingredients, and 1.1% contained three active ingredients (Annex 1, Table A8).

Across the 31 countries, of the total sales of premixes, oral powders and oral solutions, in tonnes of active ingredient, 86.65%, 12.85% and 0.48% were accounted for by products containing 1, 2 and 3 active ingredients, respectively (Figure 21).

Figure 21. Percentage of sales for veterinary use, in tonnes of active ingredient, of premixes, oral powders and oral solutions containing 1, 2, 3 and 4 antimicrobial agents, in 2017



2.7. Changes over time

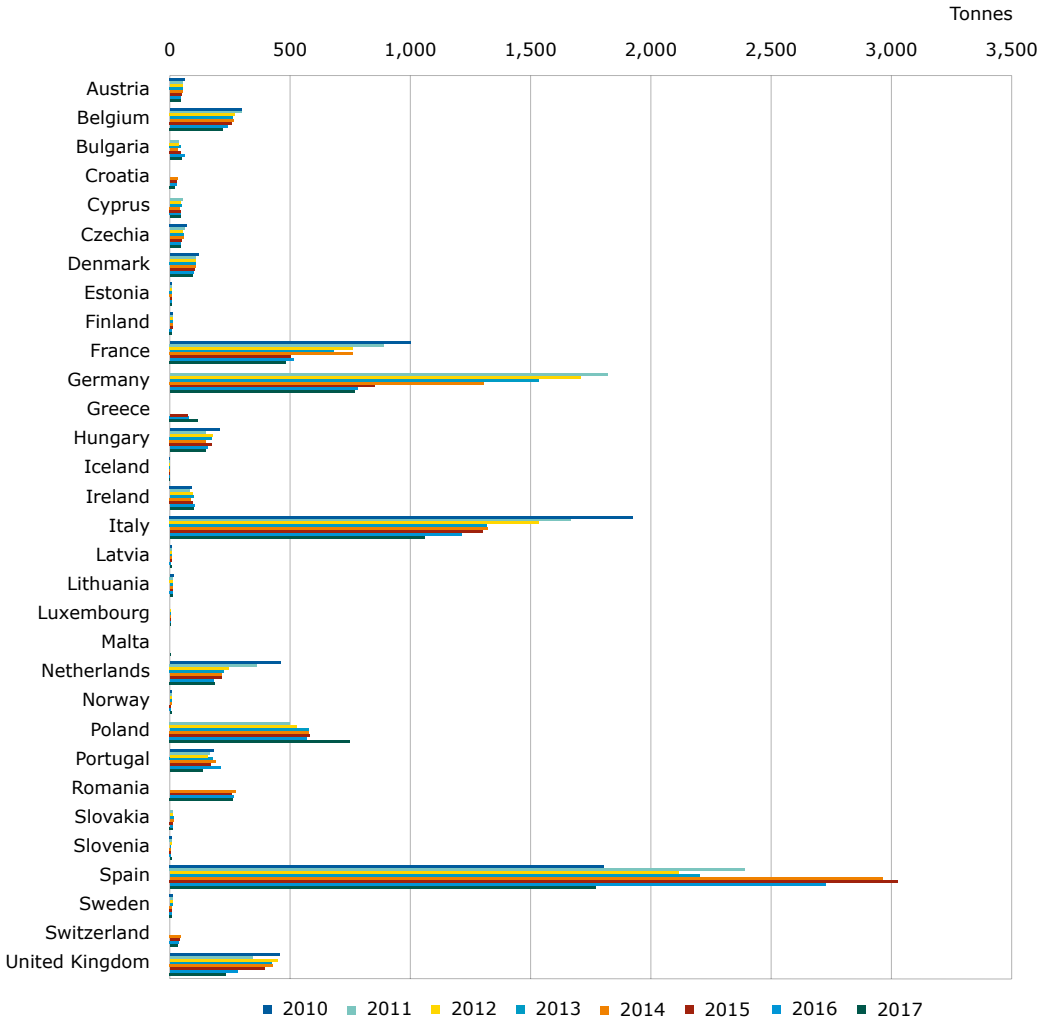
Throughout the report, there is a special focus on those antimicrobials that either belong to the high-selling classes or are among those considered of the highest importance in the AMEG categorisation, or are included in the WHO list of the highest priority CIAs (see Annex 5). Following the list of harmonised outcome indicators to assist EU Member States in assessing their progress in reducing the use of antimicrobials and antimicrobial resistance in both humans and food-producing animals, jointly established by ECDC, EFSA and EMA, the emphasis on food-producing animals lies on overall sales (mg/PCU) of antimicrobials (primary indicator) and sales of 3rd- and 4th-generation cephalosporins, quinolones (specifying the proportion of fluoroquinolones) and polymyxins (secondary indicators) for veterinary use.

Chapter 2.7 presents the changes over time for all participating countries for the most-sold classes (tetracyclines, penicillins and sulfonamides), the antimicrobials belonging to AMEG Category 2 – i.e. 3rd- and 4th-generation cephalosporins, fluoroquinolones and polymyxins, as well as those additional classes classified by the WHO as the highest priority CIAs for human medicine – i.e. macrolides and other quinolones (glycopeptides, belonging to the list of HP CIAs, are not authorised for use in food-producing animals in the countries participating in ESVAC) (Table A16).

2.7.1. Overall changes in the ESVAC participating countries

2.7.1.1. Changes in sales of tonnes of active ingredients, by country

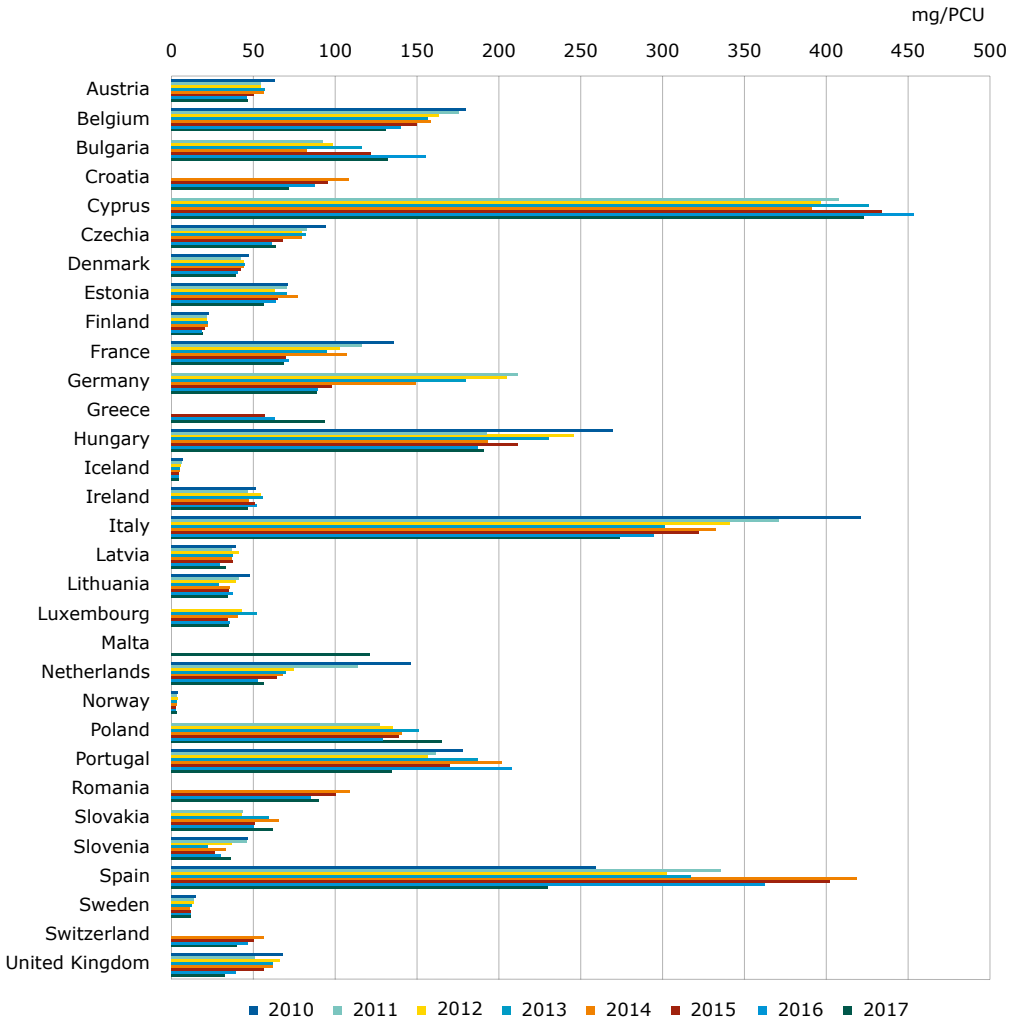
Figure 22. Sales, in tonnes of active ingredients, of veterinary antimicrobials for food-producing animals, by country, between 2010 to 2017[1-9]



[1] Corrections to sales data published in the ESVAC 2016 report are described in Chapter 1.5.
[2] Under-reported for Bulgaria for 2011, 2012 and 2014 as several wholesalers failed to report data.
[3] Strength reported as the base for most VMPs for 2011-2012 for Czechia; for 2013-2017, strength reported as in the VMPs' label.
[4] Strength reported as the base for some VMPs for 2011-2012 for the Netherlands; for 2013-2017, strength reported as in the label of the VMPs.
[5] For Portugal, under-reporting has been identified for 2010-2014 and 2017.
[6] For Romania, 2014 data were updated, as wholesalers initially failed to deliver all sales data.
[7] For Slovakia, for 2011 and 2012, the data only represents antimicrobial VMPs imported by wholesalers; from 2013, data represents all sales from wholesalers to end-users (veterinarians, pharmacies, producers of medicated feeding stuffs and farmers, obtained by import and from national manufacturers).
[8] For Spain, under-reporting has been identified for 2010 to 2013 (underestimates) and sales data providers for 2017 changed from MAHs to retailers.
[9] For the UK, high sales of certain products containing tetracyclines late in 2010 were probably used in 2011 and thus their use has been underestimated for 2011.

2.7.1.2. Changes in overall sales in mg/PCU, by country

Figure 23. Total sales of veterinary antimicrobials for food-producing species, in mg/PCU, by country, from 2010 to 2017[1-9]



[1] Corrections to sales data and/or PCU data published in the ESVAC 2016 report are described in Chapter 1.5.
[2] Under-reported for Bulgaria for 2011, 2012 and 2014 as several wholesalers failed to report data.
[3] Strength reported as the base for most VMPs for 2011-2012 for Czechia; for 2013-2017, strength reported as in the label of the VMPs.
[4] Strength reported as the base for some VMPs for 2011-2012 for the Netherlands; for 2013-2017, strength reported as in the VMPs' label.
[5] For Portugal, under-reporting has been identified for 2010-2014 and 2017.
[6] For Romania, 2014 data were updated, as wholesalers initially failed to deliver all sales data.
[7] For Slovakia, for 2011 and 2012, the data represent antimicrobial VMPs imported by wholesalers; from 2013, data represent all sales from wholesalers to end-users (veterinarians, pharmacies, producers of medicated feeding stuffs and farmers, obtained by import and from national manufacturers).
[8] For Spain, under-reporting for the years 2010 to 2013 has been identified (underestimated) and the data provider for 2017 data was changed from MAHs to retailers.
[9] For the UK, high sales of certain tetracycline-containing products late in 2010 were probably used in 2011 and thus their use has been underestimated for 2011.

For the 25 countries that reported data for all years from 2011 to 2017, a drop of more than 5% (range -7.7% to -57.9%) in sales (mg/PCU) was observed for 19 countries (Table 8). For three countries, an increase of more than 5% was noted (range 29.8% to 42.9%).

Table 8. Annual sales of veterinary antimicrobial agents for food-producing species, in mg/PCU, by country[1], from 2010 to 2017

Country	2010	2011	2012	2013	2014	2015	2016	2017	Trends 2010-2017
Austria	62.9	54.5	54.9	57.2	56.3	50.7	46.1	46.8	
Belgium	180.1	175.3	163.1	156.6	158.3	150.1	140.1	131.3	
Bulgaria[2]		92.6	98.9	116.1	82.9	121.9	155.3	132.3	
Croatia					108.6	95.6	87.9	71.5	
Cyprus		407.6	396.5	425.8	391.5	434.2	453.4	423.1	
Czechia[3]	94.3	83.0	79.8	82.2	79.5	68.1	61.2	63.6	
Denmark	47.5	42.6	44.1	44.9	44.2	42.2	40.8	39.4	
Estonia	70.9	70.7	62.9	70.4	77.1	65.2	64.0	56.7	
Finland	22.7	21.9	21.8	22.4	22.3	20.4	18.6	19.3	
France	136.0	116.5	102.7	95.0	107.0	70.2	71.9	68.6	
Germany		211.5	204.8	179.7	149.3	97.9	89.2	89.0	
Greece						57.2	63.5	93.9	
Hungary	269.9	192.5	245.8	230.7	193.1	211.4	187.1	191.0	

Country	2010	2011	2012	2013	2014	2015	2016	2017	Trends 2010-2017
Iceland	7.0	6.2	5.5	5.1	4.9	4.9	4.7	4.6	
Ireland	51.5	46.5	55.0	55.9	47.6	51.0	52.1	46.6	
Italy	421.1	371.0	341.0	301.6	332.4	322.0	294.8	273.8	
Latvia	39.5	36.7	41.5	37.7	36.7	37.6	29.9	33.3	
Lithuania	48.2	41.3	39.2	29.1	35.5	35.1	37.7	34.8	
Luxembourg			43.2	52.1	40.9	34.6	35.5	35.0	
Malta								121.0	
Netherlands[4]	146.1	113.8	74.9	69.9	68.4	64.4	52.7	56.3	
Norway	4.0	3.6	3.8	3.6	3.1	2.9	2.9	3.1	
Poland		127.3	135.2	151.5	140.8	138.9	129.4	165.2	
Portugal[5]	177.9	161.8	156.9	187.2	201.6	170.2	208.0	134.8	
Romania[6]					109.0	100.5	85.2	90.1	
Slovakia[7]		43.7	43.3	59.3	65.9	51.0	50.4	61.9	
Slovenia	46.9	46.1	37.0	22.4	33.4	26.4	30.3	36.5	
Spain[8]	259.5	335.8	302.4	317.1	418.8	402.0	362.5	230.3	
Sweden[9]	15.2	13.6	13.5	12.7	11.5	11.8	12.1	11.8	

Country	2010	2011	2012	2013	2014	2015	2016	2017	Trends 2010-2017
Switzerland					56.7	50.6	46.6	40.1	
United Kingdom[10]	67.9	51.1	66.3	62.1	62.5	56.8	39.3	32.5	

[1] Corrections to sales data and/or PCU data published in the ESVAC 2016 report are described in Chapter 1.5.
[2] Under-reported for Bulgaria for 2011, 2012 and 2014 as several wholesalers failed to report data.
[3] Strength reported as the base for most VMPs for 2011-2012 for Czechia; for 2013-2017, strength reported as in the label of the VMPs.
[4] Strength reported as base for some VMPs for 2011-2012 for the Netherlands; for 2013-2017, strength reported as in the label of the VMPs.
[5] For Portugal, under-reporting has been identified for the years 2010-2014 and 2017.
[6] For Romania, 2014 data were updated as wholesalers initially failed to deliver all sales data.
[7] For Slovakia, the data for 2011 and 2012 represent only imported antimicrobial VMPs by wholesalers; from 2013, data represent all sales from wholesalers to end-users (veterinarians, pharmacies, producers of medicated feeding stuffs and farmers, obtained by import and from national manufacturers).
[8] For Spain, under-reporting has been identified for the years 2010 to 2013 and the data provider for 2017 data was changed from MAHs to retailers.
[9] For Sweden, underreporting of sales for use in farmed fish in 2017.
[10] For the UK, high sales of certain tetracycline-containing products late in 2010 were probably used in 2011 and thus their use has been underestimated for 2011.

Spain changed its system for collecting sales data in 2014 and in 2017, and it was noted that some of the highest-selling VMPs in 2014 had not been reported by MAHs between 2011 and 2013, even though these VMPs had been marketed during that period. Thus, sales data for Spain for 2011 to 2013 are most likely underestimated. Consumption of veterinary antimicrobials in Spain is one of the highest among the countries participating in ESVAC and the biomass of animals (PCU) is among the largest. Therefore, the observed changes in sales for these 25 countries from 2011 to 2017 should be interpreted with this in mind.

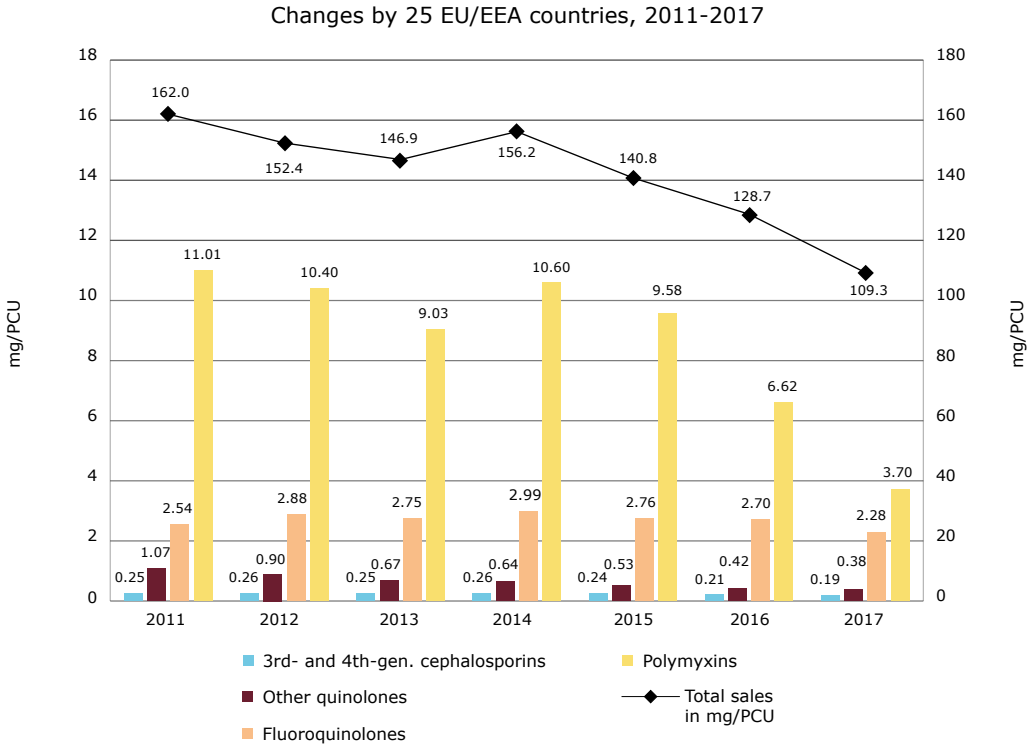
Changes in sales (mg/PCU) across 2011-2016 aggregated by 25 countries

For the 25 countries reporting sales data to the ESVAC for each year from 2011 to 2017, an overall decrease of 32.5% in sales (mg/PCU) was observed (Figure 24).

For the period 2011 to 2017, a drop in sales (in mg/PCU) of more than 5% was observed for 19 of the 25 countries. For the same period, there was an increase in sales of over 5% in three of the 25 countries (Table 8).

