

Sales of veterinary antimicrobial agents in 31 European countries in 2022

Trends from 2010 to 2022 Thirteenth ESVAC report



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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, 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 Union procedures for the authorisation and supervision of medicinal products for human use and establishing a European Medicines Agency¹, as amended. Veterinary medicinal products are authorised and supervised by 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/EC².

Principal activities

Working with the Member States and the European Commission 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 European Commission;
- 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 to support the establishment of maximum residue limits by the European Commission;
- 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 medicine evaluation and supervision in Europe, and contributes alongside the Member States and the European Commission 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 ensure 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 wellbeing, motivation and ongoing professional development of every member of the Agency.

¹ Regulation (EC) No 726/2004 of the European Parliament and of 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: <u>https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex%3A32004R0726</u>

² 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: <u>https://eur-lex.europa.eu/eli/reg/2019/6/oj</u>

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Thirteenth ESVAC report

20 November 2023 EMA/299538/2023 Veterinary Medicines Division

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Correspondence relating to this report should be made via the AskEMA form³.

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³ Use the AskEMA form to send a request for information from EMA or to make a formal request for access to EMA documents that are not already published on this website: https://www.ema.europa.eu/en/about-us/contacts/send-question-european-medicines-agency

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 European Commission (EC), a centralised marketing authorisation is valid in all EU Member States and, after implementation at national level, in the European Economic Area — European Free Trade Association (EEA-EFTA) states (Iceland, Liechtenstein and Norway).

The Agency, with the help of its Committee for Veterinary Medicinal Products (CVMP), and its Antimicrobials Working Party (AWP), has produced a strong body of scientific advice⁴ 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 thirteenth ESVAC report presents data on the sales of veterinary antibiotic agents from 31 European countries in 2022. These data are provided at package level in accordance with the data reporting protocol and data collection form published in March 2021⁵. Information on country-specific trends is published separately on the EMA website in Country Individual Reports⁶. This report focuses on the consumption of antibiotic veterinary medicinal products (VMPs) for food-producing animals at the European level and analyses the trends it has followed since 2010.

The report emphasises certain classes or subclasses of antibiotics included in Category B of the categorisation made by the EMA's Antimicrobial Advice ad hoc Expert Group (AMEG) in 2019, available on the EMA website⁷. The AMEG categories take account of the World Health Organization (WHO) categorisation of antimicrobials (6th revision)⁸, the need for the respective antimicrobials in veterinary medicine and the probability of transfer of antimicrobial resistance from animals to humans. Category B of the AMEG categorisation includes those veterinary antibiotics from which the risk to public health is estimated to be higher than from other classes of antibiotics; fluoroquinolones, other quinolones, 3rd- and 4th-generation cephalosporins and polymyxins are included in this category. Macrolides are included in Category C of the AMEG categorisation.

The data collected for ESVAC are also used in the Joint Interagency Antimicrobial Consumption and Resistance Analysis (JIACRA) report produced jointly by the European Centre for Disease Prevention and Control (ECDC), the European Food Safety Authority (EFSA) and EMA. The most recent report, the JIACRA III report published in 2021, has shown, while recognising the complexity of evaluating the association between sales of antimicrobials and occurrence of AMR in animals and humans, that reduction of antimicrobial consumption typically following interventions have a positive impact on the occurrence of AMR.

⁴ Available from the European Medicines Agency website (<u>www.ema.europa.eu/en</u>) via Home > Veterinary regulatory > Overview > Antimicrobial resistance.

⁵ Available from the European Medicines Agency website (<u>www.ema.europa.eu/en</u>) via Home > Veterinary regulatory > Overview > Antimicrobial resistance > European Surveillance of Veterinary Antimicrobial Consumption (ESVAC) > <u>Sales data reporting form and</u> protocol.

⁶ Available from the European Medicines Agency website (<u>www.ema.europa.eu/en</u>) via Home > Veterinary regulatory > Overview > Antimicrobial resistance > European Surveillance of Veterinary Antimicrobial Consumption (ESVAC) > Trends by country.

⁷ 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' (<u>https://www.ema.europa.eu/en/documents/report/categorisation-antibiotics-european-union-answer-request-european-commission-updating-scientific_ en.pdf</u>).

⁸ WHO, [']Critically Important Antimicrobials for Human Medicine, 6th revision' (<u>https://www.who.int/publications/i/item/9789241515528</u>).

ECDC, EFSA and EMA have also jointly established a list of harmonised outcome indicators⁹ 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 are: overall sales of veterinary antimicrobials; sales of 3rd- and 4th-generation cephalosporins; sales of quinolones (specifying the proportion of fluoroquinolones); and sales of polymyxins, all measured in milligrams per population correction unit (mg/PCU).

The thirteenth ESVAC report follows the same outline as in the twelfth edition, focusing on the primary and secondary indicators of antimicrobial (more specifically antibiotic) consumption for food-producing animals. All figures and tables present in previous reports can be found in the ESVAC interactive database¹⁰.

The data and information included in this report have been reviewed and approved by the ESVAC National Contact Points 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 antibiotic agents. Consequently, for each country, data from the first few years of collection should be interpreted with due caution.

The data presented in this report should not be used as a sole basis for setting management priorities; additional data on the production of animals by country and animal demography, available veterinary medicinal products and other factors such as disease incidence or outbreaks 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.

⁹ Available on the EMA website (<u>www.ema.europa.eu/en</u>) via Home > Veterinary regulatory > Overview > Antimicrobial resistance > Analysis of consumption and resistance (JIACRA) > Outcome indicators (<u>https://www.ema.europa.eu/en/documents/report/ecdc-efsa-ema-joint-scientific-opinion-list-outcome-indicators-regards-surveillance-antimicrobial_en.pdf</u>).

¹⁰ Available on the EMA website (<u>www.ema.europa.eu/en</u>) via: Home > Veterinary regulatory > Antimicrobial resistance > European Surveillance of Veterinary Antimicrobial Consumption > ESVAC interactive database accessible via: <u>https://esvacbi.ema.europa.eu/</u> analytics/saw.dll?PortalPages

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Summary

A total of 31 European countries — 29 EU/EEA countries (at the time of the calendar year covered in this report), Switzerland and the United Kingdom — submitted antibiotic¹¹ veterinary medicinal products (VMPs) sales or prescription (3 countries) data to the European Medicines Agency for 2022.

The main indicator used to express the sales of antibiotic VMPs in the current report is milligrams (mg) of active substance sold per population correction unit (PCU) — mg/PCU. The PCU is applied as a proxy for the size of the food-producing animal population (including all horses and excluding companion animals) and serves to normalise the sales data by the number of animals that could be potentially treated with antibiotics in each country.

Overall sales of antibiotic VMPs in 2022 for 31 countries

Overall aggregated sales of antibiotic VMPs for all 31 countries reporting data in 2022 were 73.9 mg/PCU. This represents a 12.7% decrease compared to 2021 (84.7 mg/PCU). A large difference continues to be observed between countries with the highest and lowest sales, ranging from 2.1 mg/PCU to 254.7 mg/PCU, while the median for all 31 countries was 45.8 mg/PCU.

The highest selling antibiotic class consisted of penicillins, accounting for 32.7% of overall sales (24.2 mg/PCU). Together with tetracyclines (17.4 mg/PCU, 23.5%) and sulfonamides (6.9 mg/PCU, 9.4%), these 3 classes accounted for 65.5% of total sales in 2022. In general, the sales patterns of the various antibiotic classes varied substantially among the 31 countries. This was also true for the antibiotic classes of EMA AMEG Category B, for which it is recommended to restrict the use — i.e. 3rd- and 4th-generation cephalosporins, fluoroquinolones, other quinolones and polymyxins — the sales of which ranged from <0.01 to 0.47 mg/PCU, <0.01 to 12.6 mg/PCU, 0 to 0.75 mg/PCU, and 0 to 10.2 mg/PCU; accounting for 0.17%, 2.8%, 0.16% and 2.8% of total aggregated sales, respectively. WHO considers these classes, in addition to macrolides and ketolides, as critically important antimicrobials (CIAs) with the highest priority for human medicine (WHO 'Critically Important Antimicrobials for Human Medicine, 6th revision'). In 2022, macrolides accounted for 8.5% (6.3 mg/PCU) of the total aggregated sales of antibiotic for food-producing animals. Ketolides are not authorised for use in animals in EU.

When analysed by product form, 85.1% of aggregated sales (mg/PCU) corresponded to product forms predominantly used for group treatment: oral solutions (63.4%), premixes (14.9%) and oral powders (6.8%). Product forms mainly intended for the treatment of individual animals presented 14.9% of total sales across all countries and included injectable products (13.6%), intramammary products (0.74%) and other forms such as oral pastes, boluses and intrauterine products (0.58%).

Sales trends of antibiotic VMPs from 2011 to 2022 for 25 countries

For the 25 countries that have provided sales data continuously between 2011 and 2022, aggregated sales (mg/PCU) declined by 53.0% over this period, i.e. from 161.2 mg/PCU in 2011 to 75.8 mg/PCU in 2022. During this reference period, overall sales (in mg/PCU) decreased in 24 countries. Of these, 21 countries showed a decrease of more than 15% (and up to 67.5%). Throughout this period, sales have increased for only 1 country (55% increase compared to 2011).

The total sales of the AMEG Category B antibiotics in these 25 countries have been declining since 2011, contributing to the overall decrease in total sales. Specifically, between 2011 and 2022, sales of 3rd- and 4th-generation cephalosporins decreased by 49.0% (from 0.24 mg/PCU to 0.12 mg/PCU), fluoroquinolones by 24.7% (from 2.5 mg/PCU to 1.9 mg/PCU), other quinolones by 89.7% (from 1.1 mg/PCU to 0.11 mg/PCU) and polymyxins by 81.0% (from 11.0 mg/PCU to 2.1 mg/PCU).

Sales trends of antibiotic veterinary medicinal product forms for food-producing animals have also changed between 2011 and 2022 for these 25 countries. While sales of oral solutions have increased over the years, sales of all other product forms (oral powders, premixes, injectables, intrauterine, intramammary and boluses) have declined. When grouped by their predominant use, sales of product forms mainly used for group treatment have undergone a higher decrease (56.3%) than those product forms predominantly used for individual treatment (14.3%) between 2011 and 2022.

¹¹ As per Article 4(12) of the Regulation (EU) 2019/6, 'antibiotic means any substance with a direct action on bacteria that is used for treatment or prevention of infections or infectious diseases'.

Farm to Fork Strategy target: 50% reduction of overall sales of antimicrobials for farmed animals and in aquaculture by 2030 in the 27 EU Member States

The EC has set clear targets in the European Green Deal as part of its actions against antimicrobial resistance. One of the main elements of this European growth roadmap, the Farm to Fork strategy calls for a 50% reduction in sales of antimicrobials for farmed animals and in aquaculture by 2030 in comparison to the reference year 2018. The reference value of 2018 for overall sales of antibiotic VMPs (118.3 mg/PCU) in the 27 EU Member States set the target for 2030 at 59.2 mg/PCU. Given that in 2022 the aggregated sales for the 27 EU Member States were 84.8 mg/PCU, in four years Member States have achieved just over half of the reduction target set for 2030. Maintaining an annual decrease of sales of approximately 5% over the remaining eight years would keep Member States on track to reach the 2030 target.

Highlights of the thirteenth ESVAC report*:

Antibiotic VMP sales in 2022 (31 participating countries)

Primary indicator:

• Total sales 73.9 mg/PCU

Secondary indicators:

- Sales of 3rd- and 4th-generation cephalosporins = 0.13 mg/PCU
- Sales of quinolones = 2.2 mg/PCU, of which fluoroquinolones made up 95%
- Sales of polymyxins = 2.1 mg/PCU

Trends from 2011 to 2022 in 25 ESVAC-participating countries:

Primary indicator:

♦ 53.0% total sales

Secondary indicators:

49.0% sales of 3rd- and 4th-generation cephalosporins
44.0% sales of all quinolones (\$ 89.7% for other quinolones and \$ 24.7% for fluoroquinolones)
81.0% sales of polymyxins

Trends from 2017 to 2022 in 31 ESVAC-participating countries:

Primary indicator:

• 30.7% total sales

Secondary indicators:

33.8% sales of 3rd- and 4th-generation cephalosporins
21.3% sales of all quinolones (\$ 73.3% for other quinolones and \$ 11.7% for fluoroquinolones)
42.1% sales of polymyxins

Farm to Fork Strategy target in 27 EU Member States:

Since 2018 (118.3 mg/PCU), sales for the 27 EU Member States have decreased by 28.3% in 2022 (84.8 mg/PCU), achieving more than half of the target to decrease overall aggregated sales to 59.2 mg/PCU by 2030.



Introduction

Terms of reference from the European Commission

In 2008, the Council of the European Union adopted the Council Conclusions on Antimicrobial Resistance (AMR)¹², 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, EMA was requested to consult ECDC, 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 from the EC 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, 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, to ensure comparability with the sale/use of antimicrobials in humans.

About ESVAC activity

Through ESVAC activity, data on sales of antibiotic VMPs have been collected at package level from the EU Member States, EEA countries, Switzerland and the United Kingdom. The collection of data started in 2010, following agreed protocols — the first one was published in 2010 — to ensure a harmonised and standardised reporting by the different participating countries. Furthermore, in 2016, ESVAC established defined daily doses for animals (DDDvet) and defined course doses for animals (DCDvet) (EMA/224954/2016¹³). To prepare for the collection of data by animal species, ESVAC published guidance in 2018 on the collection of harmonised and standardised data from Member States on the use of antimicrobials by species.

In March 2021, EMA and the main National Contact Points revised the data reporting protocol and data collection form to improve data quality, including updated ESVAC conversion factors and rules for reporting the qualitative and quantitative composition of antibiotic VMPs (variable strength).

The ESVAC network, composed of the main National Contact Points and alternates nominated by the national competent authorities in the participating countries, is responsible for the collection of sales data. The country and affiliation of the ESVAC main National Contact Points and alternates can be found in Annex 5 of this report. The tasks of the ESVAC main National Contact Points are to:

- provide sales data to the ESVAC team at EMA in response to annual data calls;
- revise the data in terms of quality and validity following requests from the ESVAC team;
- validate the animal population data used to calculate the PCU;
- provide comments on the annual ESVAC report.

¹² http://www.consilium.europa.eu/ueDocs/cms_Data/docs/pressData/en/lsa/101035.pdf

¹³ Available on the EMA website (<u>www.ema.europa.eu/en</u>) via: Home > Veterinary regulatory > Antimicrobial resistance > European Surveillance of Veterinary Antimicrobial Consumption > Units of measurement.

The ESVAC sales data activity is supported by an Expert Advisory Group (EAG), which is comprised of representatives of the ESVAC main National Contact Points and alternates network. There are also observers from EC, ECDC and EFSA. The task of the ESVAC sales EAG is to provide technical advice on the surveillance of overall sales data of antibiotic VMPs, including the collection, data analysis and reporting, and preparation of the annual reports. A list of the ESVAC EAG members and observers can be found in Annex 6 of this report.

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





ESVAC deliverables also include publication of the core graphs and tables of the ESVAC reports available on the EMA website through the ESVAC BI interactive database (web-based Oracle Business Intelligence Enterprise Edition application)¹⁴.

The thirteenth ESVAC report containing 2022 data submitted voluntarily by participating countries is the last ESVAC report. Under Regulation (EU) 2019/6 on VMPs, the collection of data on sales of veterinary antimicrobials and on use of antimicrobials in animals and the reporting of these data to the Agency becomes a mandatory activity of Member States. In turn, the Agency will publish a new series of annual reports with these data, starting in 2025 with data from 2023 and 2024.

¹⁴ Available on the EMA website (<u>www.ema.europa.eu/en</u>) via: Home > Veterinary regulatory > Antimicrobial resistance > European Surveillance of Veterinary Antimicrobial Consumption > ESVAC interactive database accessible via: <u>https://www.ema.europa.eu/en/</u> veterinary-regulatory/overview/antimicrobial-resistance/european-surveillance-veterinary-antimicrobial-consumption-esvac# interactiveesvac-database-section

1. Technical notes

1.1. Antibiotic substances included in the sales data sets

To obtain harmonised data on sales of antimicrobial VMPs from the ESVAC-participating countries, the antimicrobial substances to be included in the sales datasets are defined in the ESVAC protocol¹⁵ using ATCvet¹⁶ codes (Table 1). Although some substances may additionally be classified as antiprotozoals, e.g. metronidazole and sulfonamides, all the antimicrobials reported to ESVAC have antibiotic activity as defined in Article 4 of the Regulation (EU) 2019/6¹⁷. Furthermore, data collected for ESVAC are also used for the JIACRA report, where possible relationships between antimicrobial consumption and resistance are analysed between specific antibiotics and indicator bacteria. Therefore, throughout this report the term 'antibiotic' has been used instead of 'antimicrobial'.

The ESVAC scope covers all pharmaceutical forms, including premixes used to produce medicated feed, except for dermatological (ATCvet group QD) and sensory organ (ATCvet group QS) VMPs. The contribution of these pharmaceutical forms to the total quantity of veterinary antibiotics sold, in tonnes of active substance, is considered to be negligible for food-producing animals. The use of antimicrobial growth promoters is prohibited in ESVAC-participating countries, and therefore they are not part of the data collection. Ionophore coccidiostat feed additives and veterinary medicines containing zinc oxide¹⁸ are also not included. Other active substances that are not classified as antibiotics, e.g. antiprotozoals (without antibiotic effect), antivirals, antifungals and anti-inflammatory substances fall outside the scope of the ESVAC protocol.

To harmonise the reporting of VMP sales with the data on sales of antibiotic agents used in human medicine, the substances 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. Groups and ATCvet codes of antimicrobial substances with antibiotic activity used in veterinary medicine

 included in the ESVAC database

Groups of antimicrobial substances	ATCvet codes
Antimicrobial substances for intestinal use	QA07AA, QA07AB
Antimicrobial substances for intrauterine use	QG01AA, QG01AE, QG01BA, QG01BE, QG51AA, QG51AG
Antimicrobial substances for systemic use	QJ01
Antimicrobial substances for intramammary use	QJ51
Antimicrobial substances used as antiprotozoals	QP51AG

1.2. Product forms reported per antibiotic VMP presentation

To standardise information and facilitate data management, the ESVAC analysis applies 'product forms', which are a combination of a pharmaceutical form and the route of administration. These product forms are selected from a standardised list and include: boluses, injectable products, intramammary products for lactating cow treatment, intramammary products for dry cow treatment, intrauterine products, oral solutions (including powders and concentrates for administration in drinking water), oral pastes, oral powders (powder to be administered with feed), premixes (for

¹⁵ Available on the EMA website (<u>www.ema.europa.eu/en</u>) via: Home > Veterinary regulatory > Antimicrobial resistance > European Surveillance of Veterinary Antimicrobial Consumption > Sales data reporting form and protocol: <u>https://www.ema.europa.eu/en/</u> documents/other/european-surveillance-veterinary-antimicrobial-consumption-esvac-web-based-sales-animal-population_en.pdf

¹⁶ Available on the WHO Collaborating Centre for Drug Statistics methodology ATCvet web page: <u>www.whocc.no/atcvet/</u>

¹⁷ As per Article 4(12) of the Regulation (EU) 2019/6, 'antibiotic means any substance with a direct action on bacteria that is used for treatment or prevention of infections or infectious diseases'.

¹⁸ On 26 June 2017, the European Commission issued a decision to request the Member States to withdraw, within five years of the above date, existing marketing authorisations of veterinary medicinal products containing zinc oxide for oral administration to food-producing animals (https://ec.europa.eu/health/documents/community-register/2017/20170626136754/dec_136754_en.pdfl)

medicated feed normally produced by feed mills) and tablets. Data on intramammary products for lactating cows and dry cow treatments are collected separately but reported together throughout the report. Detailed information on the product forms to be reported to EMA for each antibiotic VMP presentation can be found in the ESVAC protocol¹⁹.

1.3. Collection and calculation of sales data

For each calendar year, the ESVAC-participating countries provide the number of packages sold within their territory for each antibiotic VMP presentation in addition to information on the name of the VMP, the pharmaceutical form, the strength of the antibiotic active substance(s) and the pack size, among others. Countries upload their data directly to the ESVAC database using the ESVAC web-based application. The quantity of antibiotic active substance, in tonnes sold, for each VMP presentation is calculated by multiplying the number of packages sold by the amount of the antibiotic active substance per package unit, the latter calculated by multiplying the strength given in the corresponding product information with the pack size. These calculations are performed automatically in a standardised and harmonised manner by the ESVAC web-based application tool, including the use of conversion factors to convert international units (IU) into mg when the strength is reported in IU or to calculate the mass of antibiotic active moiety in mg when the strength is reported as the derivative / compound strength. These conversion factors were updated in 2021 and are included in the ESVAC sales data reporting form and protocol. For fixed combination VMPs, the quantity of each antibiotic active substance is calculated separately.

1.4. Denominator: population correction unit (PCU)

The population correction unit, referred to as PCU, has been established as a denominator for reporting the sales data and serves to normalise the total quantities of antibiotic active substance sold in each country by the animal population that could be potentially treated with these in each country. The PCU only includes food-producing animals, including horses and farmed fish, as population data of companion animals such as dogs and cats are not available for all participating countries. Therefore, tablets are excluded from the data sets prior to the normalisation of sales by PCU since they are typically approved for companion animals only.

The Eurostat database²⁰ is the selected source for animal population data (both livestock and slaughtered animals), which is then corrected with data from TRACES (the Trade Control and Expert System run by EC DG SANTE) on the number of animals moved across borders within the single market for fattening or slaughter. The PCU for each terrestrial food-producing animal category (cattle, pigs, poultry, horses, sheep, goats and rabbits) is calculated by multiplying the number of livestock or slaughtered animals by their theoretical weight at the likely time of treatment. For farmed fish, the live-weight slaughtered biomass is used directly.

A summary of the PCU calculations can be found in the box below, while further details on the data sources and the methodology used 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)²¹, as well as in the ESVAC protocol. It must be emphasised that the PCU is purely a surrogate for the animal population that could potentially be treated.

