EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Sales of veterinary antimicrobial agents in 31 European countries in 2018

Trends from 2010 to 2018

Tenth ESVAC report

10 YEARS ANNIVERSARY

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 tenth ESVAC report presents data on the sales of veterinary antimicrobial agents from 31 European countries in 2018, 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 2010-2018 (Chapter 2.8).

Of note is that compared to previous editions, this report does not present changes over the years by country (chapter 2.8.2 in previous reports). Information on country specific changes in sales over the years will be published in a separate addendum.

The report emphasises certain classes or subclasses of antimicrobials included in Category B of the categorisation made by the EMA Antimicrobial Advice ad hoc Expert Group (AMEG) in 2019 (see selection criteria in Annex 5). The AMEG categories consider the World Health Organization (WHO) categorisation of antimicrobials[3], the need for those antimicrobials in veterinary medicine and the probability of transfer of antimicrobial resistance from animals to humans. The AMEG classification is published on the EMA webpage[4].

Category B of the AMEG categorisation includes those veterinary antimicrobials where the risk to public health is estimated to be higher than other classes of veterinary antimicrobials; fluoroquinolones, other quinolones, 3rd- and 4th-generation cephalosporins and polymyxins are included in this category. Macrolides are not included in Category B of the AMEG categorisation[5].

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

[3] WHO Critically Important Antimicrobials for Human Medicine. 6th revision (https://www.who.int/foodsafety/publications/antimicrobials-sixth/en/).

[4] EMA/AMEG 2019. Categorisation of antibiotics in the European Union. Answer to the request from the European Commission for updating the 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/report/categorisation-antibiotics-european-union-answer-request-european-commission-updating-scientific_en.pdf).

[5] Although macrolides are not included in Category B, the CVMP has made recommendations indicating that, among other things, 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.

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)[6]. 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 a desirable objective in order to contain AMR.

ECDC, EFSA and EMA have also jointly established a list of harmonised outcome indicators[7] 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 tenth ESVAC report places the emphasis on food-producing animals.

The data and information included in this report have 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 few years 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 should be underlined that data presented in this report should not be used for direct comparison between countries, as more detailed information and analysis would be needed.

[6] 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

[7] 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 2018.

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 2018, expressed as mg/PCU, was observed between the countries with highest and lowest sales (range 2.9 to 466.3 mg/PCU); total aggregated sales linked to aggregated PCU for all 31 countries which delivered data in 2018 was 103.2 mg/PCU, while the median was 57.0 mg/PCU.

Of the overall sales of antimicrobials in the 31 countries in 2018, the largest amounts, expressed as mg/PCU, were accounted for by tetracyclines (30.7 %), penicillins (28.8 %) and sulfonamides (8.4 %). Overall, these three classes accounted for 67.9 % 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 2018, notable variations in the proportion of antimicrobial classes included in the EMA AMEG Category B were observed between countries, i.e. 3rd- and 4th-generation cephalosporins, fluoroquinolones, other quinolones and polymyxins – with sales ranging from <0.01 to 0.9 mg/PCU, <0.01 to 10.9 mg/PCU, 0 to 2.5 mg/PCU and 0 to 12.8 mg/PCU, respectively (Table 5). For these classes, sales (mg/PCU) for food-producing animals in the 31 countries accounted for 0.2 %, 2.5 %, 0.3 % and 3.3 % of total sales, respectively. In addition to the antimicrobial classes belonging to AMEG Category B, WHO has classified macrolides as critically important antimicrobials (CIAs) with the highest priority for human medicine. Macrolides accounted for 7.7 % of the total sales of antimicrobials for food-producing animals in the 31 countries in 2018.

When aggregated for 31 countries, sales (mg/PCU) of pharmaceutical forms suitable for group treatment accounted for 87.7 % of the total sales: premixes accounted for 26.9 %; oral powders for 9.0 %; and oral solutions for 51.8 % (Figure 8). The proportion accounted for by pharmaceutical forms applicable to group treatment varied substantially between countries, ranging from 2.3 % to 95.0 % (Figure 7). Of the pharmaceutical forms intended for treatment of individual animals (12.3 % of total sales across all countries), 11.4 % of the sales were accounted for by injectable preparations, 0.6 % by intramammary preparations and 0.3 % by oral pastes, boluses and intrauterine preparations (Figure 8).

In 2018, overall in the 31 countries, the proportion of the total sales of antimicrobial veterinary medicinal products (VMPs) suitable for group treatment (oral powder, oral solution and premix) that contained one active ingredient was 87.5 %; 12.5 % contained two or more active ingredients (Figure 20).

For the 25 countries which provided sales data for all years between 2011 and 2018, an overall decline in sales (mg/PCU) of 34.6 % was observed. Overall sales fell from 161.4 mg/PCU in 2011 to 105.6 mg/PCU in 2018 in these countries (Figure 23). A fall in sales (mg/PCU) of more than 5 % was observed in 18 of these 25 countries (ranging from -6.2 % to -58.2 %), whilst there was an increase of more than 5 % in five countries during the reference period (ranging from 13.0 % to 32.7 %) (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 overall sales and resulted in the 34.6 % reduction observed during this period.

The total sales of the AMEG Category B antimicrobials in these 25 countries showed a decreasing trend, which contributed to the overall decrease. Specifically, between 2011 and 2018, sales of 3rd- and 4th-generation cephalosporins decreased by 24.4%, polymyxins decreased by 69.8%, fluoroquinolones decreased by 4.2% and sales of other quinolones decreased by 74.4%.

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 the 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 duration of treatment. Since, these factors can only partly explain the differences in the sales observed between the 31 countries, 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 in 2015) or have identified under-reporting for some of the years (e.g. Bulgaria in 2014 and Spain in 2014), which may also have an impact on the data. Overall, this emphasises that the data presented in this report should not be used for direct comparison between countries without considering, among other things, the above-mentioned differences, 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)[8], 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 data on the 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 the 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 activity, data are collected on sales of antimicrobial VMPs at package level from the EU Member States, EEA countries and Switzerland. Furthermore, in 2016, the ESVAC established defined daily doses for animals (DDDvet) and defined course doses for animals (DCDvet) (EMA/224954/2016[9]). To prepare for the collection of data by animal species, in 2018, the ESVAC published guidance on the collection of harmonised and standardised data from Member States on the use of antimicrobials by species[10].

Article 57 of Regulation (EU) 2019/6 on veterinary medicinal products[11] requests mandatory reporting of data on antimicrobial medicinal products used in animals. It states that the Agency shall cooperate with Member States and with other Union agencies to analyse data on antimicrobial sales and use and shall publish an annual report.

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

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

[10] 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: https://www.ema.europa.eu/en/documents/scientific-guideline/guidance-collection-provision-national-data-antimicrobial-use-animal-species/categories_en.pdf

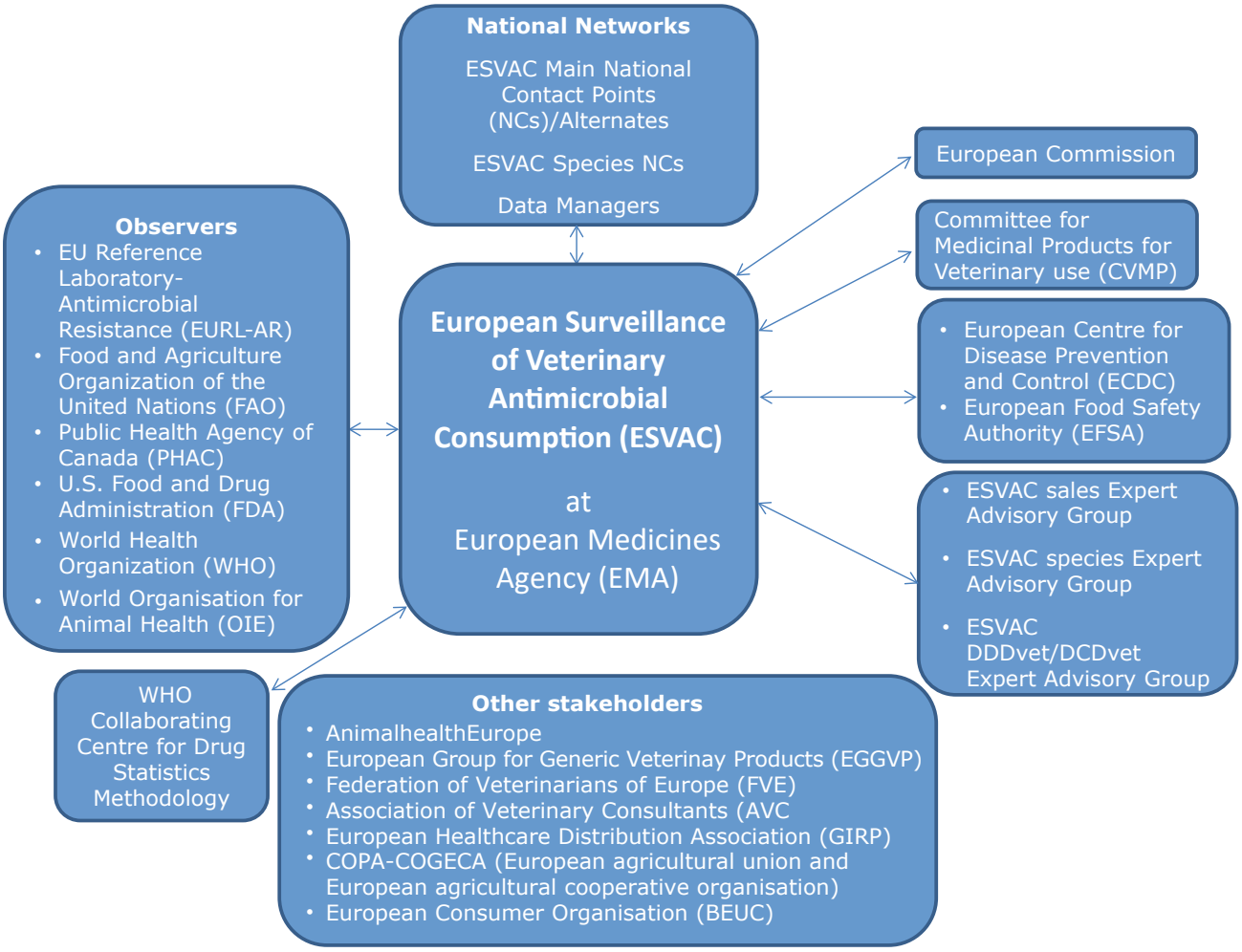
[11] Official Journal of the European Union, 2019. 'Regulation (EU) 2019/6 of the European Parliament and of the Council of 11 December 2018 on veterinary medicinal products and repealing Directive 2001/82/EC', https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32019R0006&from=EN

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

The core of the ESVAC responsible for sales data collection is the ESVAC network of main NCs and alternates, nominated by the national competent authorities in the participating countries. The 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.

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



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)[12].

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

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[13] has defined which antimicrobials are to be included in the data sets by using the Anatomical Therapeutic Chemical classification system for VMPs (ATCvet[14]) (Table 1). Of note is that all the antimicrobials included in the dataset encompass substances with an antibacterial activity. All pharmaceutical forms, including premixes used to produce medicated feed, are included except dermatological preparations (ATCvet group QD) and preparations for sensory organs (ATCvet group QS). The contribution of these pharmaceutical forms, in tonnes of active ingredient, to the total amount of veterinary antimicrobials sold is considered to be minimal, and therefore the impact of the deviation is negligible. It should be noted that the use of antimicrobial growth promoters is prohibited in the ESVAC participating countries, and therefore they are not part of the data collection. Ionophore coccidiostat feed additives and veterinary medicines containing zinc oxide[15] are not included in the data material. Also, other active ingredients, which are not classified as antibiotics, e.g. antiprotozoals (with no antibacterial effect), antivirals, antifungals and anti-inflammatory ingredients, fall out of the scope of the ESVAC protocol.

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[14] 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*	QP51AG

* Solely sulfonamides

1.2. Variables reported for each antimicrobial veterinary medicinal product

Detailed information on the variables to be reported for each antimicrobial VMP 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[16]. To standardise the information, including for the purposes of data management, the following categories of pharmaceutical forms have been applied for reporting sales data to the ESVAC: boluses, injectable preparations, 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 the product information contains instructions such as 'powder for solution' or 'powder for administration in drinking water', the form should be reported as an oral solution. Premixes are VMPs, intended for incorporation into medicated feedingstuffs, usually produced by feed mills.

[13] Available on the EMA website (www.ema.europa.eu): https://www.ema.europa.eu/en/documents/other/european-surveillance-veterinary-antimicrobial-consumption-esvac-data-collection-protocol_en.pdf

[14] www.whocc.no/atcvet/

[15] On 26 June 2017, the European Commission issued a decision to request the Member States to withdraw in five years from the above date existing marketing authorisations of veterinary medicinal products containing zinc oxide to be administered orally to food-producing animals. (C(2017) 4529 final)

[16] 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 provide the number of packages sold for each product presentation – i.e. name of VMP, pharmaceutical form, strength of active ingredient and pack size for each calendar year within the territory of the country. Data are directly uploaded into the ESVAC database by the reporting countries using the ESVAC web-based application. The volume of active antimicrobial ingredient in tonnes sold for each product presentation is calculated by multiplying the number of packages sold by the strength of active antimicrobial ingredient per unit of presentation package, as declared in corresponding product information. For fixed combination VMPs, the amount sold is calculated for each antimicrobial ingredient separately. Tonnes sold for each product presentation are automatically calculated in a standardised and harmonised manner by the ESVAC web-based application tool. This implies application of standard conversion factors to calculate from international units (IU) to mg when the strength is given in IU (Table A11) and when prodrug standard conversion factors are used to convert to mg of active antimicrobial ingredient (Table A12).

1.4. Denominator: population correction unit (PCU)

The amounts of veterinary antimicrobial agents sold in the different countries are normalised by the animal population that could potentially be 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)[17]. 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 that could potentially be treated.

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 of treatment. However, due to the limited availability of live goats data via Eurostat, this category was not included when the PCU methodology was established for the first ESVAC report[18]. For countries with a relatively high number of goats compared to other food-producing animals, this results in an underestimation of the PCU. For farmed fish, Eurostat data are given only as live-weight at slaughter rather than weight of slaughtered farmed fish; thus, for fish biomass live-weight slaughtered is used to calculate the total PCU.

For animals exported or imported for fattening or slaughter (cattle, goats, pigs, sheep and poultry), the PCU is calculated by multiplying the number of animals by a standardised weight.

The PCU of the animals exported for fattening or slaughter to another Member State — i.e. cattle, pigs, poultry, goats and sheep — is 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 is subtracted from the total PCU of livestock and slaughter animals of the importing country in order 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 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

[17] Available on the EMA website (www.ema.europa.eu) via: Home > Veterinary regulatory > Overview > Antimicrobial resistance > European Surveillance of Veterinary Antimicrobial Consumption > https://www.ema.europa.eu/en/documents/report/trends-sales-veterinary-antimicrobial-agents-nine-european-countries_en.pdf

[18] 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)

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 data above.

1 PCU = 1 kg of animal biomass.

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. The Eurostat database[19] was therefore 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 are 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 are used. Data on dogs and cats are not available in all participating countries. Therefore, these species are not included in the PCU in order to have comparable data. As tablets are typically approved only for companion animals, they are excluded from the data sets prior to the normalisation of sales by PCU.

The Eurostat data on the 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 are 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

Occasionally during data validation processes, inconsistencies in previously submitted datasets may be identified. This may be due to several reasons, e.g. new official statistics becoming available or a specific inaccuracy identified for a product presentation. In such cases, data should be rectified in all relevant datasets.

The introduction of amendments to already approved datasets is encouraged in order to present accurate sales of antimicrobial VMPs for each country per year.

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

1.5.1. Sales data

Iceland identified inconsistencies in the forms reported for a minor number of presentations for the 2010-2017 datasets. This led to revisions to sales data, which 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 2017 report[20]. For France, the data on live horses were updated for previous years, i.e. 2010-2018. For Greece, the data for slaughtered rabbits were revised for 2015 to 2017. For Poland, the data for biomass of fish produced were revised for 2011-2017. For Portugal, the data for slaughtered rabbits were amended for 2017. For Slovakia, the data for slaughtered turkeys were corrected for 2011-2017 and the number of slaughtered rabbits was modified for 2017. Although difference in mg/PCU following the updates was apparent, it was not extensive.

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

[20] Sales of veterinary antimicrobial agents in 31 European countries in 2017 (https://www.ema.europa.eu/en/documents/report/sales-veterinary-antimicrobial-agents-31-european-countries-2017_en.pdf)

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

The countries participating in the 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 data 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 and with official product information available in the registers of nationally-authorised medicinal products. 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 the 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.

1.7. Analysis and reporting of the data

Based on the assumption that tablets are almost solely used for companion animals, tablets are excluded from the dataset used to report sales for food-producing animals. All other pharmaceutical forms (including boluses) 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, exotic birds and racing pigeons. In the current report, the term 'group treatment' is used for medication administered orally, 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):

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

In this report, the term 'food-producing species' includes horses[21]. 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 distribution of 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 in 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 3 September 2020; 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 data sources/types included, by country

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

[21] Regulation (EC) No 854/2004 establishes that horses are considered to be food-producing animals. Typically, statistics on living horses cover both food-producing and non-food-producing horses. This implies that the use of medicines authorised for companion horses is also included in the surveillance.

Table 2. Summary of information on number of years of data collection, legal basis for data collection at national level, national data providers, sources for ESVAC data and characteristics of data, by country, for 2018

Country	Number of years of data collection	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[3] (Yes/No)
Austria	>5 years	Mandatory to report	Austrian Agency for Health and Food Safety	MAHs (n=10) Wholesalers (n=10)	Sales to pharmacies	Yes	No
Belgium	>5 years	Mandatory to report	Federal Agency for Medicines and Health Products	Wholesalers (n=24) Feed mills (n=48)	Sales to veterinarians and pharmacies; Sales by feed mills to farmers	Yes	No
Bulgaria	>5 years	Not mandatory	Bulgarian Food Safety Agency	Wholesalers (n=38)	Sales to veterinarians, farmers and pharmacies	Yes	No
Croatia	5 years	Mandatory to report	Ministry of Agriculture, Veterinary Directorate	Wholesalers (n=15)	Sales to pharmacies and veterinarians	Yes	No
Cyprus	>5 years	Mandatory to report	Ministry of Agriculture, Rural Development and Environment – Veterinary Services	Wholesalers (n=24) Feed mills (n=30)	Sales by wholesalers to veterinarians, pharmacies and farmers; sales by feed mills to farmers	Yes	Yes (12 %)
Czechia	>5 years	Mandatory to report	Institute for State Control of Veterinary Biologicals and Medicines	Wholesalers (n=92) Feed mills (n=27)	Sales to veterinarians, pharmacies and farmers; sales by feed mills to farmers	Yes	Yes (<0.2 %)
Denmark	>5 years	Mandatory to report	Danish Veterinary and Food Administration	VetStat (n=1) obtaining data from pharmacies (n=525) Feed mills (n=1)	Prescriptions data from pharmacies and feed mills	Yes	Yes (2.4 %)
Estonia	>5 years	Mandatory to report	State Agency of Medicines	Wholesalers (n=10)	Sales to veterinarians and pharmacies	Yes	Yes (0.7 %)
Finland	>5 years	Mandatory to report	Finnish Medicines Agency	Wholesalers (n=2) Importers of medicated feed (n=1)	Sales to pharmacies and veterinarians	Yes	Yes (5.1 %)
France	>5 years	Mandatory to report	National Agency for Veterinary Medicinal Products (Anses-ANMV)	MAHs (n=58)	Sales to wholesalers and feed mills	Yes	No
Germany	>5 years	Mandatory to report	Federal Office of Consumer Protection and Food Safety	MAHs (n=28) Wholesalers (n=14) PSURs[4] data for premixes	Sales to veterinarians	Yes	No

Country	Number of years of data collection	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[3] (Yes/No)
Greece	4 years	Mandatory to report	Greek National Organisation for Medicines	MAHs (n=84)[5]	Sales to pharmacies and veterinarians	Yes	No
Hungary	>5 years	Not mandatory	National Food Chain Safety Office Directorate of Veterinary Medicinal Products	Wholesalers (n=31)	Sales to pharmacies, 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 (9 %)
Ireland	>5 years	Mandatory to report	Health Products Regulatory Authority	MAHs (n=65)	Sales to wholesalers, pharmacies, veterinarians and licensed merchants within the country	Yes	No
Italy	>5 years	Mandatory to report	Italian Ministry of Health	MAHs (n=46)	Sales to pharmacies and farms authorised to produce medicated feed for self-consumption	Yes	No
Latvia	>5 years	Mandatory to report	Food and Veterinary Service	Wholesalers (n=27)	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 and veterinarians	Yes	No
Malta	2 years	Not mandatory	Ministry for Agriculture, Fisheries and Animal Rights	Wholesalers (n=23)	Sales to pharmacies and veterinary clinics	Yes	No
Netherlands	>5 years	Not mandatory	Federation of the Dutch Veterinary Pharmaceutical Industry (FIDIN)	MAHs (n=16)	Sales to wholesalers and veterinarians	Yes	No
Norway	>5 years	Mandatory to report	Norwegian Veterinary Institute	Wholesalers (n=5) Feed mills (n=1)	Sales to pharmacies, veterinarians and fish farmers (only as medicated feed)	Yes	Yes (2.0 %)
Poland	>5 years	Mandatory to report	Ministry of Agriculture and Rural Development	Wholesalers (n=134)	Sales to veterinarians	Yes	No

Country	Number of years of data collection	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[3] (Yes/No)
Portugal	>5 years	Mandatory to report	Directorate-General for Food and Veterinary	Wholesalers (n=64)	Sales to pharmacies, 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=83)[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=53)	Sales to pharmacies, retailers, veterinarians, farmers and feed mills	No	Yes (<1%)
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 (4.6%)
Spain	>5 years	Not mandatory	Spanish Agency for Medicines and Health Products	Retailers (n=1874) Feed mills (n=308) Pharmacies (n=391)[7]	Sales to veterinarians, farmers and pet owners	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 (n>1400)	Dispensed prescriptions[8]	Yes	Yes (5%)
Switzerland	>5 years	Mandatory to report	Federal Food Safety and Veterinary Office	MAHs (n=16)	Sales to veterinarians, pharmacies and medicated feed mills	No	No
United Kingdom	>5 years	Mandatory to report	Veterinary Medicines Directorate	MAHs (n=63)	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] Veterinary antimicrobial agents obtained on special licence/marketing authorisation or through parallel trade, i.e. obtained from another Member State and permitted to be marketed for specific animal species and indications, although the type of authorisation procedure used might differ among Member States.
[4] PSURs = periodic safety update reports.
[5] Negligible sales from a few MAHs with a very small market share, and which do not have local representatives in Greece, are not included in the dataset.
[6] For 2015–2018, data were collected from MAHs, while for 2014 the data were obtained from MAHs and wholesalers.
[7] Since 2017, data have been collected from retailers, feed mills and pharmacies.
[8] Data represent veterinary prescriptions and requisitions dispensed by pharmacies for use in their own practice.