During 2011-2017, the sales (mg/PCU) of 3rd- and 4th-generation cephalosporins decreased by 20.9%, sales of polymyxins decreased by 66.4%, and sales of fluoroquinolones declined by 10.3% and sales of other quinolones by 64.7%.

Figure 24. Changes in aggregated overall sales, as well as sales of fluoroquinolones, other quinolones, 3rd- and 4th-generation cephalosporins and polymyxins, for 25 EU/EEA countries[1], from 2011 to 2017 (note the differences in the scales of the Y axes)



[1] Austria, Belgium, Bulgaria, Cyprus, Czechia, Denmark, Estonia, Finland, France, Germany, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Netherlands, Norway, Poland, Portugal, Slovakia, Slovenia, Spain, Sweden and United Kingdom.

For those 25 countries delivering data from 2011 to 2017, a decrease in sales of all antimicrobial classes has been observed, with the exception of amphenicols and lincosamides (Figure 25). During the period 2011 to 2017, the decline in three most-selling antimicrobial classes – tetracyclines, penicillins and sulfonamides – was 44 %, 18 % and 46 %, respectively.

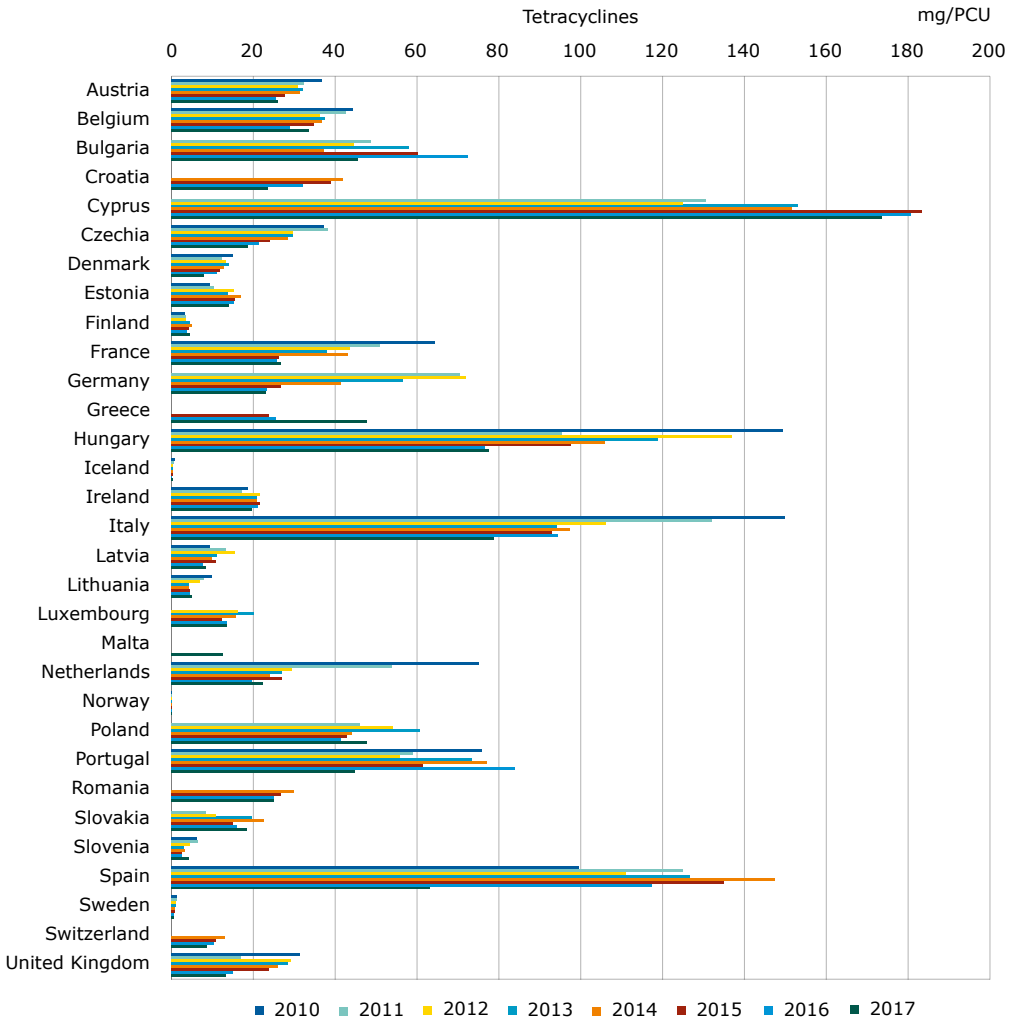
Figure 25. Changes in aggregated sales (mg/PCU) by antimicrobial class in 25 EU/EEA countries[1], from 2011 to 2017

[1] Austria, Belgium, Bulgaria, Cyprus, Czechia, Denmark, Estonia, Finland, France, Germany, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Netherlands, Norway, Poland, Portugal, Slovakia, Slovenia, Spain, Sweden and United Kingdom.
*Other antibacterials (classified as such in the ATCvet system).

2.7.1.3. Changes in sales by antimicrobial class in mg/PCU, by country

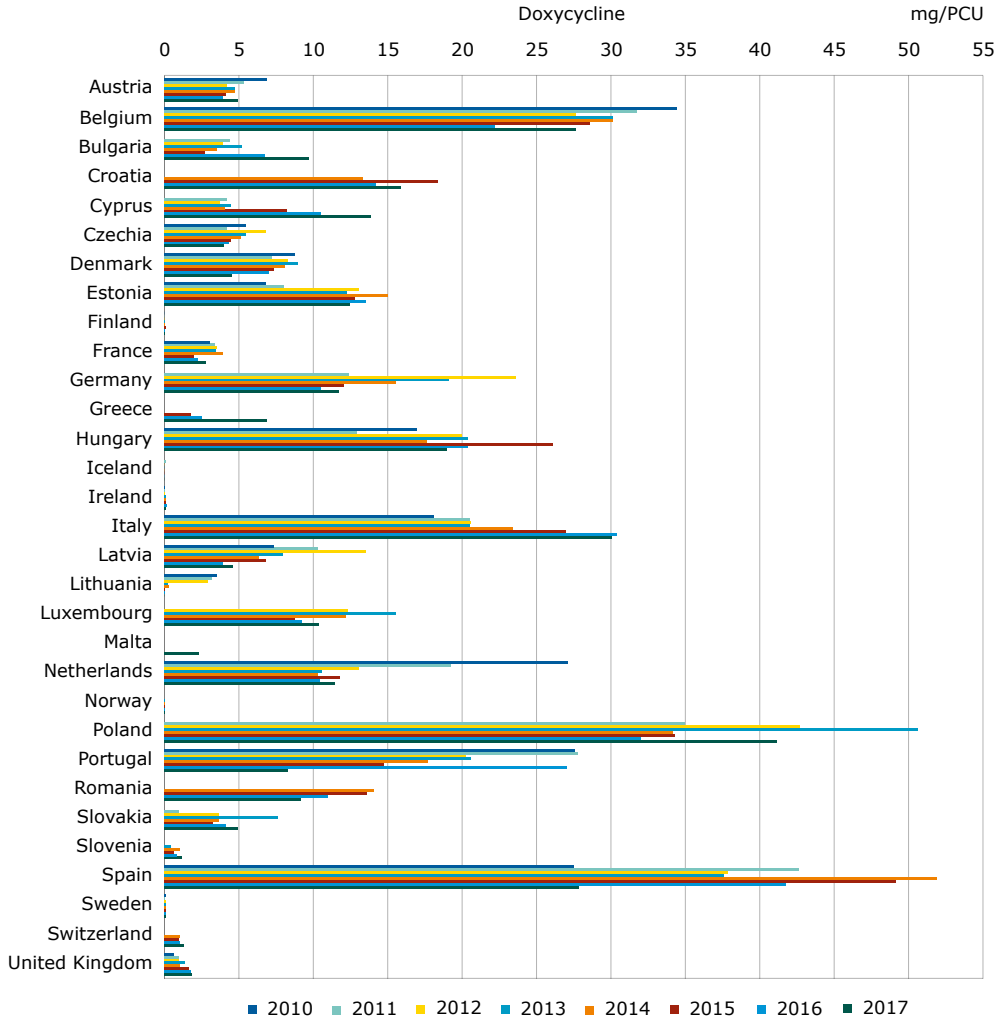
Sales of tetracyclines, a class of antimicrobials with a high volume of sales for veterinary use, are shown in Figure 26. The sales of doxycycline are also presented separately (Figure 27) because of the lower dosing used in the treatment of animals compared to other tetracyclines. Therefore, an increase in the sales of doxycycline could be associated with a reduction in total sales of tetracyclines.

Figure 26. Changes in sales of tetracyclines for food-producing species, in mg/PCU, by country, from 2010 to 2017[1]



[1] Sales in Iceland, Norway and Sweden ≤1 mg/PCU in any of the years.

Figure 27. Changes in sales of doxycycline for food-producing species, in mg/PCU, by country, from 2010 to 2017[1]



[1] No sales in Iceland since 2012, and only a negligible amount sold in 2011; in Finland, Ireland, Norway and Sweden, no sales reported for some of the years or sales were very low (≤0.14 mg/PCU); since 2015, sales of doxycycline in Lithuania have been low (<0.03 mg/PCU) with no sales reported in 2017.

Figure 28. Changes in sales of penicillins for food-producing species, in mg/PCU, by country, from 2010 to 2017

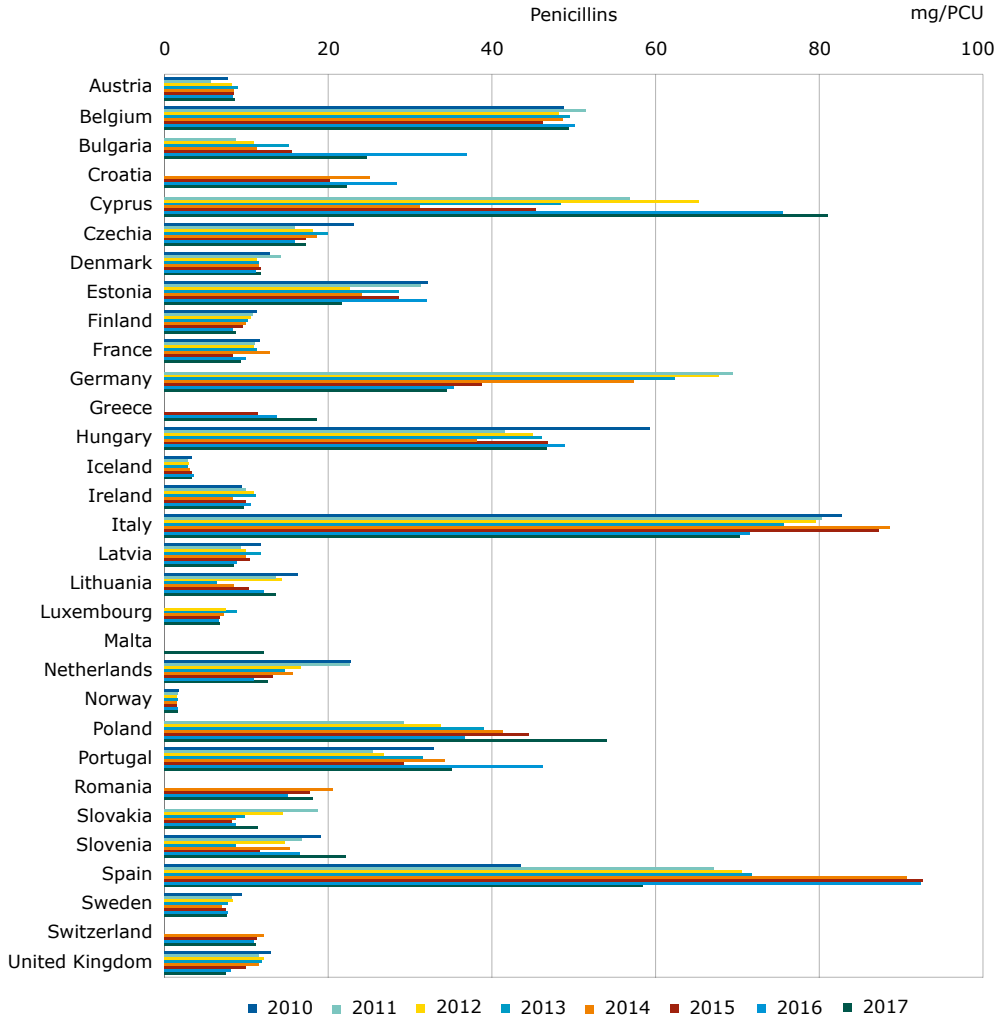
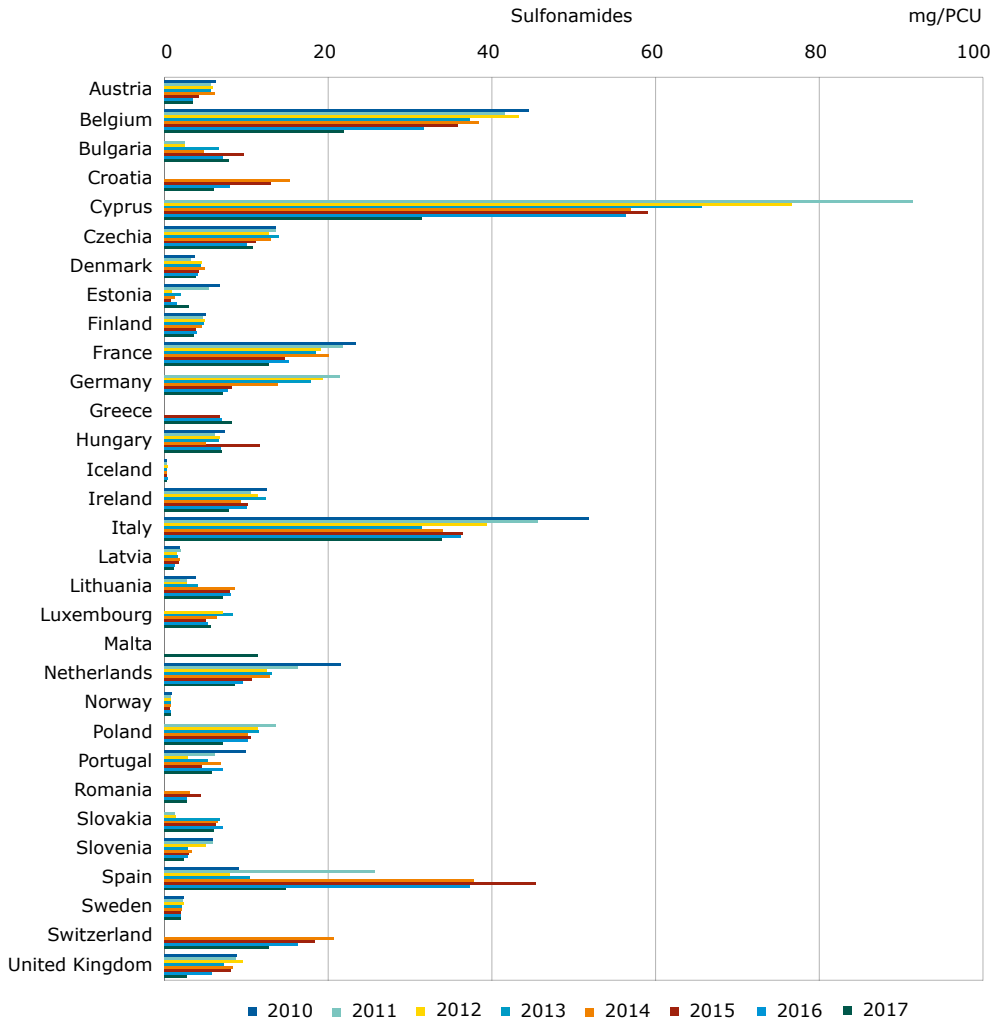


Figure 29. Changes in sales of sulfonamides for food-producing species, in mg/PCU, by country, from 2010 to 2017[1]



[1] Negligible sales in Iceland and Norway (<1mg/PCU) in any of the years.

Tables 9 to 11 and Figures 30 and 31 highlight critically important antimicrobials with the highest priority for humans, as defined by WHO, and antimicrobial classes belonging to the AMEG Category 2. More details on the selection of antimicrobial classes of WHO HP CIAs and AMEG Category 2 are provided in Annex 5, Table A16.

Table 9. Changes in sales of 3rd- and 4th-generation cephalosporins for food-producing species, in mg/PCU, by country, from 2010 to 2017[1]. Note that the scale differs between countries.

Country	2010	2011	2012	2013	2014	2015	2016	2017	Trends 2010-2017
Austria	0.3	0.3	0.3	0.3	0.2	0.2	0.2	0.2	
Belgium	0.5	0.5	0.5	0.5	0.5	0.4	0.3	0.1	
Bulgaria		0.05	0.03	0.1	0.1	0.2	0.1	0.1	
Croatia					0.1	0.2	0.2	0.2	
Cyprus		0.2	0.5	0.5	0.8	0.3	0.7	0.4	
Czechia	0.4	0.3	0.3	0.4	0.4	0.4	0.4	0.5	
Denmark	0.05	0.03	0.03	0.02	0.02	<0.01	<0.01	<0.01	
Estonia	0.4	0.5	0.6	0.7	0.6	0.6	0.7	0.8	
Finland	<0.01	0.02	0.03	0.02	0.02	0.01	<0.01	<0.01	
France	0.3	0.3	0.3	0.3	0.3	0.2	0.1	0.02	
Germany		0.4	0.4	0.4	0.4	0.4	0.4	0.4	
Greece						0.1	0.1	0.1	
Hungary	0.3	0.1	0.3	0.3	0.2	0.4	0.4	0.5	
Iceland	<0.01	0.01	<0.01	<0.01	<0.01	<0.01	<0.01	<0.01	
Ireland	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1	

Country	2010	2011	2012	2013	2014	2015	2016	2017	Trends 2010-2017
Italy	0.4	0.4	0.4	0.4	0.4	0.4	0.4	0.4	
Latvia	0.2	0.2	0.4	0.4	0.4	0.4	0.3	0.3	
Lithuania	0.02	0.04	0.1	0.2	0.2	0.1	0.1	0.2	
Luxembourg			0.7	0.7	0.6	0.6	0.7	0.6	
Malta								0.2	
Netherlands	0.2	0.2	0.02	<0.01	<0.01	<0.01	<0.01	<0.01	
Norway	<0.01	<0.01	<0.01	<0.01	<0.01	<0.01	<0.01	<0.01	
Poland		0.1	0.1	0.2	0.2	0.1	0.2	0.2	
Portugal	0.3	0.3	0.2	0.4	0.4	0.5	0.5	0.6	
Romania					0.05	0.04	0.1	0.2	
Slovakia		0.7	0.5	0.4	0.5	0.3	0.4	0.4	
Slovenia	0.1	0.1	0.2	0.1	0.1	0.2	0.2	0.2	
Spain	0.7	0.3	0.3	0.3	0.3	0.3	0.3	0.2	
Sweden	0.02	0.02	0.01	<0.01	<0.01	<0.01	<0.01	<0.01	
Switzerland					0.2	0.2	0.2	0.2	
United Kingdom	0.2	0.2	0.2	0.2	0.2	0.2	0.1	0.1	

[1] For countries where the injectable 3rd- and 4th-generation cephalosporins are almost solely marketed for dogs and cats, the data provide a considerable overestimate for food-producing animals.