¹⁹ Available on the EMA website (<u>www.ema.europa.eu/en</u>) via: Home > Veterinary regulatory > Antimicrobial resistance > European Surveillance of Veterinary Antimicrobial Consumption > Sales data reporting form and protocol: <u>https://www.ema.europa.eu/en/</u> documents/other/european-surveillance-veterinary-antimicrobial-consumption-esvac-web-based-sales-animal-population_en.pdf

 ²⁰ Available on the Eurostat website (<u>https://ec.europa.eu/eurostat/web/main/home</u>) via: Home > Data > Database: <u>https://ec.europa.eu/eurostat/data/database</u>

²¹ Available on the EMA website (<u>www.ema.europa.eu/en</u>) via: Home > Veterinary regulatory > Overview > Antimicrobial resistance > European Surveillance of Veterinary Antimicrobial Consumption > <u>https://www.ema.europa.eu/en/documents/report/trends-sales-veterinary-antimicrobial-agents-nine-european-countries_en.pdf</u>

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 animals × estimated weight at treatment

PCU export

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

PCU import

• Number of animals transported from another country for fattening or slaughter × estimated weight at treatment

Total PCU per country

- PCU = total PCU_{Domestic} + total PCU_{Export} total PCU_{Import}
- 1 PCU = 1 kg of animal biomass

1.5. Correction of historical data

Occasionally, errors or inconsistencies in previously submitted datasets are identified during the data validation process - e.g. due to availability of new official statistics regarding animal population data or identification of inaccuracies in the data provided for one or more VMP presentations. In such cases, data are corrected and the updated values are published in the ESVAC interactive database as soon as they have been validated and approved by the participating country.

Published reports are not updated when changes to data are implemented in the interactive database, therefore minor discrepancies between values in the ESVAC reports and the interactive database may occur.

1.5.1. Sales data

Following the publication of the twelfth ESVAC report and during the validation process of 2022 data, the following historical sales updates were implemented and are included in the results of this report:

- Ireland corrected the ATCvet code for two products for all years since 2010 one ATCvet code change from QJ01CR01 (ampicillin and beta-lactamase inhibitor) to QJ01CR02 (amoxicillin and beta-lactamase inhibitor) and one ATCvet code from QJ01CR02 to QJ01CA04 (amoxicillin). These corrections led to minor changes in the proportion of penicillin sales as tablets for all years. For food-producing animals, the proportion of sales as penicillins changed, with the proportion of penicillins with beta-lactamase inhibitors decreasing and penicillins with extended spectrum increasing.
- Lithuania resubmitted sales data for 2019–2021 to ESVAC. The State Food and Veterinary Service (SFVS) of Lithuania recalculated the sales data for 2019–2021, which were submitted to ESVAC. This was due to several wholesalers failing to submit their reports for this period, resulting in a discrepancy in the data. To investigate the matter, the Director of the SFVS set up a working group to review the reports for the missing years. As a result of the recalculation, the correct data were resubmitted to ESVAC and are now reflected in the ESVAC database. It is important to note that the updated datasets for 2019–2022 do not include tablet sales, unlike previous years. The updated sales data for 2019–2021 showed a significant 2.9–3.5-fold increase in sales for food-producing animals, ranging from 20.8 to 65.6 mg/PCU, 20.5 to 60.2 mg/PCU, and 20.3 to 71.2 mg/PCU in 2019, 2020 and 2021,

respectively. It is advisable to exercise caution when interpreting trends and drawing conclusions from data prior to 2019, as it is not feasible to verify their accuracy.

- Norway corrected the number of packs sold for farmed fish in 2021 (1 product), resulting in a decrease of 6.5% (from 2.5 to 2.3 mg/PCU) in the total sales for food-producing animals.
- Sweden corrected the number of packs sold for a large number of VMPs upon identifying a lack of data completeness affecting the years 2017–2021. These corrections resulted in minor increases in sales in mg/PCU for 2017, 2018 and 2019 (2.3%, 0.1% and 3.5%, respectively). Moreover, the updated 2017 sales include products for fish containing florfenicol and oxytetracycline, thus the reporting for fish is complete. The updates to 2020 and 2021 data resulted in an increase of sales for food-producing animals of 10.3% (from 11.1 to 12.2 mg/PCU) and 10.6% (from 10.9 to 12.1 mg/PCU), respectively.

1.5.2. Animal population data

There were no historical updates made to animal population data during this reporting.

1.6. Data quality check and validation of the sales and animal population data

ESVAC-participating countries submit their data directly to the ESVAC web-based application. Various reports can be created using the ESVAC BI web-based application and used for validation purposes. Each country is responsible for the quality of the sales data it delivers to EMA and is assisted by the ESVAC secretariat with data validation. This includes the identification of outliers, mainly by comparison with available data from previous years and with official product information found in the registers of nationally authorised medicinal products.

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.

1.7. Analysis and reporting of the data

The results presented in the current report focus on the primary and secondary outcome indicators of antibiotic consumption (established by ECDC, EFSA and EMA) for 2022 and their trends between 2011 and 2022. For food-producing animals, the proposed indicators for antimicrobial consumption are: 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. Further analyses are performed based on sales by antibiotic class and product form.

With regard to food-producing animals, ESVAC product forms are grouped by their predominant use for group or individual treatment. In this manner, the term 'group treatment' is used for VMPs administered orally via feed or water, i.e. the product forms' premixes, oral solutions and oral powders; while 'individual treatment' refers to boluses, injectable products, intramammary products, intrauterine products and oral pastes.

The main measurement unit (primary indicator) applied in this report to expresses the consumption of veterinary antibiotics is mg of active substance normalised by the population correction unit (mg/PCU):

$\frac{\text{Quantity sold in tonnes x } 10^9}{\text{PCU in kg}}$

When presenting total sales in mg/PCU for all the ESVAC reporting countries, these represent aggregated sales, i.e. total quantity of all antibiotic active substances sold (mg) in all countries divided by the total PCU (kg) of all countries.

The data are presented according to the antibiotic classes or subclasses defined in the ATCvet hierarchical system for the active substance(s) of each VMP, irrespective of whether it is a single or fixed-combination product. The class 'Others' can include the following subclasses: imidazole derivatives (metronidazole), nitrofuran derivatives (nifurpirinol, furazolidone) and other antibacterials (bacitracin, fosfomycin, furaltadone, nitroxoline, novobiocin, rifaximin, spectinomycin). Of note, metronidazole, nifurpirinol, furazolidone and furaltadone are included in Table 2 (prohibited substances) of the Annex to Commission Regulation (EU) No 37/2010 and are prohibited for use in food-producing animals. However, they are included in Table A4 of this report because they can be used in companion animals for which no maximum residue limits (MRLs) are required. In 2022, sales of VMPs with these four substances accounted for 0.22% of the total tonnes sold for the 31 ESVAC-participating countries.

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The data presented in this report correspond to the exact sales figures (in tonnes) calculated for each product, while in the tables and graphs the numbers are aggregated and rounded. Therefore, the total sales figures 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 in the ESVAC database on 12 September 2023. Any updates made to the data at a later stage are not included in the present data analyses.

Data on sales, including tablets used for the 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, the legal basis for the data collection at national level, systems for distribution of antibiotic VMPs, sources from which sales data were obtained, type of data and the data included are shown, by country, in Table 2.

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 data¹	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=7) Wholesalers (n=8)	Sales to pharmacies	Yes	No
Belgium	>5 years	Mandatory to report	Federal Agency for Medicines and Health Products	Wholesalers (n=19) Feed mills (n=33)	Sales to veterinarians and pharmacies; sales by feed mills to farmers	Yes	No
Bulgaria	>5 years	Mandatory to report	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=13)	Sales to pharmacies and veterinarians	Yes	No
Cyprus	>5 years	Mandatory to report	Ministry of Agriculture, Rural Development and Environment - Veterinary Services	Wholesalers (n=27) Feed mills (n=19)	Sales by wholesalers to veterinarians and pharmacies; sales by feed mills to farmers	Yes	Yes (1.6%)
Czechia	>5 years	Mandatory to report	Institute for State Control of Veterinary Biologicals and Medicines	Wholesalers (n=97) Feed mills (n=41)	Sales by wholesalers to veterinarians and pharmacies; sales by feed mills to farmers	Yes	Yes (0.17%)
Denmark	>5 years	Mandatory to report	Danish Veterinary and Food Administration	VetStat (n=1) obtaining data from pharmacies (n=580) Feed mills (n=1)	Prescriptions data from pharmacies and feed mills	Yes	Yes (2.9%)
Estonia	>5 years	Mandatory to report	State Agency of Medicines	Wholesalers (n=7)	Sales to veterinarians and pharmacies	Yes	Yes (3%)
Finland	>5 years	Mandatory to report	Finnish Medicines Agency	Wholesalers (n=3) Importers of medicated feed (n=1)	Sales to pharmacies and veterinarians	Yes	Yes (8%)
France	>5 years	Mandatory to report	National Agency for Veterinary Medicinal Products (Anses-ANMV)	MAHs (n=62)	Sales to wholesalers	Yes	N
Germany	>5 years	Mandatory to report	Federal Office of Consumer Protection and Food Safety	MAHs (n=25) Wholesalers (n=11)	Sales to veterinarians	Yes	Q
Purchase / imp MAHs = marke	 Purchase / import data from e.g. pharma MAHs = marketing authorisation holders 	pharmaceutical oddars	¹ Purchase / import data from e.g. pharmaceutical industry and/or from wholesalers in other countries. ² MAHs = marketing authorisation holders.	ers in other countries.			

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

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 data¹	Sales between wholesalers and/or MAHs ² excluded (Yes/No)	Products sold on special licence included ³ (Yes/No)
Greece	>5 years	Mandatory to report	Greek National Organisation for Medicines	MAHs (n=67) ⁴	Sales to pharmacies and veterinarians	Yes	No
Hungary	>5 years	Mandatory to report	National Food Chain Safety Office Directorate of Veterinary Medicinal Products	Wholesalers (n=31)	Sales to pharmacies, veterinarians, feed mills, farmers, retailers and animal clinics	Yes	Yes (<1%)
Iceland	>5 years	Mandatory to report	Icelandic Medicines Agency	Wholesalers (n=2)	Sales to veterinarians and pharmacies	Yes	Yes (30%)
Ireland	>5 years	Mandatory to report	Health Products Regulatory Authority	MAHs (n=60)	Sales to wholesalers, pharmacies, veterinarians and licensed merchants	Yes	Nos
Italy	>5 years	Mandatory to report	Italian Ministry of Health	Italian Drug Traceability System (n=1) obtaining data from pharmacies (n=19,773) and wholesalers (n=237) MAHs (n=19)	Dispensed e-prescription from wholesalers and pharmacies to veterinarians, farmers and companion animal owners; sales of premixes from MAHs to wholesalers	Yes	ON
Latvia	>5 years	Mandatory to report	Food and Veterinary Service	Wholesalers $(n=17)$	Sales to pharmacies, veterinarians and farmers	Yes	Yes (6.75%)
Lithuania	>5 years	Mandatory to report	State Food and Veterinary Service	Wholesalers (n=31)	Sales to pharmacies, veterinarians and farmers	Yes	No
Luxembourg	>5 years	Mandatory to report	Ministry of Health	Wholesalers (n=2)	Sales to pharmacies and veterinarians	Yes	No
Malta	>5 years	Mandatory to report	Ministry for Agriculture, Fisheries and Animal Rights	Wholesalers (n=14) Medicated feed mill (n=1) Medicated feed traders (n=3)	Sales to pharmacies, veterinarians and farmers	Yes	ON
Netherlands	>5 years	Mandatory to report	Federation of the Dutch Veterinary Pharmaceutical Industry (FIDIN)	MAHs (n=17)	Sales to wholesalers and veterinarians	Yes	Yes (0.3%)

⁵ VMPs authorised under special licence by the Department of Agriculture, Food and the Marine were not included in this analysis. The contribution from these sources to the overall figure is likely to be very small.

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Country	Number of years of data collection	basis	National data provider to ESVAC	sources for ESVAC data (approx. number)	sales data, prescription data or purchase data¹	Sales between wholesalers and/or MAHs ² excluded (Yes/No)	on special licence included ³ (Yes/No)
Norway	>5 years	Mandatory to report	Norwegian Veterinary Institute	Wholesalers (n=5) Feed mills (n=1)	Sales by wholesalers to pharmacies and veterinarians; sales by feed mills to fish farmers (only as medicated feed)	Yes	Yes (11.2%)
Poland	>5 years	Mandatory to report	Ministry of Agriculture and Rural Development	Wholesalers (n=121)	Sales to veterinarians	Yes	No
Portugal	>5 years	Mandatory to report	Directorate-General for Food and Veterinary	Wholesalers (n=86)	Sales to pharmacies and veterinarians	Yes	No
Romania	>5 years	Mandatory to report	Institute for Control of Biological Products and Veterinary Medicines	MAHs (n=84) ⁶	Sales to wholesalers	Yes	No
Slovakia	>5 years	Mandatory to report	Institute for State Control of Veterinary Biologicals and Medicaments	Wholesalers (n=24)	Sales to pharmacies, military forces, State Veterinary and Food Administration, veterinarians, farmers and feed mills	Yes	Ŷ
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 veterinarians	Yes	Yes (4.5%)
Spain	>5 years	Mandatory to report	Spanish Agency for Medicines and Health Products	Retailers (n=744) Feed mills (n=11) Pharmacies (n=4,358) 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=1446)	Dispensed veterinary prescriptions and requisitions ⁸	Yes	Yes (13.6%)
Switzerland	>5 years	Mandatory to report	Federal Food Safety and Veterinary Office	MAHs (n=14)	Sales to veterinarians, pharmacies and feed mills	No ⁹	No
United Kingdom	>5 years	Mandatory to report	Veterinary Medicines Directorate	MAHs (n=71)	Sales to wholesalers, veterinarians, feed mills and veterinary pharmacies	Yes	No
For 2015–2022 pharmacies and	⁵ For 2015–2022, data were collected from MAHs, while for 201 pharmacies and veterinarians.	ed from MAHs,	while for 2014 the data were of	For 2015–2022, data were collected from MAHs, while for 2014 the data were obtained from MAHs and wholesalers and include MAHs' sales to wholesalers and wholesalers' sales to pharmacies and veterinarians.	ers and include MAHs' sales to wh	iolesalers and wholes	alers' sales to

2. Results

2.1. Sales of antibiotic VMPs for food-producing animals in 2022

2.1.1. Overall sales of antibiotic VMPs: primary outcome indicator

This section presents the 2022 primary indicator of antibiotic consumption that corresponds to the overall sales (mg/PCU) of antibiotic VMPs in food-producing animals, which include cattle, pigs, chickens, turkeys, sheep, goats, rabbits, farmed fish and horses²². It is important to note that the overall sales in mg/PCU include the sales of all ESVAC product forms except tablets, based on the assumption that these are almost exclusively used in companion animals. Although some product forms, e.g. injectable products, are frequently marketed for both food-producing and companion animals, their sales are included in the statistics of food-producing animals given that their overall use in companion animals is minor. Moreover, some of the sales allocated to food-producing animals could be for non-food-producing animals such as companion animals, fur animals, exotic birds and racing pigeons.

In addition to the primary outcome indicator, this section also presents aggregated sales data of antibiotic VMPs for food-producing animals by product form and by antibiotic class, as well as the aggregated proportion of penicillin sales for food-producing animals by subclass in 31 European countries in 2022.



Figure 2. Spatial distribution of overall sales, in mg/PCU, of antibiotic VMPs for food-producing animals in 31 European countries in 2022¹

¹ ESVAC-participating countries' codes according to ISO 3166 — Codes for the representation of names of countries and their subdivisions.

²² 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 horses not intended for slaughter is also included in the surveillance.

In 2022, sales of antibiotic VMPs for use in food-producing animals represented 98.4% of total sales in tonnes (sales of tablets are described in Section 2.3) and ranged from 2.1 mg/PCU to 254.7 mg/PCU in the 31 participating countries (Figure 2). The total aggregated sales across all reporting countries were 73.9 mg/PCU (Table 3). It is important to highlight that the sales data for the different countries should not be directly compared given that they may be influenced by other factors, such as animal demographics, types of animal production systems, selection of antibiotic agents and treatment protocols, data sources used or collection of data, among others.

Country	Sales (tonnes) for food-producing animals	PCU (1,000 tonnes)	mg/PCU
Austria	34.3	946.4	36.2
Belgium	120.2	1,634.6	73.5
Bulgaria	37.0	358.0	103.2
Croatia	17.1	304.1	56.2
Cyprus	35.6	139.7	254.7
Czechia	32.3	696.7	46.4
Denmark	80.2	2,355.9	34.1
Estonia	5.2	114.5	45.8
Finland	7.2	484.8	14.9
France	255.2	6,561.4	38.9
Germany	531.1	7,600.9	69.9
Greece	101.7	1,141.9	89.0
Hungary	92.6	832.9	111.2
Iceland	0.6	140.2	4.4
Ireland	75.6	2,246.0	33.6
Italy	585.4	3,716.3	157.5
Latvia	3.4	163.7	20.8
Lithuania	14.5	300.1	48.2
Luxembourg	1.3	51.1	25.1
Malta	1.1	15.3	74.4
Netherlands	112.0	3,025.4	37.0
Norway	4.7	2,198.1	2.1
Poland	838.3	4,277.7	196.0
Portugal	82.0	1,062.4	77.1
Romania	136.4	2,794.4	48.8
Slovakia	9.2	223.9	41.1
Slovenia	4.7	182.4	25.7
Spain	1,027.2	8,063.3	127.4
Sweden	8.3	788.1	10.6
Switzerland	22.6	829.0	27.3
United Kingdom	181.1	7,037.5	25.7
Total 31 countries	4,458.1	60,286.7	73.9*

Table 3. Sales in tonnes of active substance of antibiotic VMPs marketed mainly for food-producing animals¹, PCU in 1,000 tonnes and sales in mg/PCU in 31 European countries in 2022

¹ Tablets are excluded as they are used almost exclusively in companion animals. On the contrary, sales of some injectable antibiotic VMPs and a few other products that are solely or also used in companion animals are included in the sales for food-producing animals given that their proportional use in companion animals is minor.

* Total mg/PCU for 31 countries represents aggregated sales (tonnes) for food-producing animals, including horses and farmed fish, normalised by the aggregated PCU (1,000 tonnes).

The aggregated sales of antibiotic VMPs for food-producing animals stratified by product form are shown in Figure 3. Oral solutions were the highest selling product form, accounting for 63.4% of the total sales (mg/PCU) of antibiotic VMPs in the 31 countries, followed by premixes (14.9%), injectable products (13.6%), oral powders (6.8%), intramammary products (0.74%); the remaining sales (0.58%) corresponded to oral pastes, boluses and intrauterine products.

Oral powders that can be administered both via feed and as oral solution are reported in ESVAC as oral powders. Although a small proportion of oral powders and oral solutions are suitable for the treatment of single animals or a very limited number of animals, the overall sales figures for these product forms, in addition to the sales of premixes, provide a reasonable estimate of sales for group treatment, including groups in one pen / farm²³. In 2022, 85.1% of total sales of antibiotic VMPs for use in food-producing animals were of VMPs predominantly used for group treatment. Detailed information on sales per product form at country level can be found in the ESVAC interactive database and in the 2022 individual country reports.

Figure 3. Proportion of aggregated sales, in mg/PCU, of antibiotic VMPs for food-producing animals by product form in 31 European countries in 2022



* 'Other forms' includes oral pastes, boluses and intrauterine products.

As shown in Figure 4, in 2022 the overall highest selling antibiotic classes were penicillins (32.7%), tetracyclines (23.5%) and sulfonamides (9.4%), accounting for 65.5% of total sales of antibiotic VMPs for food-producing animals, in mg/PCU. Among the antibiotic classes shown as 'Other classes', 1st- and 2nd-generation cephalosporins, 3rd- and 4th-generation cephalosporins, amphenicols and other quinolones accounted for 0.15%, 0.17%, 2.7% and 0.16% of the overall sales in the 31 countries, respectively.

²³ In 2020, a thorough analysis was carried out of the provisions concerning oral administration of VMPs, as detailed in Regulation (EU) 2019/6, and of the preparation and administration of medicated feed, as detailed in Regulation (EU) 2019/4 (https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/advice-implementing-measures-under-article-106-6-regulation-eu-2019/6-veterinary-medicinal-products-scientific-problem-analysis-recommendations-ensure-safe-efficient_en.pdf). One of the recommendations resulting from this analysis was that oral powders, granules or similar pharmaceutical forms administered to terrestrial animals via solid feed, including VMPs administered via top-dressing, should be restricted to use in individual animals only. Therefore, the classification of group treatment included in the ESVAC analysis could be adjusted in the future once these recommendations are fully implemented by the Member States.

Figure 4. Proportion of aggregated sales, in mg/PCU, of antibiotic VMPs for food-producing animals by antibiotic class in 31 European countries in 2022



* 'Other classes' includes amphenicols, cephalosporins, other quinolones and 'Others'. The class 'Others' includes the following subclasses: imidazole derivatives (metronidazole), nitrofuran derivatives (furazolidone) and other antibacterials (bacitracin, furaltadone, novobiocin, rifaximin and spectinomycin). Of note, some sales could be for non-food-producing animals such as companion animals, fur animals, exotic birds and racing pigeons.

The sales patterns of penicillins differed substantially between countries with regards to the various subclasses (Figure 5). In the Nordic countries and Switzerland, where the sales of penicillins are typically high, beta-lactamasesensitive penicillins²⁴ were the highest selling penicillin subclass, representing between 54% and 96% of total penicillin sales. For the remaining countries, penicillins with extended spectrum (98.1% amoxicillin, 1.9% ampicillin and <0.001% metampicillin) accounted for the main proportion of penicillin sales. A small proportion of the total penicillin sales for food-producing animals was represented by VMPs containing a fixed combination of amoxicillin and beta-lactamase inhibitors (2.2% of penicillin sales for all 31 countries).

²⁴ Beta-lactamase-sensitive penicillins belong to ATCvet code QJ01CE and, in 2022, procaine benzylpenicillin and phenoxymethylpenicillin were the two active substances from this penicillin subclass for which sales were reported.



Figure 5. Proportion of penicillin sales for food-producing animals, in mg/PCU, by subclass in 31 European countries in 2022¹

* In 2022, all penicillins included in this group were aminopenicillins (amoxicillin, ampicillin and metampicillin).