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, 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 VMPs in 2018, except in Finland, Iceland, Luxembourg, Norway, Slovenia, Sweden and the United Kingdom, where they represented 10.3%, 8.4%, 5.3%, 6.9%, 5.2%, 7.2% and 5.8% of the total sales, respectively (Table 3). Overall, sales of tablets in the 31 countries represented 1.1% 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 2018

Country	Tablets		All other pharmaceutical forms		Total tonnes
	Tonnes	% of overall sales	Tonnes	% of overall sales	
Austria	0.7	1.4%	48.0	98.6%	48.6
Belgium	2.0	1.0%	195.0	99.0%	197.0
Bulgaria	0.1	0.3%	47.8	99.7%	48.0
Croatia	0.1	0.6%	19.6	99.4%	19.7
Cyprus	0.1	0.1%	53.4	99.9%	53.5
Czechia	1.0	2.4%	40.2	97.6%	41.2
Denmark	0.8	0.8%	93.6	99.2%	94.3
Estonia	0.1	2.3%	6.1	97.7%	6.2
Finland	1.1	10.3%	9.3	89.7%	10.3
France	15.2	3.2%	456.2	96.8%	471.4
Germany	9.6	1.3%	753.1	98.7%	762.7
Greece	0.5	0.5%	113.0	99.5%	113.6
Hungary	0.3	0.2%	150.2	99.8%	150.4
Iceland	0.1	8.4%	0.6	91.6%	0.6
Ireland	0.8	0.8%	98.6	99.2%	99.4
Italy	10.3	1.1%	932.1	98.9%	942.4
Latvia	0.1	1.5%	6.0	98.5%	6.1
Lithuania	0.1	0.8%	10.7	99.2%	10.8
Luxembourg	0.1	5.3%	1.8	94.7%	1.9
Malta	0.04	1.8%	2.1	98.2%	2.2
Netherlands	3.2	1.7%	183.9	98.3%	187.1
Norway	0.4	6.9%	5.7	93.1%	6.1
Poland	1.8	0.2%	782.2	99.8%	784.0
Portugal	1.2	0.6%	191.8	99.4%	193.0
Romania	3.8	1.6%	230.7	98.4%	234.5
Slovakia	0.3	2.3%	12.1	97.7%	12.4
Slovenia	0.4	5.2%	7.8	94.8%	8.2
Spain	0.5	<0.01%	1,724.1	≥99%	1,724.6
Sweden	0.8	7.2%	9.8	92.8%	10.6
Switzerland	0.7	2.0%	32.9	98.0%	33.6
United Kingdom	13.2	5.8%	212.9	94.2%	226.2
Total 31 countries	**69.3**	**1.1%**	**6,431.4**	**98.9%**	**6,500.7**

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 PCU, ranged from 2.9 mg/PCU to 466.3 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 animals1, PCU and sales in mg/PCU, by country, for 2018

Country	Sales (tonnes) for food-producing animals	PCU (1,000 tonnes)	Sales in mg/PCU
Austria	48.0	957.2	50.1
Belgium	195.0	1,724.4	113.1
Bulgaria	47.8	399.9	119.6
Croatia	19.6	293.0	66.8
Cyprus	53.4	114.5	466.3
Czechia	40.2	704.6	57.0
Denmark	93.6	2,446.7	38.2
Estonia	6.1	114.0	53.3
Finland	9.3	496.8	18.7
France	456.2	7,107.0	64.2
Germany	753.1	8,517.6	88.4
Greece	113.0	1,243.9	90.9
Hungary	150.2	831.8	180.6
Iceland	0.6	116.4	4.9
Ireland	98.6	2,142.1	46.0
Italy	932.1	3,819.3	244.0
Latvia	6.0	167.3	36.1
Lithuania	10.7	323.8	33.1
Luxembourg	1.8	54.7	33.6
Malta	2.1	14.2	150.9
Netherlands	183.9	3,200.8	57.5
Norway	5.7	1,927.5	2.9
Poland	782.2	4,672.6	167.4
Portugal	191.8	1,028.1	186.6
Romania	230.7	2,788.2	82.7
Slovakia	12.1	246.6	49.3
Slovenia	7.8	179.8	43.2
Spain	1,724.1	7,865.4	219.2
Sweden	9.8	782.7	12.5
Switzerland	32.9	818.5	40.2
United Kingdom	212.9	7,215.7	29.5
Total 31 countries	**6,431.4**	**62,315.1**	**103.2***

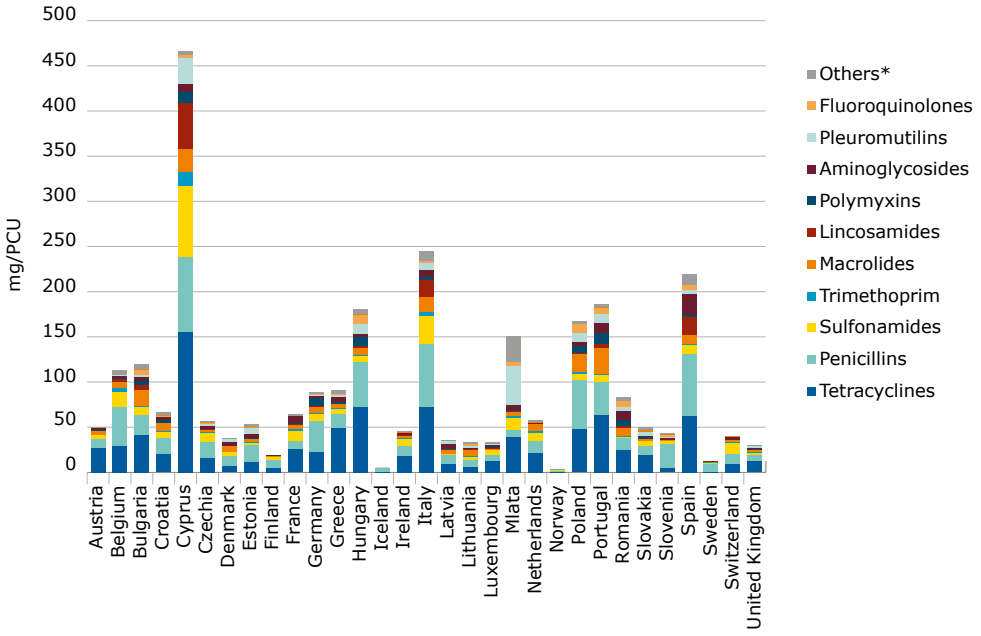
[1] Tablets are excluded as they are used almost solely in companion animals; injectable antimicrobial VMPs can also be used in companion animals; a few other products may solely be used in companion animals, but as their proportional use is minor, these are included in the sales for food-producing animals.
* 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/PCU, of the various veterinary antimicrobial classes in 31 European countries in 2018[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	26.9	0.4	9.5	0.04	0.2	4.5	0.9	3.5	0.1	0.5	0	1.3	1.9	0.3	0.1	50.1
Belgium	28.9	1.9	42.8	0.1	0.1	17.6	3.5	7.1	2.6	0.2	0.3	1.6	2.0	1.1	3.1	113.1
Bulgaria	41.5	4.9	22.1	0.02	0.1	8.5	1.0	17.8	5.9	6.0	0	5.2	3.7	2.1	0.9	119.6
Croatia	19.7	1.8	17.8	0.03	0.3	6.8	0.9	9.1	0.1	2.4	0.9	3.6	2.7	0.3	0.3	66.8
Cyprus	155.2	2.3	83.0	0.04	0.4	78.2	15.6	26.2	50.0	3.1	0.4	8.3	12.8	29.6	1.1	466.3
Czechia	16.1	0.6	17.6	0.1	0.5	9.5	1.0	3.0	0.2	1.8	<0.01	2.8	0.7	2.8	0.4	57.0
Denmark	6.6	0.6	11.5	0.03	<0.01	3.9	0.8	5.6	0.8	<0.01	0.4	3.6	<0.01	3.5	0.9	38.2
Estonia	11.2	0.5	18.3	0.1	0.9	3.2	0.6	3.0	0.7	1.2	0	3.9	0.8	7.5	1.2	53.3
Finland	4.5	0.2	8.9	0.02	<0.01	3.1	0.6	0.8	0.3	0.1	0	0.1	0	0.02	0	18.7
France	25.3	0.8	9.0	0.2	0.02	11.7	2.1	4.4	0.4	0.1	0.4	6.9	1.8	0.5	0.5	64.2
Germany	22.2	0.7	34.9	0.1	0.2	7.3	0.9	6.9	1.2	0.9	0	2.4	8.6	1.2	0.9	88.4
Greece	48.9	0.7	15.0	<0.01	0.1	6.3	0.8	4.1	0.4	2.2	2.5	6.5	1.6	1.2	0.7	90.9
Hungary	72.5	4.8	49.2	0.1	0.5	6.8	1.4	6.8	2.8	10.8	0.1	3.0	10.1	11.3	0.3	180.6
Iceland	0.3	0	3.6	0	<0.01	0.3	0.04	0	0	<0.01	0	0.7	0	0	0	4.9
Ireland[2]	18.3	1.5	11.0	0.4	0.2	7.4	0.5	3.3	0.1	0.4	0	2.6			0.4	46.0
Italy	72.6	5.6	68.7	0.1	0.4	31.9	3.5	17.1	19.1	2.3	2.0	8.8	2.7	7.1	2.1	244.0
Latvia	9.4	0.1	9.0	0.2	0.4	1.3	0.3	4.8	0.1	0.9	<0.01	4.2	1.9	3.2	0.3	36.1
Lithuania	6.3	0.6	7.7	0.2	0.3	3.1	0.7	6.9	0.4	2.3	0.1	1.7	0.2	2.0	0.6	33.1
Luxembourg	12.8	1.0	6.0	0.1	0.6	5.3	1.0	1.1	0.7	0.8	0	2.9	0.6	0.2	0.5	33.6
Malta[3]	39.0	1.3	7.9	0.2	0.2	13.0	1.9	4.9	0.4	4.6		5.4	1.8	43.3	27.0	150.9
Netherlands	21.7	1.4	13.2	0.02	<0.01	8.7	1.6	8.0	0.03	0.1	1.1	0.7	0.4	0.4	0.03	57.5
Norway	0.1	0.5	1.5	0	<0.01	0.6	0.1	<0.01	<0.01	<0.01	0.03	0.1	0	0.02	<0.01	2.9
Poland	47.3	1.8	55.2	0.1	0.3	6.6	1.3	20.3	1.4	10.9	<0.01	4.8	7.4	9.2	0.9	167.4
Portugal	63.7	2.0	36.5	0.03	0.4	7.3	1.4	27.9	4.7	7.6	<0.01	10.6	12.6	10.2	1.5	186.6
Romania	25.0	3.2	12.5	<0.01	0.2	1.8	0.3	9.9	1.5	6.0	<0.01	10.1	6.4	5.2	0.6	82.7
Slovakia	19.3	0.4	9.2	0.2	0.4	5.8	0.8	1.8	0.2	3.0	0.02	1.8	1.4	3.8	1.3	49.3
Slovenia	4.2	0.9	27.7	0.04	0.2	2.4	0.6	0.3	<0.01	2.8	0	3.0	0.2	0.9	0.1	43.2
Spain	62.3	5.6	68.7	0.03	0.4	9.4	1.6	10.0	19.3	5.6	0	22.2	3.3	4.9	6.1	219.2
Sweden[4]	0.7		8.0		<0.01	2.0	0.4	0.6	0.01		0.1	0.4			0.3	12.5
Switzerland[5]	8.9	0.6	11.1	0.1	0.2	12.6	1.0	1.8		0.2	0	3.4	0.3		0.1	40.2
United Kingdom	11.9	0.6	7.0	0.1	0.1	2.7	0.5	2.3	0.4	0.1	0	2.1	<0.01	1.3	0.4	29.5
Total sales[6] for 31 countries (mg/PCU)	**31.7**	**2.0**	**29.7**	**0.1**	**0.2**	**8.7**	**1.3**	**8.0**	**4.4**	**2.5**	**0.3**	**6.4**	**3.4**	**3.1**	**1.4**	**103.2**
Median[7] of 31 countries (mg/PCU)	**19.7**	**0.8**	**12.5**	**0.1**	**0.2**	**6.6**	**0.9**	**4.8**	**0.4**	**1.2**	**<0.01**	**3.0**	**1.6**	**1.3**	**0.5**	**57.0**

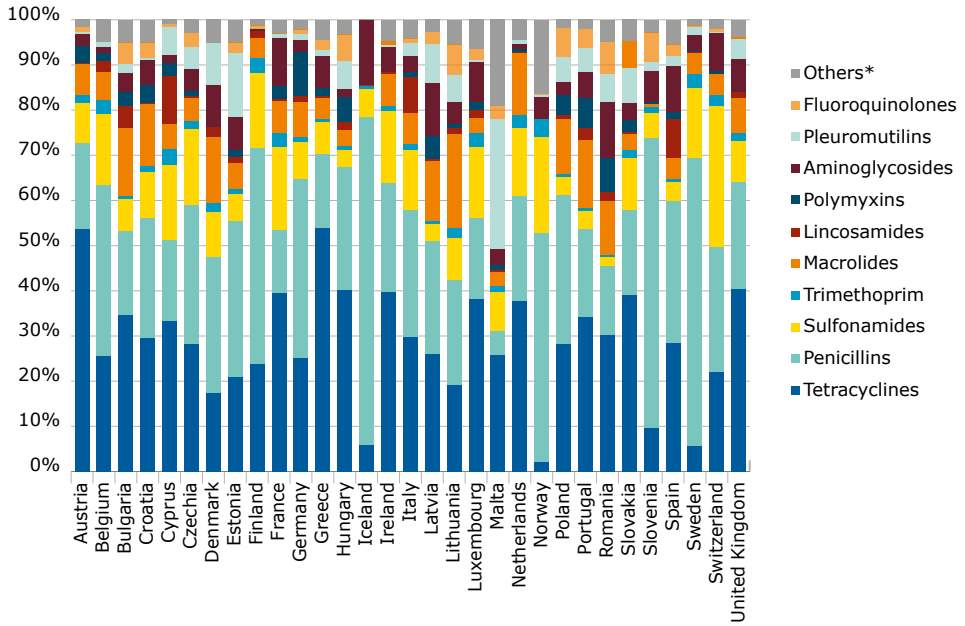
* Other antibacterials (bacitracin, fosfomycin, furaltadone, metronidazole, novobiocin, rifaximin and spectinomycin, classified as 'other antibacterials' in the ATCvet system).
[1] For the countries where the injectable 3rd- and 4th-generation cephalosporins are solely or almost solely marketed for dogs and cats, the data provide a considerable overestimate for food-producing animals.
[2] Polymyxins and pleuromutilins are aggregated with 'Others' for reasons of commercial confidentiality.
[3] For commercial confidentiality reasons, fluoroquinolones and other quinolones are aggregated.
[4] For commercial confidentiality reasons, amphenicols, polymyxins and pleuromutilins are aggregated with 'Others', 1st- and 2nd-generation cephalosporins are aggregated with 3rd- and 4th-generation cephalosporins and fluoroquinolones are aggregated with other quinolones.
[5] For commercial 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 for 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 2018[1]



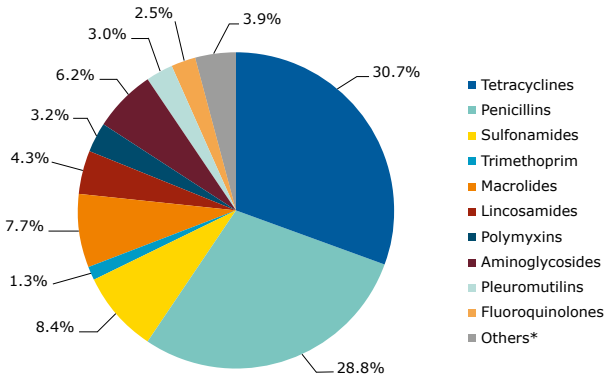
*Amphenicols, cephalosporins, other quinolones and other antibacterials (classified as such in the ATCvet system).
[1] Differences between countries can be partly explained by differences in animal demographics, in the selection of antimicrobial agents, in dosage regimes, in the type of data sources,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

Figure 3. Proportion of the total sales of the different veterinary antimicrobial classes, in mg/PCU, for 31 European countries, for 2018



* 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 2018



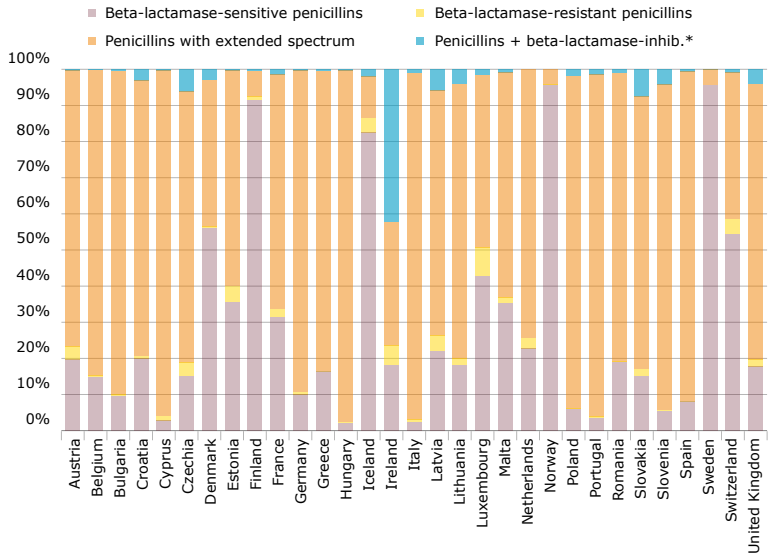
* Amphenicols, cephalosporins, other quinolones and other antibacterials (classified as such in the ATCvet system).

The sales of the different veterinary antimicrobial classes varied between countries (Figures 2 and 3). Differences between countries can be partly explained by differences in animal demographics, the selection of antimicrobial agents, dosage regimes, the type of data sources and veterinarians' prescribing habits.

Across all 31 countries, the sales of tetracyclines (30.7%), penicillins (28.8%) and sulfonamides (8.4%), in mg/PCU, accounted for 67.9% of the total sales in 2018 (Figure 4). Among the antimicrobial classes shown as 'Others' (Figure 4), of the overall sales in the 31 countries, 0.1% was accounted for by 1st- and 2nd-generation cephalosporins, 0.2% by 3rd- and 4th-generation cephalosporins, 1.9% by amphenicols and 0.3% by 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 and Switzerland, where the proportion of sales of penicillin is typically high, beta-lactamase-sensitive penicillins[22] accounted for the majority of penicillins sold (range: 54% to 96% of total penicillins sold). For countries other than the Nordics and Switzerland, penicillins with an extended spectrum (mainly represented by amoxicillin) accounted for the major proportion of penicillin sales.

Figure 5. Distribution of sales, in mg/PCU, of penicillins by subclass for food-producing species, in 31 European countries, for 2018



*In the ATCvet system, they are classified as combinations of penicillins that include beta-lactamase inhibitors. In 2018, all penicillins included in this group are aminopenicillins (amoxicillin, ampicillin and metampicillin).

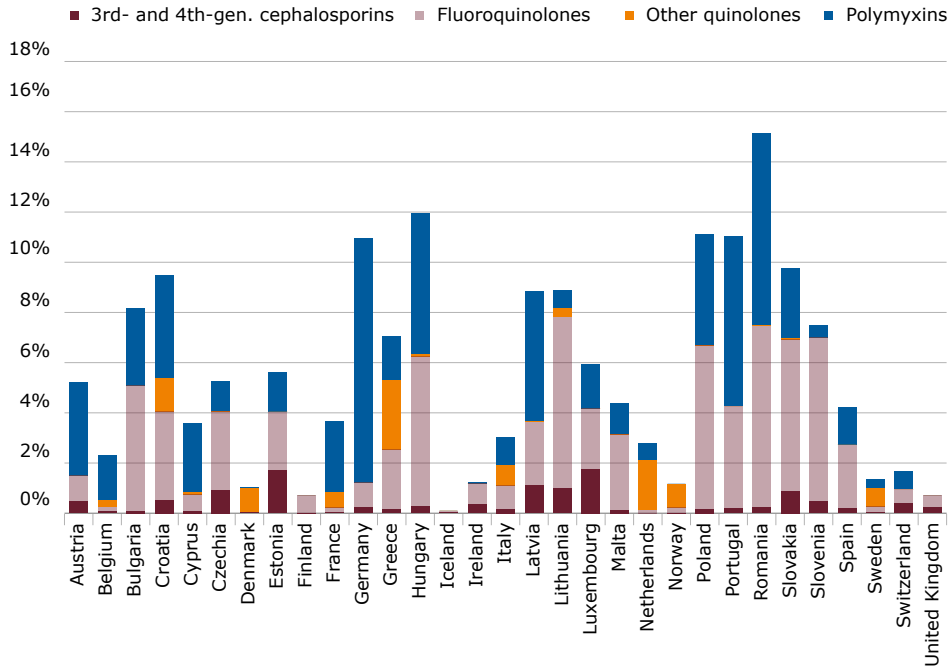
[22] Beta-lactamase-sensitive penicillins belong to ATCvet code QJ01CE. Procaine benzylpenicillin, penethamate hydriodide and phenoxymethylpenicillin accounted for the majority of sales of these penicillins.

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 2018 of antimicrobials included in the AMEG Category B and classified as the highest priority critically important antimicrobials (HP CIAs) by the WHO (see Annex 5, Table A16), i.e. 3rd- and 4th-generation cephalosporins, fluoroquinolones, other quinolones and polymyxins, varied substantially between the 31 countries, ranging from <0.01% to 1.8%, 0.01% to 7.3%, 0% to 2.8% and 0% to 9.8%, 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 Figure 31.

Overall, in the 31 countries, the sales (mg/PCU) of 3rd- and 4th-generation cephalosporins, fluoroquinolones, other quinolones and polymyxins accounted for 0.2%, 2.5%, 0.3% and 3.3%, respectively, of the total sales of antimicrobial VMPs in 2018.

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 2018[1,2,3]



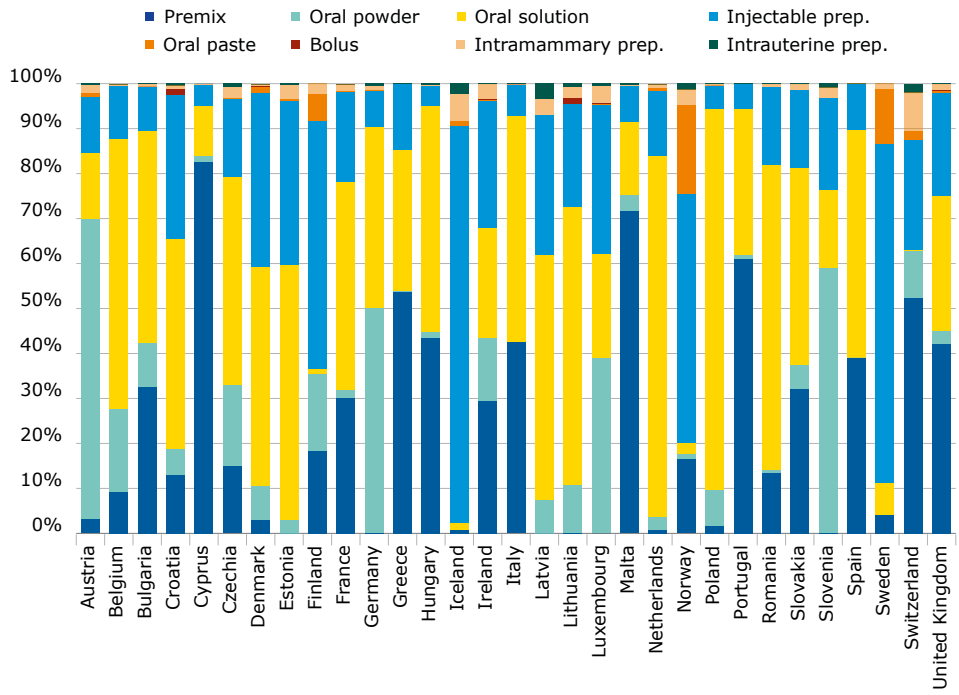
[1] Variations between the countries should be interpreted with great care due to the large differences in dosing between these classes/subclasses of antimicrobials.
[2] No sales of other quinolones in Austria, Bulgaria, Estonia, Finland, France, Germany, Iceland, Ireland, Luxembourg, Slovenia, Spain, 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 B 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 at the request of 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, 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.