Table 10. Changes in sales of fluoroquinolones for food-producing species, in mg/PCU, by country, from 2010 to 2017. Note that the scale differs between countries.

Country	2010	2011	2012	2013	2014	2015	2016	2017	Trends 2010-2017
Austria	0.6	0.6	0.5	0.6	0.5	0.5	0.5	0.5	
Belgium	0.7	0.8	0.9	1.0	1.1	1.0	0.6	0.2	
Bulgaria		5.0	6.1	6.8	1.8	5.3	4.9	5.7	
Croatia					3.5	3.3	2.6	1.9	
Cyprus		0.5	0.8	0.9	0.9	1.1	1.6	2.4	
Czechia	1.3	1.5	1.8	1.8	1.8	1.7	1.7	1.9	
Denmark	<0.01	<0.01	<0.01	<0.01	<0.01	<0.01	<0.01	<0.01	
Estonia	2.5	2.3	1.1	1.7	1.6	1.8	1.3	1.3	
Finland	0.2	0.2	0.2	0.2	0.2	0.1	0.1	0.1	
France	0.7	0.6	0.6	0.6	0.6	0.3	0.2	0.2	
Germany		0.9	1.2	1.4	1.4	1.1	1.0	1.1	
Greece						1.7	2.2	2.7	
Hungary	8.8	6.7	11.0	9.2	9.1	9.5	9.6	8.8	
Iceland	<0.01	<0.01	<0.01	<0.01	<0.01	<0.01	<0.01	<0.01	
Ireland	0.4	0.4	0.6	0.5	0.4	0.4	0.5	0.4	

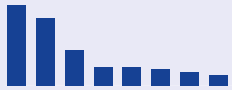
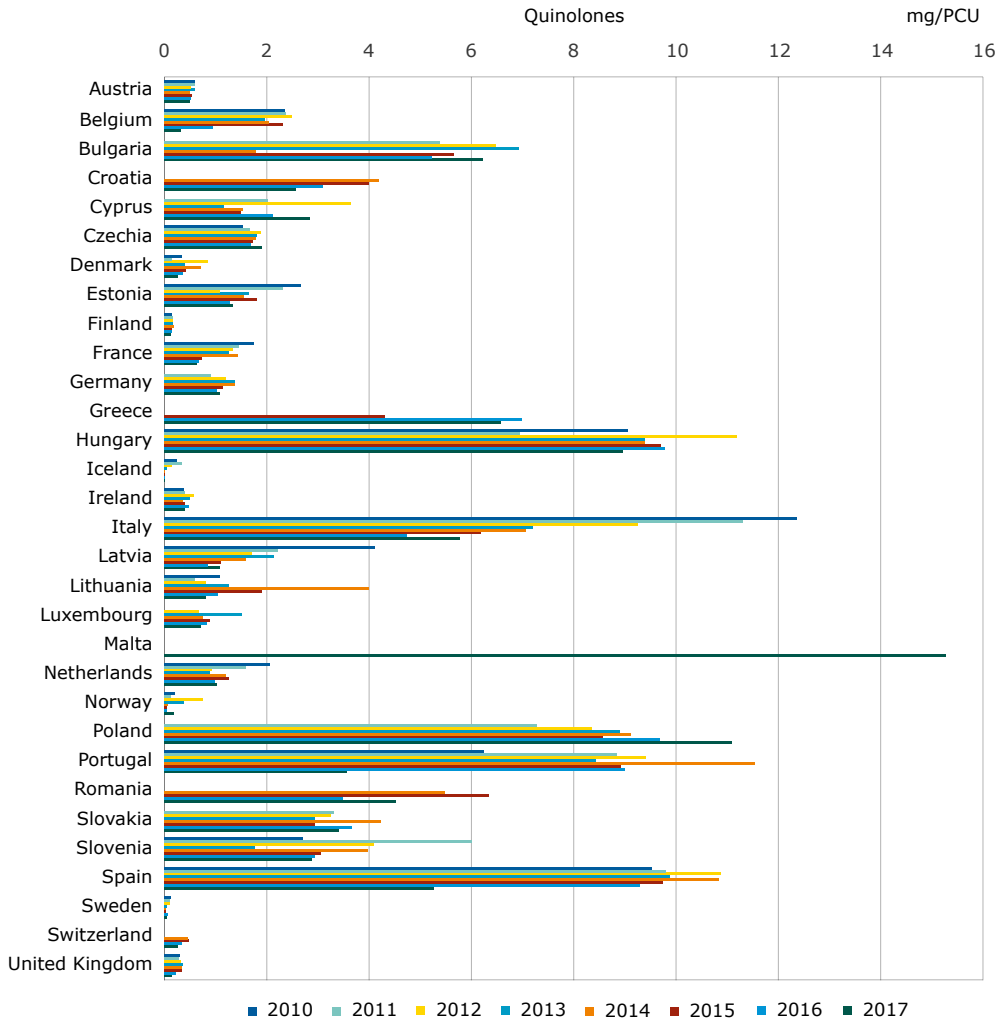
Country	2010	2011	2012	2013	2014	2015	2016	2017	Trends 2010-2017
Italy	1.7	2.2	2.5	2.3	3.1	2.9	2.3	3.0	
Latvia	4.1	2.2	1.7	2.1	1.6	1.1	0.8	1.1	
Lithuania	0.7	0.4	0.6	0.8	3.1	1.7	1.0	0.8	
Luxembourg			0.7	0.8	0.7	0.7	0.8	0.7	
Malta								14.3	
Netherlands	0.5	0.5	0.2	0.1	0.1	0.1	0.1	0.1	
Norway	0.01	0.01	<0.01	<0.01	<0.01	<0.01	<0.01	<0.01	
Poland		7.2	8.2	8.8	9.0	8.6	9.7	11.1	
Portugal	5.6	8.4	9.3	8.2	11.4	8.8	8.9	3.6	
Romania					5.3	6.1	3.3	4.3	
Slovakia		3.0	3.2	2.8	4.2	2.9	3.6	3.4	
Slovenia	2.6	5.9	4.1	1.8	4.0	3.0	2.9	2.9	
Spain	8.8	9.2	10.2	9.3	9.9	9.0	8.5	4.9	
Sweden	0.1	0.1	0.1	0.04	0.03	0.02	0.02	0.02	
Switzerland					0.5	0.5	0.3	0.3	
United Kingdom	0.3	0.3	0.3	0.4	0.4	0.3	0.2	0.2	

Figure 30. Changes in sales of quinolones (fluoroquinolones and other quinolones) for food-producing species, in mg/PCU, by country, from 2010 to 2017[1]



[1] In Austria, Denmark, Finland, Iceland, Ireland, Norway, Sweden, Switzerland and United Kingdom, combined sales of fluoroquinolones and other quinolones were <1mg/PCU in any of the years.

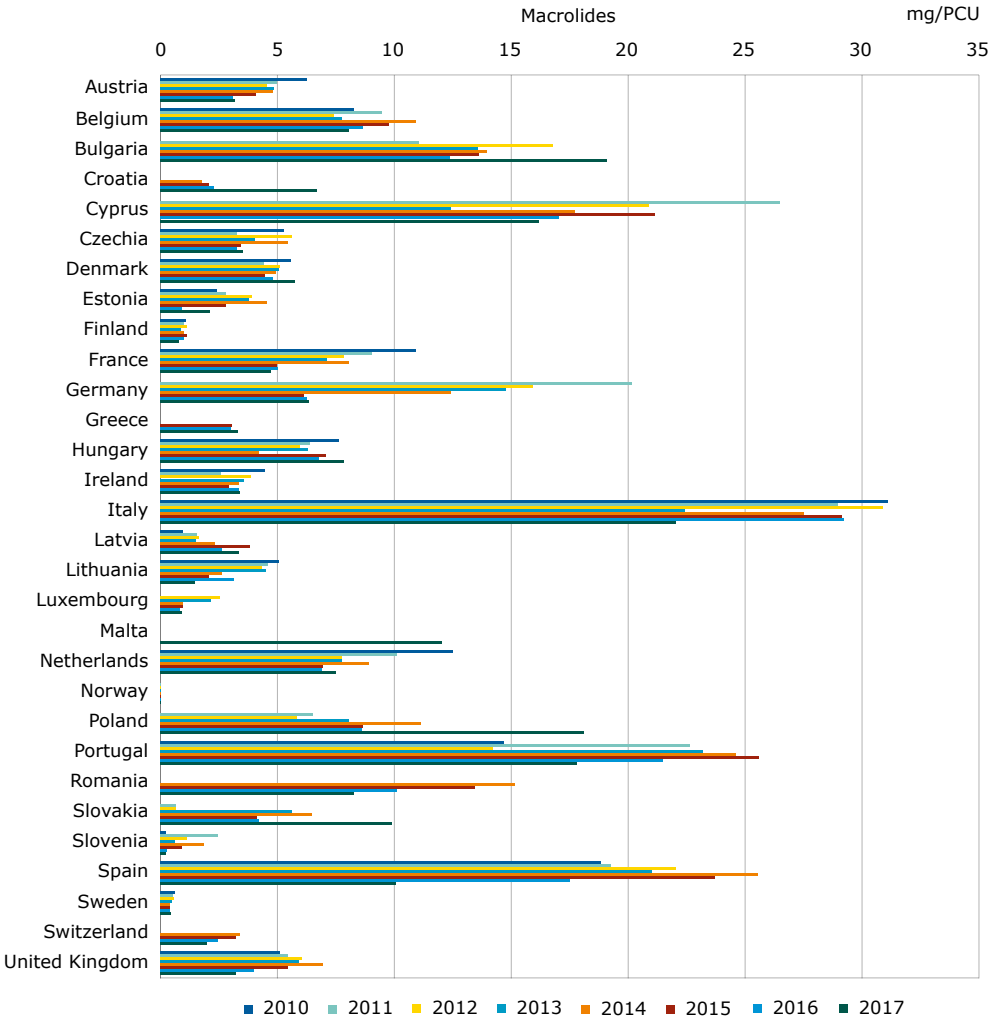
Table 11. Changes in sales of polymyxins for food-producing species, in mg/PCU, by country, from 2010 to 2017[1,2]. Note that the scale differs between countries.

Country	2010	2011	2012	2013	2014	2015	2016	2017	Trends 2010-2017
Austria	1.0	1.0	0.7	0.9	1.6	1.6	1.6	1.7	
Belgium	6.0	5.4	5.8	4.7	3.4	2.8	2.4	2.1	
Bulgaria		3.2	3.8	2.7	0.5	3.6	2.3	3.0	
Croatia					3.8	2.4	3.6	3.2	
Cyprus		8.2	8.1	8.4	11.1	12.4	11.1	10.4	
Czechia	0.9	0.6	0.9	1.1	1.0	1.0	0.8	0.6	
Denmark	0.3	0.2	0.2	0.2	0.4	0.5	0.5	0.2	
Estonia	3.5	4.3	4.9	5.8	3.1	1.3	0.7	1.1	
France	8.7	7.8	6.8	5.9	7.1	4.1	2.8	2.2	
Germany		14.8	14.8	14.6	12.2	9.2	7.9	8.5	
Greece						3.4	1.0	1.3	
Hungary	6.9	8.9	7.8	10.0	7.1	9.6	12.2	14.9	
Italy	40.2	30.7	30.1	27.6	29.4	26.1	15.1	5.2	
Latvia	1.0	1.0	2.5	1.5	0.8	0.9	0.9	1.3	

Country	2010	2011	2012	2013	2014	2015	2016	2017	Trends 2010-2017
Lithuania	1.7	1.4	1.3	0.1	0.1	0.6	1.0	0.7	
Luxembourg			1.7	3.1	2.4	1.5	1.0	1.0	
Malta								4.6	
Netherlands	2.3	1.6	1.0	0.6	0.5	0.5	0.3	0.3	
Poland		4.2	4.0	4.4	5.0	5.9	5.6	7.5	
Portugal	15.1	7.9	18.6	19.0	17.6	14.6	13.5	10.9	
Romania					6.5	7.4	5.6	4.1	
Slovakia		1.2	2.1	1.1	1.5	1.1	1.2	1.7	
Slovenia	0.1	0.1	0.1	0.04	0.1	0.1	0.1	0.1	
Spain	33.0	33.5	29.4	21.5	36.1	34.9	22.0	4.4	
Switzerland					0.9	0.6	0.5	0.4	
United Kingdom	0.1	0.1	0.1	0.1	0.1	0.1	0.02	<0.01	

[1] No sales of polymyxins in Finland, Iceland and Norway for any of the years.
[2] For reasons of commercial confidentiality, sales of polymyxins in Ireland and Sweden (≤0.1 mg/PCU in any of the years) are not included in this table.

Figure 31. Changes in sales of macrolides for food-producing species, in mg/PCU, by country, from 2010 to 2017[1]



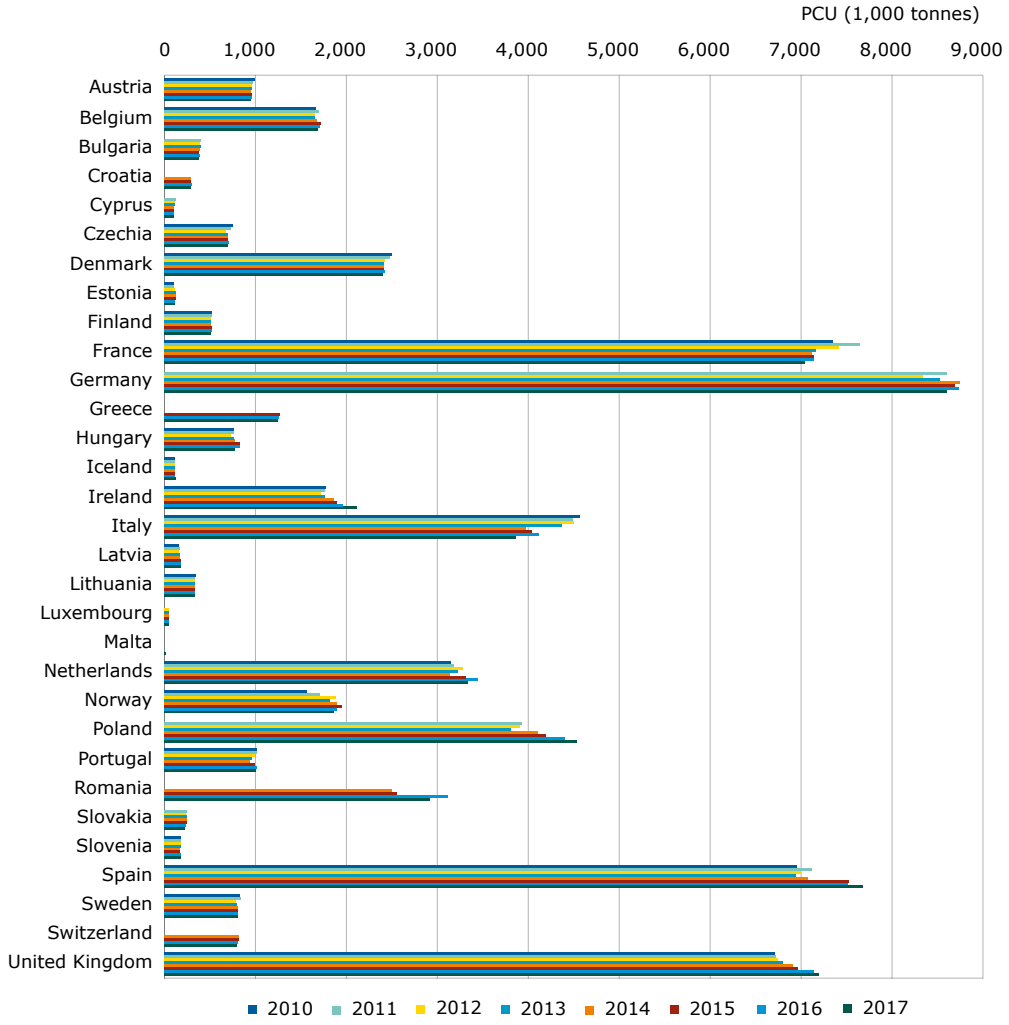
[1] No sales in Iceland; negligible sales in Norway.

2.7.1.4. Changes in the denominator (PCU) by country

From 2010 to 2017, the PCU (estimated weight at treatment of livestock and slaughtered animals) was relatively stable for most countries (Figure 32).

For three of the 25 countries (Iceland, Ireland and Poland) that provided data for at least five years, an increase of more than 10 % was observed in the PCU, while a decrease of more than 10 % was seen in Cyprus and Italy.

Figure 32. Changes in the denominator (PCU) for food-producing animals, in 1,000 tonnes, by country, between 2010 to 2017



3. Discussion

In the EU, the use of antimicrobials for growth promotion has been banned since 2006, therefore the data sets provided to ESVAC represent exclusively sales of antimicrobial agents sold as veterinary medicinal products.

Depending on the source of the data, countries requested data on sales to end-users or asked the national data providers to exclude sales among data sources (for example, between wholesalers). Consequently, it is assumed that double reporting has been avoided.

In 2017, all countries provided sales data except Denmark and Sweden, which submitted prescription data.

It should be noted that in all the participating countries, antimicrobial agents have a 'prescription only' status.

According to Directive 2001/82/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to veterinary medicinal products[22], all veterinary medicinal products, including veterinary antimicrobial agents, must be sold through distributors authorised by the competent authority in each country. This enabled all participating countries to identify all distributors of antimicrobial VMPs in their country, allowing for 100 % data-source coverage. Thus, it is reasonable to assume that the data presented in this report provide a good overview of the total sales of antimicrobial agents in the 31 participating countries.

The national sales data (numerator) cover all food-producing species, including horses, which are considered as food-producing species according to EU legislation. Thus, the animal population 'at risk' of being treated with antimicrobial agents (denominator) includes all food-producing species. However, as the use of antimicrobial agents in the various animal species varies considerably, interpretation of the data should take into account distribution of the PCU value between the species in the various countries. It should also be emphasised that the PCU represents a technical unit of measurement only and is not a real value for the animal population that could potentially be treated with antimicrobial agents.

In the current report, data presented on sales of veterinary antimicrobial agents for companion animals are based solely on the sales of tablets. For countries with a relatively low number of dogs and cats, the market for antimicrobial VMPs in the form of tablets is typically low. It is anticipated that in such countries, the proportion of human antimicrobial agents used under the 'cascade' could account for a higher proportion of antimicrobials used in companion animals than in countries with a high number of dogs and cats. Furthermore, injectable antimicrobial VMPs are used in both food-producing animals (including horses) and companion animals. Therefore, the data on sales of veterinary antimicrobial agents for companion animals presented in this report are likely to represent an underestimate, while data on sales for food-producing animals are likely to be slightly overestimated.