** In the ATCvet system, these are classified as combinations of penicillins that include beta-lactamase inhibitors. In 2022, only combinations of amoxicillin with enzyme inhibitor were reported.

¹ The aggregated proportion for 31 European countries is based on the aggregated mg/PCU — total quantity penicillins (mg) by subclass divided by total PCU (kg).

Table 4 presents the sales, in mg/PCU, of the different antibiotic classes per country and aggregated by the 31 participating countries. Overall, sales patterns of the different antibiotic classes varied between countries. Although penicillin was the overall highest selling antibiotic class in 2022 (Figure 4), tetracycline sales surpassed those of penicillins in 13 countries. As previously mentioned, differences between countries can partly be explained by differences in animal demographics, selection of antibiotic agents, dosage regimes, data sources and veterinarians' prescribing habits, among other factors.

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Country	Tetracyclines	slo zin 94qmA	Penicillins	.1st- and 2nd-gen. cephalosporins	3rd- and 4th-gen. Cephalosporins	29bim6noîlu2	Trimethoprim	Racrolides	29bimesooniJ	Fluoroquinolones	Other quinolones	səbizoɔγlponimA	snixymylog	Pleuromutilins	Others*	UD9\pm lstoT
Austria	16.7	0.4	8.5	0.1	0.2	3.4	0.7	2.7	0.1	0.4	C	1.4	1.2		0.1	36.2
Belgium	14.7	1.9	30.0	0.3	0.1	11.7	2.3	5.3	1.6	0.2	0.2	2.3	0.6	0.1	2.1	73.5
Bulgaria	37.2	3.3	22.8	0.04	0.2	5.9	0.7	12.2	2.0	7.8	0.01	5.3	3.9		0.5	103.2
Croatia	16.9	1.5	19.1	0.04	0.2	2.7	0.6	4.2	0.2	2.6	0	1.7	5.6		0.3	56.2
Cyprus	68.5	1.7	49.1	0.02	0.4	45.0	9.0	11.6	40.7	1.8	0	5.5	6.3		0.6	254.7
Czechia	11.2	0.4	16.7	0.1	0.5	6.8	0.8	2.2	0.1	1.6	0	2.5	0.6		0.3	46.4
Denmark	4.9	0.7	9.7	0.02	<0.01	3.0	0.6	5.0	0.8	<0.01	0.2	5.8	0		1.0	34.1
Estonia	13.2	0.6	11.1	0.1	0.5	3.3	0.7	1.5	0.4	0.8	0	2.3	0.4		0.6	45.8
Finland	2.6	0.2	8.2	0	<0.01	2.9	0.6	0.2	0.05	0.1	0	0.0	0		0	14.9
France	11.4	0.8	7.4	0.2	0.02	6.6	1.2	3.1	0.3	0.1	0.2	5.5	1.1		0.6	38.9
Germany	11.8	0.7	29.1	0.1	0.1	7.2	1.0	6.5	1.5	0.6	0	2.7	5.8		1.6	69.9
Greece	42.6	0.9	16.2	0.01	0.2	7.3	0.8	5.2	0.9	3.0	0.7	7.9	1.7		0.6	89.0
Hungary	36.6	3.2	32.6	0.1	0.3	6.3	1.3	4.5	1.8	6.6	0	3.6	5.8		0.8	111.2
Iceland	1.5	0	2.2	0	<0.01	0.1	0.02	0	0	<0.01	0	0.6	0	v	0.01	4.4
Ireland ²	12.2	1.1	8.8	0.5	0.1	5.3	0.3	1.9	0.4	0.2	0	2.5	0		0.3	33.6
Italy	35.6	6.4	54.6	0.1	0.1	21.8	1.9	8.0	13.4	0.9	0.4	7.3	0.6		2.2	157.5
Latvia	3.4	0.1	5.9	0.7	0.4	0.5	0.1	3.3	0.1	0.8	0	3.9	0.3		0.1	20.8
Lithuania	4.2	0.3	13.5	0.2	0.4	1.7	7.7	8.0	0.2	1.5	0	3.8	5.8		0.3	48.2
Luxembourg	5.0	1.1	6.6	0.2	0.5	4.5	0.9	1.0	0.6	0.9	0	3.2	0.2		0.5	25.1
Malta ³	20.6	0.9	9.5	0.04	0.3	12.2	2.3	3.5	0.3	12.6		4.7	0.3		2.5	74.4
Netherlands	10.7	1.4	9.4	0.03	<0.01	6.4	1.1	6.1	0.1	0.03	0.8	0.5	0.3		0.1	37.0
Norway	0.03	0.2	1.2	0	<0.01	0.5	0.1	<0.01	<0.01	<0.01	0.01	0.04	0	•	0.01	2.1
Poland	39.0	2.4	69.1	0.2	0.4	8.9	1.7	28.8	3.8	11.8	< 0.01	9.3	10.2		2.5	196.0
Portugal	25.7	1.5	17.6	0.06	0.2	2.8	0.6	7.4	5.8	5.2	0	3.6	1.8		0.6	77.1
Romania	10.7	2.4	8.7	0.01	0.1	1.9	0.4	7.5	1.3	5.5	0.1	5.1	2.7		0.6	48.8
Slovakia	9.2	0.2	10.6	0.3	0.5	5.3	0.9	0.6	0.2	3.2	0.01	4.2	1.6		0.9	41.1
Slovenia	5.9	2.4	8.5	0.05	0.2	2.3	0.5	0.3	0.02	0.9	0	4.0	0.1		0.02	25.7
Spain	28.1	5.4	44.2	0.03	0.2	9.8	1.9	5.2	15.6	3.3	0.02	9.7	0.4		2.2	127.4
Sweden ⁴	0.7		6.8		<0.01	1.5	0.3	0.4	0.05		0.02	0.6			0.1	10.6
Switzerland ⁵	5.6	0.8	10.3	0.1	0.1	6.3	0.6	0.8		0.2		2.6	0.1		0.03	27.3
United Kingdom	8.3	0.5	7.3	0.1	0.02	1.9	0.4	2.3	0.7	0.1	0	2.6	0	1.0	0.5	25.7
Total sales for 31 countries (mg/PCU) ⁶	17.4	2.0	24.2	0.1	0.1	6.9	1.1	6.3	3.9	2.1	0.1	4.8	2.1		1.1	73.9
Median of 31 countries (mg/PCU) ⁷	11.4	0.9	10.3	0.1	0.2	5.3	0.7	3.9	0.4	0.9	0.01	3.6	0.6		0.6	45.8
* The class 'Others' includes the following subclasses: imidazole di	classes: imi	dazole de	rivatives (metronida	izole), nitr	ivatives (metronidazole), nitrofuran derivatives (furazolidone) and	ivatives (furazolide	one) and		ibacteria	ls (baciti	acin, fu	raltadon	e, novob	iocin,
I For the countries where injectable 2rd and 4th concertion could be for n	t sales could	De ror IIC	n-rood-pr	producing a	nimais suc	ch as comp		animais, rur and cate th	animals	, exotic bi	ras and I	racing pi	geons.	2003 003	ion poro	0

For the countries where injectable 3rd- and 4th-generation cephalosporins are solely or also marketed for dogs and cats, the data provide a considerable overestimate for food-producing

animals.

For commercial confidentiality reasons, pleuromutilins are aggregated with 'Others'. For commercial confidentiality reasons, other quinolones are aggregated with fluoroquinolones.

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.

For commercial confidentiality reasons, pleuromutilins are grouped with 'Others' and lincosamides are grouped with macrolides.

⁶ Total aggregated sales expressed in mg/PCU consist of the total quantity of antibiotic active substances sold (mg) divided by the total PCU (kg) for 31 countries. ⁷ Median shows the 16th value ranked from smallest to largest out of 31 observed values for each antibiotic class.

2.1.2. Sales of antibiotic VMPs: secondary outcome indicators

The secondary outcome indicators of antibiotic consumption for food-producing animals correspond to the total sales (measured in mg/PCU) of those antibiotic VMPs that are included in the AMEG Category B: 3rd- and 4th-generation cephalosporins, quinolones (indicating the proportion of fluoroquinolones) and polymyxins. These antibiotics are also classified as critically important antimicrobials (CIAs) with the highest priority for human medicine by WHO (6th revision).

The proportion of total aggregated sales in 2022 corresponding to each of these antibiotic classes varied substantially between the 31 countries, ranging from <0.01% to 1.9% for 3rd- and 4th-generation cephalosporins, 0.01% to 17.0% for fluoroquinolones, 0% to 2.0% for other quinolones and 0% to 12.1% for polymyxins (Figure 6). Sales trends, in mg/PCU, of these antibiotic classes / subclasses in the 31 European countries are presented in Table 5.

Figure 6. Proportion of sales of 3rd- and 4th-generation cephalosporins, fluoroquinolones, other quinolones and polymyxins of total sales, in mg/PCU, of antibiotic VMPs for food-producing animals in 31 European countries in 2022^{1,2,3,4}



¹ Variations between the countries should be interpreted with great care due to the large differences in dosing schemes between these classes / subclasses of antibiotics.

² No sales of other quinolones were reported for Austria, Croatia, Cyprus, Czechia, Estonia, Finland, Germany, Hungary, Iceland, Ireland, Latvia, Lithuania, Luxembourg, Malta, Portugal, Slovenia, Switzerland and the United Kingdom.

³ No sales of polymyxins were reported for Denmark, Finland, Iceland, Ireland, Norway and the United Kingdom.

⁴ The aggregated proportion for 31 European countries is based on the aggregated mg/PCU — total quantity of antibiotic active substances sold (mg) divided by total PCU (kg).

2.1.2.1. Sales of 3rd- and 4th-generation cephalosporins

Sales of 3rd- and 4th-generation cephalosporins were unevenly distributed across the 31 countries (Figure 7). Sales for this antibiotic class ranged from <0.001 to 0.47 mg/PCU (Table 4) between countries and presented aggregated sales of 0.13 mg/PCU, accounting for 0.17% of total sales (Table 4 and Figure 4).

Figure 7. Spatial distribution of sales, in mg/PCU, of 3rd- and 4th-generation cephalosporins for food-producing animals in 31 European countries in 2022¹



¹ ESVAC-participating countries codes' according to ISO 3166 — Codes for the representation of names of countries and their subdivisions.

For almost all countries, the majority of 3rd- and 4th-generation cephalosporin sales for food-producing animals were of injectable products. This product form represented 92.7% of the total aggregated sales of this antibiotic class across 31 countries, while intramammary products accounted for the remaining 7.3% (Figure 8).



Figure 8. Proportion of sales, in mg/PCU, of 3rd- and 4th-generation cephalosporins for food-producing animals by product form in 31 European countries in 2022^{1,2,3,4}

¹ Sales <1 kg in Finland, Iceland and Norway.

² No sales of intramammary products reported for Denmark, Finland, Iceland, Malta, the Netherlands, Norway and Sweden.

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

⁴ The aggregated proportion for 31 European countries is based on the aggregated mg/PCU — total quantity 3rd- and 4th-generation cephalosporins (mg) by product form divided by total PCU (kg).

2.1.2.2. Sales of quinolones

Sales of quinolones (comprising fluoroquinolones and other quinolones) ranged from <0.01 to 12.6 mg/PCU between the 31 countries and presented aggregated sales of 2.2 mg/PCU, accounting for 3.0% of total sales (Table 4 and Figure 4).

Fluoroquinolones accounted for 94.7% of total quinolone sales, with this proportion varying between 1.1% and 100% in the different participating countries. Sales of this antibiotic class were unevenly distributed across the 31 countries (Figure 9), ranging from <0.01 to 12.6 mg/PCU and presented aggregated sales of 2.1 mg/PCU, accounting for 2.8% of total (all antibiotics) aggregated sales (Table 4 and Figure 4).

Figure 9. Spatial distribution of sales, in mg/PCU, of fluoroquinolones for food-producing animals in 31 European countries in 2022¹



¹ ESVAC-participating countries' codes according to ISO 3166 — Codes for the representation of names of countries and their subdivisions.

As shown in Figure 10, fluoroquinolones were mainly sold as oral solutions in 17 of the participating countries; in the remaining 14 countries, injectable products were the predominant product form. Aggregated for the 31 countries, 71.7% of total fluoroquinolone sales corresponded to oral solutions, 27.9% to injectable products and 0.37% to other product forms such as premixes, boluses and intrauterine preparations.



Figure 10. Proportion of sales, in mg/PCU, of fluoroquinolones for food-producing animals by product form in 31 European countries in 2022^{1,2}

* 'Other forms' includes negligible quantities sold as boluses, premixes and/or intrauterine products in some countries.

¹ In Iceland, sales of fluoroquinolones were <1 kg.

² The aggregated proportion for 31 European countries is based on the aggregated mg/PCU — total quantity of fluoroquinolones (mg) by product form divided by total PCU (kg).

Other quinolones accounted for only 5.3% of the aggregated quinolone sales. No sales of this antibiotic class were reported for 18 countries and showed an uneven distribution across those countries that did report sales (Figure 11), ranging from <0.01 mg/PCU to 0.75 mg/PCU (Table 4). Overall, the aggregated sales of other quinolones were 0.12 mg/PCU accounting for 0.16% of total sales (Table 4 and Figure 4).



Figure 11. Spatial distribution of sales, in mg/PCU, of other quinolones for food-producing animals in 31 European countries in 2022^{1,2}

The highest selling product form for other quinolones varied between the countries that reported sales of this antibiotic class in 2022 (Figure 12). Other quinolones were sold exclusively in 2 countries as premixes and in 1 country exclusively as oral powders; in the remaining countries oral solutions accounted for at least 78% of the sales of this antibiotic class. Regarding the aggregated sales of other quinolones across the 31 countries, 88.2% corresponded to oral solutions, 9.3% to premixes, 2.3% to oral powders and the remaining 0.2% to other forms such as oral pastes, boluses or injectable products.

 ¹ ESVAC-participating countries' codes according to ISO 3166 — Codes for the representation of names of countries and their subdivisions.
 ² No sales of other quinolones in Austria, Croatia, Cyprus, Czechia, Estonia, Finland, Germany, Hungary, Iceland, Ireland, Latvia, Lithuania, Luxembourg, Malta, Portugal, Slovenia, Switzerland and the United Kingdom.



Figure 12. Proportion of sales, in mg/PCU, of other quinolones for food-producing animals by product form and by country in 2022^{1,2}

* 'Other forms' includes negligible quantities sold as injectable products, boluses and/or oral pastes in some countries.

¹ No sales of other quinolones reported in Austria, Croatia, Cyprus, Czechia, Estonia, Finland, Germany, Hungary, Iceland, Ireland, Latvia, Lithuania, Luxembourg, Malta, Portugal, Slovenia, Switzerland and the United Kingdom.

² The aggregated proportion is based on the aggregated mg/PCU (total quantity of antibiotic active substances sold (mg) divided by total PCU (kg)) for all 31 countries.

2.1.2.3. Sales of polymyxins

Sales of polymyxins were also unevenly distributed across countries (Figure 13). Sales of this antibiotic class ranged between 0 mg/PCU and 10.2 mg/PCU over the different countries, with 6 not reporting any sales (Table 4). Overall, the aggregated sales of polymyxins were 2.1 mg/PCU accounting for 2.8% of total sales (Table 4 and Figure 4).

Figure 13. Spatial distribution of sales, in mg/PCU, of polymyxins for food-producing animals in 31 European countries in 2022^{1,2}



¹ ESVAC-participating countries' codes according to ISO 3166 — Codes for the representation of names of countries and their subdivisions. ² No sales of polymyxins in Denmark, Finland, Iceland, Ireland, Norway and the United Kingdom.

Sales of polymyxins stratified by product form differed between countries. For 19 of the 25 countries that reported polymyxin sales, polymyxins were predominantly sold as oral solutions (Figure 14). Of the aggregated sales for all countries, 90.6% corresponded to oral solutions, 4.1% to premixes, 4.7% to oral powders, and the remaining 0.6% to injectable products and other forms such as boluses, intramammary products and oral pastes.



Figure 14. Proportion of sales, in mg/PCU, of polymyxins for food-producing animals by product form and by country, in 2022^{1,2}

* 'Other forms' includes negligible quantities sold as boluses, oral pastes and/or intramammary products in some countries.

¹ No sales of polymyxins in Denmark, Finland, Iceland, Ireland, Norway and the United Kingdom.

² The aggregated proportion is based on the aggregated mg/PCU (total quantity of antibiotic active substances sold (mg) divided by total PCU (kg)) for all 31 countries.

2.2. Sales trends of antibiotic VMPs for food-producing animals

This section focuses on the primary and secondary indicators of antibiotic sales trends. In the first part of this section trends are described for the 25 countries that have the longest ESVAC observation period (2011–2022). In the second part, trends are presented for a wider European geographical area starting in 2017 — when participation of 31 countries was achieved — up until 2022. Finally, an overview of the primary and secondary indicator trends (in mg/PCU), the tonnes of antibiotics sold and PCU (in 1,000 tonnes) are provided per country in Tables 5 and 6.

2.2.1. Sales (mg/PCU) trends from 2011 to 2022, aggregated by 25 countries: primary and secondary outcome indicators

Despite modest increases of sales in 2014 and 2020, the overall aggregated sales for the 25 countries participating in ESVAC reached the lowest ever reported values in 2022, having declined 53.0% since 2011 (from 161.2 mg/PCU to 75.8 mg/PCU). In comparison to 2021 (86.5 mg/PCU), sales in 2022 decreased by 12.4% (Figure 15). From 2011 to 2022, sales (in mg/PCU) decreased in 24 countries. Of these, 21 countries show a decrease of more than 15% (and up to 67.5%). Throughout this period, sales have increased in 1 country by 55% compared to 2011 (Table 5).
Figure 15. Trends of aggregated overall sales, sales of 3rd- and 4th-generation cephalosporins, other quinolones, fluoroquinolones and polymyxins, in mg/PCU, for the 25 European countries¹ reporting data for ESVAC from 2011 to 2022 (note the different scales of the two y-axes)



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

Total sales of the AMEG Category B antibiotics for the 25 countries have also been in decline since 2011, contributing to the overall decrease in total sales. Of these antibiotic classes, polymyxin sales decreased the most, with noticeable reductions from 2016 (inclusive). Overall, between 2011 and 2022, sales of 3rd- and 4th-generation cephalosporins decreased by 49.0% (from 0.24 mg/PCU to 0.12 mg/PCU), sales of fluoroquinolones decreased by 24.7% (from 2.5 mg/PCU to 1.9 mg/PCU), sales of other quinolones decreased by 89.7% (from 1.1 mg/PCU to 0.11 mg/PCU) and sales of polymyxins decreased by 81.0% (from 11.0 mg/PCU to 2.1 mg/PCU) (Figure 15).

Sales of all other antibiotic classes have declined since 2011, apart from for amphenicols, which have increased (from 1.0 mg/PCU to 2.0 mg/PCU), albeit with fluctuations. Tetracyclines was the highest selling class up until 2019, after which penicillins accounted for the major proportion of the aggregated sales for the 25 countries. Nonetheless, tetracyclines, penicillins and sulfonamides were the top three highest selling antibiotic classes between 2011 and 2022. Overall, the sales of these three classes declined by 70.7% (from 59.2 mg/PCU to 17.4 mg/PCU), 30.2% (from 36.3 mg/PCU to 25.4 mg/PCU) and 61.5% (18.7 mg/PCU to 7.2 mg/PCU), respectively. Sales of 1st- and 2nd-generation cephalosporins have remained relatively stable, constituting the lowest selling antibiotic class throughout the entire period (0.14 mg/PCU – 0.12 mg/PCU) except in 2022 when sales of other quinolones was the lowest (0.11 mg/PCU). Sales of macrolides, classified as critically important antimicrobials with the highest priority for human medicine by WHO (6th revision), have declined by 48.0% (from 12.2 mg/PCU to 6.3 mg/PCU) (Figure 16).



Figure 16. Trends of aggregated sales (mg/PCU) by antibiotic class in 25 European countries¹ from 2011 to 2022²

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

² Antibiotic classes are sorted from highest to lowest in 2011.

* The class 'Others' includes the following subclasses: imidazole derivatives (metronidazole), nitrofuran derivatives (furazolidone) and other antibacterials (bacitracin, furaltadone, nitroxoline, novobiocin, rifaximin, spectinomycin). Of note is that some of the sales could be for non-food-producing animals such as companion animals, fur animals, exotic birds and racing pigeons.

Sales trends of antibiotic veterinary medicinal product forms for food-producing animals have also changed between 2011 and 2022 in these 25 countries (Figure 17). While sales of oral solutions have increased over the years (from 12.8 mg/PCU to 48.6 mg/PCU), sales have declined for all other product forms: oral powders (from 74.3 mg/PCU to 5.3 mg/PCU), premixes (from 61.3 mg/PCU to 10.8 mg/PCU), injectable products (from 11.3 mg/PCU to 10.0 mg/PCU) and other forms including intrauterine preparations, intramammary products, oral pastes and boluses (from 1.4 mg/PCU to 0.97 mg/PCU). Consequently, oral solutions have overtaken premixes as the highest selling product form since 2017.

In 2011, product forms predominantly suitable for group treatment accounted for 92.1% of the total sales, with 38.0% accounted for by premixes, 46.1% by oral powders and 8.0% by oral solutions. Although total sales of the product forms predominantly suited for group treatment declined by 56.3% in the period 2011–2022 (from 148.5 mg/PCU to 64.8 mg/PCU), they still accounted for the majority of sales in 2022 (85.6% of total sales), with oral solutions representing 64.2% of sales, premixes 14.3% and oral powders 7.1%. Sales of product forms predominantly used for individual treatment also declined by 14.3% between 2011 and 2022 (from 12.7 mg/PCU to 10.9 mg/PCU). Among these forms used predominantly for individual treatment, injectable products have always been the highest selling product form.



Figure 17. Proportion of sales, in mg/PCU, by product form in 25 European countries¹ from 2011 to 2022

¹ Austria, Belgium, Bulgaria, Cyprus, Czechia, Denmark, Estonia, Finland, France, Germany, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, the Netherlands, Norway, Poland, Portugal, Slovakia, Slovenia, Spain, Sweden and the United Kingdom.
 * Other forms include oral pastes, boluses, and intrauterine and intramammary products.