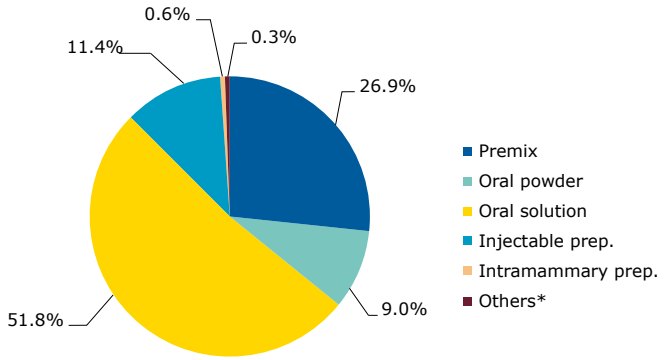
Figure 7. Distribution of sales of veterinary antimicrobial agents for food-producing animals, in mg of active substance per population correction unit (mg/PCU), by pharmaceutical form, in 31 European countries, for 2018



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 8, aggregated by the 31 countries, sales (mg/PCU) of premixes accounted for 26.9% of the overall sales, 9.0% were oral powders and 51.8% were oral solutions, i.e. 87.7% were for group treatment; 11.4% were injectable preparations, 0.6% were intramammary preparations and 0.3% were oral pastes, boluses and intrauterine preparations.

Figure 8. 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 2018



* 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

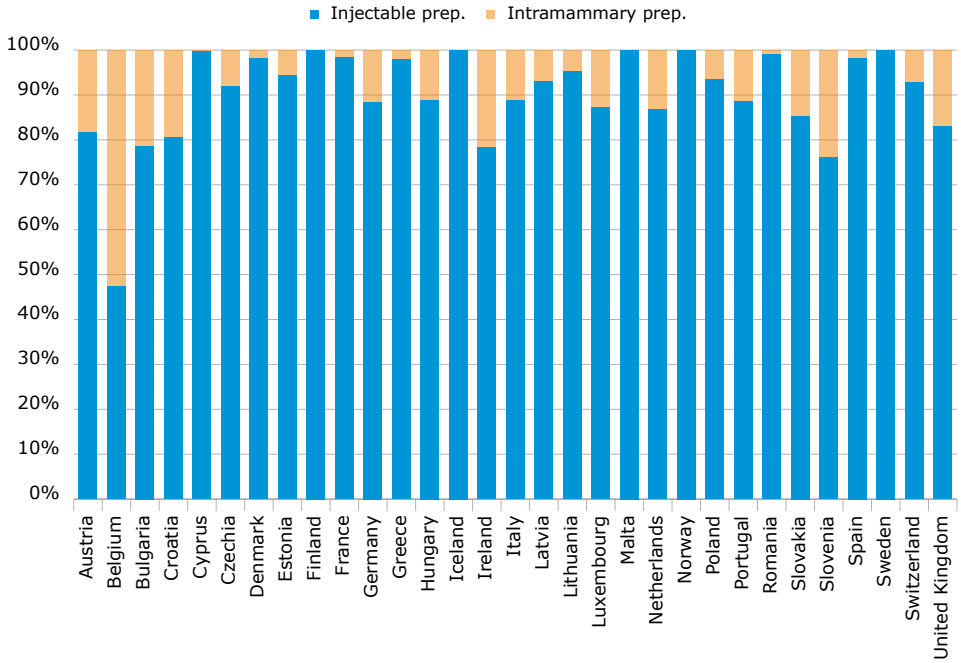
2.4.1. Distribution of overall sales of antimicrobials for food-producing animals

Figure 9. Spatial distribution of overall sales of all antimicrobials for food-producing animals, in mg/PCU, for 31 countries, for 2018

2.4.2. Distribution of sales of 3rd- and 4th-generation cephalosporins

Figure 10. Spatial distribution of sales of 3rd- and 4th-generation cephalosporins for veterinary use, in mg/PCU, by country, for 2018

Figure 11. Distribution of sales of 3rd- and 4th-generation cephalosporins for veterinary use by pharmaceutical form, in mg/PCU, by country, for 2018[1,2,3]



[1] Sales <1 kg in Finland, Iceland and Norway.
[2] No sales of intramammary preparations in Finland, Iceland, Malta, Norway and Sweden.
[3] 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.

2.4.3. Distribution of sales of fluoroquinolones

Figure 12. Spatial distribution of sales of fluoroquinolones for veterinary use, in mg/PCU, by country, for 2018

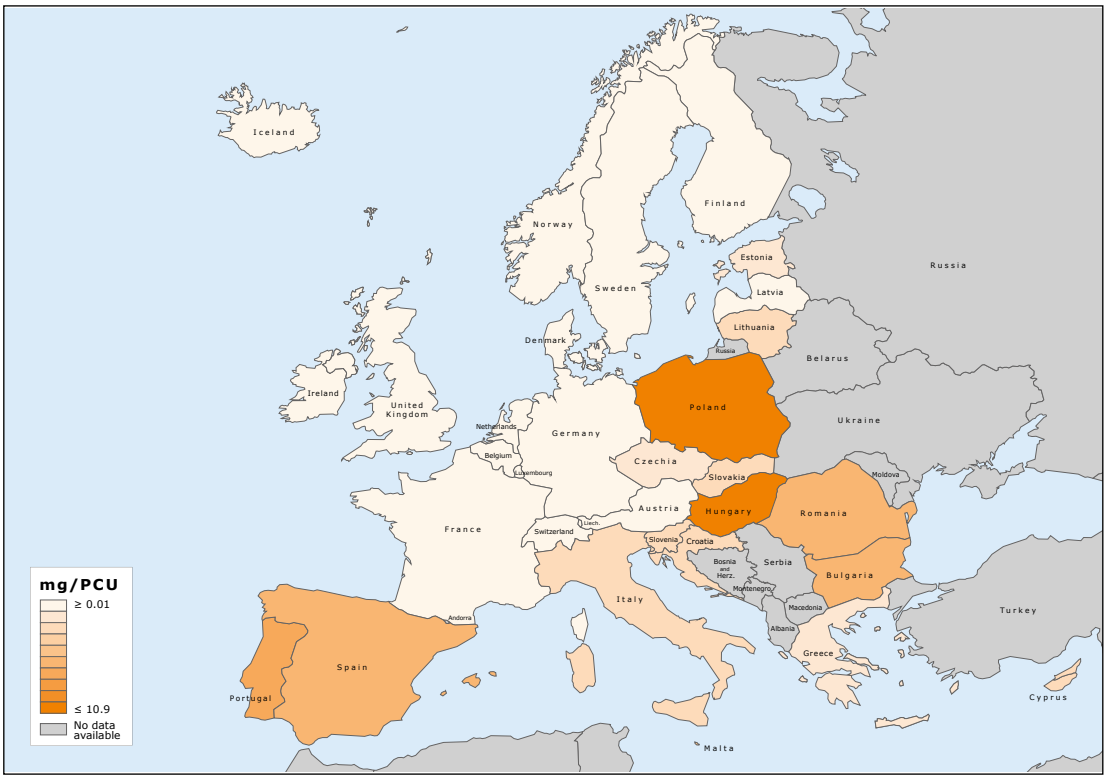
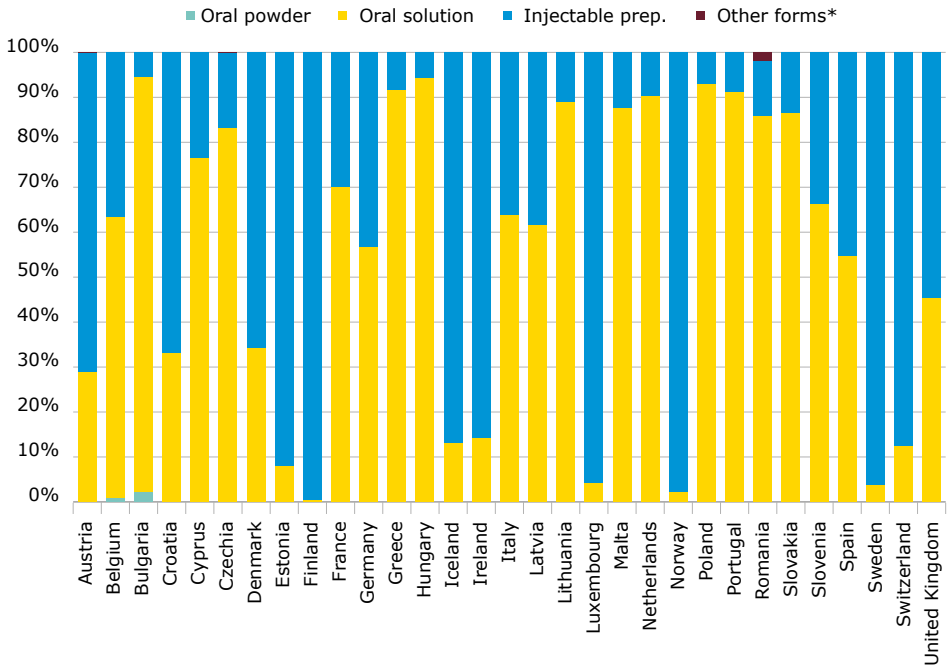


Figure 13. Distribution of sales of fluoroquinolones for veterinary use by pharmaceutical form, in mg/PCU, by country, for 2018[1]



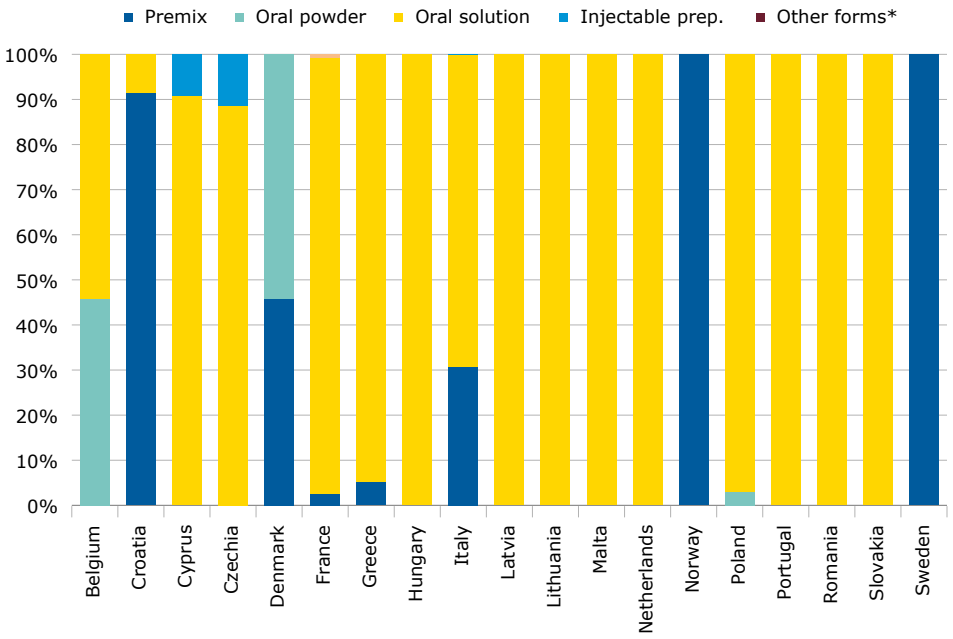
* Other forms include negligible amounts sold as boluses, premixes and/or intrauterine preparations in some countries.
[1] In Iceland, sales of fluoroquinolones were <1kg.

2.4.4. Distribution of sales of other quinolones

Figure 14. Spatial distribution of sales of other quinolones for veterinary use, in mg/PCU, by country, for 2018[1]

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

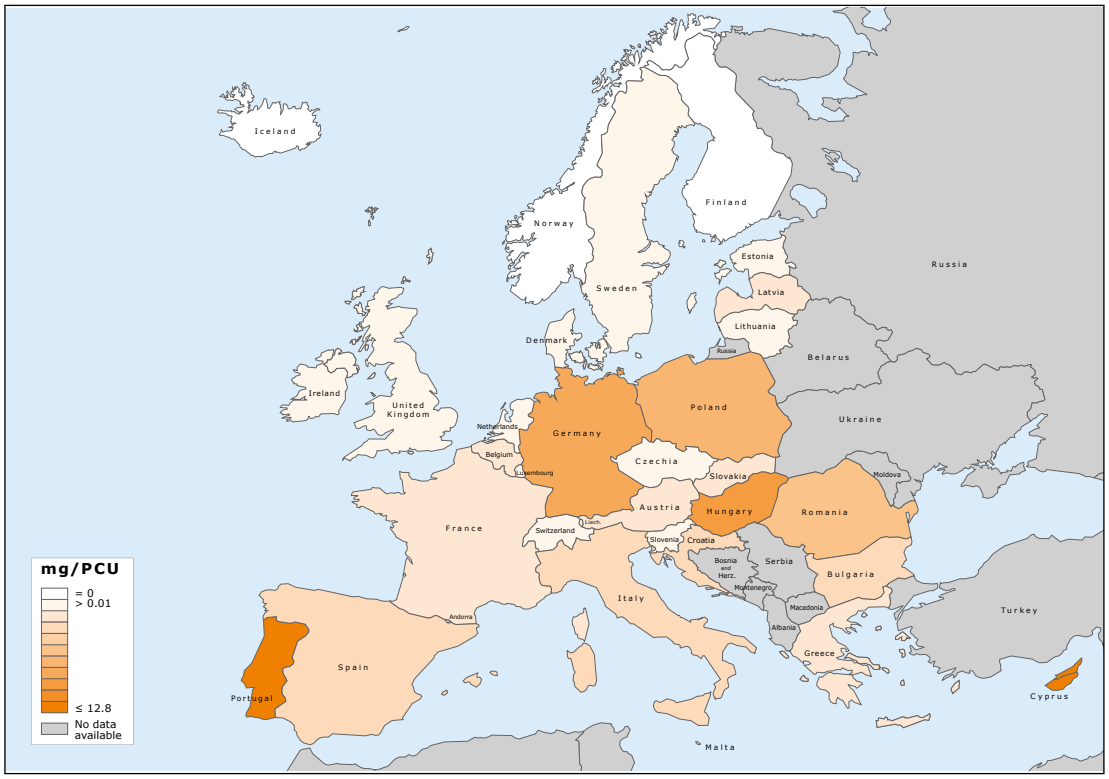
Figure 15. Distribution of sales of other quinolones for veterinary use by pharmaceutical form, in mg/PCU, by country, for 2018[1]



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

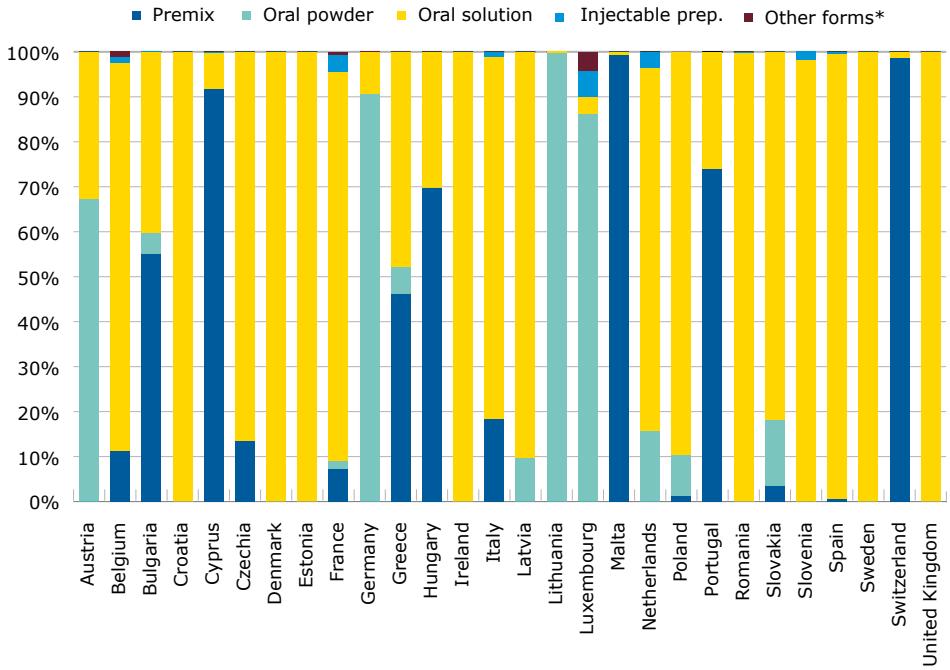
2.4.5. Distribution of sales of polymyxins

Figure 16. Spatial distribution of sales of polymyxins for veterinary use, in mg/PCU, by country, for 2018[1]



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

Figure 17. Distribution of sales of polymyxins for veterinary use by pharmaceutical form, in mg/PCU, by country, for 2018[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 2018 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 18 and 19.

Overall, pigs, cattle, poultry and sheep along with goats accounted for 32 %, 31 %, 15 % and 14 %, respectively, of the PCU in the 31 countries.

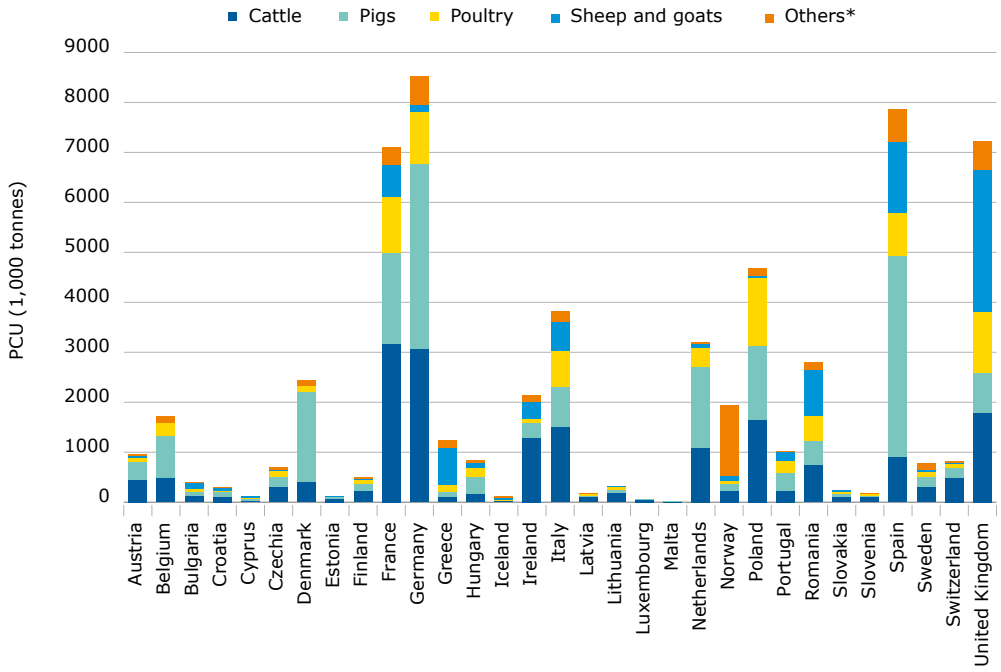
Table 6. Estimated PCU (in 1,000 tonnes) of the population of food-producing species[1,2], by country, for 2018

Country	Cattle	Pigs	Poultry	Sheep and goats	Fish	Rabbits	Horses	Total
Austria	442	361	79	38	0	0	37	957
Belgium	470	858	242	17	0	4	133	1,724
Bulgaria	117	94	52	104	7	0.01	26	400
Croatia	103	87	39	47	17	0.01	0.1	293
Cyprus	19	45	13	36	0	0.1	2	115
Czechia	289	203	127	17	24	7	37	705
Denmark	392	1,803	124	12	45	0	70	2,447
Estonia	61	40	3	6	1	0	4	114
Finland	216	142	82	13	14	0	30	497
France	3,165	1,804	1,129	641	46	42	280	7,107
Germany	3,051	3,712	1,049	138	18	29	520	8,518
Greece	89	107	137	758	142	2	9	1,244
Hungary	158	336	199	94	23	2	21	832
Iceland	20	6	6	44	19	<0.01	21	116
Ireland	1,283	286	97	339	37	0	100	2,142
Italy	1,500	808	714	576	62	35	124	3,819
Latvia	94	40	21	9	0	0.05	3	167
Lithuania	176	67	62	13	0	0.1	6	324
Luxembourg	41	11	0.1	1	0	0	2	55
Malta	4	4	2	1	0	2	0.4	14
Netherlands	1,087	1,607	395	72	5	0.5	35	3,201
Norway	225	133	64	103	1,353	0	50	1,928
Poland	1,645	1,468	1,377	22	37	1	123	4,673
Portugal	223	344	248	180	13	6	15	1,028
Romania	739	484	492	931	7	0	135	2,788
Slovakia	89	64	58	28	1	<0.01	5	247
Slovenia	97	18	43	9	2	0.02	10	180
Spain	894	4,024	870	1,418	346	61	253	7,865
Sweden	299	198	104	28	11	0	142	783
Switzerland	482	197	75	32	0	1	32	819
United Kingdom	1,788	781	1,233	2,833	204	0	378	7,216
Total 31 countries	**19,260**	**20,130**	**9,137**	**8,560**	**2,434**	**192**	**2,603**	**62,315**

[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.

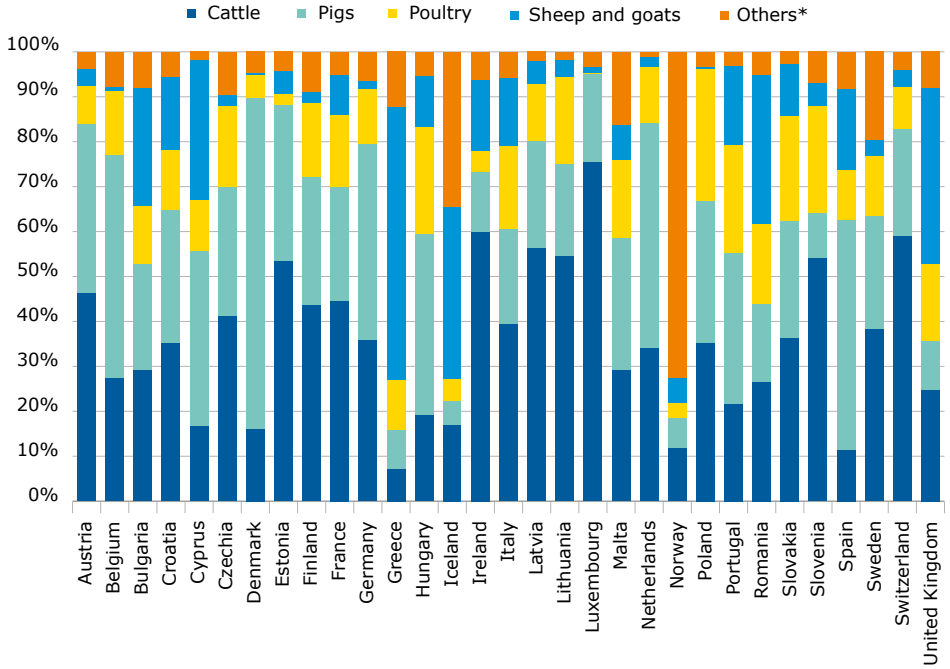
Details regarding animal species and categories included in the PCU are given in Annex 3 of this report.