Dosing of the various antimicrobial agents varies substantially between and within classes, as well as between animal species, sometimes by several orders of magnitute, as reflected by the DDDvet and DCDvet values published by EMA in 2016[23]. For example, the dose for a whole treatment (DCDvet) with an oral fluoroquinolone VMP may vary between 10 and 40 mg/kg, differing between cattle, pigs and poultry, while for an oral tetracycline VMP this may vary between 110 and 280 mg/kg. This implies that a given amount of active ingredient of fluoroquinolone can be used to treat several times as many animals as the same amount of active ingredient of a tetracycline. Furthermore, within an antimicrobial class there may be different doses for different substances; for example, the dose of doxycycline is about one-quarter that of oxytetracycline. The daily dose can also vary between oral and parenteral forms. Another consideration is that the dosage may differ significantly according to species; for fish, a typical tetracycline dosage for a complete treatment is 800 mg/kg, nearly six times higher than for terrestrial animals. Since the data in this report cover all food-producing animals together, it was not possible to take into account differences in dosing when reporting the data. Considering the above-mentioned factors, it is evident that sales data do not reflect exposure of animals and frequency of treatment. Since sales patterns and animal demographics vary substantially between countries, comparison of sales data across the countries should be done with great care.

[22] OJ L 311, 28.11.2001, p. 1. (https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=OJ:L:2001:311:FULL&from=EN)
[23] Available on the European Medicines Agency website (www.ema.europa.eu) via Home > Veterinary regulatory >Antimicrobial resistance (https://www.ema.europa.eu/en/veterinary-regulatory/overview/antimicrobial-resistance/european-surveillance-veterinary-antimicrobial-consumption/standardised-units-measurement-veterinary-antimicrobials)

The proportion of sales of small packages of oral powders and oral solutions, sufficient for treatment of only a single or a few animals, is very low compared to those suitable for group treatment; oral solutions and oral powders are typically used for group treatment. Thus, the data presented in this report on sales of oral powder and oral solutions are considered to be a reasonable estimate of sales of these forms for group treatment.

In Member States, antimicrobial medicinal products not authorised for veterinary administration may be used in companion and food-producing animals, based on the cascade principle described in Article 11 of Directive 2001/82/EC[24], in the future according to Articles 107, 113 and 114 of Regulation (EC) 2019/6[25]. Legislation includes provisions which, when no suitable authorised product is available and under exceptional circumstances, allow a veterinarian to use a veterinary medicinal product outside of its authorised conditions of use, or to use an unauthorised medicine, according to given criteria. Such sales are not included in this report.

Dermatological preparations (ATCvet group QD) and preparations for sensory organs (ATCvet group QS) were not included in the data collection. In 2016, these pharmaceutical forms represented, for example, only 0.2% in Denmark, (L. Mie Jensen, unpublished data), 0.4% in the Czechia (L.Pokludová, unpublished data), 0.52% in France (A. Chevance, unpublished data), 0.002% in Norway (https://www.vetinst.no/en/surveillance-programmes/norm-norm-vet-report) and 0.7% in the United Kingdom (S. Brown, unpublished data) of the total tonnes sold. As the annual contribution from these groups of antimicrobial agents, in tonnes of active ingredients, to the total amounts is thought to be minimal, the effect of the deviation is considered negligible.

Injectable antimicrobial agents are used both in food-producing and companion animals. With the exception of some long-acting products, injection of antimicrobial agents in companion animals is generally limited to hospitalised animals or perioperative treatments. Data from Denmark and France for 2016 showed that approximately 1.1% and 0.8% of the injectable antimicrobial VMPs sold were used for dogs and cats, respectively (L. Mie Jensen and A. Chevance, unpublished data). Therefore, in this report, sales of injectable antimicrobials are assumed to be for use in food-producing species. For countries where injectable 3rd- and 4th-generation cephalosporins are almost solely marketed for dogs and cats, data provide a considerable overestimate of use in food-producing animals.

For 2017, 11 countries (Table 2) included veterinary antimicrobial agents obtained on special licence (use under exemption from marketing authorisation, i.e. obtained from another Member State and permitted to be marketed for specific animal species, although this type of procedure might differ among Member States) in the data sets. All these countries have a comparatively low number of antimicrobial veterinary medicinal products on the market (Annex 1, Table A7). Five of them – Cyprus, Czechia, Denmark, Norway and Slovenia – reported that the proportion of sales of antimicrobial VMPs on special licence accounted for approximately 15%, <0.01%, 0.1%, 0.7% and 7 % of the total sales, respectively.

It is important to note that the results presented in this report may differ from those presented in national reports because of differences, for example, in inclusion criteria for VMPs or in the reporting of data in the national surveillance systems. For instance, concentration of an antimicrobial ingredients may be reported as the moiety of a chemical compound in the national database, while for the ESVAC the strength of an ingredient is reported as given in the summary of product characteristics or labelling of the VMP, which typically is the salt (see references to national reports in Annex 7).

Despite the different factors noted above, ESVAC sales data can be considered as valid and important from the perspective of following trends in individual countries, especially in those with well-established and stable data-collection systems.

[24] OJ L 311, 28.11.2001, p. 1
[25] OJ L 4, 7.1.2019, p 43-167

4. Concluding remarks

Variations in reported sales (mg/PCU) and in sales patterns for 2017 between the 31 countries are likely to be due in part to differences in the composition of the animal population and in the production systems in various countries. Considerable variations also exist in terms of daily dose used for the various antimicrobial agents and the various pharmaceutical forms, as well as in terms of duration of treatment. In addition, differences in the selection of sales-data providers among countries may have an impact, although such an impact is thought to be minor. However, since these factors can only partly explain the differences in sales observed among the 31 countries, other factors must also be considered.

Since the sales data (numerator) for antimicrobial agents cover all food-producing species (including horses), the animal population 'at risk' of being treated with antimicrobial agents (denominator) includes most of the food-producing species. However, the use of antimicrobial agents in the various animal species varies considerably: for example, their use in extensive production systems is generally relatively low. Therefore, interpretation of the data should take into account the distribution of the PCU value between the species in the various countries.

Tentative explanations provided by some countries for the decline in sales include, among others, the implementation of responsible use campaigns, restrictions on use, increased awareness of the threat of antimicrobial resistance, and setting antimicrobial sales or use reduction targets or changes in animal demographics. Reduced sales of veterinary antimicrobials in some countries indicate the potential for a reduction in other countries, too.

Annex 1. Additional tables and charts

Table A1. Sales, in tonnes of active ingredient, of veterinary antimicrobial agents applicable mainly for food-producing animals by antimicrobial class (presented according to the ATCvet hierarchical system), by country, for 2017 (tablets not included)

Country	Tetracyclines	Amphenicols	Penicillins	1st- and 2nd-gen. cephalosporins	3rd- and 4th-gen. cephalosporins[1]	Sulfonamides	Trimethoprim	Macrolides	Lincosamides	Fluoroquinolones	Other quinolones	Aminoglycosides	Polymyxins	Pleuromutilins	Others[2]	Total tonnes
Austria	24.9	0.4	8.2	0.05	0.2	3.4	0.7	3.1	0.1	0.5	0	1.2	1.6	0.3	0.2	44.6
Belgium	56.5	3.1	83.2	0.4	0.2	36.9	7.4	13.6	5.0	0.4	0.2	1.0	3.6	0.9	8.8	221.0
Bulgaria	17.1	3.0	9.2	<0.01	0.03	3.0	0.4	7.2	2.7	2.1	0.2	2.3	1.1	0.8	0.4	49.6
Croatia	7.0	0.5	6.6	0.1	0.1	1.8	0.3	2.0	0.04	0.6	0.2	1.0	0.9	0.1	0.1	21.1
Cyprus	18.6	1.8	8.7	<0.01	0.04	3.4	0.7	1.7	5.8	0.3	0.05	0.5	1.1	2.5	0.3	45.4
Czechia	13.0	0.9	12.0	0.2	0.3	7.5	0.8	2.4	0.1	1.3	<0.01	1.8	0.4	3.0	0.2	44.1
Denmark	19.0	1.5	28.4	0.1	0.02	9.2	1.8	13.8	2.3	<0.01	0.6	5.2	0.5	8.8	3.2	94.4
Estonia	1.6	0.1	2.4	0.02	0.1	0.3	0.1	0.2	0.1	0.1	0	0.4	0.1	0.7	0.1	6.3
Finland	2.3	0.1	4.5	0.01	<0.01	1.8	0.4	0.4	0.3	0.1	0	0.03	0	0.01	0	9.8
France	188.5	5.4	65.7	1.4	0.1	90.2	16.0	33.2	2.6	1.1	3.3	49.8	15.6	4.2	5.7	482.9
Germany	198.7	5.4	296.7	0.5	3.3	61.0	7.7	54.7	10.9	9.3	0	16.4	73.5	16.4	12.0	766.6
Greece	59.2	0.8	23.1	<0.01	0.1	10.3	1.6	4.1	0.4	3.3	4.9	5.4	1.6	1.2	0.6	116.7
Hungary	59.9	3.0	36.0	0.1	0.3	5.4	1.1	6.0	2.8	6.8	0.1	2.3	11.5	11.5	0.3	147.2
Iceland	0.04	0	0.4	0	<0.01	0.04	<0.01	0	0	<0.01	0	0.1	0	0	0	0.6
Ireland[3]	41.5	3.0	20.5	0.6	0.3	16.8	1.2	7.2	0.3	0.8	0	5.3			1.0	98.5
Italy	304.8	23.1	271.6	0.7	1.5	131.0	15.9	85.2	80.3	11.4	10.8	43.1	20.0	35.7	22.5	1,057.8
Latvia	1.5	0.01	1.5	0.03	0.1	0.2	0.04	0.6	0.02	0.2	<0.01	0.6	0.2	0.8	0.1	5.9
Lithuania	1.7	0.1	4.5	0.02	0.1	2.4	0.5	0.5	0.2	0.3	<0.01	0.5	0.2	0.3	0.3	11.6
Luxembourg	0.7	0.04	0.4	<0.01	0.03	0.3	0.1	0.05	0.02	0.04	0	0.1	0.1	0.01	0.1	1.9
Malta[4]	0.2	0.02	0.2	<0.01	<0.01	0.2	0.02	0.2	<0.01	0.2		0.1	0.1	0.4	0.2	1.8
Netherlands	74.4	4.7	42.1	0.1	<0.01	28.8	5.3	25.0	0.2	0.2	3.2	1.6	1.0	0.9	0.5	188.0
Norway	0.1	0.3	3.0	0	<0.01	1.4	0.3	<0.01	<0.01	0.01	0.3	0.3	0	0.04	<0.01	5.7
Poland	217.2	8.1	245.6	0.6	1.1	32.3	6.5	82.3	6.7	50.3	0.1	21.5	34.0	38.1	5.3	749.6
Portugal	45.0	1.0	35.2	0.1	0.6	5.8	1.2	17.9	3.0	3.6	<0.01	2.7	11.0	6.3	1.7	135.1
Romania	73.2	11.5	52.9	0.02	0.5	7.9	1.6	24.2	18.3	12.6	0.6	31.8	12.0	14.1	1.7	262.9
Slovakia	4.2	0.1	2.6	0.1	0.1	1.4	0.1	2.2	0.1	0.8	<0.01	0.4	0.4	1.2	0.3	13.9
Slovenia	0.8	0.1	4.1	0.02	0.03	0.4	0.1	0.04	0.02	0.5	0	0.4	0.02	0.1	0.04	6.7
Spain	485.2	47.8	449.2	0.2	1.8	113.6	18.8	77.3	341.0	37.8	2.6	93.4	34.1	57.0	9.7	1,769.5
Sweden[5]	0.5		6.2	<0.01	<0.01	1.6	0.3	0.4	<0.01	0.02	0.02	0.3			0.2	9.5
Switzerland[6]	6.9	0.4	8.9	0.1	0.1	10.2	0.6	1.6		0.2	0	2.4	0.3		0.2	31.9
United Kingdom	95.3	4.4	53.9	0.5	0.8	19.8	3.9	23.2	2.5	1.1	0	14.6	<0.01	10.8	3.1	233.9
Total sales for 31 countries (mg/PCU)	**2,019.6**	**130.9**	**1,787.4**	**6.0**	**11.8**	**608.3**	**95.5**	**490.0**	**485.5**	**146.0**	**27.1**	**306.5**	**225.0**	**216.8**	**78.0**	**6,634.4**

[1] For the countries where injectable 3rd- and 4th-gen. cephalosporins are almost solely marketed for dogs and cats, the data provides a considerable overestimate for food-producing animals.
[2] Bacitracin, fosfomycin, furaltadone, metronidazole, novobiocin, paromomycin, rifaximin and spectinomycin (classified as 'Other antibacterials' in the ATCvet system).
[3] Polymyxins and pleuromutilins are aggregated with 'Others' for commercial confidentiality reasons.
[4] Fluoroquinolones and other quinolones are aggregated for commercial confidentiality reasons.
[5] Amphenicols, polymyxins and pleuromutilins are aggregated with 'Others' for commercial confidentiality reasons.
[6] For reasons of commercial confidentiality, pleuromutilins are grouped with others and lincosamides are grouped with macrolides.

Table A2. Distribution of sales, in mg/PCU, of veterinary antimicrobial agents applicable mainly for food-producing animals[1], by administration route/form and country, for 2017

Country	Premix	Oral powder	Oral solution	Injectable prep.	Oral paste	Bolus	Intramam-mary prep.	Intrauterine prep.	Total mg/ PCU
Austria	1.4	32.4	5.4	6.0	0.1	0.2	1.1	0.1	46.8
Belgium	11.5	21.5	84.2	13.4	0.04	0.1	0.4	0.2	131.3
Bulgaria	43.5	15.2	58.7	14.1	0	0	0.7	0.1	132.3
Croatia	4.8	13.9	29.6	21.4	0	0.8	0.6	0.3	71.5
Cyprus	377.9	2.7	24.7	17.2	0.1	0.2	0.3	<0.01	423.1
Czechia	9.2	12.5	28.6	11.2	0.1	0.1	1.4	0.6	63.6
Denmark	0.4	3.7	19.5	15.0	0.6	<0.01	0.2	0.1	39.4
Estonia	0	2.8	33.2	18.8	0.04	0	1.7	0.2	56.7
Finland	3.1	4.4	<0.01	10.3	1.1	0	0.5	0	19.3
France	23.0	1.4	30.3	12.8	0.1	0.1	0.9	0.1	68.6
Germany	0.1	47.2	33.8	6.6	0.1	0.01	0.7	0.5	89.0
Greece	49.9	4.4	30.5	8.9	0	0	0.1	0.03	93.9
Hungary	97.2	3.7	81.4	7.5	0.02	0	0.5	0.6	191.0
Iceland	0.1	0.1	<0.01	4.0	0.1	0	0.3	0.1	4.6
Ireland	15.8	6.4	8.9	13.5	0.04	0.4	1.5	<0.01	46.6
Italy	104.1	0.7	145.2	22.9	0.2	<0.01	0.5	0.2	273.8
Latvia	0	4.4	15.3	11.3	<0.01	0	1.3	1.1	33.3
Lithuania	0.1	20.5	4.4	6.6	0	1.0	2.0	0.2	34.8
Luxembourg	0	17.4	6.0	10.3	0.1	0.04	0.8	0.3	35.0
Malta	48.8	6.6	47.9	13.8	1.4	0	2.1	0.5	121.0
Netherlands	0.4	2.6	44.1	8.2	0.3	0.02	0.5	0.1	56.3
Norway	0.3	0.1	0.1	1.8	0.7	0	0.1	0.05	3.1
Poland	4.0	17.2	134.3	8.9	0	0	0.6	0.2	165.2
Portugal	78.1	1.0	46.9	8.3	<0.01	<0.01	0.5	0.03	134.8
Romania	8.6	0.5	66.9	13.9	0	0	0.2	0.1	90.1
Slovakia	13.2	2.4	36.6	8.9	0.01	0	0.7	0.1	61.9
Slovenia	0.2	20.7	6.5	7.8	0	0	1.0	0.4	36.5
Spain	109.0	0	111.5	9.7	<0.01	<0.01	0.1	0.01	230.3
Sweden	0.2	0.05	0.7	9.3	1.5	0	0.2	<0.01	11.8
Switzerland	22.0	3.6	0.05	9.4	0.7	0.1	3.5	0.8	40.1
United Kingdom[2]	14.8	1.5	8.1	7.5	0.1	0.1	0.4		32.5

[1] Injectable antimicrobial VMPs included are also used in companion animals; tablets not included.
[2] For commercial confidentiality reasons, intrauterine prep. are aggregated with intramammary prep.

Table A3. Percentage of sales, in mg/PCU, of premixes by veterinary antimicrobial class (according to ATCvet system), by country, for 2017[1,2]

Country	Tetracyclines	Amphenicols	Penicillins	Sulfonamides	Trimethoprim	Macrolides	Lincosamides	Quinolones	Aminoglycosides	Polymyxins	Pleuromutilins	Others[3]	Total mg/PCU premixes
Austria	42%	0.2%	0%	0%	0%	56%	0%	0%	0%	0%	2%	0%	1.4
Belgium	26%	1%	59%	4%	1%	5%	0.1%	0%	0.2%	2%	1%	0.1%	11.5
Bulgaria	52%	11%	0%	3%	0%	27%	0%	0%	0.02%	5%	3%	0%	43.5
Croatia	52%	2%	0%	21%	0%	3%	0.4%	12%	11%	0%	0%	0%	4.8
Cyprus	45%	4%	17%	6%	1%	4%	14%	0%	0%	2%	6%	0%	377.9
Czechia	36%	0.1%	17%	16%	3%	20%	0.2%	0%	0%	1%	7%	0.2%	9.2
Denmark	0%	0%	4%	63%	13%	0%	0%	20%	0%	0%	0%	0%	0.4
Finland	59%	5%	0%	1%	0.3%	19%	15%	0%	0%	0%	0%	0%	3.1
France	51%	0%	5%	24%	5%	4%	0.3%	0.1%	8%	1%	1%	0%	23.0
Germany	62%	0%	13%	0%	0%	9%	0%	0%	0%	1%	15%	0%	0.1
Greece	73%	1%	9%	10%	1%	1%	0.2%	1%	0%	1%	2%	0.01%	49.9
Hungary	59%	0.3%	12%	1%	0.3%	3%	2%	0%	0%	13%	9%	0.1%	97.2
Iceland	100%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0.1
Ireland[4]	76%	0.1%	2%	9%	2%	11%	0%	0%	0.3%			1%	15.8
Italy	38%	1%	23%	14%	1%	5%	9%	1%	1%	1%	6%	1%	104.1
Lithuania	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	100%	0%	0.1
Malta	8%	0%	0%	0%	0%	0%	0%	0%	0%	9%	56%	28%	48.8
Netherlands	96%	0%	0%	0.1%	0.02%	4%	0%	0%	0%	0%	0%	0%	0.4
Norway	0%	44%	0%	0%	0%	0%	0%	56%	0%	0%	0%	0%	0.3
Poland	20%	0.2%	18%	19%	4%	30%	0%	0%	0%	4%	5%	0%	4.0
Portugal	42%	0.1%	14%	4%	1%	18%	1%	0%	1%	11%	7%	1%	78.1
Romania	29%	4%	5%	2%	0.4%	2%	1%	1%	2%	0%	51%	3%	8.6
Slovakia	74%	0.2%	4%	0%	0%	1%	0%	0%	0%	1%	20%	0%	13.2
Slovenia	0%	8%	0%	0%	0%	0%	46%	1%	0%	0%	0%	46%	0.2
Spain	35%	4%	28%	9%	2%	5%	5%	0.03%	6%	1%	6%	0.1%	109.0
Sweden[5]	0%		0%	0%	0%	75%	0%	16%	0%			10%	0.2
Switzerland[6]	31%	0%	19%	37%	2%	8%		0%	0%	2%		1%	22.0
United Kingdom	55%	1%	13%	9%	2%	14%	0.2%	0%	1%	0%	6%	0.1%	14.8

[1] Negligible amount of fluoroquinolones is included in the table together with other quinolones.
[2] No sales of premixes were reported in Estonia, Latvia and Luxembourg.
[3] Bacitracin, metronidazole, paromomycin and spectinomycin (classified as 'Other antibacterials' in the ATCvet system).
[4] Polymyxins and pleuromutilins are aggregated with 'Others' for commercial confidentiality reasons.
[5] Ampehnicols, polymyxins and pleuromutilins are aggregated with 'Others' for commercial confidentiality reasons.
[6] For reasons of confidentiality, pleuromutilins are grouped with others and lincosamides are grouped with macrolides.