2.2.2. Sales (mg/PCU) trends from 2017 to 2022, aggregated by 31 countries: primary and secondary outcome indicators

When aggregated by the 31 participating countries that have provided data for ESVAC since 2017, overall sales declined by 30.7% until 2022 (from 106.6 mg/PCU to 73.9 mg/PCU), as shown in Figure 18. Over the last six years, sales measured in mg/PCU continued to decrease, and in 28 out of 31 countries, sales declined by 7.0% to 45.9%. However, sales have increased by 19.5% in 1 country since 2017 (Table 5). When compared to 2021 (84.7 mg/PCU), sales in 2022 decreased by 12.7%.

Figure 18. Trends of aggregated overall sales, sales of 3rd- and 4th-generation cephalosporins, other quinolones, fluoroquinolones and polymyxins, in mg/PCU, aggregated by the 31 European countries reporting data for ESVAC from 2017 to 2022 (note the different scales of the two y-axes)



For the AMEG Category B antibiotics, sales have also decreased between 2017 and 2022. The most noticeable changes were observed for other quinolones and polymyxins, which showed a 73.3% (from 0.44 mg/PCU to 0.12 mg/PCU) and a 42.1% (from 3.6 mg/PCU to 2.1 mg/PCU) decrease in sales, respectively. Sales of 3rd- and 4th-generation cephalosporins decreased by 33.8% (from 0.19 mg/PCU to 0.13 mg/PCU), while sales of fluoroquinolones remained relatively stable until 2021 (from 2.3 mg/PCU to 2.4 mg/PCU) then slightly decreased in 2022 (2.1 mg/PCU) (Figure 18).

2.2.3. Sales (mg/PCU) trends, by country: primary and secondary outcome indicators

In 27 of the 31 countries that participate in ESVAC, overall sales (in mg/PCU) declined between 5.8% and 67.5%, taking 2011 as a reference or the first year of participation thereafter (Table 5). In 2 countries, sales have increased by more than 50%.

The values presented in Table 5 and Table 6 may differ from those published in previous ESVAC reports due to corrections of historical data of sales and of animal population data for the calculation of the PCU (Section 1.5). In this report, considerable differences compared to sales data previously reported for 2019–2021 for Lithuania are observed. This is due to the correction of sales data for this period, which resulted in 2.9 to 3.5-fold higher sales for food-producing animals compared to the figures reported in previous reports (from 20.8 to 65.6 mg/PCU, 20.5 to 60.2 mg/PCU, and 20.3 to 71.2 mg/PCU in 2019, 2020 and 2021, respectively). It is advisable to exercise caution when interpreting trends and drawing conclusions from data for Lithuania up to 2019, as it was not feasible to verify their accuracy or completeness.

2.2.4. Numerator (sales of active substances) and denominator (PCU) trends by country

The main indicator used in this report expresses the consumption of antibiotics in food-producing animals by normalising the sales of active substance in mg (numerator) by the PCU in kg (denominator). Table 6 offers an overview of trends for both numerator (in tonnes) and denominator (in 1,000 tonnes) and an overall trendline for the numerator for all 31 participating countries from their first reporting year until 2022.

Sales of active substances (in tonnes) have declined for most countries, while for a few others sales have fluctuated or increased. The PCU (in 1,000 tonnes) varied between a 9.8% decrease and 7.9% increase for 18 countries, declined by more than 10% for 6 countries, and increased by more than 10% for 7 countries.

Country		2010	2011	2012	2013	2014	2015	2016	2017	2018	2019	2020	2021	2022	Trend	Trends 2010-2022
Austria	Overall sales	62.9	54.4	54.8	57.2	56.3	50.7	46.1	46.7	50.2	42.6	46.3	41.3	36.2	62.9	5
															36.2	>
	3rd- and 4th-gen. cephalosporins	0.30	0.33	0.33	0.35	0.18	0.21	0.22	0.23	0.23	0.23	0.24	0.24	0.24		
	Quinolones (% fluroquinolones)	0.60 (100%)	0.60 0.59 0.52 (100%) (100%) (100%)		0.59 (100%) (0.49 (100%) (0.53 (100%) (0.51 (100%) (0.49 (100%) (0.52 (100%) (0.49 (100%) (0.52 (100%) (0.49 (100%) (]	0.44 (100%)		
	Polymyxins	0.95	1.0	0.68	0.94	1.6	1.6	1.6	1.7	1.9	1.6	1.6	1.6	1.2		
Belgium	Overall sales	179.9	175.1	162.9	156.4	158.1	149.9	139.9	131.1	113.0	101.9	103.4	95.3	73.5	73.5	J.
	3rd- and 4th-gen. cephalosporins	0.51	0.50	0.49	0.50	0.47	0.43	0.30	0.10	0.08	0.08	0.08	0.07	0.08		
	Quinolones (% fluroquinolones)	2.3 (31%)	2.4 (33%)	2.5 (34%)	2.0 (53%)	2.0 (54%)	2.3 (45%)	0.94 (62%)	0.33 (68%)	0.50 (40%)	0.54 (44%)	0.75 (35%)	0.40 (47%)	0.41 (42%)		
	Polymyxins	6.0	5.4	5.8	4.7	3.4	2.8	2.4	2.1	2.0	1.8	1.6	1.4	0.64		
Bulgaria⁴	Overall sales		92.6	98.9	116.1	82.9	121.8	155.2	129.8	119.6	112.7	120.9	124.5	103.2	155.2 82.9	\sim
	3rd- and 4th-gen. cephalosporins		0.05	0.03	0.12	0.06	0.20	0.10	60.0	60.0	60.0	0.11	0.18	0.25		
	Quinolones (% fluroquinolones)		5.4 (92%)	6.5 (95%)	6.9 (%86)	1.8 (100%)	5.7 (94%)	5.2 (93%)	6.1 (92%) (6.0 (100%) (4.1 (100%) (3.7 (100%) (3.9 (100%) (;	7.8 (100%)		
	Polymyxins		3.2	3.8	2.7	0.5	3.6	2.3	2.9	3.7	1.6	5.2	3.1	3.9		
Undates to sa	¹ Indates to sales data or PCII data as mublished in the FSVAC 2022 report are described in Section 1.5	nublished	in the FSV	VAC 2022	renort ar	e describ	coo ai po									

Table 5. Sales trends for food-producing animals (mg/PCU), including horses and farmed fish, per country^{1,2,3}, from 2010 to 2022

Country		2010	2011	2012	2013	2014	2015	2016	2017	2018	2019	2020	2021	2022	Trends 2010-2022
Croatia	Overall sales					103.5	90.5	83.6	68.0	70.8	62.8	68.6	62.7	56.2	103.5 103.5 56.2
	3rd- and 4th-gen. cephalosporins					0.12	0.19	0.16	0.20	0.33	0.29	0.22	0.22	0.23	
	Quinolones (% fluroquinolones)					4.0 (84%)	3.8 (82%)	3.0 (85%)	2.4 (75%)	3.1 (72%)	2.0 (97%)	2.4 (89%)	2.2 2.6 (100%) (100%)	2.6 (100%)	
	Polymyxins					3.6	2.3	3.4	3.0	2.6	1.5	2.7	3.2	5.6	
Cyprus	Overall sales		332.3	301.9	333.4	317.0	350.2	346.4	335.2	392.3	350.0	344.2	296.5	254.7	392.3 254.7
	3rd- and 4th-gen. cephalosporins		0.14	0.35	0.39	0.64	0.28	0.53	0.30	0.37	0.37	0.37	0.31	0.36	
	Quinolones (% fluroquinolones)		1.7 (26%)	2.8 (21%)	0.92 (78%)	1.2 (62%)	1.2 (74%)	1.6 (75%)	2.2 (84%)	2.9 (89%)	2.2 (89%)	2.3 (85%)	1.9 (97%) (100%)	1.8 (100%)	
	Polymyxins		6.6	6.2	6.6	9.0	10.0	8.5	8.3	10.8	12.3	13.9	12.7	6.3	
Czechia ⁵	Overall sales	94.3	83.0	79.8	82.2	79.8	68.0	61.2	63.5	56.9	53.8	56.2	50.0	46.4	94.3
	3rd- and 4th-gen. cephalosporins	0.37	0.28	0.34	0.41	0.40	0.41	0.41	0.47	0.53	0.53	0.54	0.49	0.46	
	Quinolones (% fluroquinolones)	1.5 (85%)	1.7 (87%)	1.9 (96%)	1.8 (97%)	1.8 (99%)	1.7 (97%)	1.7 (98%)	1.9 (99%)	1.8 (100%)	1.8 (100%)	1.9 1.8 1.8 1.9 1.6 1.6 (99%) (100%) (100%) (100%) (100%) (100%)	1.6 (100%)	1.6 (100%)	
	Polymyxins	0.89	0.58	0.92	1.1	1.0	0.99	0.84	0.60	0.67	0.63	0.59	0.54	0.59	
⁵ For Czechia, s as in the VMP	⁵ For Czechia, strength was reported as the active moiety for most VMPs for 2011–2012; for 2013–2018, strength was reported as on the VMPs' labels; since 2019, strength was reported	the active	e moiety f	for most ^v	/MPs for	2011-20	12; for 20	13-2018	, strengtl	h was rep	orted as	on the VI	APs' label	s; since	2019, strength was reported

Country		2010	2011	2012	2013	2014	2015	2016	2017	2018	2019	2020	2021	2022	Trends 2010-2022
Denmark	Overall sales	47.1	42.1	43.7	44.5	43.8	41.8	40.4	38.9	37.8	37.1	37.2	33.4	34.1	33.4
	3rd- and 4th-gen. cephalosporins	0.05	0.03	0.03	0.02	0.02	<0.01	<0.01	<0.01	<0.01	<0.01	<0.01	<0.01	<0.01	
	Quinolones (% fluroquinolones)	0.34 (1%)	0.15 (4%)	0.86 (1%)	0.40 (2%)	0.71 (1%)	0.42 (1%)	0.37 (1%)	0.26 (1%)	0.38 (1%)	0.19 (1%)	0.23 (1%)	0.15 (2%)	0.16 (1%)	
	Polymyxins	0.26	0.22	0.25	0.25	0.42	0.53	0.54	0.20	<0.01	<0.01	<0.01	0	0	
Estonia	Overall sales	70.8	70.5	62.7	70.1	76.8	64.9	63.7	56.3	52.9	53.5	49.2	46.6	45.8	76.8
	3rd- and 4th-gen. cephalosporins	0.36	0.55	0.61	0.66	0.63	0.61	0.73	0.83	0.91	0.77	0.70	0.53	0.46	
	Quinolones (% fluroquinolones)	2.7 (95%)	2.7 2.3 1.1 (95%) (100%) (100%)	1.1 (100%) (1.7 (100%) (1.6 (100%)	1.8 (100%) (1.8 1.3 1.3 (100%) (100%) (100%)	1.3 (100%) (1.1 (100%) (0.88 (100%) (0.79 (100%)	
	Polymyxins	3.5	4.3	4.9	5.8	3.1	1.3	0.73	1.1	0.83	0.47	0.27	0.19	0.41	
Finland	Overall sales	22.0	21.3	21.3	21.8	21.8	19.9	18.1	18.9	18.2	19.1	16.2	17.0	14.9	22.0
	3rd- and 4th-gen. cephalosporins	<0.01	0.02	0.03	0.02	0.02	0.01	<0.01	<0.01	<0.01	<0.01	<0.01	<0.01	<0.01	
	Quinolones (% fluroquinolones)	0.15 (100%)	0.15 0.16 0.16 (100%) (100%) (100%)		0.16 (100%) (0.18 (100%)	0.14 (100%)	0.15 (100%)	0.12 (100%)	0.13 0.10 0.11 (100%) (100%) (100%)	0.10 (100%)	0.11 (100%) (0.11 (100%) (0.10 (100%)	
	Polymyxins	0	0	0	0	0	0	0	0	0	0	0	0	0	

Country		2010	2011	2012	2013	2014	2015	2016	2017	2018	2019	2020	2021	2022	Trends 2010-2022
France	Overall sales	133.6	114.3	101.1	93.9	105.8	69.4	71.2	68.0	64.2	58.3	56.6	51.7	38.9	133.6 38.9
	3rd- and 4th-gen. cephalosporins	0.30	0.30	0.31	0.29	0.28	0.21	0.06	0.02	0.02	0.02	0.02	0.02	0.02	
	Quinolones (% fluroquinolones)	1.7 (37%)	1.4 (44%)	1.3 (46%)	1.3 (48%)	1.4 (45%)	0.73 (47%)	0.66 (33%)	0.63 (25%)	0.52 (25%)	0.46 (28%)	0.35 (29%)	0.33 (29%)	0.31 (31%)	
	Polymyxins	8.6	7.7	6.7	5.9	7.0	4.0	2.8	2.2	1.8	1.4	1.4	1.3	1.1	
Germany	Overall sales		211.5	204.8	179.7	149.3	98.2	89.2	89.1	88.4	78.6	83.8	73.2	69.9	211.5 211.5 69.9
	3rd- and 4th-gen. cephalosporins		0.40	0.44	0.43	0.42	0.41	0.38	0.39	0.20	0.16	0.15	0.15	0.14	
	Quinolones (% fluroquinolones)		0.91 (100%)	1.2 (100%) (1.4 (100%)	1.4 (100%)	1.1 (100%)	0.91 1.2 1.4 1.4 1.1 1.0 1.1 0.83 (100%) (100%) (100%) (100%) (100%) (100%) (100%)	1.1 100%) (0.88 100%) (0.70 0.76 (100%) (100%)	0.76 100%) (0.67 (100%) (0.64 (100%)	
	Polymyxins		14.8	14.8	14.6	12.2	9.2	7.9	8.5	8.6	7.9	7.3	6.3	5.8	
Greece	Overall sales						58.2	64.8	95.7	93.6	84.8	96.4	108.8	89.0	108.8 58.2
	3rd- and 4th-gen. cephalosporins						0.09	0.10	0.11	0.13	0.08	0.20	0.21	0.19	
	Quinolones (% fluroquinolones)						4.4 (39%)	7.1 (32%)	6.7 (41%)	4.9 (46%)	5.0 (33%)	3.4 (65%)	3.2 (81%)	3.7 (82%)	
	Polymyxins						3.4	1.1	1.3	1.6	1.5	2.0	1.7	1.7	

Country		2010	2011	2012	2013	2014	2015	2016	2017	2018	2019	2020	2021	2022	Trends 2010-2022
Hungary	Overall sales	269.9	192.5	245.7	230.6	193.0	211.4	187.0	190.9	180.5	184.8	163.4	155.6	111.2	269.9
	3rd- and 4th-gen. cephalosporins	0.27	0.14	0.32	0.31	0.25	0.38	0.42	0.45	0.49	0.50	0.49	0.45	0.31	
	Quinolones (% fluroquinolones)	9.1 (97%)	6.9 (97%)	11.2 (98%)	9.4 (%99)	9.4 (97%)	9.7 (%79)	9.8 (98%)	0°6) 0'6	10.9 (99%)	11.9 (99%)	11.9 11.2 (99%) (100%)	14.8 6.6 (100%) (100%)	6.6 (100%)	
	Polymyxins	6.9	8.9	7.8	10.0	7.1	9.6	12.2	14.9	10.1	9.1	7.2	12.1	5.8	
Iceland	Overall sales	6.8	6.0	5.4	4.9	4.8	4.7	4.5	4.4	4.8	3.5	3.8	3.6	4.4	6.8
	3rd- and 4th-gen. cephalosporins	<0.01	0.01	< 0.01	<0.01	<0.01	<0.01	<0.01	<0.01	<0.01	<0.01	<0.01	<0.01	<0.01	
	Quinolones (% fluroquinolones)	0.24 (2%)	0.34 (1%)	0.15 (4%)	0.04 (12%)	<0.01 (100%)	<0.01 (100%) (<0.01 (100%) (<0.01 (100%) (<0.01 (100%)	<0.01 (100%)	<0.01 (100%)	<0.01 (100%) (<0.01 (100%)	
	Polymyxins	0	0	0	0	0	0	0	0	0	0	0	0	0	
Ireland ⁶	Overall sales	51.4	46.4	54.8	55.7	47.5	50.8	52.0	46.5	45.9	40.8	47.0	42.4	33.6	55.7 V
	3rd- and 4th-gen. cephalosporins	0.06	0.07	0.12	0.10	0.13	0.11	0.13	0.14	0.16	0.13	0.16	0.16	0.07	
	Quinolones (% fluroquinolones)	0.38 (100%)	0.38 0.40 0.57 (100%) (100%) (100%)	0.57 (100%)	0.50 (100%)	0.36 (100%)	0.41 (100%) (0.48 (100%) (0.40 (100%) (0.38 (100%)	0.34 (100%)	0.36 (100%)	0.38 (100%) (0.23 (100%)	
	Polymyxins	0	<0.1	>0.1	<0.1	<0.1	<0.1	<0.1	<0.1	<0.1	<0.01	<0.01	0	0	
6 For Ireland, du	⁶ For Ireland, due to commercial confidentiality reasons, the exact sales figures of polymyxins are not included in this table.	entiality re	asons, th	e exact s	ales figur	es of poly	myxins a	are not inc	cluded in	this table	ai				

Country		2010	2011	2012	2013	2014	2015	2016	2017	2018	2019	2020	2021	2022	Trends 2010-2022	-2022
Italy ⁷	Overall sales	421.1	371.0	340.9	301.5	332.3	321.9	294.7	273.7	244.0	191.1	181.8	173.5	157.5	421.1 157 E	1
	3rd- and 4th-gen. cephalosporins	0.35	0.36	0.40	0.38	0.41	0.40	0.38	0.40	0.39	0.19	0.16	0.13	0.09	-	P
	Quinolones (% fluroquinolones)	12.4 (14%)	11.3 (19%)	9.2 (27%)	7.2 (31%)	7.1 (44%)	6.2 (47%)	4.7 (49%)	5.8 (51%)	4.3 (54%)	2.9 (63%)	2.0 (61%)	1.9 (63%)	1.3 (70%)		
	Polymyxins	40.2	30.7	30.1	27.6	29.4	26.1	15.1	5.2	2.7	0.92	0.70	0.65	0.58		
Latvia	Overall sales	39.4	36.7	41.5	37.6	36.6	37.6	29.9	33.2	35.9	28.2	29.6	25.5	20.8	41.5 20.8	The
	3rd- and 4th-gen. cephalosporins	0.22	0.23	0.40	0.40	0.37	0.36	0.26	0.34	0.40	0.39	0.45	0.42	0.36		
	Quinolones (% fluroquinolones)	4.1 (100%)	4.1 2.2 1.7 (100%) (100%) (100%)	1.7 (100%)	2.1 (100%)	1.6 (99%)	1.1 (99%)	0.85 (99%)	1.1 (99%)	0.93 (%66)	0.58 (100%)	0.88 (100%)	0.69 (100%)	0.82 (100%)		
	Polymyxins	0.98	0.99	2.5	1.5	0.79	0.94	0.89	1.3	1.9	0.33	0.22	0.34	0.28		
Lithuania [®]	Overall sales	48.2	41.1	39.1	29.0	35.5	35.0	37.4	34.2	32.7	65.6	60.2	71.2	48.2	29.0	\leq
	3rd- and 4th-gen. cephalosporins	0.02	0.04	0.05	0.17	0.18	0.05	0.13	0.17	0.32	0.34	0.28	0.30	0.42		
	Quinolones (% fluroquinolones)	1.1 (65%)	0.60 (65%)	0.81 (70%)	1.3 (61%)	4.0 (79%)	1.9 (90%)	1.0 (94%)	0.80 (99%)	2.3 (95%)	2.3 (97%)	2.5 (100%)	2.8 (100%)	1.5 (100%)		
	Polymyxins	1.7	1.4	1.3	0.11	0.12	0.61	0.97	0.65	0.24	3.7	5.9	6.5	5.8		
⁷ For Italy, sale e-prescription ⁸ For Lithuania, than those pu	⁷ For Italy, sales data represent sales from MAHs to wholesalers and feed mills for 2010–2019. Since 2020 they represent sales of premixes from MAHs to wholesalers and dispensed e-prescription for all other pharmaceutical forms obtained from wholesalers, pharmacies and others to veterinarians, farmers and companion animal owners. ⁸ For Lithuania, corrections to sales data were made for 2019–2021 during the preparation of this ESVAC report. Consequently, the mg/PCU figures for these years are 2.9–3.5-fold higher than those published in previous ESVAC reports. It is advisable to exercise caution when interpreting trends and drawing conclusions from data for Lithuania up to 2019, as it was not	om MAHs Itical form a were ma AC reports	to wholes s obtained ide for 20 . It is adv	salers and 1 from wf 19–2021 isable to	l feed mil olesalers during th exercise	ls for 201 , pharma e prepara caution w	0-2019. Icies and ation of th hen inter	Since 20, others to his ESVAC preting tr	20 they riverentiar veterinar C report. (epresent ians, farr Conseque drawing	sales of p mers and ently, the conclusi	oremixes compani mg/PCU ons from	from MAH on anima figures fo data for L	ls to who owners, r these) ithuania	vlesalers and disper ears are 2.9–3.5-fi up to 2019, as it w	nsed fold higher was not
feasible to ver	feasible to verify their accuracy or completeness.	npletenes	s. ILIS duv	ואמטוב נט	באבו כופב	רמתרוטון א		ה ביווא נו		l ulawiiiy	colleinsi			Iniualiia	מא וח בעדש, מא ור ש	701 SBV