Figure 18. The denominator (PCU) and its distribution by the food-producing animal species (1 PCU = 1 kg), by country, in 2018



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

Figure 19. Distribution of the denominator (PCU) in weight by the food-producing animal species, by country, in 2018



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

In 2018, of the 31 countries, 12 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 (1,000 tonnes) of animals for fattening or slaughter, respectively, to or from another Member State and PCU (net balance) in 2018

Country	PCU Domestic	PCU Export	Proportion, export	PCU Import	Proportion, import	PCU
Austria	1,035	14	1%	92	10%	957
Belgium	1,782	178	10%	235	14%	1,724
Bulgaria	404	1	0.3%	5	1%	400
Croatia	312	20	7%	39	13%	293
Cyprus	114	0	0.1%	0	<0.01%	115
Czechia	629	84	12%	8	1%	705
Denmark	2,041	405	17%	0	0%	2,447
Estonia	103	12	11%	1	1%	114
Finland	496	1	0.2%	0	<0.01%	497
France	6,812	333	5%	39	1%	7,107
Germany	8,657	425	5%	564	7%	8,518
Greece	1,255	0	0.01%	11	1%	1,244
Hungary	856	53	6%	77	9%	832
Iceland	116	0	0%	0	0%	116
Ireland	2,098	64	3%	20	1%	2,142
Italy	4,070	3	0.1%	254	7%	3,819
Latvia	156	16	10%	5	3%	167
Lithuania	309	26	8%	11	4%	324
Luxembourg	46	13	24%	5	9%	55
Malta	14	0	0.1%	0	1%	14
Netherlands	3,145	467	15%	412	13%	3,201
Norway	1,928	0	0%	0	0%	1,928
Poland	4,915	16	0.4%	259	6%	4,673
Portugal	1,094	29	3%	95	9%	1,028
Romania	2,775	53	2%	39	1%	2,788
Slovakia	203	64	26%	20	8%	247
Slovenia	168	19	11%	7	4%	180
Spain	7,943	107	1%	184	2%	7,865
Sweden	782	1	0.1%	0	<0.01%	783
Switzerland	818	2	0.2%	1	0.2%	819
United Kingdom	7,228	23	0.3%	35	0.5%	7,216

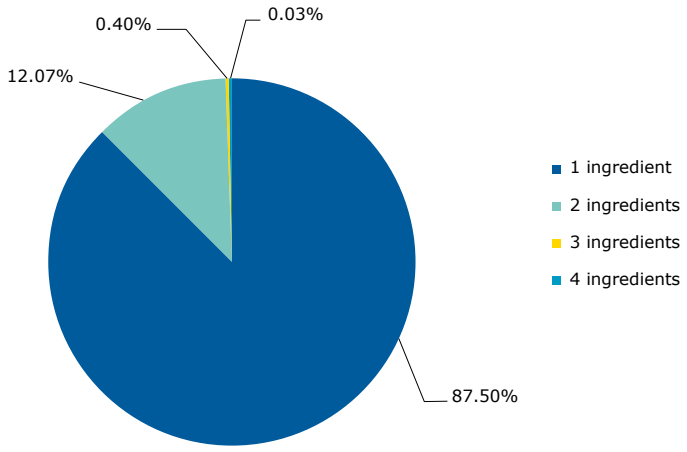
2.6. Distribution of single- and multiple-ingredient products of veterinary antimicrobial agents

Of the 9,608 product presentations (tablets excluded) for which sales were reported, 83.1% (n=7,985) contained only one active ingredient, 14.4% (n=1,387) contained two active ingredients, and 2.2% (n=209) contained three active ingredients (Annex 1, Table A7). In addition, 0.3% (n=27) 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, 87.7% of the product presentations of antimicrobial VMPs were for group treatment, i.e. premixes, oral powders and oral solutions (Figure 8). Of these, 87.4% contained one active ingredient, 11.4% 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, 87.50 %, 12.07 % and 0.40 % were accounted for by products containing 1, 2 and 3 active ingredients, respectively (Figure 20).

Figure 20. 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 2018

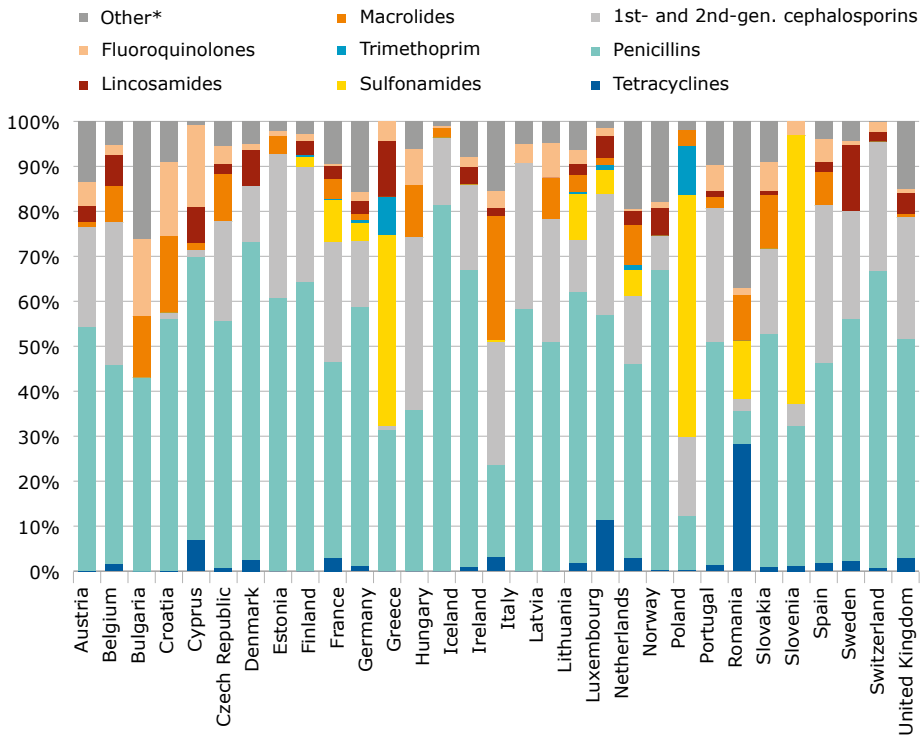


2.7. Sales of tablets by veterinary antimicrobial class for companion animals

Tablets are excluded from the dataset used to report sales for food-producing animals based on the assumption that tablets are used almost solely for companion animals. Figure 21 shows the distribution of sales of tablets, in tonnes of active ingredient, by antimicrobial class and country, for 2018. The sales patterns for tablets varied substantially between countries, but in general the most-sold tablets contained penicillins (mainly in combination with a beta-lactamase inhibitor, see Figure 22).

Data presented in Figure 21 only covers sales of tablets containing antimicrobials marketed for veterinary use and should be interpreted as such. In the current report, all injectable veterinary antimicrobial products are included in the sales data for food-producing animals, but some of the injectable preparations are also used in companion animals and a few are only marketed for companion animals. Similarly, some tablet formulations could also be authorised for use in food-producing or fur animals (e.g. foxes, nutria and mink), and their use is not necessarily exclusively for companion animals.

Figure 21. Distribution of sales of tablets, in tonnes of active ingredient, by antimicrobial class (reported according to the ATCvet hierarchical system), by country, for 2018[1,2]

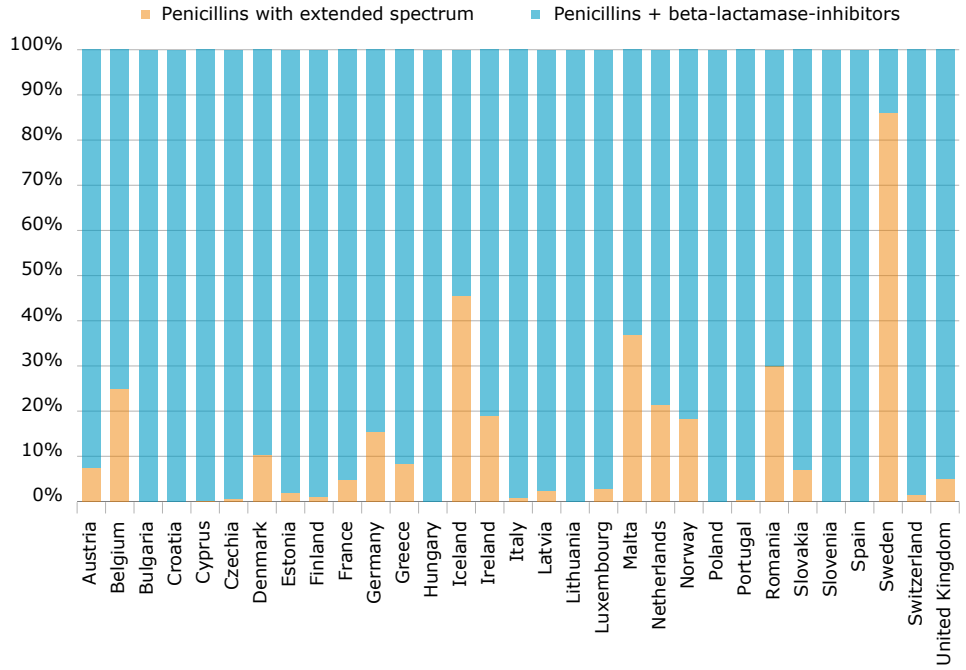


[1] Some tablet formulations are authorised for use in food-producing, fur and companion animals.
[2] In Romania, 20 % (0.7 tonnes) of tablets sold were indicated only for food-producing or non-food-producing birds.
* Small amounts of aminoglycosides, amphenicols, nitrofuran derivatives, pleuromutilins, polymyxins and other antibacterials (classified as such in the ATCvet system) were sold in some countries.

Aggregated by the 31 countries, penicillins (42.0 %), 1st- and 2nd-generation cephalosporins (22.4 %), other antibacterials (12.1 %), macrolides (7.1 %) and sulfonamides (5.8 %) were the most-sold antimicrobial classes of tablets.

The sales (tonnes of active substance) of penicillin tablets varied significantly in terms of distribution by penicillin subclasses in the 31 countries (Figure 22). Combinations of penicillins with beta-lactamase inhibitors represented 14 % to 100 % (in six countries) of the total sales of penicillin tablets (sales of clavulanic acid inhibitors as such are not included in the data submitted).

Figure 22. Distribution of sales (by weight of active ingredient) of tablets containing penicillins by subclass, by country, in 2018[1]



[1] Some tablet formulations are authorised for use in food-producing, fur and companion animals.
* In the ATCvet system, classified as combinations of penicillins which include penicillins + beta-lactamase inhibitors.

2.8. 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 with respect to food-producing animals is 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 2.8 presents the changes over time for all participating countries for the most-sold classes (tetracyclines, penicillins and sulfonamides), the antimicrobials belonging to AMEG Category B i.e. 3rd- and 4th-generation cephalosporins, fluoroquinolones, other quinolones and polymyxins, as well as those additional classes classified by the WHO as the highest priority CIAs for human medicine, i.e. macrolides (ketolides and glycopeptides, belonging to the list of HP CIAs, are not authorised for use in food-producing animals in the countries participating in the ESVAC) (Table A16).

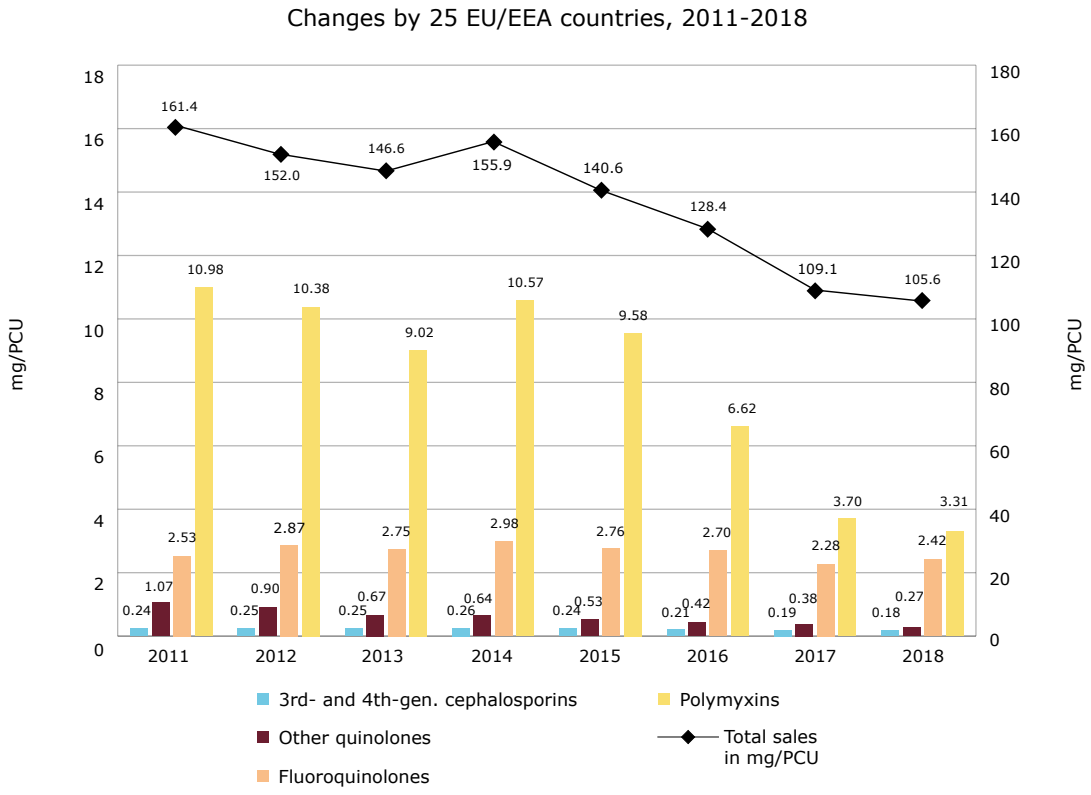
2.8.1. Changes in sales (mg/PCU) from 2011 to 2018, aggregated by 25 countries

For the 25 countries that reported sales data to the ESVAC for every year from 2011 to 2018, an overall decrease of 34.6 % in sales (mg/PCU) was observed (Figure 23).

For the period 2011 to 2018, a drop in sales (in mg/PCU) of more than 5 % was observed for 18 of the 25 countries. Over the same period, there was an increase in sales of over 5 % in five of the 25 countries (Table 8).

During the period 2011-2018, sales (mg/PCU) of 3rd- and 4th-generation cephalosporins decreased by 24.4 %, sales of polymyxins decreased by 69.8 %, sales of fluoroquinolones declined by 4.2 % and sales of other quinolones by 74.4 %.

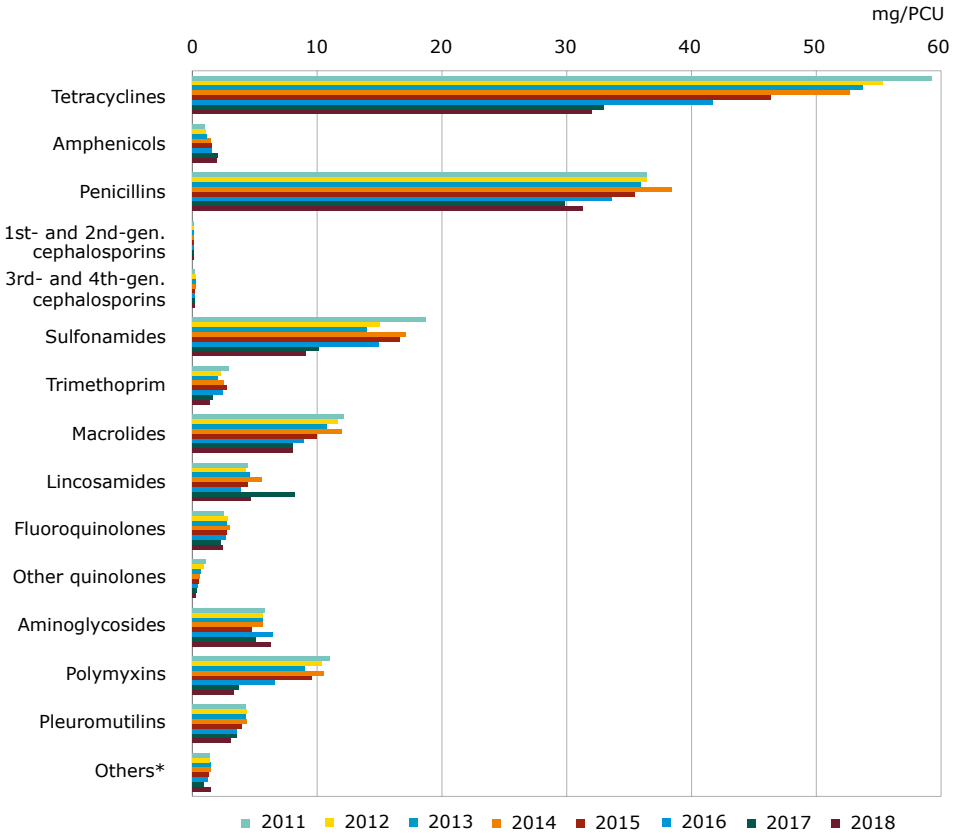
Figure 23. Changes in aggregated overall sales in mg/PCU, as well as sales of fluoroquinolones, other quinolones, 3rd- and 4th-generation cephalosporins and polymyxins, for 25 EU/EEA countries[1], from 2011 to 2018 (note the difference in the scales of the y-axes)



[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 the United Kingdom.

For those 25 countries delivering data from 2011 to 2018, a decrease in sales of all antimicrobial classes has been observed except for aminoglycosides, amphenicols, lincosamides and other antibacterials (classified as such in the ATCvet system) (Figure 24). During the period 2011 to 2018, the decline in the three most selling antimicrobial classes – tetracyclines, penicillins and sulfonamides – was 46 %, 14 % and 52 %, respectively.

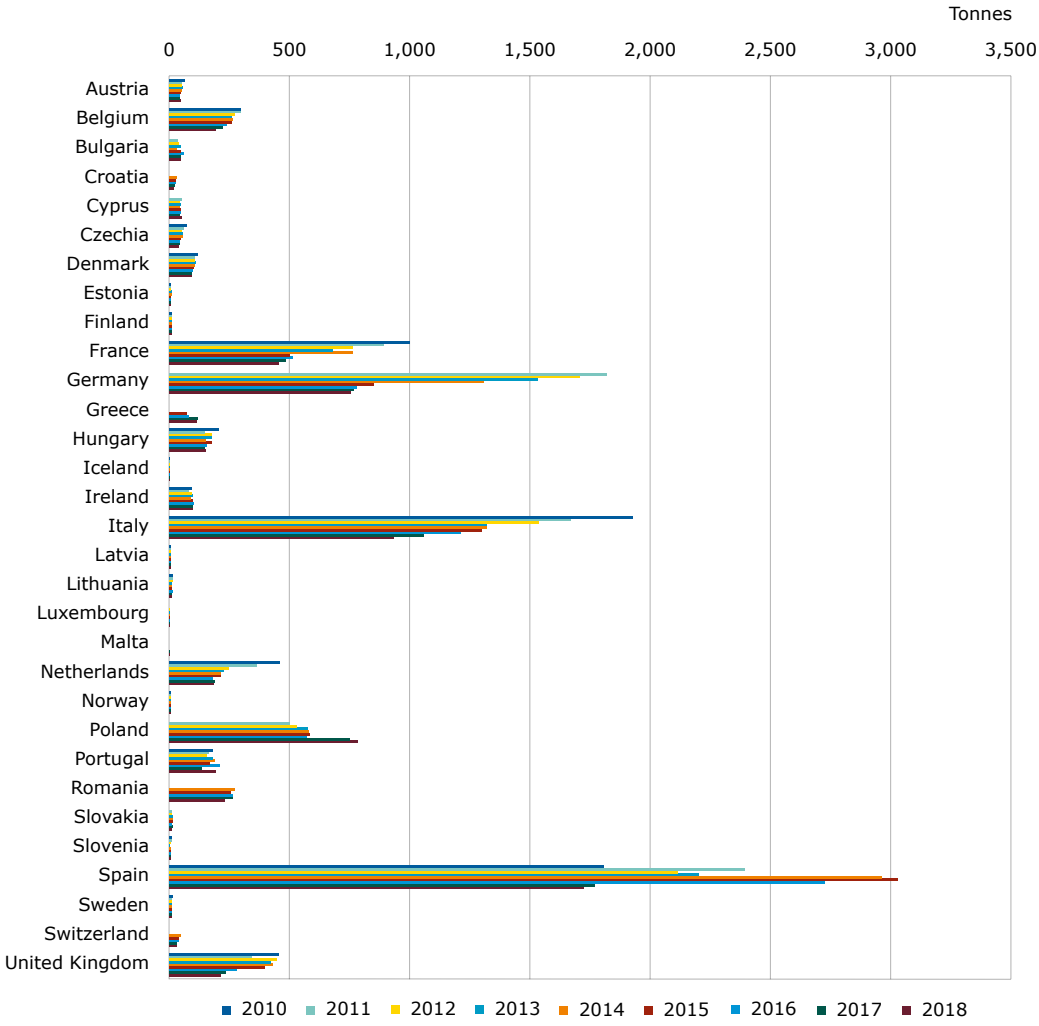
Figure 24. Changes in aggregated sales (mg/PCU) by antimicrobial class in 25 EU/EEA countries[1], from 2011 to 2018



[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 the United Kingdom.
*Other antibacterials (classified as such in the ATCvet system).

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

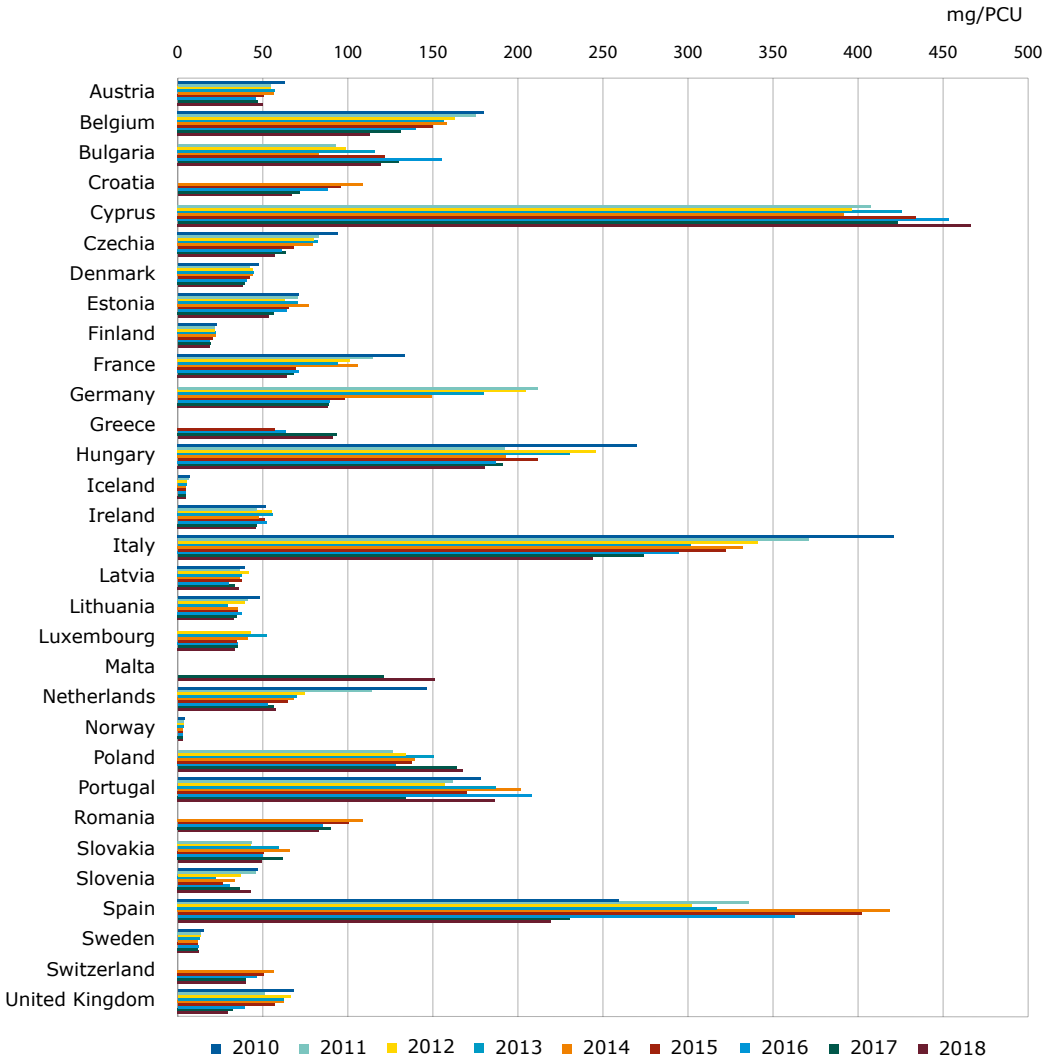
Figure 25. Sales of active ingredients, of veterinary antimicrobials for food-producing animals, in tonnes, by country, from 2010 to 2018[1-9]



[1] Corrections to sales data as published in the ESVAC 2017 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] For Croatia, double reporting was observed for sales of several VMPs between 2014 and 2017.
[4] Strength reported as the active principle for most VMPs for 2011-2012 for Czechia; for 2013-2018, strength reported as on the VMPs' labels.
[5] Strength reported as the active principle for some VMPs for 2011–2012 for the Netherlands; for 2013-2018, strength reported as on the labels of the VMPs.
[6] For Portugal, under-reporting has been identified for 2010-2014 and 2017.
[7] For Romania, 2014 data were updated, as wholesalers initially failed to deliver all sales data.
[8] For Slovakia, for 2011 and 2012, the data only 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).
[9] For Spain, under-reporting has been identified for 2010 to 2013 (underestimates) and sales data providers for 2017-2018 were changed from MAHs to retailers.
[10] For the United Kingdom, high sales of certain tetracycline-containing products late in 2010 were probably used in 2011 and thus their use has been underestimated for 2011.