Table A4. Percentages of sales, in mg/PCU, of oral powders by antimicrobial class (according to ATCvet system), by country, for 2017[1,2]

Country	Tetracyclines	Amphenicols	Penicillins	Sulfonamides	Trimethoprim	Macrolides	Lincosamides	Quinolones	Aminoglycosides	Polymyxins	Pleuromutilins	Others[3]	Total mg/PCU oral powders
Austria	71%	0%	12%	7%	1%	3%	0%	0%	0.3%	5%	1%	0%	32.4
Belgium	36%	0%	0%	52%	10%	1%	0%	0.2%	0.03%	0%	0.1%	0%	21.5
Bulgaria	44%	0%	36%	8%	0%	0.2%	1%	7%	0%	2%	0.1%	2%	15.2
Croatia	61%	0%	25%	5%	2%	0%	0%	1%	0%	6%	0%	0%	13.9
Cyprus	0%	0%	99%	0%	0%	0%	0.2%	0%	0%	0%	0%	0.5%	2.7
Czechia	69%	0%	2%	13%	2%	2%	0%	0%	4%	0%	7%	1%	12.5
Denmark	47%	1%	1%	18%	4%	14%	0%	5%	0.4%	0%	11%	0%	3.7
Estonia	0%	0%	83%	14%	3%	0%	0%	0%	0%	0%	0%	0%	2.8
Finland	30%	0%	6%	48%	10%	4%	0%	0%	0%	0%	1%	0.1%	4.4
France	35%	0%	15%	1%	0%	6%	0%	0%	20%	1%	0%	22%	1.4
Germany	19%	0.03%	47%	11%	1%	1%	0.4%	0%	1%	16%	3%	0.01%	47.2
Greece	87%	0%	3%	0%	0%	0%	0%	8%	0%	2%	0%	0%	4.4
Hungary	53%	0%	46%	0%	0%	1%	0%	0%	0%	0%	0%	0%	3.7
Iceland	0%	0%	69%	0%	0%	0%	0%	0%	31%	0%	0%	0%	0.1
Ireland	67%	0%	9%	22%	1%	0%	1%	0%	0%	0%	0%	0%	6.4
Italy	0%	9%	59%	0%	0%	7%	0%	0%	0%	0%	26%	0%	0.7
Latvia	44%	0%	39%	6%	1%	0%	0%	0%	0%	9%	0%	0%	4.4
Lithuania	21%	0%	42%	22%	5%	0%	2%	0%	0%	3%	0.2%	4%	20.5
Luxembourg	66%	0%	8%	16%	3%	0%	0%	0%	0%	5%	1%	0%	17.4
Malta	15%	0%	30%	27%	4%	22%	0%	0%	1%	0%	0.3%	1%	6.6
Netherlands	30%	0%	34%	27%	6%	1%	1%	0%	0%	1%	0%	0%	2.6
Norway	20%	0%	0%	66%	13%	0%	0%	0%	0%	0%	0%	0%	0.1
Poland	29%	0.01%	26%	1%	0.1%	6%	2%	0%	2%	23%	11%	0.2%	17.2
Portugal	0%	0%	0%	76%	15%	2%	0%	0%	0%	0%	6%	0%	1.0
Romania	0%	0%	94%	0%	0%	0%	0%	0%	6%	0%	0%	0%	0.5
Slovakia	45%	0%	1%	24%	0.3%	0%	0%	0%	30%	0%	0%	0%	2.4
Slovenia	10%	0.4%	86%	2%	1%	0%	0%	0%	0%	0%	0%	0%	20.7
Sweden	16%	0%	0%	70%	14%	0%	0%	0%	0%	0%	0%	0%	0.05
Switzerland	0.1%	0%	0%	94%	3%	0%	0%	0%	3%	0%	0%	0%	3.6
United Kingdom	36%	0%	8%	46%	9%	2%	0%	0%	0%	0%	0%	0%	1.5

[1] Negligible amount of 1st- and 2nd-gen. cephalosporins sold is included with other antibacterials.
[2] No sales of oral powders were reported in Spain.
[3] Bacitracin, furaltadone, metronidazole, paromomycin and spectinomycin (classified as 'Other antibacterials' in the ATCvet system).

Table A5. Percentage of sales, in mg/PCU, of oral solutions by antimicrobial class (according to ATCvet system), by country, for 2017[1]

Country	Tetracyclines	Amphenicols	Penicillins	Sulfonamides	Trimethoprim	Macrolides	Lincosamides	Fluoroquinolones	Other quinolones	Aminoglycosides	Polymyxins	Pleuromutilins	Others[2]	Total mg/PCU oral solutions
Austria	38%	<0.01%	26%	8%	2%	19%	0.4%	3%	0%	0%	1%	1%	2%	5.4
Belgium	26%	0.3%	41%	11%	2%	8%	3%	0.1%	0.1%	0%	2%	0.4%	5%	84.2
Bulgaria	23%	5%	26%	8%	2%	10%	11%	8%	0%	2%	1%	2%	1%	58.7
Croatia	38%	0.4%	40%	4%	1%	5%	0.1%	2%	0%	0%	8%	1%	0.3%	29.6
Cyprus	11%	0.2%	32%	22%	4%	5%	1%	8%	2%	0%	4%	3%	7%	24.7
Czechia	16%	0.4%	34%	26%	2%	4%	0.2%	5%	0.04%	0.1%	2%	10%	0.4%	28.6
Denmark	23%	0.1%	18%	2%	0.4%	25%	2%	<0.01%	0%	6%	1%	16%	6%	19.5
Estonia	38%	1%	25%	6%	1%	6%	1%	1%	0%	0%	3%	17%	2%	33.2
Finland	90%	0%	0%	0%	0%	0%	0%	10%	0%	0%	0%	0%	0%	<0.01
France	43%	0.1%	11%	21%	3%	8%	1%	0.4%	1%	2%	6%	1%	1%	30.3
Germany	39%	0.2%	25%	4%	0.2%	16%	3%	1%	0%	3%	3%	1%	4%	33.8
Greece	17%	0.1%	37%	10%	2%	7%	0.3%	8%	11%	5%	2%	0.3%	1%	30.5
Hungary	21%	4%	37%	7%	1%	6%	2%	10%	0.2%	2%	3%	8%	0.3%	81.4
Iceland	0%	0%	0%	0%	0%	0%	0%	100%	0%	0%	0%	0%	0%	<0.01
Ireland[3]	2%	1%	39%	45%	0.4%	7%	0.3%	1%	0%	2%			3%	8.9
Italy	26%	2%	28%	12%	2%	11%	7%	1%	1%	1%	3%	2%	3%	145.2
Latvia	30%	0.2%	7%	1%	0.1%	20%	0.2%	4%	0.1%	0.2%	6%	31%	1%	15.3
Lithuania	0%	0.1%	11%	27%	7%	27%	0%	15%	0.2%	0%	0.02%	12%	0%	4.4
Luxembourg	8%	0.1%	11%	29%	5%	10%	5%	1%	0%	1%	1%	0%	29%	6.0
Malta[4]	13%	1%	12%	17%	2%	22%	0.2%	28%		1%	1%	1%	3%	47.9
Netherlands	45%	0.01%	18%	14%	3%	16%	<0.01%	0.1%	2%	0.4%	1%	1%	0.4%	44.1
Norway	3%	0%	41%	0%	0%	0%	0.2%	0.2%	0%	28%	0%	26%	0.5%	0.1
Poland	30%	0.5%	34%	4%	1%	12%	1%	8%	0.01%	2%	3%	5%	1%	134.3
Portugal	21%	0.5%	47%	3%	1%	7%	5%	6%	0%	1%	5%	1%	1%	46.9
Romania	31%	2%	20%	3%	1%	11%	9%	5%	0.3%	10%	6%	1%	0.2%	66.9
Slovakia	17%	1%	18%	13%	1%	26%	1%	9%	0.1%	0.02%	4%	7%	4%	36.6
Slovenia	19%	2%	23%	16%	3%	0%	0%	31%	0%	0.2%	2%	5%	0%	6.5
Spain	22%	1%	23%	4%	0.4%	2%	35%	3%	0.3%	4%	3%	1%	1%	111.5
Sweden[5]	27%		10%	0.1%	0.02%	30%	0.4%	0.2%	0%	13%			20%	0.7
Switzerland	0%	0%	0%	0%	0%	0%	0%	97%	0%	0%	3%	0%	0%	0.05
United Kingdom	26%	1%	38%	5%	1%	9%	3%	1%	0%	5%	0.01%	7%	5%	8.1

[1] Negligible amount of 1st- and 2nd-gen. cephalosporins sold is included with other antibacterials.
[2] Bacitracin, fosfomycin, furaltadone, metronidazole, paromomycin and spectinomycin (classified as 'Other antibacterials' in the ATCvet system).
[3] Polymyxins and pleuromutilins are aggregated with 'Others' for reasons of commercial confidentiality.
[4] Fluroquinolones and other quinolones are aggregated for reasons of commercial confidentiality.
[5] Amphenicols, polymyxins and pleuromutilins are aggregated with 'Others' for commercial confidentiality reasons.

Table A6. Percentage of sales, in mg/PCU, of injectable preparations by antimicrobial class (according to ATCvet system), by country, for 2017

Country	Tetracyclines	Amphenicols	Penicillins	1st- and 2nd-gen. cephalosporins	3rd- and 4th-gen. cephalosporins[1]	Sulfonamides	Trimethoprim	Macrolides	Lincosamides	Quinolones[2]	Aminoglycosides	Polymyxins	Pleuromutilins	Others[3]	Total mg/PCU injectable prep.
Austria	9%	7%	37%	0.1%	3%	9%	2%	7%	1%	6%	19%	0%	0.03%	1%	6.0
Belgium	5%	11%	57%	1%	0.4%	6%	1%	5%	3%	1%	4%	0.2%	0.03%	6%	13.4
Bulgaria	17%	2%	26%	0.1%	1%	3%	1%	9%	2%	3%	34%	<0.01%	1%	2%	14.1
Croatia	5%	7%	30%	1%	1%	10%	2%	24%	0.3%	6%	13%	0%	0.02%	1%	21.4
Cyprus	14%	6%	36%	0%	2%	7%	1%	1%	2%	3%	24%	0.1%	1%	3%	17.2
Czechia	16%	11%	41%	2%	4%	4%	1%	2%	0.2%	3%	16%	0%	1%	0.04%	11.2
Denmark	12%	4%	54%	0%	0.04%	13%	3%	2%	3%	<0.01%	7%	0%	1%	1%	15.0
Estonia	8%	1%	53%	0.4%	4%	4%	1%	1%	1%	6%	17%	0%	3%	1%	18.8
Finland	13%	0.5%	79%	0%	0.01%	5%	1%	0.3%	0.4%	1%	0,2%	0%	0%	0%	10.3
France	11%	6%	33%	0.1%	0.1%	6%	1%	9%	1%	0.2%	32%	1%	0.03%	1%	12.8
Germany	4%	8%	45%	0%	5%	9%	2%	5%	2%	10%	6%	0.02%	1%	2%	6.6
Greece	25%	3%	27%	0%	1%	3%	1%	4%	1%	2%	31%	0.03%	0.1%	3%	8.9
Hungary	5%	10%	40%	0.4%	5%	2%	1%	4%	1%	8%	21%	0.1%	1%	1%	7.5
Iceland	7%	0%	76%	0%	0.03%	4%	1%	0%	0%	0.1%	13%	0%	0%	0%	4.0
Ireland[4]	24%	10%	32%	0.1%	1%	6%	1%	8%	0.2%	2%	15%			0.4%	13.5
Italy	6%	7%	22%	0%	2%	7%	0.4%	5%	2%	4%	37%	0.2%	0.4%	5%	22.9
Latvia	7%	0.4%	44%	1%	3%	7%	1%	3%	0.4%	4%	28%	0%	0.5%	1%	11.3
Lithuania	9%	5%	45%	0.02%	3%	8%	1%	4%	2%	2%	16%	0%	3%	1%	6.6
Luxembourg	12%	8%	43%	<0.01%	5%	11%	2%	3%	1%	7%	7%	0.2%	0%	2%	10.3
Malta	5%	8%	31%	0%	2%	3%	0.03%	0%	2%	14%	32%	0%	0%	4%	13.8
Netherlands	16%	17%	41%	0%	<0.01%	17%	3%	2%	0%	0.1%	3%	0.2%	0.1%	0%	8.2
Norway	2%	0.5%	85%	0%	0.02%	6%	1%	0.1%	0%	0.3%	5%	0%	0.2%	0%	1.8
Poland	12%	13%	32%	0.4%	3%	3%	0.4%	3%	3%	10%	18%	0.1%	1%	2%	8.9
Portugal	22%	8%	21%	0.3%	4%	4%	1%	7%	1%	6%	22%	0.03%	1%	2%	8.3
Romania	14%	15%	26%	0.01%	1%	3%	1%	3%	2%	5%	28%	0.1%	0.3%	1%	13.9
Slovakia	15%	3%	45%	3%	4%	8%	2%	2%	0.2%	3%	12%	0%	2%	0.4%	8.9
Slovenia	6%	6%	34%	1%	2%	11%	3%	3%	0%	11%	25%	0.04%	0%	0%	7.8
Spain	7%	16%	17%	0.03%	2%	2%	0.3%	17%	4%	20%	10%	0.1%	0.4%	5%	9.7
Sweden[5]	5%		81%	0.1%	0.04%	8%	2%	1%	0.1%	0.2%	2%			0.4%	9.3
Switzerland[6]	11%	5%	43%	0%	2%	8%	1%	2%		2%	26%	<0.01%		1%	9.4
United Kingdom	32%	6%	29%	0.1%	1%	4%	1%	6%	0.4%	1%	19%	0%	0.1%	0.05%	7.5

[1] For the countries where the injectable 3rd- and 4th-gen. cephalosporins are almost solely marketed for dogs and cats the data provide a considerable overestimate for food-producing animals.
[2] Negligible amount of other quinolones is included together with fluoroquinolones.
[3] Spectinomycin (classified as 'Other antibacterials' in the ATCvet system).
[4] Polymyxins and pleuromutilins are aggregated with 'Others' for reasons of commercial confidentiality.
[5] Amphenicols, polymyxins and pleuromutilins are aggregated with 'Others' for reasons of commercial confidentiality.
[6] For reasons of commercial confidentiality, pleuromutilins are grouped with others and lincosamides are grouped with macrolides.

Table A7. Number of product presentations (product name, form, strength and pack size) containing 1, 2 and 3 antimicrobial agents sold, by country, for 2017 (tablets excluded from the data)

Country	1 ingredient	2 ingredients	3 ingredients	Total number[1]
Austria	232	30	3	265
Belgium	309	45	6	360
Bulgaria	212	42	7	261
Croatia	126	21	3	155
Cyprus	112	23	3	138
Czechia	378	65	10	457
Denmark	196	46	7	249
Estonia	109	21	6	136
Finland	66	16	1	83
France	508	131	8	647
Germany	503	70	4	577
Greece	235	56	5	297
Hungary	322	45	7	375
Iceland	24	6	2	32
Ireland	247	48	6	302
Italy	578	100	12	691
Latvia	141	34	10	186
Lithuania	101	27	5	133
Luxembourg	186	44	7	237
Malta	85	46	6	139
Netherlands	183	45	3	231
Norway	47	16	2	65
Poland	532	63	11	607
Portugal	433	58	10	501
Romania	411	70	5	490
Slovakia	251	43	6	301
Slovenia	93	19	3	116
Spain	598	73	4	675
Sweden	93	21	1	115
Switzerland	139	41	35	215
United Kingdom	309	36	5	351
Total 31 countries	**7,759**	**1,401**	**203**	**9,387**

[1] In addition, 24 presentations contained 4 active ingredients (which are included in the total number), accounting for 0.3% of the product presentations in 31 countries.

Table A8. Number of product presentations (product name, form, strength and pack size) of premixes, oral powders and oral solutions sold containing 1, 2 and 3 antimicrobial agents sold, by country, for 2017[1]

Country	1 ingredient	2 ingredients	3 ingredients	Total number of product presentations for premixes, oral powder and oral solution
Austria	85	9		94
Belgium	123	19		142
Bulgaria	122	16		138
Croatia	52	8		63
Cyprus	48	9		57
Czechia	184	35	2	221
Denmark	84	9		93
Estonia	28	4		32
Finland	21	3		24
France	279	60		339
Germany	222	32		254
Greece	120	21		141
Hungary	178	18		196
Iceland	4			4
Ireland	77	12		89
Italy	317	46	6	370
Latvia	37	5		42
Lithuania	37	5		42
Luxembourg	54	21		75
Malta	51	27	5	84
Netherlands	77	16		93
Norway	14	3		17
Poland	285	27		312
Portugal	170	19		189
Romania	244	18	1	265
Slovakia	103	18	2	123
Slovenia	29	8		37
Spain	337	17		354
Sweden	26	2		28
Switzerland	43	12	28	83
United Kingdom	134	15		149
Total 31 countries	**3,585**	**514**	**44**	**4,150**

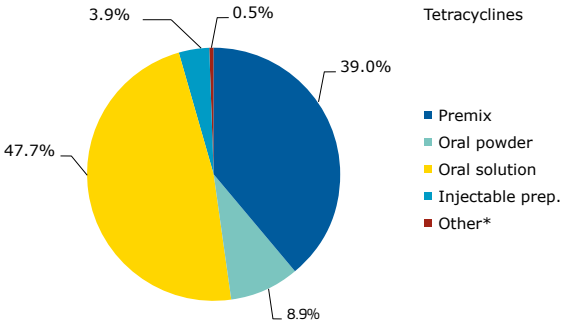
[1] In addition, 7 preparations contained 4 active ingredients (which are included in the total number), accounting for 0.2% of the product presentations for premixes, oral powders and oral solutions in 31 countries.