Luxembourg Overall sales Overall sales 3rd- and 4th-gen. Cephalosporins (% fluroquinolones) Polymyxins Malta Overall sales		43.2 0.68 (97%) 1.7	52.1 0.68	40.6	34.5								52.1	
		0.68 0.68 (97%) 1.7	0.68			35.4	35.1	33.6	29.0	29.0	27.1	25.1	25.1	J.
		0.68 (97%) 1.7	2	0.63	0.62	0.73	0.59	0.59	0.55	0.52	0.46	0.47		
		1.7	1.5 (52%)	0.75 (95%)	0.88 (84%)	0.83 (98%) (0.72 (100%) (0.81 (100%)	0.83 (100%) (0.85 (100%)	0.72 (100%)	0.86 (100%)		
			3.1	2.4	1.5	1.0	0.99	0.59	0.41	0.37	0.25	0.20		
							129.3	153.4	110.3	116.1	110.5	74.4	153.4 74.4	
3rd- and 4th-gen. cephalosporins							0.26	0.20	0.27	0.35	0.28	0.28		
Quinolones (% fluroquinolones)							16.3 (93%)	4.6 (99%)	8.5 (99%)	8.5 4.4 (99%) (100%) (8.5 (100%) (12.6 (100%)		
Polymyxins							4.9	1.9	0.08	0.52	0.32	0.31		
Netherlands ⁹ Overall sales	146.0 113.7	7 74.8	69.9	68.4	64.4	52.7	56.2	57.4	48.2	50.2	47.6	37.0	37.0	<u>}</u>
3rd- and 4th-gen. cephalosporins	0.23 0.19	0.02	<0.01	<0.01	<0.01	<0.01	<0.01	<0.01	<0.01	<0.01	<0.01	<0.01		
Quinolones (% fluroquinolones) (2.1 1.6 (26%) (28%)	5 0.93) (26%)	0.88 (14%)	1.2 (11%)	1.3 (9%)	0.98 (%)	1.0 (7%)	1.2 (6%)	0.84 (7%)	0.85 (5%)	0.66 (5%)	0.78 (4%)		
Polymyxins	2.3 1.6	0.97	0.63	0.47	0.48	0.31	0.29	0.39	0.45	0.45	0.38	0.28		

Movember Overalitiaties 31 31 32 32 33 </th <th>Country</th> <th></th> <th>2010</th> <th>2011</th> <th>2012</th> <th>2013</th> <th>2014</th> <th>2015</th> <th>2016</th> <th>2017</th> <th>2018</th> <th>2019</th> <th>2020</th> <th>2021</th> <th>2022</th> <th>Trends 2010-2022</th>	Country		2010	2011	2012	2013	2014	2015	2016	2017	2018	2019	2020	2021	2022	Trends 2010-2022
$ \frac{11}{1000000000000000000000000000000000$	Norway ¹⁰	Overall sales	3.9	3.5	3.7	3.5	3.0	2.8	2.8	3.0	2.9	2.3	2.3	2.3	2.1	3.9
- entimemonionic simplementation (2.5) (2.5) <th< th=""><th></th><th>3rd- and 4th-gen.</th><th><0.01</th><th><0.01</th><th>< 0.01</th><th><0.01</th><th><0.01</th><th><0.01</th><th><0.01</th><th><0.01</th><th><0.01</th><th><0.01</th><th><0.01</th><th><0.01</th><th><0.01</th><th>2.1</th></th<>		3rd- and 4th-gen.	<0.01	<0.01	< 0.01	<0.01	<0.01	<0.01	<0.01	<0.01	<0.01	<0.01	<0.01	<0.01	<0.01	2.1
Image: bold bold bold bold bold bold bold bold		Quinolones (% fluroquinolones)	0.21 (6%)	0.13 (9%)	0.75 (1%)	0.38 (2%)	0.06 (11%)	0.05 (12%)	0.04 (14%)	0.19 (3%)	0.03 (19%)	0.04 (10%)	0.06 (7%)	0.03 (12%)	0.02 (20%)	
Datate Overall sales 126.3 139.1 139.5		Polymyxins	0	0	0	0	0	0	0	0	0	0	0	0	0	
$ \frac{3 \text{ d-and 4th-gen.}}{\text{ cephalosporins}} & 0.09 & 0.13 & 0.17 & 0.14 & 0.15 & 0.24 & 0.28 & 0.39 & 0.39 & 0.43 \\ \frac{2 \text{ duinolones}}{2 \text{ duinolones}} & 0.39 & 0.99\% & 0.9\% & 0.9\% & 0.0\% & 100\% & 100\% & 100\% & 100\% & 100\% & 100\% & 100\% \\ \frac{2 \text{ duinolones}}{2 \text{ duinolones}} & 9.0 & 0.3 & 0.39 & 0.39\% & 0.34\% & 0.35\% & 0.34\% & 0.34\% & 0.34\% & 0.34\% & 0.34\% & 0.34\% &$	Poland	Overall sales		126.3	134.1	150.3	139.5	137.9	128.4	163.9	168.3	185.2	187.9	175.5		196.0 126.3 126.3
Image: bit is a constrained bit is constrained bit is a constrained bit is a constrained b		3rd- and 4th-gen. cephalosporins		0.09	0.13	0.17	0.17	0.14	0.15	0.24	0.28	0.40	0.38	0.39	0.43	
Polymyxins 4.1 4.0 4.4 5.0 5.5 7.4 7.4 10.6 9.1 8.1 10.2 Portugalit Overall sales 175.1 159.2 155.2 184.8 198.6 168.4 206.4 132.1 183.4 143.8 172.5 149.9 77.1 77.1 Portugalit Overall sales 0.30 0.32 0.26 0.35 0.35 0.35 0.37 206.4 77.1 Portugalit Overall sales 175.1 159.2 155.2 184.8 198.6 168.4 206.4 132.1 183.4 143.8 172.5 149.9 77.1 Portugalit Overall sales 0.32 0.32 0.36 0.46 0.45 0.45 0.56 0.37 0.37 0.34		Quinolones (% fluroquinolones)		7.2 (99%)	8.3 (99%)	8.8 (%66)	0°6 0'6	8.5 (100%)	9.6 (100%)	11.0 (100%)	10.9 (100%)	13.2 (100%)	12.9 (100%)	12.7 (100%) (11.8 (100%)	
Portugalit Overall sales 175.1 159.2 184.8 198.6 168.4 206.4 132.1 183.4 143.8 172.5 149.9 77.1 Portugalit Overall sales 175.1 159.2 184.8 198.6 168.4 206.4 132.1 183.4 143.8 172.5 149.9 77.1 3rd- and 4th-gen 0.30 0.32 0.26 0.36 0.45 0.45 0.56 0.37 0.34 0.24 Value 0.31 0.32 0.26 0.36 0.45 0.45 0.56 0.37 0.34 0.24 (% fluroquinolones) 66.1 88.3 11.4 8.8 8.9 0.35 7.2 8.8 11.8 (% fluroquinolones) (89%) (98%) (98%) (98%) (98%) (99%) (109%) (100%) (100%) (100%) (100%) 100%) 100%) 100% 10.9% 1.8 1.8 1.8 1.8 1.8 1.8 1.8 <t< th=""><th></th><th>Polymyxins</th><th></th><th>4.1</th><th>4.0</th><th>4.4</th><th>5.0</th><th>5.9</th><th>5.6</th><th>7.4</th><th>7.4</th><th>10.6</th><th>9.1</th><th>8.1</th><th>10.2</th><th></th></t<>		Polymyxins		4.1	4.0	4.4	5.0	5.9	5.6	7.4	7.4	10.6	9.1	8.1	10.2	
3rd- and 4th-gen. 0.30 0.32 0.26 0.35 0.45 0.45 0.45 0.45 0.45 0.35 0.37 0.34 0.24 cephalosporins 6.1 8.7 9.5 8.8 11.4 8.8 3.5 7.5 6.1 7.2 8.8 11.8 (% fluroquinolones) (89%) 98%) (98%) (99%) (100%) (100%) (100%) (100%) (100%) 11.8 Polymyxins 14.9 7.8 18.7 17.3 14.4 13.4 10.7 12.4 8.3 11.8 Polymyxins 14.9 7.8 18.7 17.3 14.4 13.4 10.7 12.4 8.3 11.8	Portugal ¹¹	Overall sales	175.1	159.2	155.2	184.8	198.6	168.4	206.4	132.1	183.4	143.8	172.5	149.9		206.4 W
Operation Operation 6.1 8.7 9.5 8.3 11.4 8.8 8.9 3.5 7.5 6.1 7.2 8.8 11.8 (% fluroquinolones) (89%) (98%) (98%) (98%) (98%) (98%) (100%)		3rd- and 4th-gen. cephalosporins	0.30	0.32	0.26	0.36	0.42	0.45	0.45	0.56	0.35	0.29	0.37	0.34	0.24	
Polymyxins 14.9 7.8 18.4 18.7 17.3 14.4 13.4 10.7 12.4 8.3 11.4 6.1 1.8 ¹⁰ For Norway, corrections to the number of packs sold for farmed fish in 2021 (1 product), resulted in a sales decrease of 6.5% (from 2.5 to 2.3 mg/PCU) compared to		Quinolones (% fluroquinolones)	6.1 (89%)	8.7 (95%)	9.5 (98%)	8.3 (98%)	11.4 (98%)	8.8 (98%)	6.8 (%66)	3.5 (100%)	7.5 (100%)	6.1 (100%)	7.2 (100%)	8.8 (100%) (11.8 (100%)	
¹⁰ For Norway, corrections to the number of packs sold for farmed fish in 2021 (1 product), resulted in a sales decrease of 6.5% (from 2.5 to 2.3 mg/PCU) compared to		Polymyxins	14.9	7.8	18.4	18.7	17.3	14.4	13.4	10.7	12.4	8.3	11.4	6.1	1.8	
previous ECVARD Experts. 11 For Provincial 2010 - 12012 - 2017 and 2019 calas are undersetimates due to underrenorting	¹⁰ For Norway, c previous ESV, ¹¹ For Dortingal	corrections to the numbe AC reports. 2010-2014 2017 and 2	er of packs	sold for	farmed fi: restimate	sh in 202. s dua to	1 (1 prod	luct), res	ulted in a	sales de	crease of	⁻ 6.5% (fr	om 2.5 tc	, 2.3 mg/	PCU) con	npared to figures published ir

Country		2010	2011	2012	2013	2014	C102	2016	7107	2012	2019	2020	1202	7707	ILGUAS ZULU-ZUZZ
cinemo	Outraino Seles					000	100 1	85 J	0	7 C8	ט איס	57 R	C G	α α	109.0
3								1	1.00	0.70					48.8
	3rd- and 4th-gen. cephalosporins					0.05	0.04	0.08	0.16	0.19	0.10	0.18	0.16	0.13	
	Quinolones (% fluroquinolones)					5.5 (96%)	6.3 (97%)	3.5 (94%)	4.5 (96%)	6.0 (100%)	5.3 (99%)	5.7 (99%)	8.9 (%66)	5.6 (99%)	
	Polymyxins					6.5	7.4	5.6	4.1	6.4	2.5	2.2	2.2	2.7	
Slovakia ¹²	Overall sales		43.6	43.3	59.2	65.6	50.8	50.3	61.8	49.2	42.3	51.9	41.7	41.1	65.6
	3rd- and 4th-gen. cephalosporins		0.65	0.53	0.40	0.45	0.34	0.36	0.41	0.44	0.43	0.50	0.51	0.46	
	Quinolones (% fluroquinolones)		3.3 (90%)	3.3 3.2 (90%) (100%)	2.9 (96%)	4.2 (99%)	2.9 (99%)	3.6 (99%)	3.4 (99%)	3.0 (%66)	3.2 (99%)	3.4 (99%)	3.4 3.2 (100%) (100%)	3.2 (100%)	
	Polymyxins		1.2	2.1	1.1	1.5	1.1	1.2	1.7	1.4	1.3	2.0	1.4	1.6	
Slovenia	Overall sales	46.8	46.0	36.9	22.3	33.3	26.3	30.3	36.6	43.2	44.9	33.3	31.8	25.7	46.8
	3rd- and 4th-gen. cephalosporins	0.11	0.09	0.17	0.12	0.14	0.17	0.16	0.16	0.20	0.23	0.22	0.20	0.24	
	Quinolones (% fluroquinolones)	2.7 (95%)	(%66) (%66)	6.0 4.1 (99%) (100%)	1.8 (99%)	4.0 (100%)	3.1 (100%)	2.9 (99%)	2.9 (100%)	2.8 1.8 (100%) (100%)	1.8 (100%)	0.99 (100%)	0.89 (100%) (0.89 (100%)	
	Polymyxins	0.06	0.12	0.09	0.04	0.07	0.10	0.14	0.11	0.21	0.08	0.09	0.05	0.08	
¹² For Slovakia, pharmacies,	¹² For Slovakia, for 2011 and 2012, the data only represent antibiotic 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).	data only feeding st	represen uffs and f	t antibiot Farmers, c	ic VMPs ir btained ł	nported l oy import	y wholes and from	alers; fro า national	m 2013, manufac	data repi cturers).	esent all	sales froi	n wholes	alers to e	end users (veterinarians

Country		2010	2011	2012	2013	2014	2015	2016	2017	2018	2019	2020	2021	2022	Trends 2010-2022
Spain ¹³	Overall sales	259.5	335.8	302.3	317.0	418.8	402.0	362.4	230.3	219.0	126.7	154.3	157.2	127.4	418.8 126.7
	3rd- and 4th-gen. cephalosporins	0.67	0.26	0.26	0.28	0.33	0.31	0.30	0.23	0.40	0.28	0.36	0.33	0.19	
	Quinolones (% fluroquinolones)	9.5 (93%)	9.8 (94%)	10.9 (94%)	9.9 (94%)	10.8 (92%)	9.7 (92%)	9.3 (92%)	5.3 (94%) (5.3 5.6 3.6 3.7 (94%) (100%) (100%) (100%)	3.6 (100%)	3.7 (100%)	3.7 (90%)	3.3 (99%)	
	Polymyxins	33.0	33.5	29.4	21.5	36.1	34.9	22.0	4.4	3.3	06.0	0.43	0.39	0.38	
Sweden ¹⁴	Overall sales	14.7	13.1	13.0	12.2	11.1	11.4	11.7	11.6	12.1	11.4	12.2	12.1	10.6	14.7 10.6
	3rd- and 4th-gen. cephalosporins	>0.01	>0.01	>0.01	<0.01	<0.01	<0.01	<0.01	<0.01	<0.01	<0.01	<0.01	<0.01	<0.01	
	Quinolones	0.13	0.10	0.10	0.05	0.03	0.02	0.07	0.06	0.12	0.06	0.10	0.13	0.02	
	Polymyxins	>0.1	<0.1	<0.1	<0.1	<0.1	>0.1	<0.1	<0.1	<0.1	< 0.1	<0.1	<0.1	<0.1	
Switzerland	Overall sales					56.8	50.6	46.6	40.1	40.2	35.7	34.3	32.0	27.3	56.8
	3rd- and 4th-gen. cephalosporins					0.22	0.20	0.16	0.17	0.15	60.0	0.07	0.07	0.06	
	Quinolones (% fluroquinolones)					0.46 (100%)	0.47 (100%)	0.35 (100%) (0.26 (100%) (0.23 (100%) (0.21 (100%)	0.24 (100%)	0.20 (100%) (0.16 (100%)	
	Polymyxins					0.95	0.62	0.46	0.41	0.29	0.25	0.18	0.11	<0.1	
¹³ For Spain, 20 ¹⁴ For Sweden, 1 2019 (2.3%, cline, thus col of commercial	¹³ For Spain, 2010–2013 sales are underestimates due to underreporting. Since 2017, retailers have been the sales data providers (previously MAHs). ¹⁴ For Sweden, there was no reporting of sales for use in farmed fish in 2012. Corrections were made to sales data for 2017–2021, resulting in a minor increase in sales in mg/PCU for 2019 (2.3%, 0.1% and 3.5%, respectively) compared to figures published in previous ESVAC reports. The updated 2017 sales include products for fish containing florfenicol and ox cline, thus completing the reporting for fish. The updates to 2020 and 2021 data resulted in an increase of sales for food-producing animals of 10.3% and 10.6%, respectively. For rol cline, thus completing the reporting for fish. The updates to 2020 and 2021 data resulted in an increase of sales for food-producing animals of 10.3% and 10.6%, respectively. For rol commercial confidentiality, exact sales figures of 3rd- and 4th-generation cophalosporins and polymyxins, as well as the % of fluoroquinolone sales, are not included in this table.	erestimate f sales for cively) com or fish. The iles figures	s due to u use in far npared to e updates s of 3rd- a	anderrepc med fish figures pu to 2020 a and 4th-g	in 2012. (in 2012. (Jblished ir and 2021 eneration	ce 2017, Correctior n previous data resu cephalos	retailers ns were m s ESVAC r llted in an porins an	have bee nade to sa reports. Th increase d polymyy	n the sale les data f he update of sales f kins, as w	es data p or 2017- ed 2017 s or food-p ell as the	roviders 2021, res ales inclu roducing % of flu	(previous sulting in de produ animals o proquinolo	ly MAHs), a minor ii cts for fisl of 10.3% one sales,	ncrease i ncontain and 10.6 are not	¹³ For Spain, 2010–2013 sales are underestimates due to underreporting. Since 2017, retailers have been the sales data providers (previously MAHs). ¹⁴ For Sweden, there was no reporting of sales for use in farmed fish in 2012. Corrections were made to sales data for 2017–2021, resulting in a minor increase in sales in mg/PCU for 2017– 2019 (2.3%, 0.1% and 3.5%, respectively) compared to figures published in previous ESVAC reports. The updated 2017 sales include products for fish containing florfenical and oxytetracy- cline, thus completing the reporting for fish. The updates to 2020 and 2021 data resulted in an increase of sales for food-producing animals of 10.3% and 10.6%, respectively. For reasons of commercial confidentiality, exact sales figures of 3rd- and 4th-generation cephalosporins and polymyxins, as well as the % of fluoroquinolone sales, are not included in this table.
		1					_								



Austria	Tonnes active substance	62.6	53.2	52.9	54.7	53.4	48.5	44.1	44.6	48.0	40.5	43.7	39.1	34.3	62.6
	PCU (1,000 tonnes)	994.2	976.5	965.7	957.0	948.3	956.8	957.1	953.9	957.2	950.7	942.3	945.4	946.4	
Belgium	Tonnes active substance	298.8	296.9	270.1	259.2	265.4	257.7	239.9	220.7	194.8	175.1	180.4	168.6	120.2	298.8
	PCU (1,000 tonnes)	1,660.5 1,695.3 1,658.3	1,695.3		1,657.5	1,678.0	1,719.4	1,715.1	1,683.1	1,724.4	1,717.3	1,657.5 1,678.0 1,719.4 1,715.1 1,683.1 1,724.4 1,717.3 1,745.3 1,769.5 1,634.6	1,769.5 1	,634.6	
Bulgaria³	Tonnes active substance		36.9	38.4	46.5	32.6	46.3	61.0	49.6	47.8	43.4	44.5	48.7	37.0	61.0 32.6
	PCU (1,000 tonnes)		398.6	388.2	400.9	393.5	380.0	393.2	381.9	399.9	385.5	368.4	391.3	358.0	
Croatia	Tonnes active substance					31.3	27.8	26.6	21.1	22.0	20.1	22.6	20.7	17.1	31.3
	PCU (1,000 tonnes)					302.3	307.4	317.7	310.4	311.1	319.4	328.9	330.8	304.1	
Cyprus	Tonnes active substance		51.7	45.0	47.9	41.7	46.9	46.3	45.4	53.4	49.4	48.3	45.1	35.6	53.4 W
	PCU (1,000 tonnes)		155.7	148.9	143.7	131.6	133.9	133.7	135.5	136.2	141.1	140.3	152.0	139.7	

Table 6. Trends in sales of all antibiotic active substances (tonnes) for food-producing animals and PCU (in 1,000 tonnes) by country from 2010 to 2022^{1,2}

Country		2010	2011	2012	2013	2014	2015	2016	2017	2018	2019	2020	2021	2022	Trends 2010-2022
Czechia ⁴	Tonnes active substance	71.2	60.8	53.7	57.2	56.1	47.5	43.1	44.0	40.1	37.7	39.3	35.5	32.3	71.2 32.3
	PCU (1,000 tonnes)	755.2	732.2	672.8	696.8	702.6	698.1	704.9	693.1	704.6	702.0	699.3	709.0	696.7	
Denmark	Tonnes active substance	118.0	104.4	106.0	107.5	105.8	100.9	97.7	93.4	92.6	87.7	88.7	81.9	80.2	80.2
	PCU (1,000 tonnes)	2,503.3 2,478.7 2,424.3	2,478.7	2,424.3	2,417.2	2,415.3	2,415.3 2,415.4 2,419.7		2,397.6 2,446.7 2,362.4 2,384.7 2,452.1	2,446.7	2,362.4	2,384.7		2,355.9	
Estonia	Tonnes active substance	7.6	7.5	7.3	8.5	9.8	8.0	7.2	6.2	6.0	6.1	5.7	5.3	5.2	9.8
	PCU (1,000 tonnes)	107.7	106.4	116.8	121.2	127.3	123.4	112.7	110.9	114.0	114.9	115.9	114.4	114.5	
Finland	Tonnes active substance	11.4	11.1	10.9	11.2	11.1	10.3	9.4	9.6	0.6	9.4	8.0	8.4	7.2	7.2
	PCU (1,000 tonnes)	516.9	520.0	511.1	514.4	509.4	519.0	520.7	507.5	496.8	494.4	494.4	492.0	484.8	
France	Tonnes active substance	999.5	890.1	761.5	680.8	761.3	501.4	513.6	482.9	456.0	407.4	394.4	349.3	255.2	999.5 255.2
	PCU (1,000 tonnes)	7,478.8 7,784.8 7,529.5	7,784.8	7,529.5	7,247.1	7,196.7	7,221.6	7,217.0	7,247.1 7,196.7 7,221.6 7,217.0 7,096.6 7,107.0 6,985.4 6,964.9 6,758.1	7,107.0 (5,985.4	6,964.9		6,561.4	
Germany	Tonnes active substance		1,818.9 1,708.0	1,708.0	1,531.9 1,305.9	1,305.9	853.7	779.4	766.8	753.1	654.5	684.6	590.7	531.1	1,818.9
	PCU (1,000 tonnes)		8,599.7	8,337.9	8,525.6	8,748.6 8,690.2		8,734.0 8,608.8	8,608.8	8,517.6	8,327.2	8,172.8 8,071.2	8,071.2	7,600.9	
⁴ For Czechia, st	trength was reported	as the acti	ve moiet	y for mos	t VMPs fo	r 2011–2	012; for	2013-20:	18, streng	jth was r€	sported a	s on the	VMPs' lab	els; since	⁴ For Czechia, strength was reported as the active moiety for most VMPs for 2011–2012; for 2013–2018, strength was reported as on the VMPs' labels; since 2019, strength was reported

as in the VMPs' Summary of Product Characteristics.