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

Figure 26. Total sales of veterinary antimicrobials for food-producing species, in mg/PCU, by country, from 2010 to 2018[1-9]



[1] Corrections to sales data or to PCU data as published in the ESVAC 2017 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] For Croatia, double reporting was observed for sales of several VMPs between 2014 and 2017.
[4] Strength reported as the active principle for most VMPs for 2011-2012 for Czechia; for 2013-2018, strength reported as on the labels of the VMPs.
[5] Strength reported as the active principle for some VMPs for 2011-2012 for the Netherlands; for 2013-2018, strength reported as on the VMPs' labels.
[6] For Portugal, under-reporting has been identified for 2010-2014 and 2017.
[7] For Romania, 2014 data were updated, as wholesalers initially failed to deliver all sales data.
[8] 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).
[9] For Spain, under-reporting for the years 2010 to 2013 has been identified (underestimates) and the data providers for 2017-2018 data were changed from MAHs to retailers.
[10] For the United Kingdom, 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 2018, a drop of more than 5% (range -6.2% to -58.2%) in sales (mg/PCU) was observed for 18 countries (Table 8). For five countries, an increase of more than 5% was noted (range 13.0% to 32.7%).

Table 8. Annual sales of veterinary antimicrobial agents for food-producing species, in mg/PCU, by country[1], from 2010 to 2018

Country	2010	2011	2012	2013	2014	2015	2016	2017	2018	Trends 2010-2018
Austria	62.9	54.5	54.9	57.2	56.3	50.7	46.1	46.8	50.1	
Belgium	180.1	175.3	163.1	156.6	158.3	150.1	140.1	131.3	113.1	
Bulgaria[2]		92.6	98.9	116.1	82.9	121.9	155.3	129.8	119.6	
Croatia[3]					108.6	95.6	87.9	71.5	66.8	
Cyprus		407.6	396.5	425.8	391.5	434.2	453.4	423.1	466.3	
Czechia[4]	94.3	83.0	79.8	82.2	79.5	68.1	61.2	63.6	57.0	
Denmark	47.5	42.6	44.1	44.9	44.2	42.2	40.8	39.4	38.2	
Estonia	70.9	70.7	62.9	70.4	77.1	65.2	64.0	56.7	53.3	
Finland	22.7	21.9	21.8	22.4	22.3	20.4	18.6	19.3	18.7	
France	133.7	114.4	101.2	94.0	105.8	69.4	71.2	68.0	64.2	
Germany		211.5	204.8	179.7	149.3	97.9	89.2	89.0	88.4	
Greece						57.1	63.4	93.7	90.9	
Hungary	269.9	192.5	245.8	230.7	193.1	211.4	187.1	191.0	180.6	
Iceland	7.0	6.2	5.5	5.1	4.9	4.9	4.7	4.6	4.9	

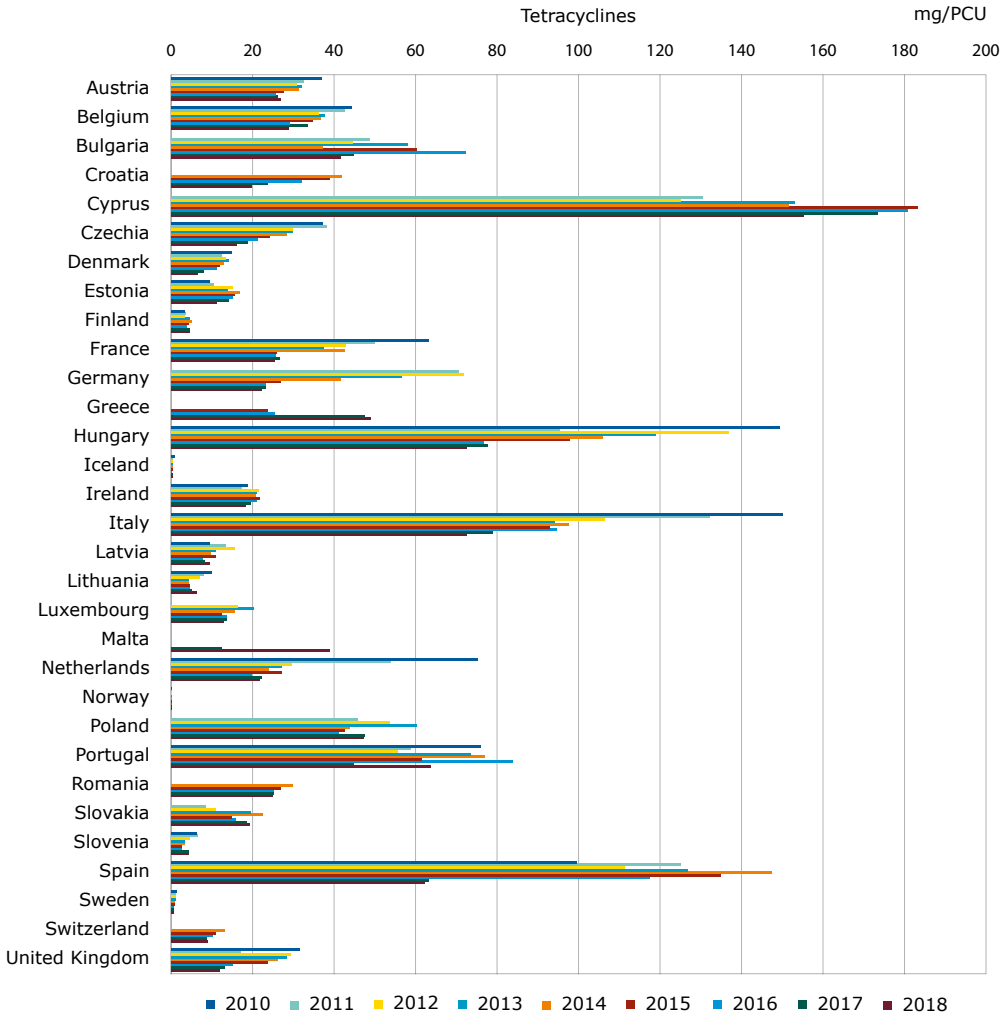
Country	2010	2011	2012	2013	2014	2015	2016	2017	2018	Trends 2010-2017
Ireland	51.5	46.5	55.0	55.9	47.6	51.0	52.1	46.6	46.0	
Italy	421.1	371.0	341.0	301.6	332.4	322.0	294.8	273.8	244.0	
Latvia	39.5	36.7	41.5	37.7	36.7	37.6	29.9	33.3	36.1	
Lithuania	48.2	41.3	39.2	29.1	35.5	35.1	37.7	34.8	33.1	
Luxembourg			43.2	52.1	40.9	34.6	35.5	35.0	33.6	
Malta								121.0	150.9	
Netherlands[5]	146.1	113.8	74.9	69.9	68.4	64.4	52.7	56.3	57.5	
Norway	4.0	3.6	3.8	3.6	3.1	2.9	2.9	3.1	2.9	
Poland		126.2	134.0	150.3	139.6	137.8	128.3	163.9	167.4	
Portugal[6]	177.9	161.8	156.9	187.2	201.6	170.2	208.0	134.1	186.6	
Romania[7]					109.0	100.5	85.2	90.1	82.7	
Slovakia[8]		43.6	43.2	59.1	65.6	50.8	50.2	61.8	49.3	
Slovenia	46.9	46.1	37.0	22.4	33.4	26.4	30.3	36.5	43.2	
Spain[9]	259.5	335.8	302.4	317.1	418.8	402.0	362.5	230.3	219.2	
Sweden[10]	15.2	13.6	13.5	12.7	11.5	11.8	12.1	11.8	12.5	
Switzerland					56.7	50.6	46.6	40.1	40.2	
United Kingdom[11]	67.9	51.1	66.3	62.1	62.5	56.8	39.3	32.5	29.5	

[1] Updates to sales data or PCU data as published in the ESVAC 2017 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] For Croatia, double reporting was observed for sales of several VMPs between 2014 and 2017.
[4] Strength reported as the active principle for most VMPs for 2011-2012 for Czechia; for 2013-2017, strength reported as on the labels of the VMPs.
[5] Strength reported as the active principle for some VMPs for 2011-2012 for the Netherlands; for 2013-2017, strength reported as on the labels of the VMPs.
[6] For Portugal, under-reporting has been identified for the years 2010 - 2014 and 2017.
[7] For Romania, 2014 data were updated as wholesalers initially failed to deliver all sales data.
[8] 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).
[9] For Spain, under-reporting has been identified for the years 2010 to 2013 and sales data providers for 2017-2018 data were changed from MAHs to retailers.
[10] For Sweden, there was underreporting of sales for use in farmed fish in 2017.
[11] For the United Kingdom, high sales of certain tetracycline-containing products late in 2010 were probably used in 2011 and thus their use has been underestimated for 2011.

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

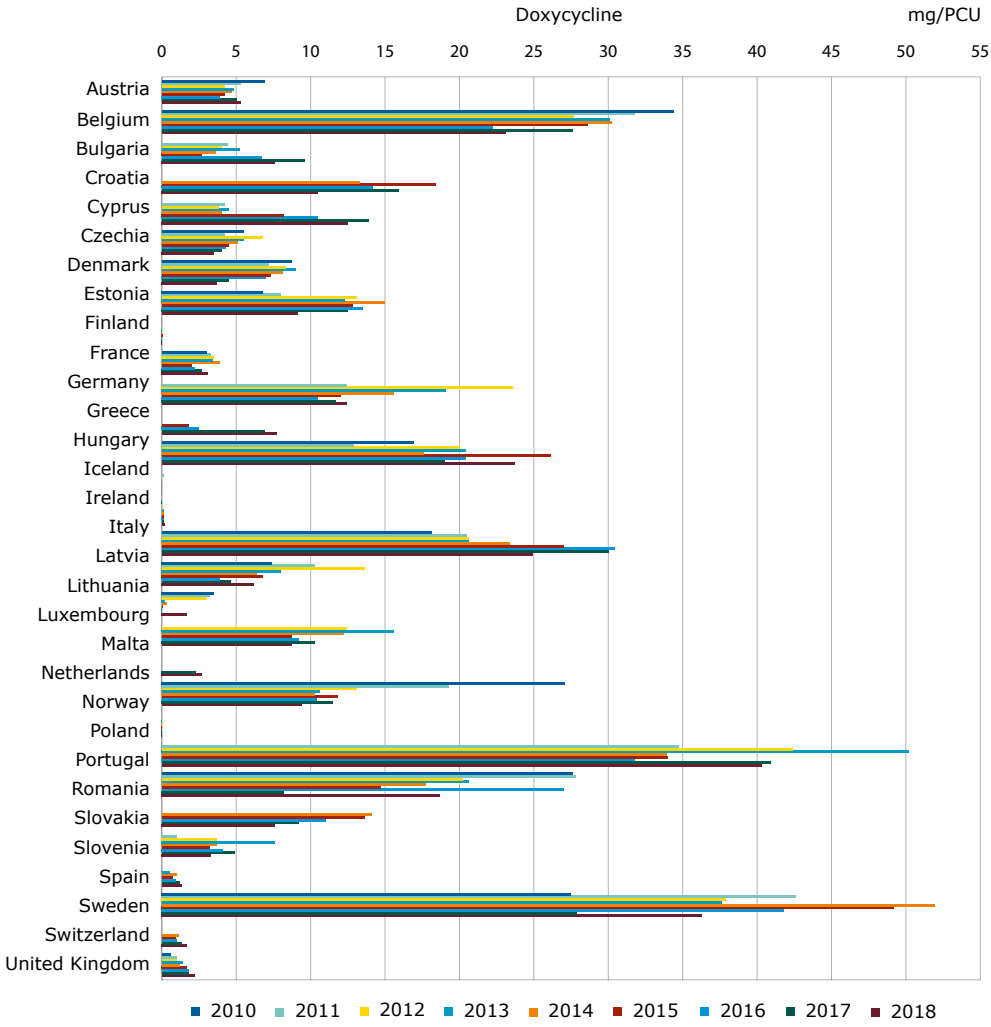
Sales of tetracyclines, a class of antimicrobials with a high volume of sales for veterinary use, are shown in Figure 27. Sales of doxycycline are also presented separately (Figure 28) because of the lower dosing used in the treatment of animals compared to other tetracyclines. Therefore, an increase in the sales of doxycycline could be associated with a reduction in total sales of tetracyclines.

Figure 27. Changes in sales of tetracyclines for food-producing species, in mg/PCU, by country, from 2010 to 2018[1]



[1] Sales in Iceland, Norway and Sweden ≤1 mg/PCU for all years.

Figure 28. Changes in sales of doxycycline for food-producing species, in mg/PCU, by country, from 2010 to 2018[1,2]



[1] No sales in Iceland since 2012, and only a negligible amount sold in 2011; in Finland, Ireland and Norway no sales were reported for some of the years or sales were very low (≤0.2 mg/PCU).
[2] For reasons of commercial confidentiality, sales of doxycycline in Sweden (≤0.1 mg/PCU for all years) are not included in this graph.

Figure 29. Changes in sales of penicillins for food-producing species, in mg/PCU, by country, from 2010 to 2018

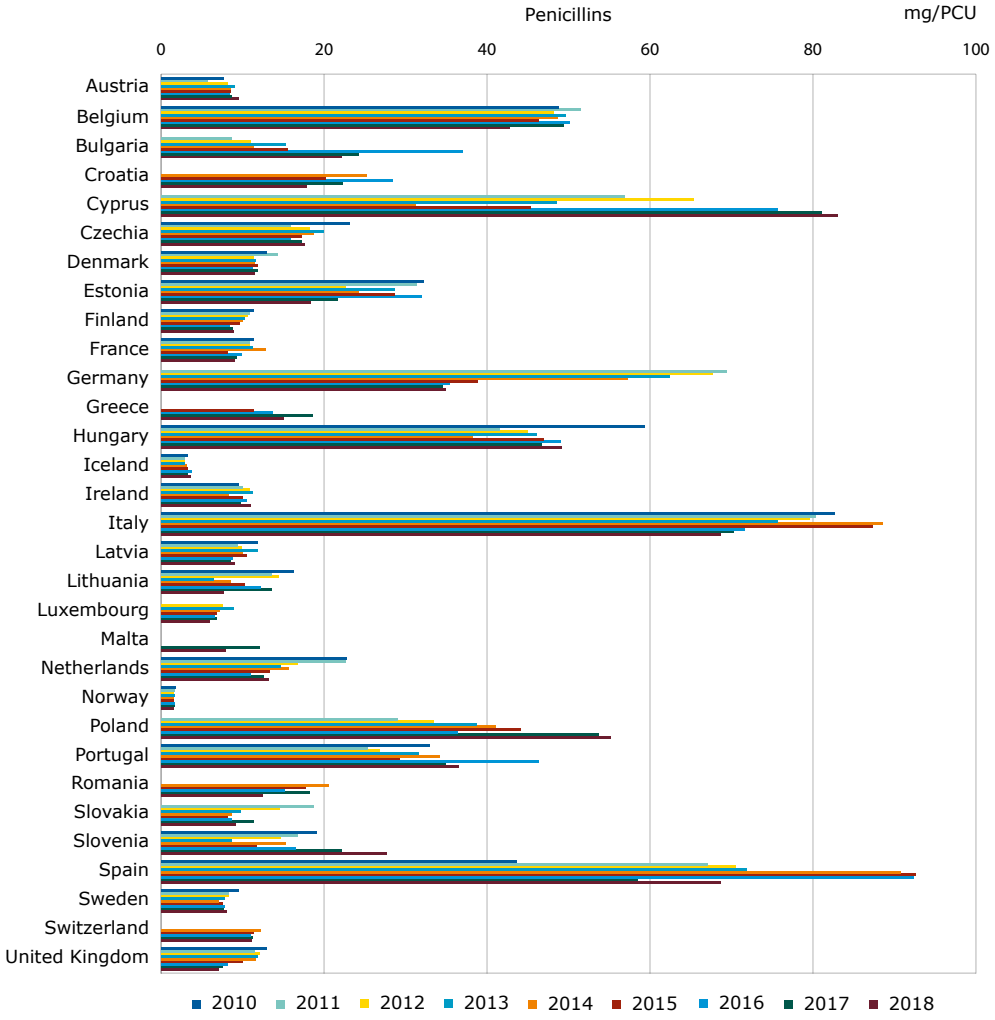
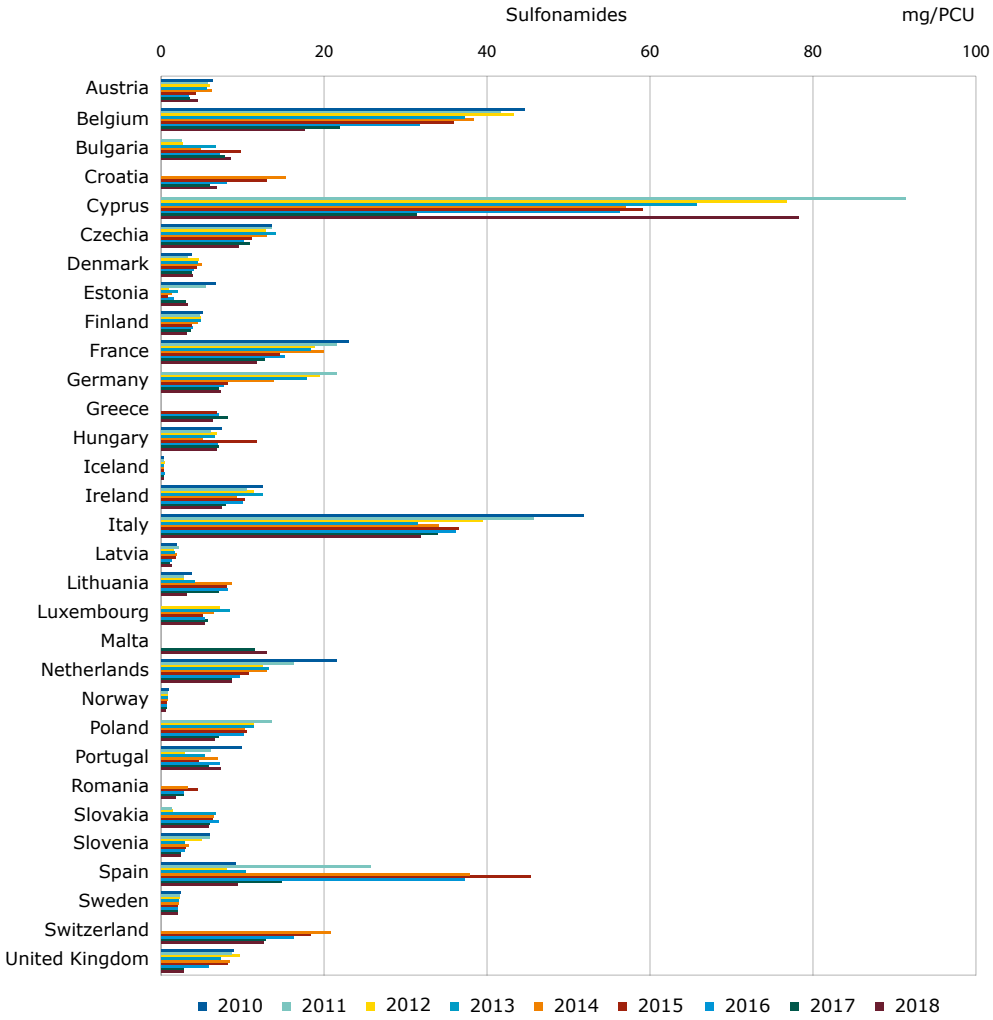


Figure 30. Changes in sales of sulfonamides for food-producing species, in mg/PCU, by country, from 2010 to 2018[1]

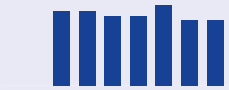
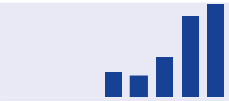


[1] Negligible sales in Iceland and Norway (<1mg/PCU) for all years.

Tables 9 to 11 and Figures 31 and 32 highlight critically important antimicrobials with the highest priority for humans, as defined by the WHO, and antimicrobial classes belonging to the AMEG Category B. More details on the selection of antimicrobial classes of the WHO HP CIAs and AMEG Category B 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 2018[1,2]. Note that the scale differs between countries

Country	2010	2011	2012	2013	2014	2015	2016	2017	2018	Trends 2010-2018
Austria	0.3	0.3	0.3	0.3	0.2	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	0.1	
Bulgaria		0.05	0.03	0.1	0.1	0.2	0.1	0.1	0.1	
Croatia					0.1	0.2	0.2	0.2	0.3	
Cyprus		0.2	0.5	0.5	0.8	0.3	0.7	0.4	0.4	
Czechia	0.4	0.3	0.3	0.4	0.4	0.4	0.4	0.5	0.5	
Denmark	0.05	0.03	0.03	0.02	0.02	<0.01	<0.01	<0.01	<0.01	
Estonia	0.4	0.5	0.6	0.7	0.6	0.6	0.7	0.8	0.9	
Finland	<0.01	0.02	0.03	0.02	0.02	0.01	<0.01	<0.01	<0.01	
France	0.3	0.3	0.3	0.3	0.3	0.2	0.1	0.02	0.02	
Germany		0.4	0.4	0.4	0.4	0.4	0.4	0.4	0.2	
Greece						0.1	0.1	0.1	0.1	
Hungary	0.3	0.1	0.3	0.3	0.2	0.4	0.4	0.5	0.5	
Iceland	<0.01	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	0.2	

Country	2010	2011	2012	2013	2014	2015	2016	2017	2018	Trends 2010-2017
Italy	0.4	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	0.4	
Lithuania	0.02	0.04	0.1	0.2	0.2	0.1	0.1	0.2	0.3	
Luxembourg			0.7	0.7	0.6	0.6	0.7	0.6	0.6	
Malta								0.2	0.2	
Netherlands	0.2	0.2	0.02	<0.01	<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	<0.01	
Poland		0.1	0.1	0.2	0.2	0.1	0.2	0.2	0.3	
Portugal	0.3	0.3	0.2	0.4	0.4	0.5	0.5	0.6	0.4	
Romania					0.05	0.04	0.1	0.2	0.2	
Slovakia		0.7	0.5	0.4	0.5	0.3	0.4	0.4	0.4	
Slovenia	0.1	0.1	0.2	0.1	0.1	0.2	0.2	0.2	0.2	
Spain	0.7	0.3	0.3	0.3	0.3	0.3	0.3	0.2	0.4	
Switzerland					0.2	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	0.1	

[1] For countries where injectable 3rd- and 4th-generation cephalosporins are solely or almost solely marketed for dogs and cats, the data provide a considerable overestimate for food-producing animals.
[2] For reasons of commercial confidentiality, sales of 3rd- and 4th-generation cephalosporins in Sweden (<0.01 mg/PCU since 2013) are not included in this table.