Table A9. Sales, in tonnes of active ingredient, of antimicrobial agents sold as premixes, oral powders and oral solutions containing 1, 2 and 3 active ingredients, by country, for 2017[1]

Country	1 ingredient		2 ingredients		3 ingredients		Total tonnes for premixes, oral powder and oral solution
	Tonnes	%	Tonnes	%	Tonnes	%	
Austria	34.2	91%	3.2	9%		0%	37.4
Belgium	146.8	74%	50.3	26%		0%	197.2
Bulgaria	39.1	89%	4.9	11%		0%	44.0
Croatia	12.6	88%	1.0	7%		0%	14.3
Cyprus	38.2	88%	5.3	12%		0%	43.5
Czechia	28.2	81%	6.0	17%	0.7	2%	34.8
Denmark	49.3	87%	7.1	13%		0%	56.4
Estonia	3.6	91%	0.4	9%		0%	4.0
Finland	2.5	65%	1.3	35%		0%	3.8
France	288.5	75%	96.4	25%		0%	384.9
Germany	643.9	92%	54.0	8%		0%	697.8
Greece	94.5	90%	10.9	10%		0%	105.4
Hungary	130.9	93%	9.6	7%		0%	140.5
Iceland	0.0	100%		0%		0%	0.02
Ireland	59.5	90%	6.3	10%		0%	65.7
Italy	699.3	72%	249.7	26%	16.6	2%	965.9
Latvia	3.4	97%	0.1	3%		0%	3.5
Lithuania	5.8	69%	2.6	31%		0%	8.3
Luxembourg	1.0	76%	0.3	24%		0%	1.3
Malta	1.3	89%	0.1	9%	0.04	2%	1.5
Netherlands	132.9	84%	24.4	16%		0%	157.3
Norway	0.8	88%	0.1	12%		0%	0.9
Poland	658.8	93%	47.1	7%		0%	705.9
Portugal	111.3	88%	15.0	12%		0%	126.3
Romania	211.2	95%	9.7	4%	0.8	0.3%	221.7
Slovakia	8.5	73%	3.1	26%	0.1	1%	11.7
Slovenia	4.6	92%	0.4	8%		0%	5.0
Spain	1,569.0	93%	125.2	7%		0%	1,694.3
Sweden	0.7	95%	0.03	5%		0%	0.7
Switzerland	5.7	28%	4.7	23%	10.0	49%	20.4
United Kingdom	152.0	87%	23.3	13%		0%	175.3
Total 31 countries	**5,138.2**	**87%**	**762.3**	**13%**	**28.2**	**0.5%**	**5,929.7**

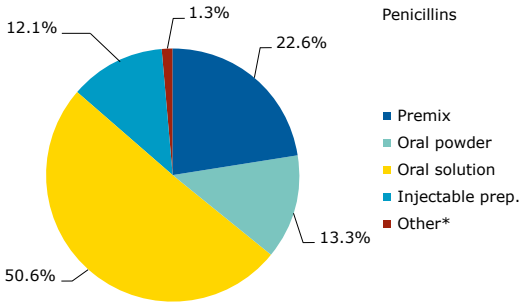
[1] In addition, 0.02% of the total sales of premixes, oral powders and oral solutions preparations contained 4 active ingredients, accounting for 1.0 tonne (which is included in the total tonnes of premixes, oral powders and oral solutions).

Figure A1. Distribution of sales of tetracyclines for food-producing animals, in mg/PCU, by the major pharmaceutical forms sold, aggregated by the 31 European countries, for 2017



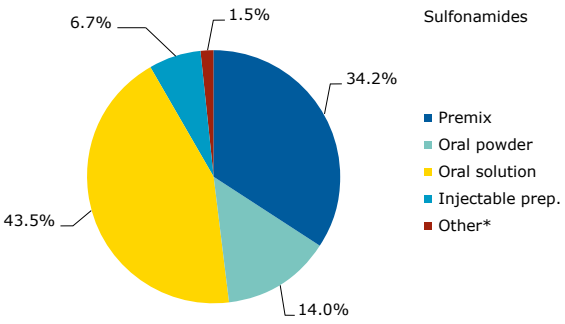
* Other forms include boluses, oral pastes, intramammary and intrauterine preparations.

Figure A2. Distribution of sales of penicillins for food-producing animals, in mg/PCU, by the major pharmaceutical forms sold, aggregated by the 31 European countries, for 2017



* Other forms include boluses, oral pastes, intramammary and intrauterine preparations.

Figure A3. Distribution of sales of sulfonamides for food-producing animals, in mg/PCU, by the major pharmaceutical forms sold, aggregated by the 31 European countries, for 2017



* Other forms include boluses, oral pastes, intramammary and intrauterine preparations.

Figure A4. Distribution of sales of 3rd- and 4th-generation cephalosporins for food-producing animals, in mg/PCU, by the major pharmaceutical forms sold, aggregated by the 31 European countries, for 2017

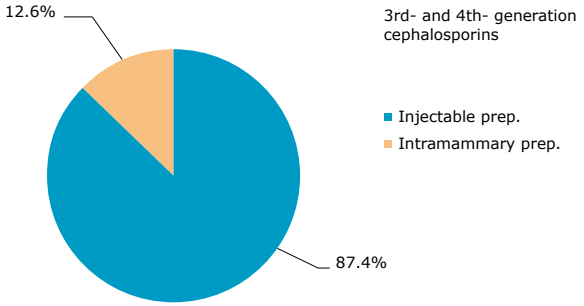
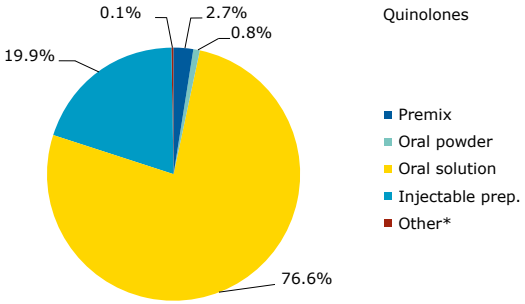
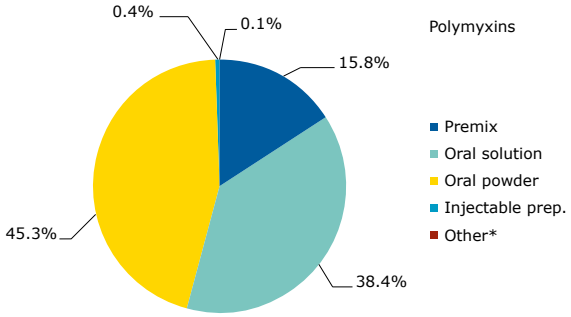


Figure A5. Distribution of sales of quinolones for food-producing animals, in mg/PCU, by the major pharmaceutical forms sold, aggregated by the 31 European countries, for 2017



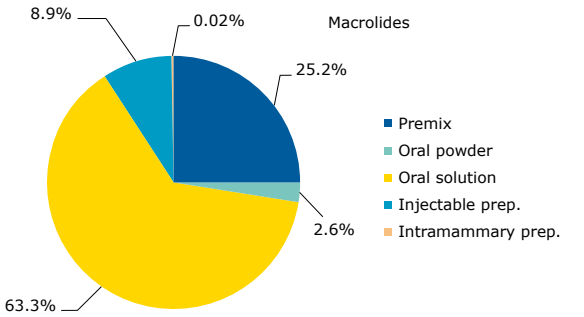
* Other forms include boluses, oral pastes and intrauterine preparations.

Figure A6. Distribution of sales of polymyxins for food-producing animals, in mg/PCU, by the major pharmaceutical forms sold, aggregated by the 31 European countries, for 2017



* Other forms include boluses and intramammary preparations.

Figure A7. Distribution of sales of macrolides for food-producing animals, in mg/PCU, by the major pharmaceutical forms sold, aggregated by the 31 European countries, for 2017



Annex 2. Variables to be reported or used for calculation of active ingredient for each antimicrobial veterinary medicinal product; standardisation of the data

Table A10. Variables reported to the ESVAC for each antimicrobial veterinary medicinal product, for 2017

	Variable	Description of variable	Justification
	COUNTRY	ISO code (http://www.iso.org/iso/country_codes)	To identify place of collected sales data.
	YEAR		To identify time period for collected sales data.
	MA	**Marketing authorisation number**	To allow for the unique identification of the veterinary medicinal product (VMP) and enable a link with other databases. To allow for market analysis if all the products are available.
PRODUCT INFORMATION	**ID**	**Medicinal product package code value** Digit code is a unique identifier for each package size, strength and formulation of the VMP. Because it is a key variable in many databases, it must be stable over time, so that VMPs that are no longer available on the market or no longer registered can still be identified to enable the analysis of historical data.	To enable the analysis of historical data. To enable identification of duplicate reporting of sales.
	NAME	**Medicinal product name (in national language)** e.g. Harmony vet tablets 2 × 30; Harmony vet long-acting injection 10 ml.	For validation purposes. To allow, for example, for analysis of use of, for example, long-acting preparations and antimicrobial resistance.
	FORM	**Pharmaceutical form** Bolus (BOLUS), Injection (INJ), Intramammary preparation (INTRAMAM), Intramammary preparation dry cow (INTRAMAM-DC), Oral solution (ORAL SOLU), Oral paste (ORAL PASTE), Oral powder (ORAL POWD), Premix (PREMIX), Capsules and Tablets, etc. (TABL), Intrauterine preparation (INTRAUT).	Important to avoid misinterpretation of pharmaceutical form if given in a language other than English. Allows for reporting of data as individual or group treatment.
	LONG ACTING	**Long-acting injectable preparations** This refers to injectable preparations that, once injected, maintain their antimicrobial activity over a long period of time.	Optional.
	PACKSIZE	**Content quantity in package: pack size (numerical only)** e.g. 100 for 100 tablets or 100 intramammary prep.; 10 for 10 ml injection; package of 2 kg premix: 2; box of 10 blisters of 30 tablets: 300; box of 12 injectors: 12.	To enable calculation of the amount of active ingredient in each package/product.
	PACKSIZEU	**Content unit of measurement** e.g. ML, L, G, KG, PIECE (for example, for tablets, capsules, boluses and intramammary prep.).	To enable calculation of amount of active ingredient in each package/product.
	ATCvet – 5th LEVEL	**ATCvet: Anatomical Therapeutic Chemical (Classification) Veterinary** WHO ATCvet code last version to be used.	Generally, a classification system needs to have a common language when reporting use and analysing data with data on AMR, e.g. for 3rd- and 4th-generation cephalosporins. To have a common language for defining confidentiality of the data (can be converted into ATCvet 3rd level).

	Variable	Description of variable	Justification
	SPECIES	**Animal species** All the animal species for which the VMP is approved, e.g. cattle (CA), poultry (POU).	Optional.
	NO SOLD	**Number of packages sold/year/country**	To calculate weight of active ingredient sold.
INGREDIENT	**INGR**	**Active ingredient name (ATCvet name)** In case of multi-ingredient VMP, the ATCvet names of all the ingredients must be given.	Important to avoid misinterpretation of ingredient name if given in a language other than English. Use of ATCvet names facilitates the identification of active ingredients as well as standardised reporting.
	SALT	**Salt of active ingredient** e.g. colistin sulfate and colistin methanesulfonate.	Only in cases when the strength is given in IU, IU/ML or IU/UNIT and when different salts exist, to allow for conversion to weight of active ingredient.
	PRODRUG	**Prodrug name (ATCvet name)** E.g. procaine penicillin which is the prodrug for benzylpenicillin.	Only in cases when a product contains a prodrug.
	STRENGTH	**Quantity of the active ingredient in each unit as declared on SPC/label: strength (numerical only)** e.g. 10 for 10 MG/TABLET, 10 IU/TABLET, 10 MG/ML, 10 IU/ML, 10 MG/PIECE or 10 IU/PIECE. In case of a multi-ingredient VMP, strength must be given for each ingredient separately.	To enable calculation of amount of active ingredient in each package/product and to validate INGR CONTENT.
	STRENGTHU	**Unit of measurement for strength** e.g. IU, IU/G, IU/ML, IU/PIECE, G, G/KG, G/L, MG, MG/ML, MG/PIECE. In case of a multi-ingredient VMP, unit of measurement strength has to be given for each ingredient on a separate line.	To enable calculation of the amount of active ingredient in each package/product and to validate INGR CONTENT.
	CONV FACT IU	**Conversion factor IU** When strength is given in IU, IU/ML or IU/PIECE.	When strength is only given as IU, IU/ML or IU/PIECE, to enable calculation of weight of the active ingredient in the package.
	CONV FACT PRODR	**Conversion factor prodrug** Used when strength is given for the prodrug and not for the active ingredient (e.g. procaine penicillin which is the prodrug for benzylpenicillin).	To enable calculation of the weight of the active ingredient in the package.
	INGR CONTENT	**Content of active ingredient in package** In case of a multi-ingredient VMP, the content in the package has to be given separately for each ingredient on a separate line.	Optional: to enable validation of the ESVAC calculations.
	CONT UNIT (G)	**Unit of active ingredient in package** To be given in grams (g) for all substances. In case of a multi-ingredient VMP, the content unit has to be given separately for each ingredient on a separate line.	Optional: to enable validation of the ESVAC calculations.
	TONNES SOLD	**Tonnes sold of active ingredient**	

For antimicrobial veterinary medicinal products containing more than one active ingredient, information on the active ingredient name, strength and strength unit must be given for each ingredient separately.

Table A11. Conversion factors used to convert from international units (IU) to weight (mg) of active ingredient, based on WHO International Standards for Antibiotics[1]

Active ingredient	IU/mg	Conversion factor (mg/IU)
Bacitracin	74	0.01351
Benzylpenicillin (and prodrugs to benzylpenicillin)[2]	1,667	0.00060
Chlortetracycline[3]	900	0.00111
Colistin sulphate	20,500	0.00005
Colistin methane sulphonate[4]	12,700	0.00008
Dihydrostreptomycin	820	0.00122
Erythromycin	920	0.00109
Gentamicin	620	0.00161
Kanamycin	796	0.00126
Neomycin	755	0.00133
Framycetin	670	0.00149
Oxytetracycline	870	0.00115
Paromomycin[3]	675	0.00148
Polymyxin B	8,403	0.00012
Spiramycin	3,200	0.00031
Streptomycin	785	0.00127
Tetracycline	982	0.00102
Tobramycin	875	0.00114
Tylosin	1,000	0.00100

[1] WHO International Standards for Antibiotics (ISA) – Reference Standards (https://crs.edqm.eu/db/4DCGI/search?vSelect-Name=4&vContains=1&vtUserName=ISA&OK=Search).
[2] Martindale (http://www.medicinescomplete.com/#/content/martindale/141-b).
[3] WHO Pharmacopoeia (http://apps.who.int/phint/en/p/docf/).
[4] WHO International Biological Reference Preparations (http://www.who.int/bloodproducts/catalogue/AntiJan10.pdf).

Table A12. Conversion factors used to convert from prodrug content to content of active ingredient[1]

Prodrug	Conversion factor	Active ingredient
Benethamine benzylpenicillin	0.65	Benzylpenicillin
Benzathine benzylpenicillin	0.74	Benzylpenicillin
Cefapirin benzathine	0.41	Cefapirin
Cefalexin benzathine	0.36	Cefalexin
Cloxacillin benzathine	0.43	Cloxacillin
Oxacillin benzathine	0.69	Oxacillin
Penethamate hydriodide	0.63	Benzylpenicillin
Procaine penicillin	0.61	Benzylpenicillin

[1] Martindale (http://www.medicinescomplete.com/#/content/martindale/141-b).

Annex 3. Population correction unit (PCU)

Table A13. Animal categories included in the calculation of the population correction unit (PCU) and data types to be reported

Animal category
Cattle (heads/number of animals)
Slaughtered cows
Slaughtered heifers
Slaughtered bullocks and bulls
Slaughtered calves and young cattle
Slaughtered bovine - Import
Slaughtered bovine - Export
Fattening bovine - Import
Fattening bovine - Export
Living dairy cows
Pigs (heads/number of animals)
Slaughtered pigs
Slaughtered pigs - Import
Slaughtered pigs - Export
Fattening pigs - Import
Fattening pigs - Export
Living sows
Poultry (heads/number of birds)
Slaughtered broilers
Slaughtered turkeys
Slaughtered poultry - Import
Slaughtered poultry - Export
Caprinae (heads/number of animals)
Slaughtered sheep and goats
Slaughtered sheep - Import
Slaughtered sheep - Export
Fattening sheep - Import
Fattening sheep - Export
Living sheep
Slaughtered goats - Import
Slaughtered goats - Export
Fattening goats - Import
Fattening goats - Export
Equidae (heads/number of animals)
Living horses
Rabbits (heads/number of animals)
Slaughtered rabbits
Fish (tonnes)
Biomass fish live weight of farmed fish produced

Table A14. Weights used to calculate the population correction unit (PCU)

Animal category	Weight in kg
Slaughtered or livestock (Eurostat)	
Slaughtered cows	425
Slaughtered heifers	200
Slaughtered bullocks and bulls	425
Slaughtered calves and young cattle	140
Dairy cows	425
Slaughtered pigs	65
Living sows	240
Broilers	1
Turkeys	6.5
Slaughtered sheep and goats	20
Living sheep	75
Horses	400
Rabbits	1.4
Imported/exported for fattening or slaughter (TRACES data)	
Slaughtered bovine	425
Fattening bovine	140
Slaughtered pigs	65
Fattening pigs	25
Slaughtered poultry	1
Slaughtered sheep	20
Fattening sheep	20
Slaughtered goats	20
Fattening goats	20

Annex 4. List of antimicrobial classes/active ingredients reported in the ESVAC

Table A15 includes all the substances for which sales have been reported, divided by class or subclass. Note that in the ESVAC, sales are reported by classes/subclasses whether or not this refers to a single or a combination product – i.e. not by ATCvet classes. An exception to this is combinations of penicillins, including beta-lactamase inhibitors, which are included as the combination penicillins + beta-lactamase inhibitors reported as such in Figure 5.

Pharmacologically active substances that may be used in food-producing animals must be listed in Table 1 of the Annex to Commission Regulation (EU) No 37/2010. The table details, among others, the food-producing animal species for which those substances can be used. Table 2 of that annex contains substances that are prohibited for use in any food-producing species; some of these are included in Table A15 below because they are used in companion animals for which no maximum residue limits (MRLs) are required.