Terres Torres active substance Torres active substance Torres <	Country		2010	2011	2012	2013	2014	2015	2016	2017	2018	2019	2020	2021	2022	Trends 2010-2022
Image: Difference of the problem of the pr	Greece	Tonnes active substance						72.6	79.9		112.9	8.66	108.4	119.7	101.7	119.7 72.6
Interactive substance 2074 147.5 178.6 178.0 155.5 147.2 150.1 152.1 131.6 92.6 92.6 I, 000 tommes 768.4 766.5 727.0 763.1 779.1 832.5 81.7 770.9 831.8 823.1 833.0 845.8 832.9 I I, 000 tommes 0.77 0.69 0.62 0.57 0.55 0.56 0.55 0.55 0.56 0.55 <		PCU (1,000 tonnes)						1,247.1	1,232.7	1,218.2	1,206.1	1,175.8	1,124.1	1,099.9	1,141.9	
PCU (1,000 tornes) 768.4 766.5 727.0 763.1 779.1 832.5 831.7 770.9 831.8 823.1 833.0 845.8 832.9 Intersective substance 0.77 0.69 0.65 0.55 0	Hungary	Tonnes active substance	207.4	147.5					155.5	147.2	150.1	152.1	136.1	131.6	92.6	207.4 207.4 207.4 207.6
Interactive substance 0.77 0.69 0.62 0.55 0.55 0.55 0.55 0.55 0.55 0.55 0.65		PCU (1,000 tonnes)	768.4	766.5		763.1		832.5	831.7	770.9	831.8	823.1	833.0	845.8	832.9	
Image: Condition connective control connective connectine connectine connective connective connective connective connect	Iceland	Tonnes active substance	0.77	0.69				0.55	0.54	0.55	0.55	0.46	0.52	0.53	0.62	0.8
Tonnes active substance 91.3 82.0 94.5 98.1 88.6 96.1 102.0 98.3 87.5 102.9 93.2 75.6 75.6 (1,000 tonnes) 1,778.5 1,769.7 1,775.1 1,761.6 1,866.4 1,892.3 1,962.7 2,114.1 2,144.0 2,189.8 2,196.1 2,246.0 Tonnes active 1,925.6 1,534.1 1,318.3 1,321.9 1,292.8 1,057.5 931.8 731.3 689.3 661.7 585.4 585.4 (1,000 tonnes) 4,572.5 4,499.9 4,371.9 3,977.4 4,037.6 4,115.8 3,863.8 3,819.3 3,812.6 3,716.3 3,85.4 585.4		PCU (1,000 tonnes)	112.7	113.5		115.2		116.4	120.1	125.1	116.4	131.3	135.3	144.8	140.2	
PCU 1,778.5 1,769.7 1,761.6 1,866.4 1,892.3 1,962.7 2,114.1 2,144.0 2,189.8 2,196.1 2,246.0 Tonnes active 1,925.6 1,668.1 1,534.1 1,318.3 1,321.9 1,299.8 1,213.0 1,057.5 931.8 731.3 689.3 661.7 585.4 PCU 1,925.6 1,668.1 1,534.1 1,318.3 1,213.0 1,057.5 931.8 731.3 689.3 661.7 585.4 PCU 9.00 tonnes 4,572.5 4,499.9 4,371.9 3,977.4 4,037.6 4,115.8 3,863.8 3,819.3 3,812.6 3,716.3	Ireland	Tonnes active substance	91.3	82.0			88.6		102.0	98.2	98.3	87.5	102.9	93.2	75.6	
Tonnes active 1,925.6 1,668.1 1,534.1 1,318.3 1,299.8 1,213.0 1,057.5 931.8 731.3 689.3 661.7 585.4 substance 0 4,572.5 4,496.7 4,499.9 4,371.9 3,977.4 4,037.6 4,115.8 3,863.8 3,819.3 3,812.6 3,716.3		PCU (1,000 tonnes)	1,778.5	1,769.7	1,725.1	1,761.6	1,866.4	1,892.3	1,962.7	2,114.1	2,142.1	2,144.0	2,189.8	2,196.1	2,246.0	
4,572.5 4,496.7 4,499.9	Italy ⁵	Tonnes active substance	1,925.6	1,668.1	1,534.1	1, 318.3	1,321.9	1,299.8	1,213.0	1,057.5	931.8	731.3	689.3	661.7	585.4	1,925.6
		PCU (1,000 tonnes)	4,572.5	4,496.7	4,499.9		3,977.4	4,037.6	4,115.8	3,863.8	3,819.3	3,827.5	3,790.4	3,812.6	3,716.3	

Country		2010	2011	2012	2013	2014	2015	2016	2017	2018	2019	2020	2021	2022	Trends 2010-2022
Latvia	Tonnes active substance	6.5	6.3	6.7	6.3	6.3	6.8	5.4	5.9	6.0	4.5	4.7	3.9	3.4	6.8 3.4
	PCU (1,000 tonnes)	164.7	170.7	161.9	167.1	173.0	180.3	180.0	176.3	167.3	161.3	157.6	152.6	163.7	
Lithuania	Tonnes active substance	16.5	13.8	13.3	9.9	11.9	11.9	12.7	11.5	10.7	20.4	18.2	21.1	14.5	21.1 9.9
	PCU (1,000 tonnes)	341.7	336.5	339.4	339.5	335.0	338.9	339.5	336.8	327.6	310.7	302.6	296.6	300.1	
Luxembourg	Tonnes active substance			2.2	2.7	2.1	1.8	1.9	1.9	1.8	1.6	1.6	1.5	1.3	2.7 1.3
	PCU (1,000 tonnes)			50.4	51.0	52.0	52.8	54.6	54.7	54.7	53.8	54.4	54.2	51.1	
Malta	Tonnes active substance								1.8	2.1	1.5	1.7	1.6	1.1	2.1 1.1
	PCU (1,000 tonnes)								13.7	14.0	13.8	14.7	14.8	15.3	
Netherlands ⁷	Tonnes active substance	460.8	362.3	245.3	225.4	214.4	213.6	181.6	187.9	183.8	153.1	156.4	147.2	112.0	460.8
	PCU (1,000 tonnes)	3,155.3 3,185.9 3,279.1	3,185.9	3,279.1 3	3,226.3	3,135.2	3,318.0	3,445.7	3,226.3 3,135.2 3,318.0 3,445.7 3,340.7 3,200.8 3,172.4 3,114.9 3,091.9 3,025.4	3,200.8	3,172.4	3,114.9	3,091.9 3	3,025.4	
6 For Lithuania, aubliched in au	For Lithuania, corrections to sales data were made for 2019–2021 during the preparation of this ESVAC report. Consequently, figures for these years are 2.9 - 3.5-fold higher than the	lata were m	ade for 2	019-202	1 during	the prepa	aration of	this ESV/	AC report	. Consequ	uently, fig	ures for	chese yea	rs are 2.	⁶ For Lithuania, corrections to sales data were made for 2019–2021 during the preparation of this ESVAC report. Consequently, figures for these years are 2.9 - 3.5-fold higher than those

published in previous ESVAC reports. It is advisable to exercise caution when interpreting trends and drawing conclusions from data for Lithuania up to 2019, as it was not feasible to verify their accuracy or completeness. For the Netherlands, strength was reported as the active moiety for some VMPs for 2011–2012; for 2013–2018, strength was reported as on the labels of the VMPs; since 2019, strength was reported as in the VMPs' Summary of Product Characteristics.

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Norway* Tonnes active substance 6.2 6.0 6.9 6.4 5.4 5 Image (1,000 tonnes) 1,572.4 1,715.3 1,886.5 1,901.6 1,948.0 1,896 Poland Tonnes active substance 500.3 528.5 576.6 578.4 582.6 579 Poland Tonnes active substance 3,962.8 3,941.1 3,837.5 4,145.1 4,226.2 4,442 Poland Tonnes active 181.5 164.5 156.6 1794 1000 169.8 211 Portugal* Tonnes active 181.5 164.5 156.6 1794 190.0 169.8 2102 Portugal* Tonnes active 181.5 164.5 156.6 1794 190.0 169.8 2102 Portugal* Tonnes active 181.5 164.5 156.6 1794 190.0 169.8 1022 Portugal* Tonnes active 181.5 164.5 1503.1 1,003.1 1,022 2102 <	2014 2015 2016 2017 2018 2019 2020 2021 2022 Trends 2010-2022
(1,000 tonnes) 1,572.4 1,715.3 1,886.5 1,824.1 1, Tonnes active 500.3 528.5 576.6 576.6 Tonnes active 3,962.8 3,941.1 3,837.5 4, Tonnes active 181.5 164.5 156.6 179.4 Tonnes active 1,036.6 1,033.1 1,009.3 971.0 Tonnes active 1,036.6 1,033.1 1,009.3 2, Tonnes active 10.00 10.2 2, 2, Tonnes active 10.8 10.2 2, 3,	5.6
Tonnes active substance 500.3 528.5 576.6 substance 3,962.8 3,941.1 3,837.5 4, (1,000 tonnes) 3,962.8 3,941.1 3,837.5 4, Tonnes active 181.5 164.5 156.6 179.4 (1,000 tonnes) 181.5 164.5 156.6 179.4 Tonnes active 181.5 164.5 156.6 179.4 Tonnes active 181.5 164.5 156.6 179.4 (1,000 tonnes) 1,036.6 1,033.1 1,009.3 971.0 Tonnes active 1,036.6 1,033.1 1,009.3 971.0 (1,000 tonnes) 1,036.6 1,033.1 1,009.3 971.0 Tonnes active 1,036.6 1,033.1 1,009.3 2, (1,000 tonnes) 10.08 10.2 2, Tonnes active 10.8 10.2 2,	5 1,824.1 1,901.6 1,948.0 1,896.4 1,861.2 1,927.5 1,999.6 2,030.8 2,196.9 2,198.1
Tonnes active 3,962.8 3,941.1 3,837.5 4, Tonnes active 181.5 164.5 156.6 179.4 Tonnes active 1,036.6 1,033.1 1,009.3 971.0 Tonnes active 2, 2, 2, 2, Tonnes active 10.8 10.2 14.6	578.4
Tonnes active substance 181.5 164.5 156.6 179.4 Substance 1,036.6 1,033.1 1,009.3 971.0 (1,000 tonnes) 1,036.6 1,033.1 1,009.3 971.0 Tonnes active substance 1,036.6 1,033.1 1,009.3 971.0 Tonnes active substance 1,036.6 1,033.1 1,009.3 2, Tonnes active substance 10.8 10.2 14.6	3,837.5 4,145.1 4,226.2 4,442.8 4,574.4 4,672.6 4,538.0 4,541.7 4,417.2 4,277.7
PCU (1,000 tonnes) 1,036.6 1,033.1 1,009.3 971.0 Tonnes active substance Tonnes active 2, 2, Tonnes active substance 10.8 10.2 14.6	190.0
Tonnes active substance (1,000 tonnes) Tonnes active 10.8 10.2 14.6 substance	957.0 1,008.3 1,022.1 1,023.2 1,046.1 1,039.8 1,031.2 1,063.3 1,062.4
PCU (1,000 tonnes) Tonnes active 10.8 10.2 14.6 substance	
Tonnes active 10.8 10.2 14.6 16.3 12.6 substance	2,501.8 2,558.6 3,116.1 2,916.2 2,788.2 3,134.6 3,003.7 2,942.8 2,794.4
	16.3
PCU (1,000 tonnes) 248.2 236.0 247.2 249.2 247.3 242	249.2

⁹ FORTIGN, 2010–2014, 2017 and 2019 sales are underestimates due to underreporting. ¹⁰ For Slovakia, for 2011 and 2012, the data only represent antibiotic 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).

Country		2010	2011	2012	2013	2014	2015	2016	2017	2018	2019	2020	2021	2022	Trends 2010-2022
Slovenia	Tonnes active substance	8.8	8.4	6.8	4.0	5.7	4.6	5.4	6.7	7.8	7.9	5.9	5.8	4.7	8.4
	PCU (1,000 tonnes)	179.8	181.6	183.4	180.2	171.2	173.1	178.1	183.9	179.8	177.1	176.0	183.7	182.4	
Spain ¹¹	Tonnes active substance	1,804.6 2,390.7 2,115.1	2,390.7	2,115.1	2,201.3	2,964.2	3,027.8	2,724.7	2,201.3 2,964.2 3,027.8 2,724.7 1,769.6 1,722.5 1,007.2 1,244.5 1,296.5 1,027.2	1,722.5	1,007.2	1,244.5	1,296.5	1,027.2	3,027.8
	PCU (1,000 tonnes)	6,955.1 7,120.2 6,996.1	7,120.2	6,996.1	6,943.6 7,077.1	7,077.1	7,531.8	7,517.7	7,517.7 7,684.5	7,865.4 7,950.0 8,067.5	7,950.0	8,067.5	8,245.0 8,063.3	3,063.3	
Sweden ¹²	Tonnes active substance	12.2	10.9	10.2	9.7	9.0	9.2	9.4	9.3	9.6	8.9	9.6	9.5	8.3	8.3
	PCU (1,000 tonnes)	832.3	836.0	782.6	795.6	810.8	808.4	805.0	804.1	782.7	781.1	786.0	787.6	788.1	
Switzerland	Tonnes active substance					46.4	41.2	37.6	31.9	32.9	29.2	27.7	25.9	22.6	22.6
	PCU (1,000 tonnes)					818.0	814.4	805.8	795.9	818.5	817.4	806.1	809.8	829.0	
United Kingdom	Tonnes active substance	455.0	342.9	447.1	425.2	431.1	393.4	278.6	231.1	209.4	216.2	215.2	199.5	181.1	455.0 V
	PCU (1,000 tonnes)	6,714.0 6,724.4 6,749.2	6,724.4	6,749.2	6,799.1	6,914.7	6,961.4	7,142.4 7,202.1		7,215.7	7,099.9	7,115.2	7,053.9	7,037.5	
¹¹ For Spain, 20 ¹² For Sweden, 1 2017-2019 (2 oxytetracyclin	For Spain, 2010-2013 sales are underestimates due to underreporting. Since 2017, retailers have been the sales data providers (previously MAHs). For Sweden, there was no reporting of sales for use in farmed fish in 2012. Corrections were made to sales data for 2017-2021, resulting in a minor increase in sales 2017-2019 (2.2%, 0.1% and 3.3%, respectively) compared to figures published in previous ESVAC reports. The updated 2017 sales include products for fish contain oxytetracycline, thus completing the reporting for fish. The updates to 2020 and 2021 data resulted in an increase of sales in tonnes of 9.6% and 9.9%, respectively.	iderestimat g of sales f 6, respectiv 1e reporting	es due to or use in 'ely) com J for fish.	o underre farmed f pared to . The upd	Porting. S Tish in 201 figures p ates to 20	Since 201 L2. Corre ublished 220 and 3	7, retaile ctions we in previou 2021 data	rrs have b re made us ESVAC a resulted	een the s to sales d reports. ' in an inc	ales data ata for 20 The updat rease of s	provider 017-2021 ted 2017 sales in to	s (previou L, resultin sales inc onnes of 9	usly MAH: g in a mi lude prod 9.6% and	s). nor incre lucts for 1 1 9.9%, ri	¹¹ For Spain, 2010–2013 sales are underestimates due to underreporting. Since 2017, retailers have been the sales data providers (previously MAHs). ¹² For Sweden, there was no reporting of sales for use in farmed fish in 2012. Corrections were made to sales data for 2017–2021, resulting in a minor increase in sales in tonnes for 2017–2019 (2.2%, 0.1% and 3.3%, respectively) compared to figures published in previous ESVAC reports. The updated 2017 sales include products for fish containing florfenicol and oxytetracycline, thus completing the reporting for fish. The updates to 2020 and 2021 data resulted in an increase of sales in tonnes of 9.6% and 9.9%, respectively.
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2.3. Sales of tablet antibiotic VMPs for companion animals in 2022

This section presents overall tablet sales, which are excluded from the analysis for food-producing animals (in mg/PCU) because it is assumed that tablets are almost solely used for companion animals, and animal population data of dogs and cats are not available for all participating countries. Nevertheless, some tablet formulations are not exclusively marketed for companion animals and are also authorised for use in food-producing or fur animals, e.g. foxes, nutria and mink. Therefore, the data presented in this section should be interpreted with caution. Direct comparisons between reporting countries are also not advised because the tablet sales data are not normalised by the biomass of animals that could be treated with these products.

Tablets All other products forms Total Country Tonnes % of overall Tonnes % of overall tonnes sales sales Austria 0.54 1.5% 34.3 98.5% 34.8 1.9% 120.2 Belgium 2.4 98.1% 122.6 Bulgaria 0.17 0.45% 37.0 99.5% 37.1 Croatia 0.18 1.1% 17.1 98.9% 17.3 Cyprus 0.07 0.20% 35.6 99.8% 35.7 Czechia 1.3 3.8% 32.3 96.2% 33.6 Denmark 0.64 0.79% 80.2 99.2% 80.9 Estonia 0.19 3.6% 5.2 96.4% 5.4 Finland 0.77 9.7% 7.2 90.3% 8.0 France 17.3 6.3% 255.2 93.7% 272.5 10.8 2.0% 541.9 Germany 531.1 98.0% 0.61 0.59% 101.7 99.4% 102.3 Greece Hungary 0.60 0.65% 92.6 99.4% 93.2 0.05 Iceland 7.3% 0.62 92.7% 0.67 Ireland 0.93 1.2% 75.6 98.8% 76.5 Italy 6.6 1.1% 585.4 98.9% 592.0 Latvia 0.22 6.0% 3.4 94.0% 3.6 Lithuania¹ 0 0% 14.5 100.0% 14.5 Luxembourg 0.13 9.4% 1.3 90.6% 1.4 Malta 8.5% 91.5% 1.2 0.11 1.1 Netherlands 2.7 2.4% 112.0 97.6% 114.7 Norway 0.38 7.6% 4.7 92.4% 5.1 Poland 3.7 0.43% 838.3 99.6% 842.0 Portugal 1.4 1.7% 82.0 98.3% 83.4 Romania 3.2 2.3% 136.4 97.7% 139.6 Slovakia 0.35 3.7% 9.2 9.6 96.3% Slovenia 0.37 7.3% 4.7 92.7% 5.1 2.0 0.19% 1,027.2 99.8% 1,029.2 Spain Sweden 0.61 6.8% 8.3 93.2% 9.0 Switzerland 0.70 3.0% 22.6 97.0% 23.4 United Kingdom 193.0 11.9 6.2% 181.1 93.8% **Total 31 countries** 70.8 1.6% 4,458.1 98.4% 4,528.9

Table 7. Overall sales, in tonnes of active substance, split by tablets (used mainly in companion animals) and all other product forms (used mainly in food-producing animals), by country, in 2022

¹ Lithuania did not report tablet sales for 2019–2022.

In 2022, tablet sales accounted for a minor proportion (1.6%) of the total sales, in tonnes, of antibiotic VMPs in the 31 countries reporting data for ESVAC. However, at country level, tablet sales ranged between 0.19% (excluding Lithuania as tablet sales were not reported for 2022) and 9.7% of total sales, and in 10 countries represented more than 5% of total sales (Table 7).

Figure 19 shows the proportion of tablet sales, in tonnes of active substance, by antibiotic class and country in 2022. Although tablet sales patterns varied substantially between countries, penicillins constituted the highest selling tablet antimicrobial class in 28 countries. Aggregated by all countries, penicillins accounted for 48.8% (34.5 tonnes) of all tablet sales, followed by 1st- and 2nd-generation cephalosporins with 19.8% (14.0 tonnes), macrolides with 4.7% (3.3 tonnes), and tetracyclines and sulfonamides, representing 4.1% (2.9 tonnes) and 3.9% (2.8 tonnes) of tablet sales, respectively (Figure 19).

Figure 19. Proportion of tablet sales, in tonnes of active substance, by antibiotic class (reported according to the ATCvet hierarchical system) in 31 European countries in 2022^{1,2,3,4}



* 'Other classes' includes small quantities of aminoglycosides (0.62%), amphenicols (0.03%), pleuromutilins (<0.001%), polymyxins (<0.001%) and 'Others' (12.3%). The class 'Others' includes sales of the following subclasses: imidazole derivatives (metronidazole), nitrofuran derivatives (nifurpirinol and furazolidone) and other antibacterials (furaltadone).

¹ Some tablet formulations are authorised for use in food-producing. fur and companion animals.

² In Romania, 20.0% (0.63 tonnes) of tablets sold were indicated for food-producing or non-food-producing birds.

³ Lithuania did not report tablet sales for 2019–2022.

⁴ Average proportion of tablet sales per antibiotic class (tonnes) divided by the total sales of tablets (tonnes).

The sales patterns of penicillins as tablets did not differ substantially between the 31 countries with regards to their various subclasses (Figure 20). For 28 countries, sales of penicillins in combination with beta-lactamase inhibitors accounted for 74–100% of all penicillin tablet sales and for the remaining 2 countries accounted for less than 56%. Overall, sales of penicillins with beta-lactamase inhibitors aggregated by all countries represented 94.1% of all penicillin tablet sales corresponding to penicillins with extended spectrum.



Figure 20. Proportion of tablet sales (in tonnes of active substance) containing penicillins by subclass in 31 European countries in 2022^{1,2,3,4}

* In 2022, all penicillins included in this group were aminopenicillins (amoxicillin, ampicillin).

** In the ATCvet system, these are classified as combinations of penicillins that include beta-lactamase inhibitors. In 2022, only combinations of amoxicillin with enzyme inhibitor were reported.

¹ Some tablet formulations are authorised for use in food-producing, fur and companion animals.

² No sales of penicillins with extended spectrum in Bulgaria, Croatia, Cyprus and Slovenia.

³ Lithuania did not report tablet sales for 2022.

⁴ Average proportion of tablet sales containing penicillins per subclass (tonnes) divided by the total sales of tablets containing penicillins (tonnes) for all countries.

2.4. Farm to Fork Strategy targets: reducing overall EU sales of antimicrobials for farmed animals and aquaculture by 50%

The EU's Farm to Fork Strategy^{25,26} aims to accelerate the transition to a sustainable food system at the EU level that is fairer, healthier and more environmentally friendly. Sitting at the heart of the European Green Deal²⁷, focused on the transformation of the EU into a modern, resource-efficient and competitive economy, the Farm to Fork Strategy is essential to achieve its climate and environmental goals.