Table 10. Changes in sales of fluoroquinolones for food-producing species, in mg/PCU, by country, from 2010 to 2018. Note that the scale differs between countries

Country	2010	2011	2012	2013	2014	2015	2016	2017	2018	Trends 2010-2018
Austria	0.6	0.6	0.5	0.6	0.5	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	0.2	
Bulgaria		5.0	6.1	6.8	1.8	5.3	4.9	5.6	6.0	
Croatia					3.5	3.3	2.6	1.9	2.4	
Cyprus		0.5	0.8	0.9	0.9	1.1	1.6	2.4	3.1	
Czechia	1.3	1.5	1.8	1.8	1.8	1.7	1.7	1.9	1.8	
Denmark	<0.01	<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	1.2	
Finland	0.2	0.2	0.2	0.2	0.2	0.1	0.1	0.1	0.1	
France	0.6	0.6	0.6	0.6	0.6	0.3	0.2	0.2	0.1	
Germany		0.9	1.2	1.4	1.4	1.1	1.0	1.1	0.9	
Greece						1.7	2.2	2.7	2.2	
Hungary	8.8	6.7	11.0	9.2	9.1	9.5	9.6	8.8	10.8	
Iceland	<0.01	<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	0.4	

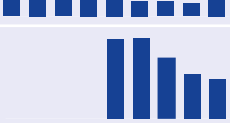
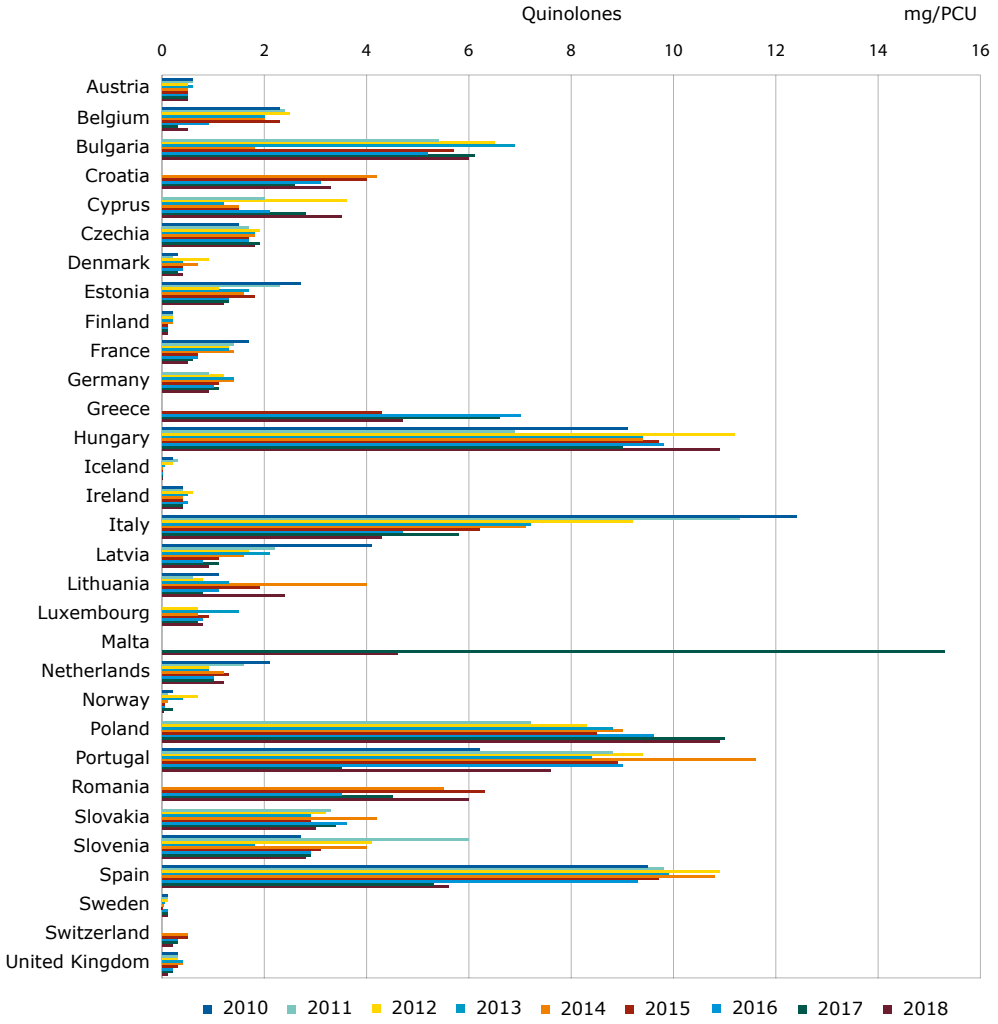
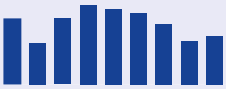
Country	2010	2011	2012	2013	2014	2015	2016	2017	2018	Trends 2010-2018
Italy	1.7	2.2	2.5	2.3	3.1	2.9	2.3	3.0	2.3	
Latvia	4.1	2.2	1.7	2.1	1.6	1.1	0.8	1.1	0.9	
Lithuania	0.7	0.4	0.6	0.8	3.1	1.7	1.0	0.8	2.3	
Luxembourg			0.7	0.8	0.7	0.7	0.8	0.7	0.8	
Malta								14.3	4.6	
Netherlands	0.5	0.5	0.2	0.1	0.1	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	<0.01	
Poland		7.1	8.2	8.8	9.0	8.5	9.6	11.0	10.9	
Portugal	5.6	8.4	9.3	8.2	11.4	8.8	8.9	3.5	7.6	
Romania					5.3	6.1	3.3	4.3	6.0	
Slovakia		3.0	3.2	2.8	4.2	2.9	3.6	3.4	3.0	
Slovenia	2.6	5.9	4.1	1.8	4.0	3.0	2.9	2.9	2.8	
Spain	8.8	9.2	10.2	9.3	9.9	9.0	8.5	4.9	5.6	
Sweden	0.1	0.1	0.1	0.04	0.03	0.02	0.02	0.02	0.03	
Switzerland					0.5	0.5	0.3	0.3	0.2	
United Kingdom	0.3	0.3	0.3	0.4	0.4	0.3	0.2	0.2	0.1	

Figure 31. Changes in aggregated sales of fluoroquinolones and other quinolones for food-producing species, in mg/PCU, by country, from 2010 to 2018[1]



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

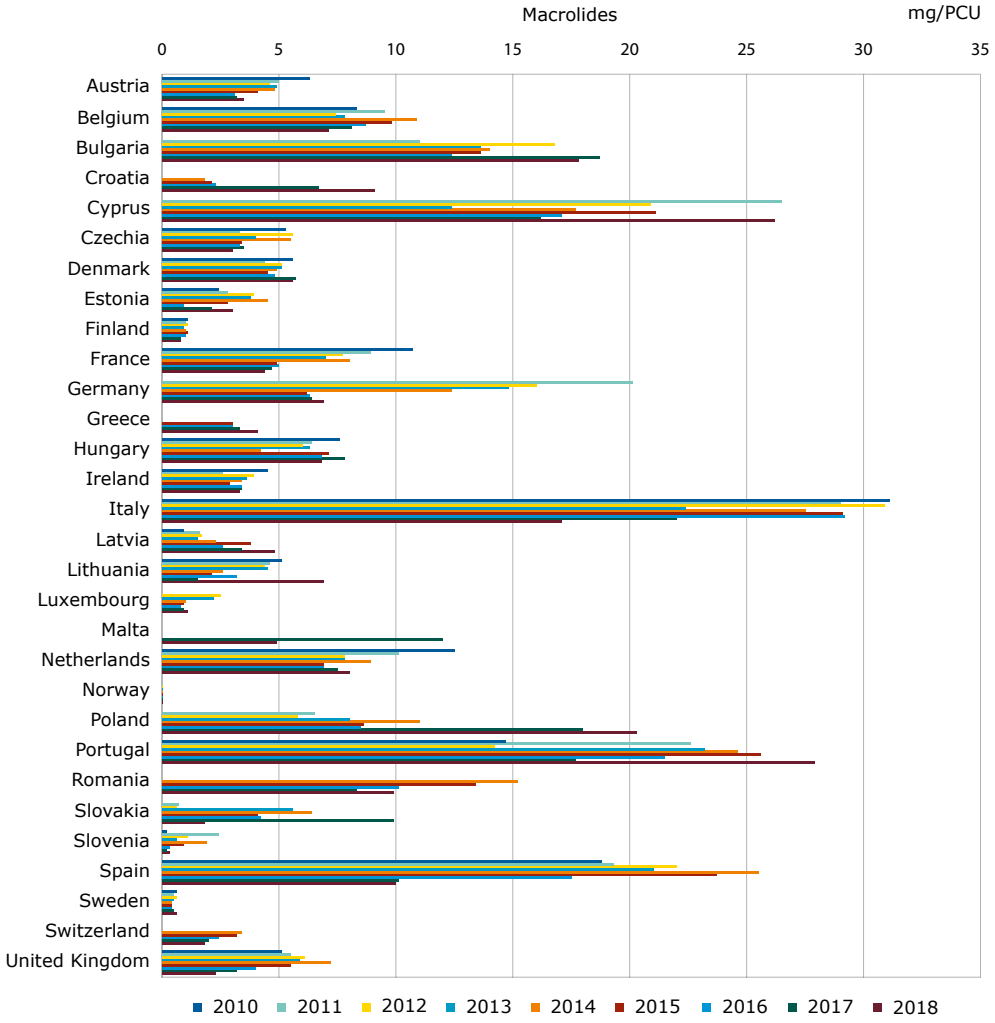
Table 11. Changes in sales of polymyxins for food-producing species, in mg/PCU, by country, from 2010 to 2018[1,2]. Note that the scale differs between countries

Country	2010	2011	2012	2013	2014	2015	2016	2017	2018	Trends 2010-2018
Austria	1.0	1.0	0.7	0.9	1.6	1.6	1.6	1.7	1.9	
Belgium	6.0	5.4	5.8	4.7	3.4	2.8	2.4	2.1	2.0	
Bulgaria		3.2	3.8	2.7	0.5	3.6	2.3	2.9	3.7	
Croatia					3.8	2.4	3.6	3.2	2.7	
Cyprus		8.2	8.1	8.4	11.1	12.4	11.1	10.4	12.8	
Czechia	0.9	0.6	0.9	1.1	1.0	1.0	0.8	0.6	0.7	
Denmark	0.3	0.2	0.2	0.2	0.4	0.5	0.5	0.2	<0.01	
Estonia	3.5	4.3	4.9	5.8	3.1	1.3	0.7	1.1	0.8	
France	8.6	7.7	6.7	5.9	7.0	4.0	2.8	2.2	1.8	
Germany		14.8	14.8	14.6	12.2	9.2	7.9	8.5	8.6	
Greece						3.4	1.0	1.3	1.6	
Hungary	6.9	8.9	7.8	10.0	7.1	9.6	12.2	14.9	10.1	
Italy	40.2	30.7	30.1	27.6	29.4	26.1	15.1	5.2	2.7	
Latvia	1.0	1.0	2.5	1.5	0.8	0.9	0.9	1.3	1.9	

Country	2010	2011	2012	2013	2014	2015	2016	2017	2018	Trends 2010-2018
Lithuania	1.7	1.4	1.3	0.1	0.1	0.6	1.0	0.7	0.2	
Luxembourg			1.7	3.1	2.4	1.5	1.0	1.0	0.6	
Malta								4.6	1.8	
Netherlands	2.3	1.6	1.0	0.6	0.5	0.5	0.3	0.3	0.4	
Poland		4.1	4.0	4.4	5.0	5.9	5.6	7.4	7.4	
Portugal	15.1	7.9	18.6	19.0	17.6	14.6	13.5	10.9	12.6	
Romania					6.5	7.4	5.6	4.1	6.4	
Slovakia		1.2	2.1	1.1	1.5	1.1	1.2	1.7	1.4	
Slovenia	0.1	0.1	0.1	0.04	0.1	0.1	0.1	0.1	0.2	
Spain	33.0	33.5	29.4	21.5	36.1	34.9	22.0	4.4	3.3	
Switzerland					0.9	0.6	0.5	0.4	0.3	
United Kingdom	0.1	0.1	0.1	0.1	0.1	0.1	0.02	<0.01	<0.01	

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

Figure 32. Changes in sales of macrolides for food-producing species, in mg/PCU, by country, from 2010 to 2018[1]



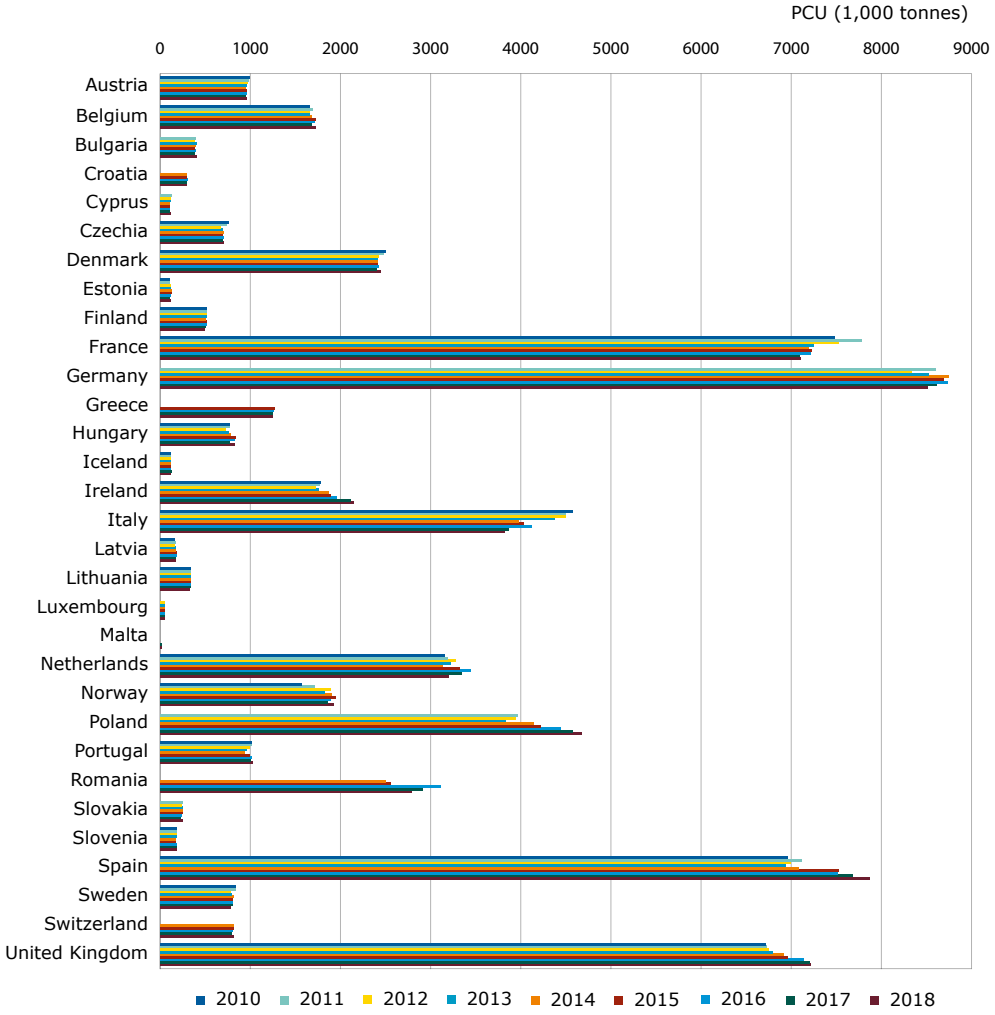
[1] No sales in Iceland; negligible sales (<1 mg/PCU) in Norway and Sweden for all years.

2.8.5. Changes in the denominator (PCU) by country

From 2010 to 2018, the PCU (estimated weight at treatment of livestock and slaughtered animals) was relatively stable for most countries (Figure 33).

For four of the 25 countries (Ireland, Norway, Poland and Spain) 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 Italy.

Figure 33. Changes in the denominator (PCU) for food-producing animals, in 1,000 tonnes, by country, from 2010 to 2018



3. Discussion

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

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[23], all VMPs, including veterinary antimicrobial agents, must be sold through distributors authorised by the competent authority in each country. This enables 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 reporting countries.

In 2018, all countries provided sales data except Denmark, which submitted prescription data, and Sweden, which submitted prescription and requisition data.

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

The national sales data (numerator) cover all food-producing species, including horses, which are considered to be food-producing species according to EU legislation. Thus, the animal population that could potentially be 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 Member States, based on the cascade principle described in Article 11 of Directive 2001/82/EC[24] (and in the future according to Articles 107, 112, 113 and 114 of Regulation (EC) 2019/6[25]), where there is no authorised VMP for treatment of companion or food-producing animals, the administration of other medicinal products may be permitted in exceptional circumstances. Sales of human medicinal products fall out of scope of ESVAC protocol. In addition, when antimicrobial sales data are submitted to the ESVAC, they do not include details as to whether or not a VMP was used under the cascade.

Dosing of the various antimicrobial agents varies substantially between and within classes, as well as between animal species, sometimes by several orders of magnitude, as reflected by the DDDvet and DCDvet values published by EMA in 2016[26]. For example, the dose for a complete 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 is not possible to take into account differences in dosing when reporting the data. Considering the above-mentioned factors, sales data do not reflect the real exposure of animals to antimicrobials or 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.

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, as well as of premixes, are considered to be a reasonable estimate of sales of these forms for group treatment.

[23] 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).
[24] OJ L 311, 28.11.2001, p. 1.
[25] OJ L 4, 7.1.2019, p 43-167.
[26] 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).

Dermatological preparations (ATCvet group QD) and preparations for sensory organs (ATCvet group QS) were not included in the data collection. In 2018, these pharmaceutical forms represented, for example, only 0.2% in Denmark, (L. Mie Jensen, unpublished data), 0.77% in Czechia (L. Pokludová, unpublished data), 0.68% in France (A. Chevance, unpublished data) and 1.1% 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.

In the current report, data presented on sales of veterinary antimicrobial agents for companion animals solely represent sales of tablets. Parenteral preparations of antimicrobial agents are used both in food-producing and companion animals. With the exception of some long-acting products, parenteral administration of antimicrobial agents in companion animals is generally limited to hospitalised animals or perioperative treatments. Data from Denmark and France for 2018 showed that approximately 1.3% and 0.9% 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, the data provide a considerable overestimate of use in food-producing animals.

For 2018, 12 countries (Table 2) included veterinary antimicrobial agents obtained on special licence/marketing authorisation or through parallel trade – i.e. obtained from another Member State and permitted to be marketed for specific animal species and indications, although the type of marketing authorisation procedure applied might differ among Member States – in the data sets. All these countries have a comparatively low number of antimicrobial VMPs on the market (Annex 1, Table A7). Ten of them – Cyprus, Czechia, Denmark, Estonia, Finland, Iceland, Norway, Slovakia, Slovenia and Sweden— reported that the proportion of sales of antimicrobial VMPs on special licence accounted for approximately 12%, 0.2%, 2.4%, 0.7%, 5.1%, 9%, 2.0%, <1%, 4.6% and 5% 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 under surveillance or in the reporting of data obtained through the national surveillance systems. For instance, the strength of an antimicrobial ingredient may be reported as the strength of its active principle in the national database, while for the ESVAC the strength of an antimicrobial ingredient is reported as given in the product information and can represent the strength of the active principle or the whole chemical compound (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 at the European level and in individual countries, especially in those with well-established and stable data-collection systems.

4. Concluding remarks

Variations in reported sales (mg/PCU) and in sales patterns for 2018 between the 31 countries are likely to be due in part to differences in the composition of the animal population, production systems and prescription guidelines or habits in the different countries. Considerable variations 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, which may impact the data. In addition, differences in the selection of sales data providers among countries may have an impact, although the effect of this is thought to be minor. However, since these factors can only partly explain the differences in sales observed among the 31 countries, other country-specific factors must also be taken into account and individual consideration should be given when evaluating results on a country-by-country basis.

It should be noted that the sales data (numerator) and major food-producing species (denominator) cover the animal population that could potentially be treated with antimicrobial agents. 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, prescription control measures, increased awareness of the threat of antimicrobial resistance, setting targets for reductions in antimicrobial sales or use, and changes in animal demographics. Reduced sales of veterinary antimicrobials in some countries indicate the potential for a reduction in other countries as well.

Annex 1. Additional tables and charts

Table A1. Sales, in tonnes of active ingredient, of veterinary antimicrobial agents applicable mainly to food-producing animals by antimicrobial class (presented according to the ATCvet hierarchical system), by country, for 2018 (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	25.7	0.4	9.0	0.04	0.2	4.3	0.9	3.4	0.1	0.5	0	1.2	1.8	0.3	0.1	48.0
Belgium	49.8	3.3	73.8	0.2	0.1	30.4	6.1	12.3	4.5	0.3	0.5	2.8	3.5	1.9	5.4	195.0
Bulgaria	16.6	2.0	8.8	<0.01	0.04	3.4	0.4	7.1	2.4	2.4	0	2.1	1.5	0.9	0.4	47.8
Croatia	5.8	0.5	5.2	<0.01	0.1	2.0	0.3	2.7	0.04	0.7	0.3	1.1	0.8	0.1	0.1	19.6
Cyprus	17.8	0.3	9.5	<0.01	0.1	9.0	1.8	3.0	5.7	0.4	0.04	0.9	1.5	3.4	0.1	53.4
Czechia	11.3	0.4	12.4	0.1	0.4	6.7	0.7	2.1	0.1	1.3	<0.01	2.0	0.5	1.9	0.3	40.2
Denmark	16.3	1.6	28.1	0.1	0.01	9.4	1.9	13.6	2.1	<0.01	0.9	8.7	<0.01	8.7	2.3	93.6
Estonia	1.3	0.1	2.1	0.02	0.1	0.4	0.1	0.3	0.1	0.1	0	0.4	0.1	0.9	0.1	6.1
Finland	2.2	0.1	4.4	0.01	<0.01	1.5	0.3	0.4	0.1	0.1	0	0.03	0	<0.01	0	9.3
France	180.0	5.8	64.0	1.6	0.1	82.8	15.1	31.4	2.6	0.9	2.8	48.9	13.0	3.5	3.7	456.2
Germany	189.2	5.9	297.7	0.7	1.7	62.0	7.9	58.6	9.9	7.5	0	20.4	73.5	10.2	7.9	753.1
Greece	60.8	0.8	18.7	<0.01	0.2	7.8	1.0	5.1	0.5	2.7	3.1	8.1	1.9	1.5	0.8	113.0
Hungary	60.3	4.0	40.9	0.1	0.4	5.6	1.2	5.6	2.4	9.0	0.1	2.5	8.4	9.4	0.2	150.2
Iceland	0.03	0	0.4	0	<0.01	0.03	<0.01	0	0	<0.01	0	0.1	0	0	0	0.6
Ireland[3]	39.2	3.3	23.6	0.8	0.3	15.8	1.0	7.1	0.3	0.8	0	5.5			0.8	98.6
Italy	277.4	21.5	262.2	0.6	1.5	122.0	13.2	65.4	73.0	8.9	7.4	33.7	10.2	27.2	7.9	932.1
Latvia	1.6	0.02	1.5	0.03	0.1	0.2	0.04	0.8	0.02	0.2	<0.01	0.7	0.3	0.5	0.1	6.0
Lithuania	2.1	0.2	2.5	0.1	0.1	1.0	0.2	2.2	0.1	0.7	0.04	0.5	0.1	0.6	0.2	10.7
Luxembourg	0.7	0.1	0.3	<0.01	0.03	0.3	0.1	0.1	0.04	0.04	0	0.2	0.03	<0.01	0.03	1.8
Malta[4]	0.6	0.02	0.1	<0.01	<0.01	0.2	0.03	0.1	<0.01	0.1		0.1	0.03	0.6	0.4	2.1
Netherlands	69.6	4.4	42.4	0.1	<0.01	27.8	5.1	25.6	0.1	0.2	3.7	2.3	1.2	1.4	0.1	183.9
Norway	0.1	0.9	2.9	0	<0.01	1.2	0.2	<0.01	<0.01	0.01	0.1	0.3	0	0.03	<0.01	5.7
Poland	221.0	8.2	257.7	0.5	1.3	30.6	6.2	95.0	6.7	51.0	0.04	22.4	34.6	42.9	4.0	782.2
Portugal	65.4	2.1	37.5	0.03	0.4	7.6	1.5	28.7	4.9	7.8	<0.01	10.9	13.0	10.5	1.6	191.8
Romania	69.7	8.9	34.9	0.02	0.5	5.0	0.9	27.6	4.2	16.7	0.02	28.2	17.7	14.5	1.7	230.7
Slovakia	4.8	0.1	2.3	0.04	0.1	1.4	0.2	0.4	0.05	0.7	<0.01	0.4	0.3	0.9	0.3	12.1
Slovenia	0.8	0.2	5.0	<0.01	0.04	0.4	0.1	0.05	<0.01	0.5	0	0.5	0.04	0.2	0.02	7.8
Spain	489.6	44.3	540.1	0.2	3.1	73.9	12.6	78.5	151.5	43.9	0	174.2	25.7	38.9	47.7	1,724.1
Sweden[5]	0.6		6.2		<0.01	1.5	0.3	0.5	0.01		0.1	0.3			0.3	9.8
Switzerland[6]	7.3	0.5	9.1	0.1	0.1	10.3	0.8	1.5		0.2	0	2.8	0.2		0.1	32.9
United Kingdom	85.9	4.4	50.3	0.5	0.5	19.4	3.8	16.5	3.1	1.1	0	15.5	<0.01	9.1	3.0	212.9
Total 31 countries	**1,973.3**	**124.0**	**1853.6**	**5.7**	**11.5**	**544.1**	**83.8**	**495.5**	**274.4**	**158.8**	**19.1**	**397.9**	**210.0**	**190.8**	**88.8**	**6,431.4**