Table A15. List of substances reported sold in the ESVAC 2010-2017

Class/subclass	Substances		
Tetracyclines			
	Chlortetracycline	Doxycycline	Oxytetracycline
	Tetracycline		
Amphenicols			
	Chloramphenicol[1]	Florfenicol	Thiamphenicol
Penicillins			
Beta-lactamase-sensitive penicillins			
	Benzathine benzylpenicillin	Benzathine phenoxymethylpenicillin	Benzylpenicillin
	Penethamate hydriodide	Phenoxymethylpenicillin	Pheneticillin
	Procaine benzylpenicillin		
Beta-lactamase-resistant penicillins			
	Cloxacillin	Dicloxacillin	Nafcillin
	Oxacillin		
Penicillins with extended spectrum			
	Amoxicillin	Ampicillin	Metampicillin[2]
Combinations of penicillins with beta-lactamase inhibitors			
	Amoxicillin	Ampicillin	
Cephalosporins[3]			
First-generation cephalosporins			
	Cefacetrile	Cefadroxil[2]	Cefalexin
	Cefalonium	Cefapirin	Cefazolin
	Cefalotin		

Class/subclass	Substances		
Third-generation cephalosporins			
	Cefoperazone	Cefovecin[2]	Ceftiofur
Fourth-generation cephalosporins			
	Cefquinome		
Sulfonamides and trimethoprim			
Sulfonamides			
	Formosulfathiazole	Phthalylsulfathiazole	Sulfacetamide
	Sulfachlorpyridazine	Sulfaclozine	Sulfadiazine
	Sulfamonomethoxine	Sulfadimethoxine	Sulfadimidine
	Sulfadoxine	Sulfafurazole	Sulfaguanidine
	Sulfalene	Sulfamerazine	Sulfamethizole
	Sulfamethoxazole	Sulfamethoxypyridazine	Sulfanilamide
	Sulfapyridine	Sulfaquinoxaline	Sulfathiazole
	Sulfazuinoxaline		
Trimethoprim and derivatives			
	Trimethoprim		
Macrolides and lincosamides			
Macrolides			
	Erythromycin	Gamithromycin	Oleandomycin
	Spiramycin	Tildipirosin	Tilmicosin
	Tulathromycin	Tylosin	Tylvalosin
Lincosamides			
	Clindamycin[2]	Lincomycin	Pirlimycin
Aminoglycosides			
	Amikacin[2]	Apramycin	Dihydrostreptomycin
	Framycetin	Gentamicin	Kanamycin
	Neomycin	Streptomycin	
Quinolones			
Fluoroquinolones			
	Danofloxacin	Difloxacin	Enrofloxacin
	Ibafloxacin[2]	Marbofloxacin	Norfloxacin[2]
	Orbifloxacin[2]	Pradofloxacin[2]	
Other quinolones			
	Cinoxacin[2]	Flumequine	Oxolinic acid
Imidazole derivatives			
	Metronidazole[1]		

Class/subclass	Substances		
Pleuromutilins			
	Tiamulin	Valnemulin	
Polymyxins			
	Colistin	Polymyxin B[2]	
Nitrofuran derivatives			
	Furazolidone[1]		
Other antibacterials			
	Bacitracin	Fosfomycin	Furaltadone[1]
	Natamycin	Nitroxoline	Novobiocin
	Paromomycin	Rifaximin	Spectinomycin

[1] Included in Table 2 (prohibited substances) of the Annex to Commission Regulation (EU) No 37/2010.
[2] MRLs not established for any food-producing species.
[3] MRLs not established for poultry (not allowed to be used).

Annex 5. Selection of antimicrobial classes of WHO CIAs and AMEG Category 2 highlighted in the report

The WHO list of critically important antimicrobials for human medicine[26] and the list of antimicrobials categorised by the EU Antimicrobial Advice ad hoc Expert Group (AMEG)[27,28] were used as a basis to select the classes of antimicrobials highlighted in this report. The classes/subclasses highlighted are those antimicrobials used in veterinary medicine that are categorised as highest priority in the WHO list of CIAs for human medicine and also belong to AMEG Category 1 or 2: 3rd- and 4th-generation cephalosporins, macrolides[29], polymyxins and fluoroquinolones (Table A16).

Table A16. Antimicrobial classes highlighted in the report and their classification

Antimicrobial class	AMEG classification	WHO classification
3rd- and 4th-generation cephalosporins	Category 2	Highest priority CIAs (3rd- and higher-generation cephalosporins)
Fluoroquinolones and other quinolones	Category 2 (other quinolones not included)	Highest priority CIAs
Macrolides	Category 1	Highest priority CIAs
Polymyxins	Category 2	Highest priority CIAs
Aminoglycosides	Provisionally included in Category 2 (but no risk profiling has been provided)	CIAs
Certain penicillins (amoxicillin, ampicillin, metampicillin)	Provisionally included in Category 2 (but no risk profiling has been provided)	CIAs

Aminoglycosides and certain penicillins (aminopenicillins, i.e. amoxicillin, ampicillin and metampicillin) have been recently revised by the CVMP without suggesting a category for those groups of antimicrobials[30]. A revision of the classification of AMEG is currently ongoing and it is expected that updated scientific advice on AMEG on the categorisation of antimicrobials will be finalised by the end of 2019[31].

[26] WHO Critically important antimicrobials for human medicine. 6th revision. (https://www.who.int/foodsafety/publications/antimicrobials-sixth/en/)
[27] EMA/AMEG 2014. Answers to the request for scientific advice on the impact on public health and animal health of the use of antibiotics in animals (https://www.ema.europa.eu/en/documents/other/answers-requests-scientific-advice-impact-public-health-animal-health-use-antibiotics-animals_en.pdf)
[28] EMA/AMEG 2016. Updated advice on the use of colistin products in animals within the European Union: development of resistance and possible impact on human and animal health (https://www.ema.europa.eu/en/documents/scientific-guideline/updated-advice-use-colistin-products-animals-within-european-union-development-resistance-possible_en-0.pdf)
[29] According to the WHO classification, macrolides include also ketolides, which are not marketed in the EU/EEA countries for veterinary use.
[30] See the EMA website (www.ema.europa.eu): via Home> Veterinary regulatory> Research and development > Scientific guidelines > Safety and residues > Antimicrobials (https://www.ema.europa.eu/en/veterinary-regulatory/research-development/scientific-guidelines/safety-residues/safety-residues-antimicrobials)
[31] EC request for an update of the advice on the impact on public health and animal health of the use of antibiotics in animals: https://www.ema.europa.eu/en/documents/other/mandate-antimicrobial-advice-ad-hoc-expert-group-ameg_en.pdf

Annex 6. Distribution of veterinary medicines; legal framework and data sources by country

Austria

Distribution of veterinary medicines

In Austria, all veterinary medicinal products (VMPs) are prescription-only medicines. They are dispensed by pharmaceutical companies or wholesalers to veterinarians. Only veterinarians are allowed to sell VMPs to farmers. Veterinarians must confirm the distribution of veterinary drugs to owners of food-producing animals and horses if used for food production. Distribution of VMPs to farmers is restricted to VMPs registered for topical or oral use. Distribution of VMPs for intramammary use or for systemic use (injection) and premixes is restricted to farms that are members of the Austrian Animal Health Service. Sales of VMPs by public pharmacies must be prescribed by a veterinarian; such sales are negligible for farm animals.

Legal basis for the monitoring of sales

The collection of sales data by pharmaceutical companies and wholesalers is based on the national law on animal drug control: BGBl. II Nr. 83/2014 Veterinär-Antibiotika-MengenströmeVO.

Data sources

Sales data have to be uploaded into the national database by those pharmaceutical companies either producing or importing VMPs, and by wholesalers assigned by the industry to distribute a product.

Belgium

Distribution of veterinary medicines

In Belgium, all VMPs containing antimicrobial agents are prescription-only medicines. This includes medicated premixes containing antimicrobial agents as pharmaceutically active substances.

VMPs (pharmaceutical formulation) are distributed through wholesaler-distributors to veterinarians and pharmacists; the wholesaler-distributor obtains the VMPs from a wholesaler or the authorised producer. Antimicrobial VMPs are only available to animal owners via delivery from a pharmacy, on veterinary prescription, or directly from the veterinarian.

Premixes are distributed through wholesalers or wholesaler-distributors directly to feed mills. Only farmers are receivers from feed mills. Medicated feed is always on veterinary prescription.

Note: since 1 June 2014, the Federal Agency of Medicines and Health Products (FAHMP) has imposed a fee per package, according to the active ingredient content, for all veterinary antibiotics on the Belgian market on behalf of the MAHs. A higher fee is imposed if it concerns critically important antibiotics such as cephalosporins, quinolones or macrolides. Since 1 April 2018, the fees have increased (+75%).

Legal basis for the monitoring of sales

The collection of sales data is based on the national law on medicines of 25 March 1964 (Art. 12) and on the Royal Decree of 14 December 2006 on medicines for human and veterinary use (Arts. 221 and 228). Wholesaler-distributors and feed mills are obliged to keep records of all sales and to deliver these records to the FAHMP on a yearly basis.

Data sources

To avoid double counting, all wholesaler-distributors are asked to provide sales data for the antimicrobial VMPs delivered to pharmacies and veterinarians, while sales data for antimicrobial premixes are provided by the Belgian feed mills licensed to produce medicated feed and to deliver it to Belgian farmers.

Data collection for both concerned parties is organised via a secure web application with a login and password delivered by letter.

Import data on medicated feed produced in another EU country and delivered to Belgian farmers are not included in the material.

Bulgaria

Distribution of veterinary medicines

In Bulgaria, all VMPs containing antimicrobial agents are prescription-only medicines. This includes medicated premixes containing pharmaceutically active substances like antimicrobial agents. VMPs are distributed through wholesalers to veterinarians, farms and pharmacists; the wholesalers acquire the VMPs from another wholesaler or the authorised manufacturer. Antimicrobial VMPs are only available to animal owners by delivery from a pharmacy or wholesaler, on veterinary prescription, or directly from the veterinarian. Premixes are distributed through wholesalers directly to feed mills. Only farmers receive feed from feed mills. Medicated feed is always on veterinary prescription.

Legal basis for the monitoring of sales

The collection of sales data is based on the national law on veterinary activities, promulgated in the State Gazette (SG), Issue №7/25.01.2013. At the request of the Executive Director of Bulgarian Food Safety Agency (BFSA), in view of pharmacovigilance, the holder of a marketing authorisation for VMPs shall provide data on the volume of VMP sales. Wholesalers, pharmacies and farmers are obliged to keep records of all sales and purchases, and to deliver them to the BFSA on request.

Data sources

Sales data are collected from all manufacturers, importers and wholesalers, which are also either MAHs or official representatives of MAHs in Bulgaria (to avoid double counting, sales of other wholesalers are excluded). The data include the sales to veterinarians, farms and pharmacies.

Croatia

Distribution of veterinary medicines

In Croatia, all antimicrobial VMPs are prescription-only medicines. They are dispensed by pharmaceutical companies or wholesalers of VMPs to veterinary practices (surgery, station and hospital), veterinary pharmacies and feed mills. Animal owners can only buy antimicrobial VMPs on veterinary prescription in a veterinary pharmacy.

Large farms have authorised their own veterinary practices for their animals and can buy premixes on veterinary prescription from a veterinary pharmacy to use in feed mills. Feed mills should have a record of veterinary prescriptions covering each amount of antimicrobial VMP used.

Legal basis for the monitoring of sales

The collection of sales data by wholesalers is based on the national law, published in the Official Gazette of the Republic of Croatia, No: 84/08, 56/13, 94/13, 15/15 and 32/19.

Data sources

The veterinary antimicrobial agents' sales data are obtained each year from the authorised wholesalers.

Cyprus

Distribution of veterinary medicines

In Cyprus, all VMPs containing antimicrobials are prescription-only medicines. They are dispensed either by pharmacies or veterinary clinics. Veterinarians are only allowed to administer VMPs to those animals under their direct personal responsibility. The supply of VMPs to pharmacies and veterinary clinics is conducted by authorised wholesalers.

Medicated feeding stuffs containing antimicrobials are manufactured on a prescription basis, and only by authorised feed mills. Feeding stuffs manufactured in or imported into Cyprus are distributed by authorised suppliers and only administered on prescription by a veterinarian.

Legal basis for the monitoring of sales

The data are provided under legal requirements for the wholesaler/veterinarian/pharmacist to give any information requested.

Data sources

The data on sales of the veterinary antimicrobial agents included are collected each year from all authorised wholesalers and licensed feed mills in Cyprus.

Czechia

Distribution of veterinary medicines

In Czechia, all VMPs containing antimicrobial agents are prescription-only medicines. This includes medicated feeding stuffs manufactured from medicated premixes containing antimicrobials. There are five categories of receivers of antimicrobial VMPs from wholesalers: wholesalers (when selling to each other), veterinarians, pharmacies, farmers, and feed mills, while only farmers are receivers from feed mills. Medicated feed has to be prescribed by veterinarians and produced by feed mills authorised by the Institute for State Control of Veterinary Biologicals and Medicaments.

Legal basis for the monitoring of sales

The collection of sales data is based on a national law on pharmaceuticals, Act No. 378/2007 Coll.

Data sources

Sales data are collected from all wholesalers and feed mills licensed in Czechia.

Brief description of data collection

Manufacturers/wholesalers fill in the template with their quarterly sales data, divided into five categories (no data about customers); only sales for veterinarians, pharmacies and farmers are used to calculate consumption.

In the case of medicated premixes, the data reported by manufacturers of medicated feeding stuffs are used for calculation. Sales to wholesalers and manufacturers of medicated feeding stuffs are used for the verification of VMP sales.

Denmark

Distribution of veterinary medicines

In Denmark, all VMPs are prescription-only medicines and can only be dispensed either through pharmacies or via a small number of dispensing companies approved by the Danish Medicines Agency to dispense VMPs on the same legal terms as those to which the pharmacies are subject. Both pharmacies and dispensing companies are supplied by pharmaceutical companies and wholesalers. An exemption from the pharmacy/dispensing-company monopoly has been granted for medicated feeds, i.e. feeds into which VMPs formulated as premix are mixed prior to sale. Medicated feed must be prescribed by veterinarians and produced by feed mills authorised by the Danish Medicines Agency.

Legal basis for the monitoring of sales

All sales of prescription medicines by pharmacies, dispensing companies and feed mills are mandated to be reported to the VetStat database, owned by the Ministry of Environment and Food of Denmark. The pharmacy/dispensing-company sales records include sales of all prescription medicines to animal owners, as well as medicines purchased by veterinary practitioners for use in their practice. Furthermore, it is mandatory for the veterinarians to report to the VetStat medicines used in their own practices for food-production animals. Antimicrobial sales for companion animals are gathered from sales reported by pharmacies to veterinarians.

Data sources

Data on sales of all prescription medicines at package level from pharmacies, dispensing companies, veterinarians and feed mills are retrieved from the VetStat database.

Estonia

Distribution of veterinary medicines

In Estonia, antimicrobial VMPs are prescription-only medicines. VMPs have to be dispensed through pharmacies (general and veterinary) and veterinarians, who are supplied by wholesalers.

Legal basis for the monitoring of sales

Wholesalers are obliged to report the sales of VMPs to the State Agency of Medicines under the Medicinal Products Act of 2005.

Data source

The State Agency of Medicines collects sales data at package level from wholesalers. Only sales to pharmacies (general and veterinary) and veterinarians are accounted for, to avoid double reporting by including sales to other wholesalers.

Finland

Distribution of veterinary medicines

In Finland, all VMPs that contain antimicrobials are prescription-only medicines, which are available either from pharmacies on veterinarian prescription or directly from veterinarians. Veterinarians are allowed to dispense medicines for the treatment of animals under their care but are not allowed to profit from the sales. Pharmacies and veterinarians are supplied by wholesalers. Medicated feeds may either be produced by feed mills or imported into Finland, but always require a prescription from a veterinarian.

Legal basis for the monitoring of sales

Wholesalers are obliged to provide information on the sales of VMPs to the Finnish Medicines Agency in accordance with the Medicines Act (375/1987). Production and imports of medicated feeds must be reported to the Finnish Food Safety Authority in accordance with the Decree on Medicated Feeds (10/EEO/2008).

Data source

The sales data are obtained at package level from wholesalers by the Finnish Medicines Agency, which monitors the sales of VMPs. Sales of antimicrobial agents in medicated feed are monitored by the Finnish Food Authority which collects data from feed mills and other importers.

France

Distribution of veterinary medicines

In France, all VMPs are available on prescription only. VMPs are distributed mainly through wholesalers to veterinarians and pharmacists; wholesalers obtain the VMPs from marketing authorisation holders.

Legal basis for the monitoring of sales

A new law published at the end of 2014 makes the provision of data on antimicrobial sales to the competent authority mandatory.

Data sources

The sales data are collected from marketing authorisation holders at package level by Anses-ANMV (French Agency for Veterinary Medicinal Products), in collaboration with the French Veterinary Medicine Industry Association. Double reporting is avoided because the data are not provided by the wholesalers but directly by the MAHs which do not trade among one another.

Germany

Distribution of veterinary medicines

In Germany, all VMPs containing antimicrobial agents are prescription-only medicines. Veterinarians are allowed to dispense drugs directly to the farmer for the treatment of animals in their care. Veterinarians are supplied with VMPs directly from pharmaceutical companies or wholesalers. Very few animal owners acquire VMPs from pharmacies.

Premixes have to be prescribed by veterinarians and medicated feed is produced by officially authorised feed mills thereafter.

Legal basis for the monitoring of sales

The collection of sales data from pharmaceutical companies and wholesalers is based on German medicines law which is further specified in a specific regulation.

Data sources

Data on sales to veterinarians are collected by pharmaceutical companies and wholesalers which dispense antimicrobial agents to veterinarians located in Germany. In the case of premixes, sales data are taken from periodic safety update reports, because premixes are provided to feed mills on prescription and thus are not included in the data on sales to veterinarians.

Greece

Distribution of veterinary medicines

In Greece, all antimicrobial veterinary medicinal products are prescription-only medicines. MAHs or local representatives provide VMPs to wholesalers and retailers. Wholesalers can also provide VMPs to retailers. Only retailers can provide VMPs to the customer with a valid prescription.

Legal basis for the monitoring of sales

The collection of sales data by MAHs is based on the joint ministerial law: KYA 282371/16-06-2006.

Data sources

In 2017, sales for veterinary antimicrobial agents were reported to the ESVAC for the third time. Data were provided by 81 marketing authorisation holders. Negligible sales from a few MAHs with a very small market share, and without local representatives in the country, were not included in the 2015, 2016 and 2017 datasets.

Hungary

Distribution of veterinary medicines

In Hungary, all VMPs that contain antimicrobials are prescription-only medicines. All VMPs have to be dispensed through authorised retailers, which are only supplied by authorised wholesalers. Wholesalers are authorised by the county government office, and retailers are authorised by the district government office.

Antimicrobial VMPs can be bought from a wholesaler by other wholesalers, retailers, veterinarians, farmers or feed mills. The route of VMPs must be documented as it must be possible to control the journey of each batch from the manufacturer to the farmer.

According to EU rules, medicated feeds are classified as feed and not as VMPs. They have to be prescribed by veterinarians, and produced by feed mills authorised by the government office. Medicated feeds may be imported into Hungary, but require a prescription by a veterinarian, like other medicated feeds. Importation of medicated feeds is supervised by the office which authorises importers and distributors.

Legal basis for the monitoring of sales

There is no legal basis for mandatory reporting of sales data; monitoring of sales takes place voluntarily.

Data sources

Data are collected from wholesalers in Hungary. These wholesalers only submit data for those products they have sold to veterinarians, feed mills, farmers and retailers, but not to other wholesalers (i.e. there is no double reporting).

Iceland

Distribution of veterinary medicines

In Iceland, all antimicrobial VMPs and almost all other VMPs are prescription-only medicines. They must be dispensed to animal owners by veterinarians (or used by the veterinarians in their practices), or pharmacies, i.e. veterinarians are allowed to dispense VMPs in the same way as pharmacies. Veterinarians and pharmacies can only purchase VMPs from licensed wholesalers. No medicated feeding stuffs for livestock are produced by feed mills in Iceland.