One of the major public health issues addressed in this strategy is that of AMR, which contributes to approximately 35,000 human deaths every year in the EU/EEA alone²⁸. The development and spread of resistance is accelerated by the use of antimicrobials, including necessary use and misuse, in both human and animal healthcare sectors and by inadequate infection control and prevention. AMR can be transmitted between humans, animals and the environment through the food chain or direct contact. Ecological analyses have shown links between the quantities of antimicrobials consumed in humans and food-producing animals and the levels of resistance occurring in bacteria from those populations respectively, but also some associations have been demonstrated between antimicrobial consumption in animals and levels of resistance in humans²⁹.

²⁵ Farm to Fork Strategy web page: <u>https://food.ec.europa.eu/horizontal-topics/farm-fork-strategy_en</u>

²⁶ Farm to Fork Strategy action plan: https://food.ec.europa.eu/system/files/2020-05/f2f_action-plan_2020_strategy-info_en.pdf

²⁷ European Green Deal web page: https://ec.europa.eu/info/strategy/priorities-2019-2024/european-green-deal_en

²⁸ Estimated deaths according to ECDC: <u>https://www.ecdc.europa.eu/en/news-events/eaad-2022-launch</u>

²⁹ Available on the EMA website (<u>www.ema.europa.eu/en</u>) via: Home > Veterinary regulatory > Antimicrobial resistance > Analysis of consumption and resistance (JIACRA) > Report on 2016-2018 (new): <u>https://www.ema.europa.eu/en/documents/report/ema/ecdc/</u> <u>efsa-third-joint-report-integrated-analysis-consumption-antimicrobial-agents-occurrence_en.pdf</u>

Recognising that AMR is a One Health problem that affects both human and animal health, the EC has taken action by aiming to reduce the overall EU sales of antimicrobials for farmed animals and aquaculture by 50% by the year 2030. In its recommendations to the 27 EU Member States as regards the strategic plan for the Common Agriculture Policy (CAP), the EC has published baseline and target values using the 2018 reference value of overall sales of antibiotic VMPs based on data from the 10th ESVAC report for the 27 EU Member States³⁰. Therefore, even though individual country figures are also provided, only the total EU-27 figure for farmed animals and aquaculture needs to be tracked. Thus, the 2018 reference value for overall aggregated sales of antibiotic VMPs (118.3 mg/PCU) in the 27 EU Member States sets the 2030 target at 59.2 mg/PCU³¹ (Figure 21).

Figure 21. Current progress of the Farm to Fork Strategy target of reducing total EU sales of antibiotics for farmed animals and aquaculture by 50% by 2030 in 27 EU Member States



In 2022, the aggregated sales for the 27 EU Member States were 84.8 mg/PCU, which corresponds to a reduction of 33.5 mg/PCU (28.3%) in comparison to the 2018 reference value. Hence, Member States have already reached more than half of the reduction target set for 2030 in only the first four years of the twelve-year period between 2018 and 2030. Member States will have to continue taking action in order to comply with the Farm to Fork Strategy objective by further reducing the aggregated sales of antimicrobials by another 25.6 mg/PCU within the next eight years.

³⁰ European Commission: Recommendations to the Member States as regards their strategic plan for the Common Agricultural Policy (COM/2020/846 final): https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A52020DC0846 Z

³¹ Discrepancies between reference and updated 2018 values can be explained by historical data corrections following the update to conversion factors in the ESVAC protocol in March 2021, as well as other historical updates to sales and PCU data for the 27 Member States that were made after the publication of the 10th ESVAC 2018 report. These updates are not reflected in the static reference and target values set by the EC.

3. Discussion

Scope, data coverage, completeness and quality

ESVAC was established in 2009 with the purpose of conducting continuous surveillance of antimicrobial consumption in food-producing animals using sales of antibiotic VMPs as a proxy. Since then, ESVAC has proven to be a useful surveillance project to overview the consumption of antibiotic VMPs at EU/EEA level and has also acted as a data source for other publications, such as the JIACRA report produced by the ECDC, EFSA and EMA.

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 products³², all VMPs, including veterinary antibiotic agents, must be sold through distributors authorised by the competent authority in each country. This enables all participating countries to identify all distributors of antibiotic VMPs in their territory, 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 antibiotic VMPs in the 31 European countries reporting data for ESVAC. The use of antimicrobials for growth promotion has been banned in the EU since 2006. Therefore, the data sets provided to ESVAC exclusively represent sales of antibiotic agents sold as VMPs.

In Member States where there is no authorised VMP for an indication concerning animal species, the administration of other medicinal products may be permitted in exceptional circumstances in accordance with Article 10 and Article 11 of Directive 2001/82/EC (and as of 28 January 2022 according to Articles 107, 112, 113 and 114 of Regulation (EU) 2019/6³³). For antibiotic sales data that are submitted to ESVAC, details regarding whether or not a VMP was used outside the terms of marketing authorisation are not included. Sales of human medicinal products fall outside the scope of the ESVAC protocol.

In 2022, data sets for 12 countries included antibiotic VMPs obtained on special licence / marketing authorisation or through parallel trade, i.e. obtained from another Member State and permitted to be used for specific animal species and indications where there is no marketed / authorised VMP for the indication and species in question. The proportion of sales of antibiotic VMPs on special licence ranged from 0.17% to 30% of total sales according to the country.

Dermatological products (ATCvet group QD) and products for sensory organs (ATCvet group QS) are not included in the data collection. The effect of their exclusion is considered negligible as their annual contribution, in tonnes of active substance, to total sales is regarded as being minimal.

The sales data (numerator) cover all species considered to be food-producing animals according to EU legislation, which includes farmed fish and horses. Thus, the animal population that could potentially be treated with antibiotic agents (denominator) includes animals of these species. However, as the use of antibiotic agents varies considerably between different animal species, interpretation of the data should consider the distribution of the PCU value between species in the various countries. It is also important to note that some animal categories are not present in the current denominator/PCU. For example, due to the incompleteness of the data held by Eurostat on numbers of live goats, this category was excluded when the PCU methodology was established for the first ESVAC report. As a result, for countries with a large goat population this can lead to an underestimation of their total PCU and, consequently, an overestimation of sales measured in mg/PCU.

In the current report, data presented on sales of antibiotic VMPs for companion animals are solely represented by sales of tablets. Parenteral preparations of antibiotic agents are used both in food-producing and companion animals. With the exception of some long-acting products, parenteral administration of antibiotic agents in companion animals is more often limited to hospitalised animals or perioperative treatments. For instance, data from Denmark for 2022 showed that approximately 1.7% of the injectable antimicrobial VMPs sold were used for dogs and cats, respectively (L. Mie Jensen, unpublished data). In this report, sales of injectable antibiotic VMPs are assumed to be for use in food-producing animals. Therefore, for countries where injectable 3rd- and 4th-generation cephalosporins are solely or also marketed for dogs and cats, the data provide a considerable overestimate of use in food-producing animals.

Inconsistencies in previously submitted datasets are sometimes identified during the data validation process due to reasons such as availability of new official animal population data statistics, identification of inaccuracies in the information reported for specific VMP presentations or under or over reporting of sales data, among others.

³² 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: <u>https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex%3A32001L0082</u>

³³ 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/eli/reg/2019/6/oj

Subsequently, efforts are made to address and correct such inaccuracies. For some countries, the final animal population statistics for the reporting year are not available at the time of PCU validation and projections or validated figures from the previous year are used instead. Moreover, some countries have changed their national data collection systems over the years in order to improve sales data collection, quality and completeness, e.g. Slovenia in 2013, Spain in 2014 and 2017, Romania in 2015 and Italy in 2020. Whenever corrected data (sales and animal population) become available, these are validated and approved by the participating countries and then published in the ESVAC interactive database. It is important to note that these updates are not implemented in former published reports, so minor discrepancies may occur between the values presented therein and those displayed in the interactive database.

Thirteenth ESVAC report — main results

Total sales and sales trends vary between the different reporting countries. For instance, in 2022, total sales of antibiotic VMPs for food-producing animals ranged from 2.1 mg/PCU to 254.6 mg/PCU across the 31 countries reporting data to ESVAC. The variation between countries can be explained, in part, by differences in the composition of the animal population, disease incidence, production systems, prescription practices, daily doses used for the various antimicrobial agents and pharmaceutical forms, as well as treatment duration. In addition, differences among countries in the selection of sales data sources may also have an impact on the sales data, although this is thought to be minor. These and other country-specific factors must be taken into account when evaluating results on a country-by-country basis and direct comparisons between countries should be avoided.

Aggregated sales declined significantly in 2022, impacting all trends monitored in this report. For all 31 countries aggregated, sales were 12.7% lower than in 2021 (a reduction of 10.7 mg/PCU). Lower sales of premixes in 2022 accounted for 69% of the overall sales reduction in 2022 (minus 7.4 mg/PCU). At country level, a decrease in the sale of premixes was most noticeable for those countries where this product form represented at least 30% of total national sales in 2021 (sales reduction in 2022 ranging between minus 1.6-60.6 mg/PCU). Interestingly, despite such a noticeable reduction of premix sales in 2022 (40%), the data reported to ESVAC for 2022 suggest that treatments with premixes have not been replaced by treatments with other pharmaceutical forms or antibiotic classes, since aggregated sales decreased for all classes except 'Others' (increase of 17%, from 0.96 mg/PCU in 2021 to 1.1 mg/PCU in 2022). To better understand the decrease in sales and changes in patterns of use, future analyses should examine in more detail changes at the product form and substance level due to the differences in the duration of treatment and dosing schedules between and within antibiotic classes.

Despite more moderate reductions in recent years, between 2011 and 2022, overall sales decreased by 53% for the 25 countries that continuously reported data to ESVAC throughout this period. Similarly, total sales of AMEG Category B antibiotics in these 25 countries have also decreased since 2011, with sales of 3rd- and 4th-generation cephalosporins, fluoroquinolones, other quinolones and polymyxins decreasing by 49.0%, 24.7%, 89.7% and 81.0%, respectively. The overall decrease of polymyxin sales is aligned to the Agency's recommendation for Member States to reduce the use of colistin in animals³⁴, with most countries (18 out of 31) presenting polymyxin sales between 0 and 1.0 mg/PCU and only 6 countries having sales higher than 5 mg/PCU in 2022. Furthermore, since 2011, sales for the 25 countries have reduced significantly for most antibiotic classes, with the decline in sales of the three highest selling antibiotic classes — tetracyclines (-70.7%), penicillins (-30.2%) and sulfonamides (-61.5%) — contributing greatly to the overall reduction of total sales. Since 2019, penicillins has overtaken tetracyclines as the highest selling antibiotic class.

The proportion of sales of small packages of oral powders and oral solutions sufficient for treatment of only a single animal or a few animals is low compared to that of sales of those suitable for group treatment. Thus, the data presented in this report on sales of oral powder, oral solutions and premixes are considered to be reasonable estimates of sales of antibiotic VMPs for group treatment. This analytical approach could be adjusted in the future following the CVMP recommendations for ensuring safe and efficient administration of oral VMPs via routes other than medicated feed³⁵.

³⁴ At the request of the EC, following the discovery of a gene that causes bacteria to become resistant to colistin, the 2013 AMEG advice on the use of colistin in animals was revised and the updated advice published on the EMA website: <u>https://www.ema.europa.eu/en/documents/</u> scientific-guideline/updated-advice-use-colistin-products-animals-within-european-union-development-resistance-possible_en-0.pdf

³⁵ A thorough analysis of the provisions concerning oral administration of veterinary medicinal products, as detailed in Regulation (EU) 2019/6, and of the preparation and administration of medicated feed, as detailed in Regulation (EU) 2019/4 was carried out (<u>https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/advice-implementing-measures-under-article-106-6-regulation-eu-2019/6-veterinary-medicinal-products-scientific-problem-analysis-recommendations-ensure-safe-efficient_en.pdf). One of the recommendations was that oral powders, granules or similar pharmaceutical forms administered to terrestrial animals via solid feed, including VMPs administered via top-dressing, should be restricted to use in individual animals only. Therefore, the classification of group treatment included in the ESVAC analysis could be adjusted in the future, once these recommendations are fully implemented by the Member States.</u>

Although aggregated sales for the 25 countries of product forms predominantly destined for group treatment have declined by 56.3% between 2011 and 2022, they still accounted for a major part of sales in 2022 (85.6% of total sales). Since 2017, oral solutions have overtaken premixes as the highest selling product form. In the first ESVAC reporting years, some powders for solution in water were incorrectly reported as oral powders and thus sales of oral solutions were underestimated, but this alone does not explain the accentuated increase of oral solutions over the years.

Historically, premixes have more frequently been used for the prevention of disease or metaphylaxis as they are easy to administer over longer periods of time, while products for administration via drinking water tend to be administered for acute stages of clinical diseases, and also for shorter durations. Consequently, the substitution of premixes with oral solutions over time could mean that animal exposure times to antibiotics are reducing. Multiple factors have likely played a role in this pattern change, such as the introduction of new technologies (e.g. of feeding) that facilitated or contributed to the switch in the type of medication, or a change in the food-producing animal demographics at EU and country level. Over the reporting period of 2011–2022, the total PCU of poultry, pigs and farmed fish — the species most exposed to group treatment — increased by 13.1% in the case of poultry and 12.7% for farmed fish while decreasing by 4.6% for pigs across the 25 European countries. However, the proportion that each of these species contributes to the total aggregated PCU has remained stable, indicating that the reduction in aggregated sales was not affected by changes in the animal population at the aggregated level (data not shown). It could be interesting to investigate the extent to which changes in animal demographics at the national level have played a role in the reduction of sales, both nationally and in Europe.

Farm to Fork Strategy in 27 EU Member States

In May 2020, the EC adopted the Farm to Fork Strategy^{36,37} as a tool to help shape the EU's path towards a more sustainable food system that is located at the heart of the European Green Deal³⁸ and monitored under the EU Zero Pollution Action plan^{39,40}. One of its objectives is the 50% reduction of overall EU sales of antimicrobials for farmed animals and in aquaculture by 2030, using the 2018 reference value of overall sales of antibiotic VMPs (118.3 mg/PCU) in the EU-27 Member States to set the targeted consumption levels at 59.2 mg/PCU by 2030⁴¹. Already after four years, the EU-27 Member States have attained more than half of this targeted reduction, with the pointer currently sitting at 84.8 mg/PCU. Despite the achievement, Member States will have to continue taking action in order to further reduce their overall aggregated sales of antimicrobials and reach the 2030 goal within the next eight years. Maintaining an annual decrease of sales of approximately 5% over the remaining eight years would keep Member States on track to reach the 2030 target.

EU legislation on prudent use of antimicrobials in veterinary medicine: the future of EU veterinary antimicrobial consumption surveillance

Regulation (EU) 2019/6⁴² on VMPs sets a range of concrete measures aimed at limiting the development of AMR while ensuring that necessary treatments remain available for animals and humans following a One Health approach. These new provisions include: the preventive use of antimicrobials in animals is only to be permitted under exceptional circumstances; introducing the possibility to restrict or prohibit the use of certain important antimicrobials in animals by reserving them for treatment of certain conditions in humans; and limiting the use of certain medicinal products outside the terms of the marketing authorisation. Additionally, the bans on the use of growth-promoting antimicrobials and on the use of antimicrobials reserved for human use also apply to producers of third countries seeking to export animals or products of animal origin to the EU. Moreover, Regulation (EU) 2019/4⁴³ imposes a ban on the preventive use

³⁶ Farm to Fork Strategy web page: <u>https://food.ec.europa.eu/horizontal-topics/farm-fork-strategy_en</u>

³⁷ Farm to Fork Strategy action plan: https://food.ec.europa.eu/system/files/2020-05/f2f_action-plan_2020_strategy-info_en.pdf

³⁸ European Green Deal web page: https://ec.europa.eu/info/strategy/priorities-2019-2024/european-green-deal_en

³⁹ Zero pollution action plan web page: https://environment.ec.europa.eu/strategy/zero-pollution-action-plan_en

⁴⁰ Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the regions — Pathway to a Healthy Planet for All EU Action Plan: 'Towards Zero Pollution for Air, Water and Soil' (<u>https://</u>eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A52021DC0400).

⁴¹ Discrepancies between the 2018 reference values can be explained by the historical data updates following the update to the ESVAC protocol in March 2021 and the update of conversion factors, as well as other historical updates to sales and PCU data for the 27 Member States that were made after the publication of the 10th ESVAC 2018 report. These updates are not reflected in the static reference and target values set by the EC.

⁴² 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/?uri=CELEX:32019R0006

⁴³ Regulation (EU) 2019/4 of the European Parliament and of the Council of 11 December 2018 on the manufacture, placing on the market and use of medicated feed, amending Regulation (EC) No 183/2005 of the European Parliament and of the Council and repealing Council Directive 90/167/EEC: https://eur-lex.europa.eu/eli/reg/2019/4/oj

of antimicrobials via medicated feed and restrictions on prescribing antimicrobials in medicated feed. Some of the data presented in this report may already reflect the first effects of these regulations entering into force in January 2022. Sales of premixes, for instance, have been declining since 2011 due to countries' continued efforts in implementing their own national legislation and restrictions that seem to have led to the shift in the use of premix to oral solutions, also in anticipation of the implementation of Regulation 2019/6 and Regulation 2019/4. However, during the validation of 2022 data for this report, many countries have indicated that the accentuated decrease in sales (mostly premixes) is a direct result of the entering into force of these regulations in January 2022.

With regard to veterinary antimicrobial consumption surveillance, Article 57 of Regulation (EU) 2019/6 introduces the mandatory collection and reporting of data to the Agency on the volume of sales and on the use of antimicrobial medicinal products used in animals, which will enable the direct or indirect evaluation of the use of such products in food-producing animals. In comparison to the ESVAC project, the reporting of data will no longer be voluntary and the scope of reported antimicrobials will go beyond the current antibiotic classes in the ESVAC report. From 2024 onwards, it will become mandatory for EU/EEA countries to provide antimicrobial use data by animal species in a stepwise approach, starting with data from 2023 for the main food-producing animal species. The Commission Delegated Regulation (EU) 2021/578 of 29 January 2021⁴⁴ and the Commission Implementing Regulation (EU) 2022/209 of 16 February 2022⁴⁵ respectively establish the requirements and format for the collection of data on the volume of sales and on the use of antimicrobial medicinal products in animals.

Altogether, these measures will be instrumental in achieving the EU Farm to Fork Strategy objective of reducing overall EU sales of antimicrobials for farmed animals and in aquaculture by 50% by 2030.

⁴⁴ Commission Delegated Regulation (EU) 2021/578 of 29 January 2021 supplementing Regulation (EU) 2019/6 of the European Parliament and of the Council with regard to requirements for the collection of data on the volume of sales and on the use of antimicrobial medicinal products in animals: https://eur-lex.europa.eu/eli/reg_del/2021/578/oj

⁴⁵ Commission Implementing Regulation (EU) 2022/209 of 16 February 2022 establishing the format of the data to be collected and reported in order to determine the volume of sales and the use of antimicrobial medicinal products in animals in accordance with Regulation (EU) 2019/6 of the European Parliament and of the Council: <u>https://eur-lex.europa.eu/eli/reg_impl/2022/209/oj</u>

4. Concluding remarks

The numerical value of the main outcome indicator used in this report to express the consumption of veterinary antibiotics, i.e. overall sales in mg/PCU, has declined considerably between 2011 and 2022 for the 25 countries that have reported data for all years during this period. Furthermore, substantial progressive reduction over this same period has also been observed for the values of the secondary outcome indicators, namely sales in mg/PCU of 3rd- and 4th-generation cephalosporins, quinolones and polymyxins. Finally, in four years, more than half of the target to reduce sales of veterinary antimicrobial sales by 2030, established by the EC in the Farm to Fork Strategy, has already been reached.

Overall, these results indicate that efforts at both national and EU/EEA levels to reduce the overall use of antimicrobial VMPs in food-producing animals — i.e. national campaigns for the responsible and prudent use of antibiotics in animals, restriction of use of certain antimicrobials in food-producing animals, prescription control measures, awareness-raising campaigns and EU guidance, among others — have been successful in most participating European countries and indicate the potential for a reduction in other countries as well. Nonetheless, as the pace of the decline of antibiotic VMP sales appears to have slowed since 2017, efforts to sustain this descending trend must be maintained and reinforced in order for the Farm to Fork Strategy goal on sales of veterinary antimicrobials to be achieved by 2030.

This report, the Thirteenth ESVAC Report, containing 2022 data submitted voluntarily by participating countries, will be the last of its kind. Throughout the duration of the ESVAC project, which reaches the conclusion with the publication of this report, vast amounts of data have been collected and provided valuable insights that supported the identification and understanding of patterns of antibiotic consumption in food-producing animals. The sales data collected by the ESVAC project have provided a basis for monitoring the progress of countries towards the prudent use of antimicrobials. On an annual basis, the data presented in the ESVAC reports served as evidence of the impact of educational and regulatory measures and interventions. Moreover, data collected for ESVAC are used for the JIACRA reports, where possible associations between antimicrobial consumption and the occurrence of antimicrobial resistance in bacteria from humans and food-producing animals are analysed, thus supporting a One Health response to AMR in Europe.

Last but not least, the success of the project is a testament to the dedication and collective effort of those involved – from countries who voluntarily provided their data to the Agency and developed national strategies to encourage responsible antibiotic use, to the practitioners and farmers in the field. The experience gained under ESVAC serves as an important leverage point for compliance with the new EU legislative obligations regarding collecting and reporting data on the sales and use of antimicrobials in animals, to be featured in the Agency's future reports, starting in 2025 with data from 2023 and 2024.