[1] For the countries where 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] Bacitracin, fosfomycin, furaltadone, metronidazole, novobiocin, 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] For commercial confidentiality reasons, amphenicols, polymyxins and pleuromutilins are aggregated with 'Others', 1st- and 2nd-generation cephalosporins are aggregated with 3rd- and 4th-generation cephalosporins, and fluoroquinolones are grouped with other quinolones.
[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 to food-producing animals[1], by administration route/form and country, for 2018

Country	Premix	Oral powder	Oral solution	Injectable prep.	Oral paste	Bolus	Intramammary prep.	Intrauterine prep.	Total mg/PCU
Austria	1.6	33.5	7.3	6.3	0.4	<0.01	0.9	0.1	50.1
Belgium	10.3	20.8	68.0	13.2	0.1	0.1	0.4	0.2	113.1
Bulgaria	38.9	11.6	56.3	11.9	0	0	0.7	0.1	119.6
Croatia	8.7	3.8	31.2	21.4	0	0.9	0.5	0.3	66.8
Cyprus	385.1	5.7	52.5	20.8	0.1	0.2	2.0	<0.01	466.3
Czechia	8.5	10.3	26.4	9.9	0.1	0.1	1.4	0.5	57.0
Denmark	1.1	2.8	18.7	14.8	0.6	<0.01	0.2	0.1	38.2
Estonia	0	1.6	30.2	19.5	0.1	0	1.8	0.1	53.3
Finland	3.4	3.2	0.2	10.3	1.1	0	0.4	0	18.7
France	19.3	1.0	29.8	12.8	0.1	0.1	0.9	0.1	64.2
Germany	0.04	44.3	35.4	7.2	0.2	0.01	0.8	0.5	88.4
Greece	48.7	0.2	28.5	13.3	<0.01	0	0.1	0.04	90.9
Hungary	78.3	2.5	90.7	8.1	0.01	0	0.5	0.5	180.6
Iceland	0.03	0	0.1	4.4	0.1	0	0.3	0.1	4.9
Ireland	13.5	6.4	11.2	13.1	0.03	0.1	1.6	<0.01	46.0
Italy	103.5	0.03	123.0	16.6	0.2	<0.01	0.5	0.2	244.0
Latvia	0	2.7	19.6	11.2	0	0	1.3	1.2	36.1
Lithuania	0.01	3.5	20.4	7.6	0	0.5	0.8	0.2	33.1
Luxembourg	<0.01	13.1	7.8	11.1	0.1	0.1	1.3	0.2	33.6
Malta	108.0	5.4	24.6	12.0	0.1	0	0.5	0.4	150.9
Netherlands	0.4	1.6	46.2	8.2	0.4	0.03	0.5	0.1	57.5
Norway	0.5	0.03	0.1	1.6	0.6	0	0.1	0.04	2.9
Poland	2.8	13.1	141.9	8.8	0	0	0.6	0.2	167.4
Portugal	113.7	1.7	60.6	10.2	<0.01	0	0.3	0.02	186.6
Romania	11.2	0.5	56.1	14.3	0	0	0.6	0.1	82.7
Slovakia	15.8	2.6	21.6	8.6	0.02	<0.01	0.6	0.1	49.3
Slovenia	0.1	25.4	7.5	8.9	0	0	1.0	0.4	43.2
Spain	85.5	0	111.0	22.5	<0.01	<0.01	0.2	0.01	219.2
Sweden	0.5	<0.01	0.9	9.5	1.5	0	0.2	<0.01	12.5
Switzerland	21.0	4.2	0.03	9.9	0.8	0.02	3.4	0.8	40.2
United Kingdom	12.4	0.9	8.8	6.8	0.1	0.1	0.5	<0.01	29.5
Total 31 countries	**27.7**	**9.3**	**53.5**	**11.7**	**0.2**	**0.03**	**0.6**	**0.2**	**103.2**

[1] Injectable preparations included in the analysis also encompass those antimicrobial VMPs that are used for treatment of companion animals; tablets are eliminated from these data.

Table A3. Percentage of sales, in mg/PCU, of premixes by veterinary antimicrobial class (according to ATCvet system), by country, for 2018[1]

Country	Tetracyclines	Amphenicols	Penicillins	Sulfonamides	Trimethoprim	Macrolides	Lincosamides	Other quinolones	Aminoglycosides	Polymyxins	Pleuromutilins	Others[2]	Total mg/PCU premixes
Austria	42%	0%	0%	0%	0%	56%	0%	0%	0%	0%	2%	0%	1.6
Belgium	32%	2%	55%	0.2%	0.04%	5%	0.02%	0%	0.2%	2%	4%	0.02%	10.3
Bulgaria	56%	6%	0%	1%	0%	29%	0%	0%	<0.01%	5%	3%	0%	38.9
Croatia	41%	0.2%	0%	19%	0%	19%	0%	9%	11%	0%	0%	0%	8.7
Cyprus	38%	0.3%	11%	18%	4%	6%	13%	0%	0%	3%	7%	0%	385.1
Czechia	28%	0.1%	22%	17%	3%	21%	0.2%	0%	0%	1%	6%	2%	8.5
Denmark	0%	2%	1%	69%	14%	0%	0%	15%	0%	0%	0%	0%	1.1
Finland	45%	6%	0%	19%	4%	18%	8%	0%	0%	0%	0%	0%	3.4
France	48%	0%	7%	26%	5%	4%	0.2%	0.05%	8%	1%	1%	0%	19.3
Germany[3]	76%	0%		0%	0%	0%	0%	0%	0%	0%		24%	0.04
Greece	75%	1%	9%	7%	1%	3%	0.2%	0.3%	0%	1%	2%	0%	48.7
Hungary	63%	0.3%	13%	1%	0.2%	4%	2%	0%	0%	9%	8%	0%	78.3
Iceland	100%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0.03
Ireland[4]	74%	0.1%	2%	9%	2%	13%	0%	0%	0.5%	0%		1%	13.5
Italy	37%	1%	26%	15%	1%	5%	9%	1%	1%	0.5%	5%	0.4%	103.5
Lithuania	0%	100%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0.01
Luxembourg	0%	0%	0%	0%	0%	0%	50%	0%	0%	0%	0%	50%	<0.01
Malta	29%	0%	0%	5%	1%	0%	0%	0%	0%	2%	40%	23%	108.0
Netherlands	80%	0%	0%	17%	3%	0%	0%	0%	0%	0%	0%	0%	0.4
Norway	2%	92%	0%	0%	0%	0%	0%	6%	0%	0%	0%	0%	0.5
Poland	26%	0.1%	21%	13%	3%	27%	0%	0%	0%	3%	7%	0%	2.8
Portugal	42%	1%	13%	4%	1%	20%	0.2%	0%	1%	8%	8%	1%	113.7
Romania[5]	51%	2%	13%	1%	0.3%	2%	0.3%	1%	1%	0%	26%	2%	11.2
Slovakia	73%	0.01%	5%	0%	0%	2%	0%	0%	0%	0.3%	20%	0%	15.8
Slovenia	0%	100%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0.1
Spain	34%	0.6%	41%	6%	1%	5%	5%	0%	3%	0.02%	5%	0.02%	85.5
Sweden[6]													0.5
Switzerland[7]	33%	0%	19%	36%	3%	7%	0%	0%	0%	1%		1%	21.0
United Kingdom	55%	1%	12%	11%	2%	11%	0.3%	0%	2%	0%	6%	0%	12.4
Total 31 countries	**41.0%**	**0.8%**	**26.3%**	**10.2%**	**1.4%**	**6.9%**	**4.3%**	**0.2%**	**2.1%**	**1.3%**	**5.2%**	**0.2%**	**27.7**

[1] In 2018, no sales of premixes were reported in Estonia and Latvia.
[2] Bacitracin, metronidazole and spectinomycin (classified as 'Other antibacterials' in the ATCvet system).
[3] Penicillins and pleuromutilins are aggregated with 'Others' for commercial confidentiality reasons.
[4] Pleuromutilins are aggregated with 'Others' for commercial confidentiality reasons.
[5] No sales of other quinolones were reported in Romania. Sales indicated in this table correspond to sales of fluoroquinolones.
[6] For reasons of commercial confidentiality, data at class level cannot be shown in this table.
[7] For reasons of commercial confidentiality, pleuromutilins are grouped with 'Others'.

Table A4. Percentages of sales, in mg/PCU, of oral powders by antimicrobial class (according to ATCvet system), by country, for 2018[1]

Country	Tetracyclines	Amphenicols	Penicillins	Sulfonamides	Trimethoprim	Macrolides	Lincosamides	Other quinolones[2]	Aminoglycosides	Polymyxins	Pleuromutilins	Others[3]	Total mg/PCU oral powders
Austria	69%	0%	14%	8%	2%	4%	0%	0%	0.2%	4%	0.1%	0%	33.5
Belgium	26%	0%	18%	45%	9%	1%	0%	1%	<0.01%	0.01%	0.2%	0%	20.8
Bulgaria	61%	0%	21%	15%	0%	0%	0%	1%	0%	2%	0%	0%	11.6
Croatia	0%	0%	97%	3%	0%	0%	0%	0%	0%	0%	0%	0%	3.8
Cyprus	0%	0%	94%	0%	0%	0%	2%	0%	0%	0%	0%	4%	5.7
Czechia	71%	0%	2%	14%	2%	1%	0%	0%	3%	0%	6%	0%	10.3
Denmark	52%	0%	1%	9%	2%	16%	0%	7%	1%	0%	12%	0%	2.8
Estonia	0%	0%	76%	20%	4%	0%	0%	0%	0%	0%	0%	0%	1.6
Finland	51%	0%	9%	33%	7%	0%	0%	0%	0%	0%	1%	0%	3.2
France	33%	0%	13%	6%	0%	15%	0%	0%	30%	3%	0%	0%	1.0
Germany[4]	18%		50%	11%	1%	1%	0%	0%		18%	1%	1%	44.3
Greece	0%	0%	54%	0%	0%	0%	0%	0%	0%	46%	0%	0%	0.2
Hungary	75%	0%	0%	0%	0%	1%	0%	0%	0%	0%	24%	0%	2.5
Ireland	72%	0%	6%	21%	1%	0%	1%	0%	0%	0%	0%	0%	6.4
Italy[5]	21%	0%	0%	2%	0%	75%	0%	0%	0%	0%	0%	2%	0.03
Latvia	0%	0%	78%	13%	3%	0%	0%	0%	0%	7%	0%	0%	2.7
Lithuania	61%	0%	24%	4%	1%	0%	3%	0%	0%	7%	0%	0%	3.5
Luxembourg	73%	0%	0%	19%	4%	0%	0%	0%	0%	4%	0%	0%	13.1
Malta	35%	0%	23%	15%	2%	22%	0%	0%	3%	0%	0.4%	0.1%	5.4
Netherlands	44%	0%	0%	39%	8%	4%	1%	0%	0%	4%	0%	0%	1.6
Norway	75%	0%	0%	20%	4%	0%	0%	0%	0%	0%	0%	0%	0.03
Poland	2%	0.03%	85%	<0.01%	<0.01%	0.04%	0%	<0.01%	3%	5%	4%	0%	13.1
Portugal	50%	0%	3%	39%	8%	0.1%	0%	0%	0%	0%	0%	0%	1.7
Romania	0%	0%	87%	0%	0%	0%	0%	0%	13%	0%	0%	0%	0.5
Slovakia	46%	0%	0%	20%	0%	0%	0%	0%	26%	8%	0%	0%	2.6
Slovenia	7%	0.3%	90%	2%	1%	0%	0%	0%	0%	0%	0%	0%	25.4
Sweden	0%	0%	0%	83%	17%	0%	0%	0%	0%	0%	0%	0%	<0.01
Switzerland	<0.01%	0%	0%	85%	4%	0%	0%	0%	11%	0%	0%	0%	4.2
United Kingdom	57%	0.5%	17%	21%	4%	0%	0%	0%	0%	0%	<0.01%	0%	0.9
Total 31 countries	**23.4%**	**0.04%**	**45.6%**	**12.7%**	**1.8%**	**1.2%**	**0.04%**	**0.1%**	**1.3%**	**12.4%**	**1.5%**	**<0.01%**	**9.3**

[1] In 2018, no sales of oral powders were reported in Iceland and Spain.
[2] Negligible amounts of fluoroquinolones for Belgium and Bulgaria are included with other quinolones.
[3] Represents sales of spectinomycin (classified as 'Other antibacterials' in the ATCvet system).
[4] Amphenicols and aminoglycosides are aggregated with 'Others' for commercial confidentiality reasons.
[5] Negligible amounts of 1st- and 2nd-generation cephalosporins sold in Italy are included with other antibacterials.

Table A5. Percentage of sales, in mg/PCU, of oral solutions by antimicrobial class (according to ATCvet system), by country, for 2018

Country	Tetracyclines	Amphenicols	Penicillins	Sulfonamides	Trimethoprim	Macrolides	Lincosamides	Fluoroquinolones	Other quinolones	Aminoglycosides	Polymyxins	Pleuromutilins	Others[1]	Total mg/PCU oral solutions
Austria	36%	<0.01%	20%	12%	2%	14%	0.3%	2%	0%	2%	8%	3%	1%	7.3
Belgium	28%	0.4%	37%	11%	2%	9%	3%	0.2%	0.2%	2%	3%	1%	3%	68.0
Bulgaria	18%	4%	30%	10%	2%	10%	10%	10%	0%	1%	3%	2%	1%	56.3
Croatia	47%	1%	25%	6%	2%	7%	0.04%	2%	0.3%	0%	9%	1%	0.1%	31.2
Cyprus	8%	0.2%	54%	17%	3%	2%	0.3%	5%	1%	6%	2%	1%	1%	52.5
Czechia	16%	1%	37%	23%	2%	4%	0.3%	6%	0.01%	3%	2%	6%	1%	26.4
Denmark	19%	0.1%	17%	2%	0.4%	26%	2%	<0.01%	0%	13%	0.01%	16%	4%	18.7
Estonia	32%	1%	18%	6%	1%	9%	1%	0.3%	0%	3%	3%	23%	2%	30.2
Finland[2]	1%	0%	11%	0%	0%	86%	0%	0.3%	0%	0%	0%	0%	1%	0.2
France	47%	0.1%	10%	19%	3%	7%	1%	0.3%	1%	4%	5%	1%	1%	29.8
Germany	38%	0.1%	25%	4%	0.3%	18%	3%	1%	0%	4%	2%	2%	2%	35.4
Greece	33%	0.04%	26%	8%	1%	8%	0.4%	7%	8%	5%	3%	0.3%	1%	28.5
Hungary	22%	4%	40%	6%	1%	4%	2%	11%	0.2%	2%	3%	5%	0.2%	90.7
Iceland	0%	0%	99%	0%	0%	0%	0%	1%	0%	0%	0%	0%	0%	0.1
Ireland[3]	3%	4%	47%	36%	0.4%	5%	0.2%	0.5%	0%	3%			2%	11.2
Italy	26%	2%	30%	12%	2%	9%	8%	1%	1%	4%	2%	2%	0.5%	123.0
Latvia	39%	0.2%	6%	0.4%	0.1%	22%	0.1%	3%	0.04%	4%	9%	16%	0.1%	19.6
Lithuania	15%	1%	16%	9%	2%	31%	1%	10%	1%	2%	<0.01%	10%	2%	20.4
Luxembourg	22%	0.03%	9%	21%	4%	10%	7%	0.4%	0%	22%	0.3%	2%	3%	7.8
Malta[4]	19%	2%	10%	28%	3%	15%	0.3%	16%		1%	0.1%	1%	4%	24.6
Netherlands	42%	0.04%	20%	14%	2%	17%	<0.01%	0.1%	2%	1%	1%	1%	0.1%	46.2
Norway	6%	0%	48%	0%	0%	0%	0.1%	0.2%	0%	25%	0%	20%	0.1%	0.1
Poland	32%	0.4%	28%	4%	1%	14%	1%	7%	<0.01%	2%	5%	6%	0.5%	141.9
Portugal	21%	0.1%	31%	2%	0.3%	8%	7%	11%	<0.01%	11%	5%	2%	1%	60.6
Romania	30%	2%	12%	2%	0.4%	17%	2%	9%	0.01%	10%	11%	4%	0.2%	56.1
Slovakia	23%	1%	21%	21%	3%	6%	1%	12%	0.1%	0.2%	5%	2%	5%	21.6
Slovenia	18%	1%	19%	14%	3%	0%	0%	25%	0%	7%	3%	11%	0%	7.5
Spain	29%	2%	26%	4%	0.5%	3%	11%	3%	0%	16%	3%	1%	2%	111.0
Sweden[5]														0.9
Switzerland	0%	0%	0%	0%	0%	0%	0%	88%	0%	0%	12%	0%	0%	0.03
United Kingdom	27%	1%	36%	7%	1%	6%	4%	1%	0%	6%	<0.01%	6%	5%	8.8
Total 31 countries	**31.0%**	**1.2%**	**26.1%**	**7.1%**	**1.2%**	**9.8%**	**5.2%**	**3.6%**	**0.5%**	**7.0%**	**3.4%**	**2.7%**	**1.2%**	**53.5**

[1] Bacitracin, fosfomycin, furaltadone, metronidazole and spectinomycin (classified as 'Other antibacterials' in the ATCvet system).
[2] Negligible amounts of 1st- and 2nd-generation cephalosporins sold in Finland are included with other antibacterials.
[3] Polymyxins and pleuromutilins are aggregated with 'Others' for reasons of commercial confidentiality.
[4] Fluoroquinolones and other quinolones are aggregated for reasons of commercial confidentiality.
[5] For reasons of commercial confidentiality, data at class level cannot be disclosed.

Table A6. Percentage of sales, in mg/PCU, of injectable preparations by antimicrobial class (according to ATCvet system), by country, for 2018[1]

Country	Tetracyclines	Amphenicols	Penicillins	1st- and 2nd-gen. cephalosporins	3rd- and 4th-gen. cephalosporins[1]	Sulfonamides	Trimethoprim	Macrolides	Lincosamides	Fluoroquinolones[2]	Aminoglycosides	Polymyxins	Pleuromutilins	Others[3]	Total mg/PCU injectable prep.
Austria	9%	7%	38%	0%	3%	10%	2%	7%	1%	6%	16%	0%	0.02%	1%	6.3
Belgium	4%	11%	60%	0%	0.3%	7%	1%	4%	3%	1%	2%	0.2%	0.04%	6%	13.2
Bulgaria	18%	2%	23%	0.1%	1%	4%	1%	8%	2%	3%	35%	<0.01%	0.4%	3%	11.9
Croatia	5%	7%	29%	0%	1%	10%	2%	24%	1%	7%	12%	0%	0%	1%	21.4
Cyprus	21%	5%	31%	0%	2%	5%	1%	3%	1%	4%	24%	0.1%	1%	2%	20.8
Czechia	17%	3%	49%	0.03%	5%	5%	1%	1%	0.2%	3%	14%	0%	1%	0.4%	9.9
Denmark	11%	4%	55%	0%	0.04%	13%	3%	2%	3%	<0.01%	7%	0%	1%	1%	14.8
Estonia	9%	1%	53%	0.3%	4%	4%	1%	1%	1%	6%	16%	0%	3%	1%	19.5
Finland	13%	0.3%	80%	0%	<0.01%	5%	1%	0.2%	0.4%	1%	0.2%	0%	0%	0%	10.3
France	11%	6%	33%	0.04%	0.1%	7%	1%	10%	1%	0.3%	29%	1%	0.03%	1%	12.8
Germany	4%	9%	49%	0%	2%	13%	3%	5%	2%	5%	6%	0.1%	0.2%	2%	7.2
Greece	23%	1%	24%	0%	1%	3%	1%	3%	1%	1%	38%	0.02%	0.1%	3%	13.3
Hungary	8%	12%	38%	0.1%	5%	3%	1%	3%	1%	8%	19%	0.1%	1%	1%	8.1
Iceland	6%	0%	75%	0%	0.03%	4%	1%	0%	0%	0.1%	15%	0%	0%	0%	4.4
Ireland[4]	26%	8%	32%	0%	1%	6%	1%	8%	0.2%	3%	15%	0%		0.4%	13.1
Italy	12%	11%	29%	0%	2%	12%	1%	7%	3%	5%	13%	0.2%	0.2%	6%	16.6
Latvia	5%	1%	45%	0.3%	3%	8%	2%	4%	0.4%	3%	27%	0%	0.4%	1%	11.2
Lithuania	11%	6%	42%	1%	4%	9%	2%	7%	1%	3%	12%	0%	0%	1%	7.6
Luxembourg	12%	9%	41%	0.01%	5%	10%	2%	2%	1%	7%	9%	0.3%	0%	2%	11.1
Malta	3%	7%	34%	0%	2%	0.2%	0.05%	0%	3%	5%	41%	0%	0%	6%	12.0
Netherlands	15%	16%	42%	0%	<0.01%	17%	3%	2%	0%	0.1%	3%	0.2%	0.1%	0%	8.2
Norway	2%	0.5%	87%	0%	0.02%	6%	1%	0.1%	0%	0.4%	4%	0%	0.2%	0%	1.6
Poland	12%	13%	33%	0.1%	3%	3%	0.4%	3%	2%	9%	18%	0.1%	1%	1%	8.8
Portugal	24%	10%	21%	0.02%	3%	4%	1%	6%	1%	7%	23%	0.1%	0.4%	1%	10.2
Romania	16%	15%	26%	0%	1%	3%	1%	3%	1%	5%	28%	0.1%	0.3%	1%	14.3
Slovakia	18%	2%	43%	1%	4%	9%	2%	2%	0.2%	5%	12%	0%	3%	0.4%	8.6
Slovenia	5%	7%	35%	0%	2%	11%	2%	3%	0%	11%	25%	0.04%	0%	0%	8.9
Spain	6%	13%	19%	<0.01%	2%	1%	0.2%	7%	10%	11%	11%	0.1%	0.3%	19%	22.5
Sweden[5]	5%		82%		0.1%	7%	1%	2%	0.1%	0.3%	2%			0.5%	9.5
Switzerland[6]	11%	6%	44%	0%	1%	8%	1%	2%		2%	24%	<0.01%		0.2%	9.9
United Kingdom	32%	6%	27%	<0.01%	1%	6%	1%	6%	1%	1%	19%	0%	0.2%	0%	6.8
Total 31 countries	**11.8%**	**9.6%**	**33.0%**	**0.02%**	**1.4%**	**6.4%**	**1.1%**	**5.8%**	**3.6%**	**5.1%**	**15.4%**	**0.1%**	**0.3%**	**6.1%**	**11.7**

[1] For the 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] Negligible amounts of other quinolones for Cyprus, Czechia and Italy are included with fluoroquinolones.
[3] Represents sales of spectinomycin (classified as 'Other antibacterials' in the ATCvet system).
[4] Pleuromutilins are aggregated with 'Others' for reasons of commercial confidentiality.
[5] For commercial confidentiality reasons, amphenicols, polymyxins and pleuromutilins are aggregated with 'Others' and 1st- and 2nd-generation cephalosporins are grouped with 3rd- and 4th-generation cephalosporins.
[6] For reasons of commercial confidentiality, pleuromutilins are grouped with 'Others' and lincosamides are grouped with macrolides.