Legal basis for the monitoring of sales

Wholesalers in Iceland are mandated to provide sales statistics for both human and veterinary medicinal products, as well as for medicated feeding stuffs, to the Icelandic Medicines Agency.

Data sources

The data on sales of the included veterinary antimicrobial agents at package level are provided by wholesalers in Iceland, of which there are only two.

Ireland

Distribution of veterinary medicines

In Ireland, antimicrobial veterinary medicinal products may only be supplied on prescription. The products are supplied to the trade by wholesalers authorised by the Department of Agriculture, Food and the Marine. In accordance with the prescription of the prescribing veterinarian, the prescribed products can be dispensed either by the veterinarian or by a pharmacist. By way of an exception to this rule, intramammary antimicrobial substances can also be dispensed by licensed agricultural merchants. Medicated feeds containing antimicrobials are prepared from authorised premixes, again under veterinary prescription. They are incorporated into the feed under a special authorisation granted by the Department of Agriculture, Food and the Marine. The licences for incorporation are granted either to feed mills or to farms that have the appropriate facilities for inclusion. It should be noted that the sale, supply or possession of any unauthorised veterinary medicine in Ireland is a criminal offence.

Legal basis for the monitoring of sales

There is currently no legal basis requiring wholesalers to supply data relating to the volume of sales of authorised veterinary medicinal products. However, marketing authorisation holders are obliged to report sales data.

Data sources

Each year, the Health Products Regulatory Authority (HPRA) collects data from veterinary pharmaceutical manufacturers currently holding Irish marketing authorisations. These holders are requested by the HPRA to only report sales in Ireland. The HPRA checks the information provided against data collected for previous years. Fluctuations in the data from year to year are followed up with the individual company to guard against data errors. The importation of medicated feed is permitted. However, in practice, given the logistics involved, this is not seen as a major route of supply into the country.

Italy

Distribution of veterinary medicines

In Italy, antimicrobial agents for use in animals are prescription-only medicines. Therefore, their sale to the end-user can only take place upon presentation of a veterinary prescription. The sale of veterinary medicines (including antimicrobial agents) on Italian territory may take place as described below:

Wholesale of veterinary medicines

This type of sale includes all forms of business transaction except sales to the end-user. It can only be done on storage premises authorised for the purpose by the local competent authority.

Wholesale of veterinary medicinal products includes transactions between:

- marketing authorisation holders or their representatives and wholesalers;
- marketing authorisation holders or their representatives and pharmacies;
- wholesalers;
- wholesalers and pharmacies;
- wholesalers and feed mills authorised to produce medicated feeds (premixes for medicated feed).

Direct sale of veterinary medicinal products

Holders of authorised wholesale veterinary medicines storage premises may, as a result of further authorisation by the local competent authority, also make direct sales of such products to breeders, pet owners, veterinarians and veterinary care facilities. This type of transaction also includes the sale of premixes for medicated feed by wholesalers, pharmacies and manufacturers to farms authorised to produce medicated feed for self-consumption. Such sales may take place only in the presence of a pharmacist and, in the case of antimicrobial agents, only under veterinary prescription.

Retail veterinary medicinal products

The retail sale of veterinary medicinal products containing antibiotics can only take place at pharmacies, under veterinary prescription, and only in the presence of a pharmacist.

Farmers, veterinarians, breeding and healthcare facilities may, on request, be authorised by the local competent authority to hold stocks of veterinary medicinal products. Stocks of veterinary drugs, including antibiotics, can only be purchased under veterinary prescription. Farms cannot hold stocks of antibiotics in the form of medicated feed or veterinary drugs administered in feed, water or liquid feed. Only small quantities can be held, not exceeding a treatment period of seven days.

Veterinarians cannot sell veterinary drugs (including antibiotics). When required by professional intervention, veterinarians are allowed to deliver open packages of veterinary medicines from their stocks to the breeder or the animal owner to start the therapy. For companion animals, the veterinarian may also deliver unopened packages.

Legal basis for the monitoring of sales

The collection of sales data by pharmaceutical companies is based on the national law 193/2006 (art. 32(3)) transposing EC Directive 2004/28.

Data sources

Sales data are collected from pharmaceutical companies producing or importing VMPs.

Latvia

Distribution of veterinary medicines

In Latvia, all VMPs containing antimicrobial agents are prescription-only medicines. This includes medicated feed manufactured from medicated premixes containing antimicrobial agents. VMPs are distributed through wholesalers to pharmacies, veterinarians and licensed farms. VMPs for licensed farms must have been ordered by the veterinarian contracted to provide routine healthcare services. Animal owners without the licence can only purchase VMPs containing antibiotics on veterinary prescription in pharmacies.

Legal basis for the monitoring of sales

Sales data are collected by the Food and Veterinary Service. This task is mandated by the Law of Pharmacy and the related Regulation of the Cabinet of Ministers.

Data sources

Sales data are collected from all wholesalers in Latvia at package level by the Food and Veterinary Service. Wholesalers are asked to report in detail what medicines are sold, to determine real consumption of VMPs, and to avoid double reporting or export of VMPs.

Lithuania

Distribution of veterinary medicines

In Lithuania, all VMPs that contain antimicrobial agents are prescription-only medicines. All VMPs must be dispensed to veterinarians or farmers through wholesalers or pharmacies. Medicated feed is also subject to prescription by a veterinarian.

Legal basis for the monitoring of sales

Wholesalers are obliged to provide information on sales of VMPs to the State Food and Veterinary Service of the Republic of Lithuania, in accordance with national law.

Data sources

Data on sales of antimicrobial VMPs at package level are obtained from wholesalers by the State Food and Veterinary Service of the Republic of Lithuania.

Luxembourg

Distribution of veterinary medicines

In Luxembourg, all veterinary medicinal products (VMPs) containing antimicrobial agents are prescription-only medicines. This includes medicated premixes containing pharmaceutical agents.

VMPs containing antimicrobial agents are distributed through wholesalers to pharmacies or to veterinarians (via pharmacies' records). Veterinarians are allowed to keep VMPs in stock and to dispense them to farmers for the treatment of animals in their care.

Legal basis for monitoring

Wholesalers, pharmacies, veterinarians and farmers are legally obliged to keep records of all sales. They are legally bound to provide any data or information requested of them.

Data sources

The data on sales of veterinary antimicrobial agents at package level are obtained from the authorised wholesalers on a yearly basis.

Malta

Distribution of veterinary medicines

In accordance with Regulation 60 of Subsidiary Legislation 437.47, a veterinary prescription is required for dispensing to the public veterinary medicinal products for food-producing animals. In all cases of medicated feed, a veterinary prescription is required in accordance with Subsidiary Legislation 437.73. All veterinary medicinal products that contain antimicrobials are registered as prescription-only medicines. In accordance with Regulation 58 of Subsidiary Legislation 437.47, distribution of veterinary medicinal products is subject to the holding of an authorisation. In the case of medicated feed, the authorised medicated feed mill or the authorised feed trader can also distribute the finished medicated feed directly to farms.

Legal basis for monitoring

There is no legal basis for reporting of veterinary antimicrobial sales data in Malta, and monitoring is done on a voluntarily basis by the Veterinary Medicines Section, which falls under the administration of the Ministry for the Environment, Sustainable Development and Climate Change.

Data sources

Once a year, the Veterinary Medicines Section collects sales data on antimicrobials from all authorised veterinary distributors, medicated feed mills and medicated feed traders.

Netherlands

Distribution of veterinary medicines

In the Netherlands, antimicrobial VMPs are available on prescription only. Veterinarians purchase approximately 40% of their VMPs directly from the manufacturers and approximately 60% through wholesalers. About 98% of the total volume of antimicrobial VMPs is dispensed by marketing authorisation holders who are either direct members of the Dutch federation of the veterinary pharmaceutical industry (FIDIN) or are represented by FIDIN members. An estimated 2% are sold by authorisation holders not associated with FIDIN. Veterinarians sell the products directly to animal owners. Pharmacies dispense only minor quantities of VMPs.

Legal basis for the monitoring of sales

Currently, there is no legal basis for mandatory reporting of sales data; monitoring of sales takes place voluntarily.

Data sources

The sales data are obtained at package level from the MAHs who are (represented by) members of FIDIN. Since sales data are obtained from marketing authorisation holders only, including both their sales to wholesalers and their direct sales to veterinarians, there is no double reporting of wholesalers' sales.

Norway

Distribution of veterinary medicines

In Norway, all VMPs are prescription-only medicines, which are generally dispensed through pharmacies supplied by drug wholesalers. Veterinarians, in general, are not allowed to dispense VMPs. Medicated feeds are not used for food-producing animals except for farmed fish; this is due to the small size of livestock herds compared to those in most other European countries. However, group/flock treatment of livestock with antimicrobial agents is possible, again subject to veterinary prescription, through drinking water or as top dressing on feed by using an oral solution or oral powder, respectively.

Legal basis for the monitoring of sales

Wholesalers and feed mills in Norway are mandated to provide sales statistics for both human and veterinary medicinal products, as well as for medicated feedstuffs, to the Norwegian Institute of Public Health (NIPH).

Data sources

Data on the sales of the veterinary antimicrobial agents included at package level are obtained from the NIPH, which collects its data from authorised wholesalers and feed mills (only relevant for aquaculture). To avoid double reporting by including sales among the wholesalers, the wholesalers and feed mills are asked by the NIPH to only report sales to pharmacies and animal owners in Norway.

Poland

Distribution of veterinary medicines

Most VMPs, including antimicrobial VMPs, are prescription-only medicines. VMPs are distributed by wholesalers to veterinarians. Antimicrobial VMPs are only available to animal owners if the veterinarian delivers them. Veterinarians and medicated-feed producers are allowed to buy medicated premixes from wholesalers. However, before purchase, medicated-feed producers must obtain confirmation from the district veterinary officer.

Legal basis for the monitoring of sales

In accordance with national pharmaceutical law, wholesalers are obliged to provide data on sales of VMPs.

Data sources

Sales data are collected from wholesalers who deliver VMPs directly to veterinarians. Wholesalers fill in the template with their quarterly sales data.

Portugal

Distribution of veterinary medicines

In Portugal, all VMPs containing antimicrobial agents are prescription-only medicines. This includes medicated premixes containing pharmaceutically active substances, like antimicrobial agents. VMPs containing antimicrobial agents are provided by wholesaler-distributors to retailers of veterinary medicinal products (both human and animal pharmacies), farmers, veterinarians, producers' organisations, veterinary clinics and hospitals, and feed mills.

Wholesaler-distributors obtain the VMPs from a wholesaler or from the MAH/manufacturer. Antimicrobial VMPs are only available to animal owners/farmers by means of an official veterinary prescription. Veterinarians do not sell VMPs and can only charge for those they use to treat animals in their care. Premixes are distributed through wholesalers or wholesaler-distributors directly to feed mills. Only farmers are receivers from feed mills. Medicated feeds containing antimicrobial premixes also have to be prescribed by a veterinarian and can only be manufactured by officially authorised feed mills.

Legal basis for the monitoring of sales

The collection of sales data is based on the national law no. 148/2008, dated 29 July (Art. 120), amended and reprinted by national law no. 314/2009, dated 28 October.

Data sources

Data are provided by wholesalers who are authorised to sell veterinary medicinal products containing antibiotics.

Romania

Distribution of veterinary medicines

In Romania, all VMPs containing antimicrobial agents are prescription-only medicines.

Wholesalers must supply medicinal products only to those authorised to provide retail activities or those who are legally allowed to purchase medicinal products from wholesalers. Retail distribution of the veterinary medicinal products is performed only by those authorised to carry out such operations in accordance with the national legislation.

Marketing of veterinary medicinal products is carried out according to the veterinary legislation in force, i.e. only through veterinary pharmaceutical establishments which are authorised by the National Sanitary Veterinary and Food Safety Directorate.

Legal basis for the monitoring of sales

The collection of sales data is based on the national law on veterinary activities – Order of the National Sanitary Veterinary and Food Safety President - promulgated in the Official Monitor from 15 October 2015.

The MAHs are obliged to report sales of the antimicrobials each year before 15 March, and to deliver these records to the Institute for Control of Biological Products and Veterinary Medicines, which reports the data to the ESVAC.

Data sources

For 2014, the sales data were collected from 37 wholesalers and those 11 MAHs which distributed their own products. The data include the sales to veterinarians, farmers and pharmacies. From 2015, according to the updated veterinary law, the sales data are collected from MAHs only.

Slovakia

Distribution of veterinary medicines

In Slovakia, all VMPs containing antimicrobial agents are prescription-only medicines, including medicated feeding stuffs manufactured from medicated premixes containing antimicrobial agents. There are four categories of receiver of antimicrobial VMPs from wholesalers to wholesalers (when selling to each other), veterinarians, pharmacies and feed mills, while only farmers are receivers from feed mills. Medicated feed has to be prescribed by veterinarians and produced by feed mills authorised by the Institute for State Control of Veterinary Biologicals and Medicaments Nitra.

Legal basis for the monitoring of sales

The collection of import data is based on a national law on pharmaceuticals, Act No. 362/2011 Coll.

Data sources

For 2011 and 2012, import data were collected from all wholesalers licensed in the Slovak Republic; from 2013, data represent sales from wholesalers to end-users.

Brief description of data collection

Wholesalers send their quarterly import data (number of packs, pack size, name of the product, batch number, etc.) and manufacturers send their quarterly production data to the Institute for State Control of Veterinary Biologicals and Medicaments Nitra.

Slovenia

Distribution of veterinary medicines

In accordance with applicable legislation, antimicrobial VMPs are dispensed in the Republic of Slovenia on the basis of a veterinary prescription only. Wholesalers deliver antimicrobial VMPs to retailers, i.e. pharmacies and veterinary organisations, and to approved medicated-feed mills.

Legal basis for the monitoring of sales

Wholesalers are required by law to report to the competent authority on the turnover (sales) of all medicinal products.

Data sources

Data on sales of veterinary antimicrobial agents at package level were obtained from the wholesalers.

Spain

Distribution of veterinary medicines

In Spain, all VMPs containing antimicrobials are prescription-only medicines, so they can only be dispensed under veterinary prescription. All suppliers to final users of VMPs (wholesalers, retailers, pharmacies and farmers' co-operatives) are authorised according to national law and have a mandatory pharmacist control service. Dispensing is most frequently done by retailers. Veterinarians in Spain are allowed to use VMPs in their daily practice, but they cannot sell VMPs to animal owners.

Medicated feeds containing antimicrobial premixes also have to be prescribed by a veterinarian and can only be manufactured by feed mills authorised by regional competent authorities according to specific legislation and to the feed hygiene regulation (Hazard Analysis and Critical Control Point principles).

Legal basis for the monitoring of sales

There is a legal basis for mandatory reporting of sales data from the distributors of such products, while monitoring sales from the MAHs takes place voluntarily.

Data sources

For 2017, the sales data are collected from retailers at package level by the Spanish Agency for Veterinary Medicinal Products (AEMPS), in collaboration with the Spanish veterinary medicine industry association (Veterindustria) and the Spanish business association of additives and premixes for animal health and nutrition (Adiprem).

Sweden

Distribution of veterinary medicines

In Sweden, antimicrobial VMPs may only be sold on prescription. VMPs must be dispensed through pharmacies, which are supplied by drug wholesalers or MAHs. Feed mills may only mix antimicrobial VMPs in feed if they are controlled and authorised by the Swedish Board of Agriculture. Sales of medicated feed to farmers are only allowed on prescription (i.e. the farmer presents the prescription to the feed mill). Mixing of antimicrobials in feed may also take place on farms, provided that the Swedish Board of Agriculture has controlled and authorised the establishment for this purpose. In such cases, the premix is purchased on prescription and dispensed by a pharmacy.

Legal basis for the monitoring of sales

All pharmacies in Sweden are required to provide sales statistics on a daily basis to a central database. Until and including 2013, this was an infrastructure company owned by the state, Apotekens Service AB. Since 1 January 2014, all activities within that company have been transferred to the Swedish eHealth Agency. All feed mills and farms authorised to mix medicated feed are requested to report their purchases and sales on a yearly basis to the Swedish Board of Agriculture.

Data sources

Pharmacy data on dispensation of prescriptions to animal owners or requisitions by a veterinarian (e.g. sales from pharmacies to animal owners or to veterinarians for use in practice) at package level have been obtained from Apotekens Service AB/the Swedish eHealth Agency.

Switzerland

Distribution of veterinary medicines

In Switzerland, all VMPs are prescription-only medicines and have to be dispensed by either the treating veterinarian or a pharmacy. Medicated feeds for livestock (terrestrial animals) are either produced in feed mills using authorised premixes, or incorporated on-site following prescription and dispensing by veterinarians. Group treatment of livestock with antimicrobial agents is possible, subject to veterinary prescription and supervision, through medicated feed, drinking water or as top dressing.

Legal basis for the monitoring of sales

The legal basis for data collection is Art. 35 of the Federal Ordinance on Veterinary Medicines, enacted in September 2004. Art. 36 requests the Federal Office of Food Safety and Veterinary Affairs to "specifically establish a statistic about usage of veterinary antimicrobials for the purpose of monitoring resistances". Sales of veterinary antimicrobials are published yearly in the ARCH-VET report covering sales and resistances to veterinary antimicrobials. Note that figures published in the national ARCH-VET report differ from figures in the present report since all ATCvet groups are included in the national report.

It must be highlighted that since 1 January 2019 the regulatory framework for data collection in Switzerland has been moved to a new legislative text.

Data sources

Data are obtained at package level from the MAHs. They are requested, processed and analysed by the Federal Food Safety and Veterinary Office.

Data coverage

Coverage is assumed to be nearly 100% for the sales of authorised antimicrobial agents. Since no prescription figures are currently available at national level, sales figures cannot be further validated. Veterinarians may import VMPs for companion and food-producing animals, including products containing antimicrobial agents, based on a single authorisation valid for one year and delivered by Swissmedic, the Swiss Agency for Therapeutic Products. As these products are not sold by marketing authorisation holders or wholesalers in Switzerland, and since these single authorisations are not delivered for a defined quantity, these products cannot be monitored and are therefore not included in the statistics.

United Kingdom

Distribution of veterinary medicines

In the United Kingdom, antimicrobial veterinary medicinal products may only be supplied on prescription. The products can be dispensed either by the veterinarian or by a veterinary pharmacist and, in turn, can only be supplied by a wholesale dealer authorised by the United Kingdom Veterinary Medicines Directorate. Medicated feeds have to be prescribed by veterinarians and manufactured either by authorised feed mills or by authorised farms. Medicated feeds are used primarily for pig and poultry production.

Legal basis for the monitoring of sales

Manufacturers are legally required to supply data relating to the volume of sales of authorised veterinary medicinal products at the request of the Veterinary Medicines Directorate.

Data sources

The United Kingdom Veterinary Medicines Directorate collects data from those veterinary pharmaceutical manufacturers that hold current United Kingdom marketing authorisations.

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Annex 8. Country and affiliation of the ESVAC national contact points/alternates

Table A17. List of ESVAC national contact points/alternates 2019

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Annex 9. ESVAC sales advisory expert group members and observers

Table A18. List of ESVAC sales advisory expert group members

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Trends from 2010 to 2017
Ninth ESVAC report
EMA/294674/2019

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