Annex 1. Additional tables regarding 2022 data

Table A1. Sales, in tonnes of active substance, of antibiotic VMPs applicable mainly to food-producing animals by antibiotic class (presented according to the ATCvet hierarchical system), by country, in 2022 (tablets not included)

uə6-puz p	uə6-q1 7 p	sporins¹	səpim	oprim	səp	səbim	onoloniu	ənoloniu	lycoside	suix	snilitun		səuu
Penicilli 1st- and cephalo	orendaa		oisnqəc Sulfona	Trimeth	Macrolio	lesoonid	Fluorog	Ofher q	gonimA	νίμην	Pleuron	Ofµers²	ot letoT
8.0 0.05	ы	0		0.6	2.6	0.1	0.4		1.3	1.1	0.3	0.1	34.3
9.0 0.5	ß	0		3.8	8.7	2.6	0.3	0.4	3.7	1.0	0.2	3.5	120.2
	1	0		0.3	4.4	0.7	2.8	< 0.01	1.9	1.4	0.5	0.2	37.0
5.8 0.01	н,	0		0.2	1.3	0.1	0.8		0.5	1.7	0.2	0.1	17.1
6.9 <0.01	н,	0		1.3	1.6	5.7	0.3	0	0.8	0.9	2.0	0.1	35.6
11.6 0.1	г,	0		0.6	1.5	0.1	1.1		1.7	0.4	1.8	0.2	32.3
	4	<0.0		1.4	11.7	2.0	<0.01	0.4	13.7		6.0	2.3	80.2
1.3 0.02	2	0		0.1	0.2	0.05	0.1		0.3	0.05	1.2	0.1	5.2
4.0		<0.0		0.3	0.1	0.02	0.05		0.02				7.2
	2	0		7.7	20.1	2.3	0.6	1.4	36.1	7.3	2.1	3.9	255.2
	~	1		7.5	49.3	11.7	4.9		20.8	44.4	8.0	12.0	531.1
V		0		0.9	6.0	1.0	3.4	0.8	9.0	1.9	1.3	0.7	101.7
27.1 0.1	1	0		1.1	3.7	1.5	5.5		3.0	4.8	6.5	0.7	92.6
		<0.0		<0.01		0	<0.01	0	0.08		0	0	0.62
19.7 1.1		0		0.8	4.3	1.0	0.5		5.6			0.7	75.6
	2	0		7.1	29.7	50.0	3.3	1.4	27.2	2.2	15.9	8.0	585.4
		0		0.02	0.5	0.02	0.1		0.6	0.05	0.2	0.02	3.4
	н	0		2.3	2.4	0.1	0.4		1.1	1.8	0.2	0.1	14.5
0.3 0.01		0.0		0.04	0.1	0.03	0.04	0	0.2	0.01	<0.01	0.02	1.3
V		<0.0		0.03	0.1	<0.01	0.2		0.1	<0.01	0.1	0.1	1.1
28.4 0.1	H	<0.0		3.4	18.6	0.2	0.1	2.3	1.5	0.9	0.3	0.2	112.0
		<0.0		0.2	<0.01	<0.01	<0.01	0.03	0.1		0.04	<0.01	4.7
	6	1		7.3	123.3	16.2	50.6	< 0.01	39.9	43.5	33.0	10.8	838.3
18.6 0.1	H	0		0.6	7.9	6.1	5.5	0	3.8	1.9	4.8	0.6	82.0
24.3 0.03	e	0		1.0	20.9	3.7	15.5	0.2	14.3	7.5	5.3	1.7	136.4
2.4 0.1		0		0.2	0.1	0.1	0.7	< 0.01	0.9	0.4	0.8	0.2	9.2
1.6 0.01		0.0		0.1	0.05	<0.01	0.2		0.7	0.01	0.1	<0.01	4.7
356.0 0.2	2	Η.		15.3	41.7	125.6	26.8	0.2	78.2	3.1	10.8	17.9	1,027.2
5.4	·	<0.0		0.2	0.3	0.04		0.02	0.5			0.1	8.3
8.5 0.1	1	0		0.5	0.6		0.1		2.1	<0.01		0.03	22.7
51.2 0.8	8	0.1	1 13.1	2.6	16.2	5.1	0.7		18.5	0	6.9	3.5	181.1
1.456.3 6.8	80	7.		67.5	377.8	235.8	125.0	7.0	288.3	126.3	108.8	67.3	4,458.1

producing animals.

The class 'Others' includes the following subclasses: imidazole derivatives (metronidazole), nitrofuran derivatives (furazolidone) and other antibacterials (bacitracin, furaltadone,

novobiocin, rifaximin, spectinomycin). Of note is that some of the sales could be for non-food-producing animals such as companion animals, fur animals, exotic birds and racing pigeons.

For commercial confidentiality reasons, pleuromutilins are aggregated with 'Others'. For commercial confidentiality reasons, fluoroquinolones and other quinolones are aggregated.

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. For commercial confidentiality reasons, pleuromutilins are grouped with 'Others' and lincosamides are grouped with macrolides.

Country	Cattle	Pigs	Poultry	Sheep and goats	Fish	Rabbits	Horses	Total
Austria	433	342	91	38	0	0	42	946
Belgium	466	784	248	19	0	3	115	1,635
Bulgaria	102	91	50	84	13	< 0.01	18	358
Croatia	81	86	50	48	27	0.01	13	304
Cyprus	29	42	14	45	8	0.1	2	140
Czechia	293	190	133	14	19	7	41	697
Denmark	377	1,737	117	15	41	0	70	2,356
Estonia	60	41	3	5	1	< 0.01	5	114
Finland	199	141	87	11	16	0	30	485
France	2,911	1,720	990	595	45	36	265	6,561
Germany	2,751	3,171	986	132	18	23	520	7,601
Greece	77	100	150	680	130	2	2	1,142
Hungary	180	321	201	74	27	5	24	833
Iceland	19	6	6	37	51	0	21	140
Ireland	1,352	290	102	358	45	0	100	2,246
Italy	1,458	797	667	537	54	27	177	3,716
Latvia	92	38	23	7	0	0.07	3	164
Lithuania	156	69	55	10	4	0.03	5	300
Luxembourg	42	9	0.4	0	0	0	0	51
Malta	4	4	3	1	0	0.1	3	15
Netherlands	1,015	1,562	331	72	6	0.4	39	3,025
Norway	220	116	74	93	1,646	0	50	2,198
Poland	1,480	1,203	1,411	21	45	2	115	4,278
Portugal	216	366	244	179	17	4	36	1,062
Romania	663	659	517	868	7	< 0.01	80	2,794
Slovakia	82	50	55	28.1	2	0.2	6	224
Slovenia	97	18	45	10	2	0.01	11	182
Spain	1,012	4,270	880	1,298	302	47	254	8,063
Sweden	284	204	116	30	12	0	142	788
Switzerland	476	192	82	32	0	1	45	829
United Kingdom	1,740	803	1,187	2,749	220	0	339	7,038
Total 31 countries	18,367	19,423	8,917	8,091	2,757	159	2,573	60,287

Table A2. Estimated PCU (in 1,000 tonnes) of the population of food-producing animals¹, by country, in 2022

¹ When PCU is given as zero it indicates no reported production of animals of a specific species.

Table A3. Sales, in tonnes of active substance, of VMP presentations¹ sold as premixes, oral powders and oral solutions containing 1, 2 and 3 active substances, by country, in 2022²

	1 subst	ance	2 substa	ances	3 substa	nces	Total tonnes (premixes, oral
Country	Tonnes	%	Tonnes	%	Tonnes	%	powders and oral solutions)
Austria	24.5	90%	2.8	10%			27.3
Belgium	75.2	75%	24.7	25%			99.9
Bulgaria	28.5	90%	3.0	10%			31.5
Croatia	12.5	95%	0.6	5%			13.1
Cyprus	25.6	76%	8.2	24%			33.8
Czechia	21.0	83%	4.1	16%	0.2	1%	25.3
Denmark	41.3	89%	5.1	11%			46.4
Estonia	3.0	88%	0.4	12%			3.4
Finland	1.0	55%	0.8	45%			1.9
France	125.1	73%	45.3	27%			170.4
Germany	413.2	89%	50.9	11%			464.2
Greece	78.2	92%	6.4	8%			84.5
Hungary	74.5	91%	7.1	9%			81.6
Iceland	0.2	100%					0.2
Ireland	41.9	90%	4.5	10%			46.4
Italy	373.3	70%	152.1	29%	4.1	1%	529.7
Latvia	1.5	99%	0.01	1%			1.5
Lithuania	8.6	76%	2.6	23%	0.1		11.3
Luxembourg	0.4	66%	0.2	34%			0.6
Malta	0.7	74%	0.2	21%	0.04	4%	1.0
Netherlands	69.4	83%	13.8	17%			83.2
Norway	0.6	99%	< 0.01	0.8%			0.6
Poland	728.3	93%	57.3	7%			785.5
Portugal	70.3	95%	3.7	5%			74.0
Romania	100.3	93%	6.8	6%	0.8	1%	108.0
Slovakia	5.9	81%	1.3	18%	0.1	1%	7.3
Slovenia	2.8	89%	0.4	11%			3.2
Spain	809.7	89%	99.3	11%			909.0
Sweden	0.8	99%	0.01	1%			0.8
Switzerland	5.6	48%	3.3	28%	2.9	24%	11.8
United Kingdom	119.2	87%	17.6	13%			136.8
Total 31 countries	3,263.2	86.0%	522.6	13.8%	8.1	0.2%	3,794.2

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

² In addition, 0.01% of the total sales of premixes, oral powders and oral solution preparations contained 4 active substances, accounting for 0.3 tonnes (which is included in the total tonnes of premixes, oral powders and oral solutions).

Annex 2. List of antibiotic classes or active substances reported in ESVAC

Table A4 includes all of the substances for which sales have been reported, divided by class or subclass. This includes sales reported for all product forms, including tablets, which are excluded from the analysis in mg/PCU for food-producing animals based on the assumption that they are intended for companion animals. Note that in ESVAC, sales are reported by classes / subclasses irrespective of whether the VMP sold is a single or a fixed-combination product, i.e. not by ATCvet classes. Exceptions to this are penicillin and beta-lactamase inhibitor combinations that are reported as such, as 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 (MRLs) have been established. Table 2 of that annex contains substances that are prohibited for use in any food-producing animals; some of these are included in Table A4 below because they are used in companion animals for which no MRLs are required.

Class	Subclass	Substances
Tetracyclines		Chlortetracycline Doxycycline Oxytetracycline Tetracycline
Amphenicols		Chloramphenicol ² Florfenicol Thiamphenicol
	Beta-lactamase-sensitive penicillins	Benzathine benzylpenicillin Benzathine phenoxymethylpenicillin Benzylpenicillin Penethamate hydriodide Phenoxymethylpenicillin Procaine benzylpenicillin
Penicillins	Beta-lactamase-resistant penicillins	Cloxacillin Dicloxacillin Nafcillin Oxacillin
	Penicillins with extended spectrum	Amoxicillin Ampicillin Metampicillin ³
	Combinations of penicillins with beta-lactamase inhibitors	Amoxicillin Ampicillin
Cephalosporins⁴	1st-generation cephalosporins	Cefacetrile Cefadroxil ³ Cefalexin Cefalonium Cefapirin Cefazolin Cefalotin
	3rd-generation cephalosporins	Cefoperazone Cefovecin ³ Ceftiofur
	4th-generation cephalosporins	Cefquinome
Sulfonamides and trimethoprim	Sulfonamides	Formosulfathiazole Phthalylsulfathiazole Sulfacetamide Sulfachlorpyridazine Sulfaclozine Sulfadiazine Sulfadimethoxine Sulfadimidine Sulfadoxine Sulfadoxine Sulfafurazole

Table A4. List of substances reported sold as VMPs in ESVAC participating countries, 2010-2022¹

Class	Subclass	Substances
		Sulfaguanidine Sulfalene Sulfamerazine Sulfamethizole Sulfamethoxazole Sulfamethoxypyridazine Sulfamonomethoxine Sulfanilamide Sulfapyridine Sulfapyridine Sulfaquinoxaline Sulfathiazole Sulfazuinoxaline
	Trimethoprim and derivatives	Trimethoprim
Macrolides and lincosamides	Macrolides	Erythromycin Gamithromycin Oleandomycin Spiramycin Tildipirosin Tilmicosin Tulathromycin Tylosin Tylvalosin
	Lincosamides	Clindamycin ³ Lincomycin Pirlimycin
Aminoglycosides		Amikacin ³ Apramycin Dihydrostreptomycin Framycetin Gentamicin Kanamycin Neomycin Paromomycin Streptomycin
Quinolones	Fluoroquinolones	Danofloxacin Difloxacin Enrofloxacin Ibafloxacin ³ Marbofloxacin Norfloxacin ³ Orbifloxacin ³ Pradofloxacin ³
	Other quinolones	Cinoxacin ³ Flumequine Oxolinic acid
Imidazole derivatives		Metronidazole ²
Pleuromutilins		Tiamulin Valnemulin
Polymyxins		Colistin Polymyxin B ³
Nitrofuran derivatives		Furazolidone ² Nifurpirinol ²
Other antibacterials		Bacitracin Fosfomycin Furaltadone ² Nitroxoline ³ Novobiocin Rifaximin Spectinomycin

¹ Previously published lists of substances sold and reported to ESVAC since 2010 included pheneticillin (reported instead of penethamate hydriodide) and natamycin (its use indication and administration fall outside the ESVAC scope) due to reporting errors.
 ² Included in Table 2 (prohibited substances) of the Annex to Commission Regulation (EU) No 37/2010.
 ³ MRLs not established for any food-producing animals.
 ⁴ In accordance with the Commission Implementing Decision C(2012) 182 of 13 January 2012 (<u>https://ec.europa.eu/health/documents/community-register/html/vo22101.htm</u>), the use of 3rd- and 4th-generation cephalosporins in poultry is prohibited.
Annex 3. Distribution of veterinary medicines: legal framework and data sources by country

Austria

Distribution of veterinary medicines

In Austria, all VMPs are prescription-only medicines and 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. VMPs sold 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: BGBI. II Nr. 83/2014 (as amended by BGBI. II Nr. 127/2022) Veterinär-Antibiotika-MengenströmeVO.

Data sources

Sales data must be uploaded to 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 that are 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 only distributed 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 MAHs. A higher fee is imposed for critically important antibiotics such as cephalosporins, quinolones and macrolides. Since 1 April 2018, the fees have increased by 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 FAHMP on a yearly basis.

Data sources

To avoid double reporting, 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 sales data.

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, farmers 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 distributed only 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 the Bulgarian Food Safety Agency (BFSA), in the interests 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 send them to 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 reporting, 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, Nos 84/08, 56/13, 94/13, 15/15 and 32/19.

Data sources

Sales data for veterinary antimicrobial agents 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 wholesalers / veterinarians / pharmacists to give any information requested.

Data sources

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, such deliveries are notified to avoid double reporting), veterinarians, pharmacies, farmers and feed mills. Only farmers are receivers from feed mills (only the amount finally sold / delivered to farmers in Czechia territory is counted; deliveries of VMPs from wholesalers to feed mills are notified but not counted in the final consumption figures to avoid double reporting). 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 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 that apply to pharmacies. 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 premixes 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's sales records include sales of all prescription medicines to animal owners, as well as of medicines purchased by veterinary practitioners for use in their practice. Furthermore, it is mandatory for the veterinarians to report to VetStat the medicines used in their own practices for food-production animals. Data on 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 account, in order to avoid double reporting caused by 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 veterinary 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 to the Finnish Medicines Agency on the sales of VMPs 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 only available on prescription. 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 law published at the end of 2014 makes the provision to the competent authority of data on antimicrobial sales mandatory.

Data sources

The sales data are collected from MAHs at package level by Anses-ANMV (the 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 with one another.

Germany

Distribution of veterinary medicines

In Germany, all VMPs containing antimicrobial agents are prescription-only medicines. Veterinarians are allowed to dispense drugs for the treatment of animals under their care, and are supplied with VMPs by either pharmaceutical companies or wholesalers. Sales of antimicrobial VMPs by public pharmacies require a prescription from a veterinarian; such sales are considered negligible in Germany.

Medicated feeds may be produced by authorised feed mills but always require a prescription from a veterinarian.

Legal basis for the monitoring of sales

Since 2022 there has been a change to the legal basis. The collection of sales data from pharmaceutical companies and wholesalers is now regulated in the newly implemented German Veterinary Medicinal Products Act.

Data sources

Sales data for antimicrobial VMPs dispensed to veterinarians located in Germany are reported by pharmaceutical companies and wholesalers. Since prescribed premixes are directly dispensed to feed mills and not to veterinarians, they are not included in the national system of data reporting. Sales data for premixes are thus derived from periodic safety update reports.

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, but 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 2022, sales of veterinary antimicrobial agents were reported to ESVAC for the eight time. Data were provided by 67 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; 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. Animal farms can only be served by the retailer. 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, as with nationally produced medicated feeds. The importation of medicated feeds is supervised by the office that authorises importers and distributors.

Legal basis for the monitoring of sales

The reporting of sales data is mandatory. The legal basis is: 128/2009. (X.6). FVM (Hungary's Ministry of Agriculture and Rural Development) decree 76. § (7).

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 by 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. 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 HPRA to only report sales in Ireland. 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, so their sale to the end user can only take place upon presentation of a veterinary prescription. Since April 2019, electronic veterinary prescriptions have been mandatory. 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. Such sales can only be made 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 VMPs

Holders of authorised wholesale veterinary medicine 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 their own use. Such sales may take place only in the presence of a pharmacist and, in the case of antimicrobial agents, only by electronic veterinary prescription.

Retailing of VMPs

The retail selling of VMPs containing antibiotics can only take place at pharmacies, by electronic veterinary prescription, and only in the presence of a pharmacist.

Farmers, veterinarians, and 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 if an electronic veterinary prescription has been issued. Farms cannot hold stocks of antibiotics in the form of medicated feed or veterinary drugs administered in feed, water or liquid feed. However small quantities can be held, but these must not exceed a treatment period of seven days.

Veterinarians cannot sell veterinary drugs (including antibiotics). When required for professional reasons, veterinarians are allowed to deliver open packages of veterinary medicines from their stocks to breeders or animal owners in order to start the therapy. For companion animals, the veterinarian may 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. The collection of sales data through the electronic veterinary prescription system is based on the national decree of 8 February 2019 and, since 28 January 2022, is based on Article 57 of Regulation (EU) 2019/6.

Data sources

Sales data for premixes are collected from pharmaceutical companies producing these VMPs. Data of sales along the veterinary medicine supply chain for all other pharmaceutical forms are collected though the national computerised traceability system, resulting from the issuing of an e-prescription.

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 a licence can only purchase VMPs containing antibiotics by 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 provide detailed reports of medicines sold in order to determine the real consumption of VMPs and to avoid double reporting or the 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

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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 and pharmacies 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 the dispensing of VMPs for food-producing animals to the public. For all types 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

Stakeholders are obliged to provide sales data. A clearer and more direct legal obligation is being proposed so as to unequivocally clarify this obligation.

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 only available on prescription. 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

Since January 2022, the legal basis for the mandatory reporting of sales data is found in the Regulation (EU) 2019/6; in previous years monitoring of sales took 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 only from MAHs, 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 with the exception of 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.

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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 NIPH, which collects its data from authorised wholesalers and feed mills (only relevant for aquaculture). To avoid double reporting through the inclusion of sales between wholesalers, the wholesalers and feed mills are asked by 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 and are distributed by wholesalers to veterinarians. Antimicrobial VMPs are only available to animal owners if delivered by the veterinarian. Veterinarians and medicated feed producers are allowed to buy medicated premixes from wholesalers.

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, such as 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. Feed mills only distribute to farmers. 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 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 perform 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.

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 ESVAC.

Data sources

For 2014, the sales data were collected from 37 wholesalers and the 11 MAHs that 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 only been collected from MAHs.

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 seven categories of receivers of antimicrobial VMPs from wholesalers: wholesalers (when selling to each other), pharmacies, veterinarians, farmers, military forces, the State Veterinary and Food Administration and feed mills. 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 in 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 in Nitra.

Slovenia

Distribution of veterinary medicines

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

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 via veterinary prescription. All suppliers of VMPs (retailers, pharmacies and farmers' co-operatives) to end users are authorised in accordance with the relevant national law and are subject to 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 the 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 MAHs and also use data by retailers of VMPs. This legal basis is found in the Royal Decree 1157/2021.

Data sources

Since 2017, sales data at package level were collected from all suppliers of VMPs (retailers, pharmacies and farmers' cooperatives) to end users 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 to a central database at the Swedish eHealth Agency. The eHealth Agency is required to share data on sales with the Swedish Board of Agriculture and the National Veterinary Institute, which are required to maintain statistical confidentiality. All feed mills and farms authorised to mix medicated feed are requested to report their purchases and sales on a yearly basis to the 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 are obtained from 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

Since 1 January 2019, the regulatory framework for data collection in Switzerland has been governed by a new legislation. The legal basis for data collection is Article 4 of the Ordinance on the Information System on Antibiotics in Veterinary Medicine (Verordnung über das Informationssystem Antibiotika in der Veterinärmedizin, ISABV-V), enacted in October 2018. It requires MAHs to transmit sales data at least once a year to the Federal Food Safety and Veterinary Office in order to publish statistics on the sales of antibiotics (Article 6 ISABV-V). Sales of veterinary antimicrobials are published yearly in the ARCH-VET report, which covers sales and resistance to veterinary antimicrobials. Note that figures published in the national ARCH-VET report differ from figures in the present report as all ATCvet groups are included in the national report.

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 the collection of prescription figures at national level is still in a development phase, sales figures cannot yet be validated further. Veterinarians may import VMPs for companion and food-producing animals, including products containing antimicrobial agents, based on either a declaration or an authorisation (e.g. for VMPs containing critical antibiotics) delivered by the Federal Food Safety and Veterinary Office. There are currently no aggregated data available about the quantities imported.

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; wholesale dealers must be 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

MAHs 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 MAHs that hold current United Kingdom marketing authorisations.

Annex 4. References to national reports

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Ireland. Health Products Regulatory Authority, Report on sales of veterinary antibiotics in Ireland from 2009 to 2021 (<u>https://www.hpra.ie/docs/default-source/default-document-library/report-on-sales-of-veterinary-antibiotics-in-ireland-from-2009-to-2021.pdf?sfvrsn=0).</u>

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Annex 5. Country and affiliation of the ESVAC national contact points/alternates

 Table A5.
 List of ESVAC national contact points / alternates 2022

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Annex 6. ESVAC sales advisory expert group members and observers

The members of the ESVAC sales advisory expert group are listed below. For affiliations, please see Table A5.

- Kari Grave (chair)
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- Iva Gruden Zdunic
- Katariina Kivilahti-Mäntylä
- Laura Mie Jensen
- Lucie Pokludová
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Table A6. List of ESVAC sales advisory expert group observers from the European Commission, ECDC and EFSA

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Sales of veterinary antimicrobial agents in 31 European countries in 2022 Trends from 2010 to 2022 Thirteenth ESVAC report EMA/299538/2023