Table A7. Number of product presentations[1] containing 1, 2, 3 and 4 antimicrobial agents sold, by country, for 2018 (tablets excluded from the data)

Country	1 ingredient	2 ingredients	3 ingredients	4 ingredients	Total number
Austria	217	26	2		245
Belgium	290	43	5		338
Bulgaria	218	42	7		267
Croatia	116	18	3	5	142
Cyprus	118	23	2		143
Czechia	376	63	12	4	455
Denmark	186	43	6		235
Estonia	107	23	5		135
Finland	65	17	1		83
France	492	121	8		621
Germany	478	60	6		544
Greece	235	49	5	1	290
Hungary	326	44	10	1	381
Iceland	24	6	2		32
Ireland	235	43	6	1	285
Italy	561	94	10	1	666
Latvia	132	32	10	2	176
Lithuania	103	28	5	1	137
Luxembourg	190	43	9		242
Malta	72	43	6	2	123
Netherlands	169	42	3		214
Norway	44	15	2		61
Poland	535	69	11	1	616
Portugal	432	55	8		495
Romania	398	75	5	4	482
Slovakia	254	43	10	2	309
Slovenia	95	17	3	1	116
Spain	977	126	9		1,112
Sweden	105	19	1		125
Switzerland	134	39	32		205
United Kingdom	301	26	5	1	333
Total number of product presentations in 31 countries	**7,985**	**1,387**	**209**	**27**	**9,608**

[1] Presentation of a VMP, in this context, is determined by differences in any of the characteristics of a medicinal product, i.e. pharmaceutical form, pack size, composition or strength.

Table A8. Number of product presentations[1] of premixes, oral powders and oral solutions containing 1, 2, 3 and 4 antimicrobial agents sold, by country, for 2018

Country	1 ingredient	2 ingredients	3 ingredients	4 ingredients	Total number of product presentations for premixes, oral powders and oral solutions
Austria	82	8			90
Belgium	118	20			138
Bulgaria	135	15			150
Croatia	44	8		3	55
Cyprus	53	8			61
Czechia	194	35	2		231
Denmark	81	10			91
Estonia	28	4			32
Finland	21	4			25
France	276	55			331
Germany	213	23			236
Greece	123	12			135
Hungary	185	14			199
Iceland	3				3
Ireland	75	11			86
Italy	304	41	5	1	351
Latvia	33	5			38
Lithuania	31	6			37
Luxembourg	60	18			78
Malta	43	26	5	1	75
Netherlands	73	16			89
Norway	14	3			17
Poland	296	29			325
Portugal	168	14			182
Romania	238	25	1	2	266
Slovakia	105	17	4		126
Slovenia	31	5			36
Spain	451	22			473
Sweden	29	1			30
Switzerland	42	12	28		82
United Kingdom	129	12			141
Total 31 countries	**3,678**	**479**	**45**	**7**	**4,209**

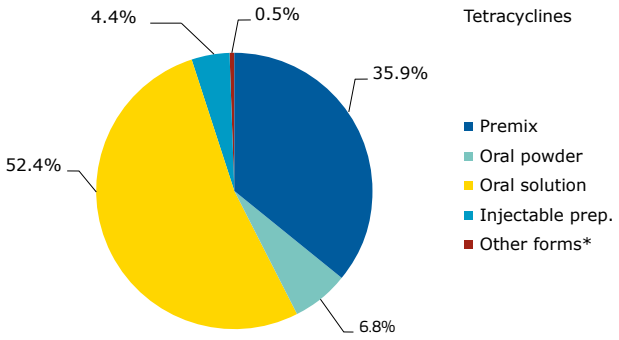
[1] Presentation of a VMP, in this context, is determined by differences in any of the characteristics of a medicinal product, i.e. pharmaceutical form, pack size, composition or strength.

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 2018[1]

Country	Presentations with 1 ingredient		Presentations with 2 ingredients		Presentations with 3 ingredients		Total tonnes (premixes, oral powders and oral solutions)
	Tonnes	%	Tonnes	%	Tonnes	%	
Austria	36.5	90%	4.1	10%			40.5
Belgium	130.4	76%	40.5	24%			170.9
Bulgaria	38.8	91%	3.9	9%			42.7
Croatia	10.6	83%	0.9	7%			12.8
Cyprus	39.1	77%	11.7	23%			50.8
Czechia	26.1	82%	5.2	16%	0.5	2%	31.8
Denmark	48.5	88%	6.9	12%			55.4
Estonia	3.2	88%	0.4	12%			3.6
Finland	2.4	70%	1.0	30%			3.4
France	269.0	75%	87.5	25%			356.6
Germany	632.3	93%	46.8	7%			679.1
Greece	89.3	93%	7.0	7%			96.3
Hungary	135.0	95%	7.6	5%			142.6
Iceland	0.01	100%					0.01
Ireland	60.4	90%	6.4	10%			66.8
Italy	621.0	72%	232.4	27%	11.6	1%	865.2
Latvia	3.6	97%	0.1	3%			3.7
Lithuania	6.7	87%	1.0	13%			7.8
Luxembourg	0.9	75%	0.3	25%			1.1
Malta	1.7	87%	0.2	11%	0.04	2%	2.0
Netherlands	130.5	85%	23.9	15%			154.4
Norway	1.1	99%	0.02	1%			1.1
Poland	693.7	94%	43.6	6%			737.4
Portugal	168.8	93%	12.1	7%			180.9
Romania	181.0	96%	6.9	4%	0.9	0.5%	188.8
Slovakia	5.4	55%	4.3	44%	0.1	1%	9.8
Slovenia	5.6	94%	0.3	6%			5.9
Spain	1,448.1	94%	97.6	6%			1,545.7
Sweden	1.1	100%	<0.01	0.05%			1.1
Switzerland	6.6	32%	4.9	23%	9.3	45%	20.7
United Kingdom	136.6	86%	23.0	14%			159.6
Total 31 countries	**4,934.1**	**87.5%**	**680.5**	**12.1%**	**22.5**	**0.4%**	**5,638.7**

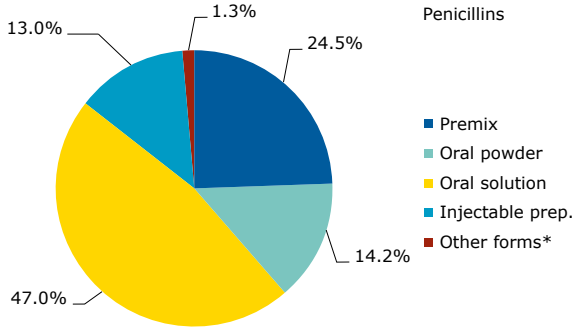
[1] In addition, 0.03% of the total sales of premixes, oral powders and oral solutions preparations contained 4 active ingredients, accounting for 1.6 tonnes (which is included in the total tonnes of premixes, oral powders and oral solutions).

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 2018



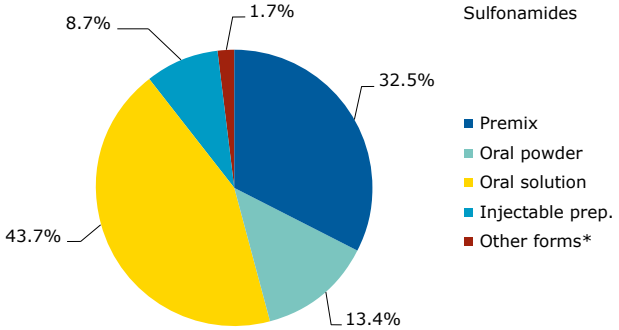
* Other forms include boluses, oral pastes, intramammary and intrauterine preparations.

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 2018



* 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 2018



* 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 2018

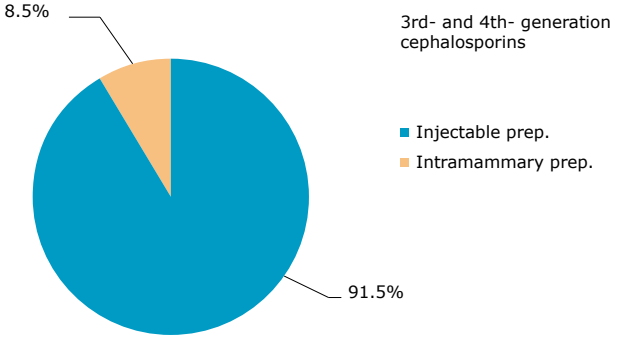
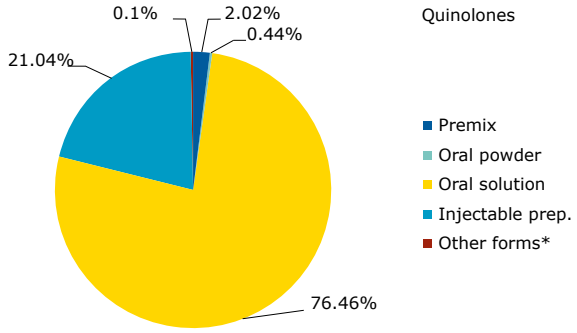
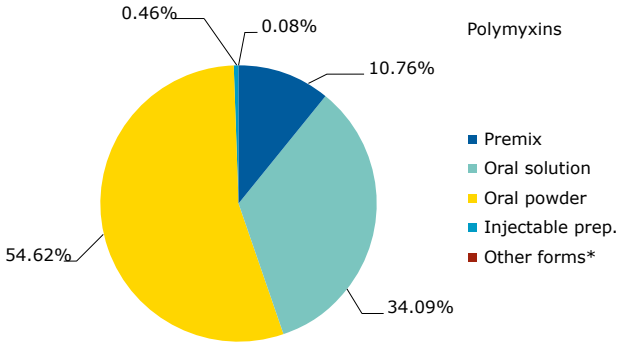


Figure A5. Distribution of aggregated sales of fluoroquinolones and other quinolones for food-producing animals, in mg/PCU, by the major pharmaceutical forms sold, aggregated by the 31 European countries, for 2018



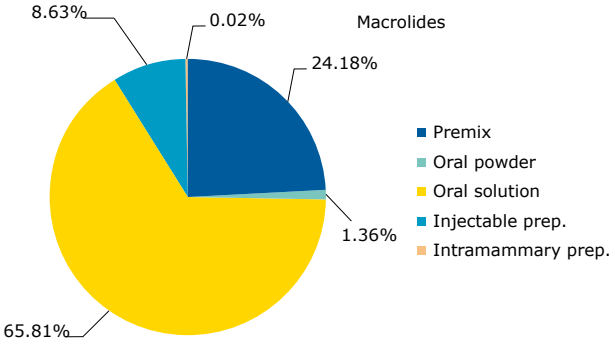
* Other forms include boluses, oral pastes and intrauterine preparations.

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 2018



* 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 2018



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 2018

	Variable	Description of variable	Justification
	COUNTRY	**ISO Country Code**: 2 letter code (alpha-2 code), according to the International Standard for country codes. (http://www.iso.org/iso/country_codes)	To identify the country for which sales data are reported.
	YEAR	Four-digit number	To identify the calendar year for collected and reported sales data.
PRODUCT INFORMATION	**MA**	**Marketing Authorisation Identification** Number or number and letter combination or name of the marketing authorisation holder.	To enable the unique identification of the medicinal product and enable a link with other databases.
	PRESENTATION ID	**Identification Number of Product Presentation** Medicinal product package code value (can be a number or number and letter combination). The code is a unique identifier for each presentation of the medicinal product (name, package size, strength and formulation). As a key variable in many databases it should be stable over time, so that medicinal products that are no longer marketed or registered can still be identified to enable the analysis of historical data.	To enable the identification of all antimicrobial medicinal product presentations marketed in a country. To enable the validation and analysis of each presentation package size in which the VMP is sold. To enable the analysis of historical data. To enable the identification of duplicate reporting of sales.
	NAME	**Medicinal Product Name (in national language)** Name of medicinal product as per the product information (summary of product characteristics, package leaflet and labelling). e.g. Harmony vet 50 mg tablets 2 × 30; Harmony vet long-acting injection 10 mg/ml injection 10 ml.	To identify and validate recorded details.
	FORM	**Pharmaceutical Form** Bolus (BOLUS), injectable preparation (INJ), intramammary preparation (INTRAMAM), intramammary dry cow treatment preparation (INTRAMAM-DC), oral solution and oral powder for administration in drinking water (ORAL SOLU), oral paste (ORAL PASTE), oral powder (ORAL POWD), premix (PREMIX), capsules and tablets, etc. (TABL), intrauterine preparation (INTRAUT).	To enable the analysis of data by administration route/ pharmaceutical form.
	LONG ACTING	**Long-acting Injectable Preparations** This refers to injectable preparations that provide sustained concentrations at the site of infection. A single administration of a long-acting/extended release formulation, as noted in the product information, provides therapeutic levels for a longer period of time.	Optional.
	PACKSIZE	**Content Quantity in Package: Pack Size** Numerical value only to indicate the pack size e.g. 100 for 100 tablets or 100 intramammary prep.; 10 for 10 ml injection; 2 for a package of 2 kg premix; 300 for a box of 10 blisters of 30 tablets; 12 for a box of 12 injectors.	To enable the calculation of the amount of antimicrobial ingredient in each product presentation.

	Variable	Description of variable	Justification
	PACKSIZEU	**Content Unit of Measurement** e.g. ML, L, G, KG, PIECE (e.g. tablets, capsules, boluses and intramammary preparations).	To enable the calculation of the amount of antimicrobial ingredient in each product presentation.
	ATCvet	**ATCvet- 5th level: Anatomical Therapeutic Chemical (Classification) Veterinary** Value to be selected as per the latest version of the ATCvet index.	To ensure a standardised language for analysis and reporting of data per antimicrobial class as well as anatomical and therapeutic groups.
	SPECIES	**Animal Species** All the animal species for which the VMP is approved, e.g. cattle (CA), poultry (POU).	Optional.
	NO PACKS	**Number of Packages Sold** Numerical value to indicate the number of packages of product presentation sold within the reporting period (year) in the reporting country**.**	To calculate the weight of antimicrobial ingredient sold for each product presentation.
	INGR_ID	**Ingredient Code Value** Automatically attributed by the macro or ESVAC web application tool.	Serves as a unique identifier for each ingredient for each product. Needed for data management purposes.
INGREDIENT	**INGR**	**Antimicrobial Ingredient Name** Name to be selected from the defined list of antimicrobial ingredient names as presented according to the latest version of the ATCvet index. In the case of fixed combination products, all the antimicrobial ingredients' names must be provided separately.	Important to avoid misinterpretation of an ingredient name if given in a language other than English. The system only accepts the latest version of names published in the ATCvet index.
	SALT	**Salt of Antimicrobial Ingredient when Strength is Expressed in IU** Name to be selected from the defined list of names of salt of antimicrobial ingredients. Currently only applicable to colistin sulfate and colistin methane sulfonate.	Only in cases where the strength of an antimicrobial ingredient is given in IU (IU/G, IU/ML or IU/PIECE) and when different salts exist, to allow for conversion to weight of (active) antimicrobial ingredient.
	PRODRUG	**Prodrug Name (ATCvet name)** Name to be selected from the defined list of prodrugs, e.g. procaine penicillin, which is the prodrug for benzylpenicillin.	Only in cases when a product contains a prodrug. To enable the calculation of the weight of the (active) antimicrobial ingredient.
	STRENGTH	**Quantity of the Antimicrobial Ingredient** Numerical value of strength or quantity of the antimicrobial ingredient in mg/g/IU per relevant unit ml/mg/l/g/kg/piece as declared in the product information (e.g. 10 for 10 MG/ML). In the case of fixed combinations, the strengths of all the antimicrobial ingredients per presentation must be provided separately.	To enable the calculation of the amount of antimicrobial ingredient in each product presentation.
	STRENGTHU	**Unit of Measurement for Strength** Unit of measurement of strength to be chosen from a defined list (e.g. IU/G, IU/ML, IU/PIECE, G/KG, G/L, G/PIECE, MG/ML, MG/G, MG/PIECE). In the case of fixed combinations, the unit of measurement of all the antimicrobial ingredients per presentation must be provided separately.	To enable the calculation of the amount of antimicrobial ingredient in each product presentation.
	CONV FACT IU	**Conversion Factor when Strength is given in IU** When strength unit is e.g. IU/ML or IU/PIECE, a conversion factor from a defined list is assigned automatically by the macro or ESVAC web application tool for the harmonised calculation of the weight of an antimicrobial ingredient.	To enable the calculation of the weight of (active) antimicrobial ingredient per product package.

	Variable	Description of variable	Justification
	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 the calculation of the weight of the (active) antimicrobial ingredient per product package.
	INGR CONTENT	**Content of Antimicrobial Ingredient in Package** As a clarifying step in the calculation of the volume of the antimicrobial ingredient, this variable provides the weight of antimicrobial ingredient per one unit of product package.	To enable the calculation of the volume of sales.
	CONTENT UNIT	**Unit of Antimicrobial Ingredient in Package** The unit of antimicrobial ingredient per product package is given in grams for all antimicrobial agents.	To enable the calculation of the volume of sales.
	TONNES SOLD	**Tonnes of Antimicrobial Ingredient Sold** Based on all the details provided, this represents the volume of the antimicrobial ingredient in tonnes per product presentation.	Provides the volume of the antimicrobial ingredient sold or used in tonnes.

For antimicrobial VMPs containing more than one antimicrobial 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 of 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
Framycetin	670	0.00149
Gentamicin	620	0.00161
Kanamycin	796	0.00126
Neomycin	755	0.00133
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 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 other things, the food-producing animal species for which the maximum residue limits have been established. 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 2010-2018

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]			
1st-generation cephalosporins			
	Cefacetrile	Cefadroxil[2]	Cefalexin
	Cefalonium	Cefapirin	Cefazolin
	Cefalotin		
3rd-generation cephalosporins			
	Cefoperazone	Cefovecin[2]	Ceftiofur
4th-generation cephalosporins			
	Cefquinome		

Class/subclass	Substances		
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	Paromomycin	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]		
Pleuromutilins			
	Tiamulin	Valnemulin	
Polymyxins			
	Colistin	Polymyxin B[2]	
Nitrofuran derivatives			
	Furazolidone[1]	Nifurpirinol[1]	
Other antibacterials			
	Bacitracin	Fosfomycin	Furaltadone[1]
	Natamycin	Nitroxoline	Novobiocin
	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] In accordance with the Commission Implementing Decision C(2012) 182 of 13 January 2012 (https://ec.europa.eu/health/documents/community-register/html/vo22101.htm), the use of 3rd- and 4th-generation cephalosporins in poultry is prohibited.

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

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

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

Antimicrobial	AMEG classification	WHO classification
3rd- and 4th-generation cephalosporins	Category B	Highest priority CIAs (3rd- and higher-generation cephalosporins)
Fluoroquinolones and other quinolones	Category B	Highest priority CIAs
Macrolides	Category C	Highest priority CIAs
Polymyxins	Category B	Highest priority CIAs

[27] WHO Critically important antimicrobials for human medicine, 6th revision. (https://www.who.int/foodsafety/publications/antimicrobials-sixth/en/)

[28] EMA/AMEG 2019. Categorisation of antibiotics in the European Union. Answer to the request from the European Commission for updating the 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/report/categorisation-antibiotics-european-union-answer-request-european-commission-updating-scientific_en.pdf)

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

Austria

Distribution of veterinary medicines

In Austria, all 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 must 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 and 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 (Article 12) and on the Royal Decree of 14 December 2006 on medicines for human and veterinary use (Articles 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 No. 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 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 (surgeries, clinics and hospitals), 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 veterinary antimicrobial agents 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 must 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 to 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 must 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 taken into accounted, in order to avoid double reporting through the inclusion of 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 by feed mills for premixes and through wholesalers to veterinarians and pharmacists for all other pharmaceutical forms; wholesalers and feed mills obtain the VMPs from MAHs.

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 MAHs 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 must 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 VMPs 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 delivering data for 2018, sales of veterinary antimicrobial agents were reported to the ESVAC for the fourth time. Data were provided by 84 MAHs. Negligible sales from a few MAHs with a very small market share, and without local representatives in the country, were not included in the reported datasets.

Hungary

Distribution of veterinary medicines

In Hungary, all VMPs that contain antimicrobials are prescription-only medicines. All VMPs must 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. All VMPs must be tracked and documented, as it must be possible to trace 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 must 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 the mandatory reporting of sales data; monitoring of sales takes place voluntarily.

Data sources

Data are collected from wholesalers in Hungary. The 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 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 VMPs 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 VMPs. However, MAHs 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 VMPs includes transactions between:

- MAHs or their representatives and wholesalers;
- MAHs 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 VMPs 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 VMPs. 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 (Article 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 in order 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 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

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

Legal basis for monitoring

There is no legal basis for the 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 Agriculture, Fisheries and Animal Rights).

Data sources

The Veterinary Medicines Section collects sales data on antimicrobials once a year 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 manufacturers and approximately 60 % through wholesalers. About 98 % of the total volume of antimicrobial VMPs is dispensed by MAHs 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, but no antimicrobial VMPs.

Legal basis for the monitoring of sales

Currently, there is no legal basis for the 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 MAHs 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. The exception is medicated feed, which is dispensed by feed mills to fish farmers. 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 feed, to the Norwegian Institute of Public Health (NIPH).

Data sources

Data on sales of veterinary antimicrobial agents 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 through the inclusion of 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 the 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 VMPs (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 must also 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 (Article 120), amended and reprinted as national law No. 314/2009, dated 28 October.

Data sources

Data are provided by wholesalers who are authorised to sell VMPs 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 VMPs is performed only by those authorised to carry out such operations in accordance with the national legislation.

Marketing of VMPs 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 Authority.

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 of 15 October 2015.

The MAHs are obliged to report sales of 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 the 11 MAHs which distributed their own products. The data include sales to veterinarians, farmers and pharmacies. Since 2015, in accordance with the updated veterinary law, the sales data have been 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 receivers of antimicrobial VMPs from wholesalers – wholesalers (when selling to each other), veterinarians, pharmacies and feed mills – while farmers and wholesalers are very seldom receivers from feed mills. Medicated feed must 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; since 2013, data have represented 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 are 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 end-users of VMPs (retailers, pharmacies and farmers' co-operatives) are authorised according to the 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 must also be prescribed by a veterinarian and can only be manufactured by feed mills authorised by regional competent authorities according to specific legislation and the feed hygiene regulation (Hazard Analysis and Critical Control Point principles).

Legal basis for the monitoring of sales

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

Data sources

For 2017, sales data at package level were collected from retailers 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 at 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 the 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 must 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 Article 35 of the Federal Ordinance on Veterinary Medicines, enacted in September 2004. Article 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, which covers 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 needs to be highlighted that since 1 January 2019, the regulatory framework for data collection in Switzerland has been governed by new legislation.

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 available at national level for the year 2018, 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 MAHs 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 VMPs 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 must 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 VMPs 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 2020

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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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