EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Sales of veterinary antimicrobial agents in 31 European countries in 2021

Trends from 2010 to 2021
Twelfth ESVAC report

An agency of the European Union

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

The founding legislation of the Agency is Regulation (EC) No 726/2004 of the European Parliament and the Council of 31 March 2004 laying down Union procedures for the authorisation and supervision of medicinal products for human use and establishing a European Medicines Agency[1], 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/EC[2].

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 well-being, 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: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex%3A32004R0726

[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: https://eur-lex.europa.eu/eli/reg/2019/6/oj

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Correspondence

Correspondence relating this report should be made via the AskEMA form[3].

[3] Use the AskEMA form to send a request for information from the 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 advice[4] 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 twelfth ESVAC report presents data on the sales of veterinary antibiotic agents from 31 European countries in 2021. These data are provided at package level in accordance with a data reporting protocol and data collection form published in March 2021[5]. Information on country-specific changes is published separately on the EMA website in Country Individual Reports[6]. This report focuses on the consumption of antibiotic veterinary medicinal products (VMPs) 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 Antimicrobial Advice Ad Hoc Expert Group (AMEG) in 2019, available on the EMA website[7]. The AMEG categories take account of the World Health Organization (WHO) categorisation of antimicrobials[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 interventions to reduce antimicrobial consumption have a positive impact on the occurrence of AMR.

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

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

[6] Available from the European Medicines Agency website (www.ema.europa.eu) 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' (https://www.ema.europa.eu/en/documents/report/categorisation-antibiotics-european-union-answer-request-european-commission-updating-scientific_en.pdf).

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

ECDC, EFSA and EMA have also jointly established a list of harmonised outcome indicators[9] 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, measured in milligrams per population correction unit (mg/PCU).

The outline of the twelfth ESVAC report has been slightly modified compared to that of previous years in order to focus on the primary and secondary indicators of antimicrobial (more specifically antibiotic) consumption in food-producing animals. The changes include updates to the graphic representation of data to accommodate the growing number of years from which data are available and the following new sections: trend analysis on product form (included in Section 2.2.1), trend analysis for the primary and secondary indicators for all participating countries since 2017 (Section 2.2.2), a dedicated section for tablets (Section 2.3) and a section on the specific antibiotic sales reduction target of the EU Farm to Fork Strategy[10,11], which is at the heart of the European Green Deal and monitored under the EU Zero Pollution Action plan[12,13] (Section 2.4). Nevertheless, all figures and tables present in previous reports can be found in the ESVAC interactive database[14].

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

[10] Farm to Fork Strategy web page: https://food.ec.europa.eu/horizontal-topics/farm-fork-strategy_en

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

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

[13] 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' (https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A52021DC0400).

[14] Available on the EMA website (www.ema.europa.eu) via: Home > Veterinary regulatory > Antimicrobial resistance > European Surveillance of Veterinary Antimicrobial Consumption > ESVAC interactive database accessible via: https://esvacbi.ema.europa.eu/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 antibiotic[15] veterinary medicinal products (VMPs) sales or prescription (3 countries) data to the European Medicines Agency for 2021.

The main indicator used in the current report to express the sales of antibiotic VMPs 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 2021 for 31 countries

Overall aggregated sales of antibiotic VMPs for all 31 countries reporting data in 2021 were 84.4 mg/PCU. This represents a 4.9% decrease compared to 2020 (88.8 mg/PCU). A large difference continues to be observed between countries with the highest and lowest sales, ranging from 2.5 mg/PCU to 296.5 mg/PCU, while the median for all 31 countries was 47.6 mg/PCU.

Penicillins was the highest selling antibiotic class accounting for 31.2% of overall sales (26.3 mg/PCU). Together with tetracyclines (21.8 mg/PCU, 25.8%) and sulfonamides (8.3 mg/PCU, 9.9%), these 3 classes accounted for 66.9% of total sales in 2021. 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 AMEG Category B — i.e. 3rd- and 4th-generation cephalosporins, fluoroquinolones, other quinolones and polymyxins — the sales of which ranged from <0.01 to 0.5 mg/PCU, <0.01 to 14.8 mg/PCU, 0 to 0.69 mg/PCU, and 0 to 12.7 mg/PCU; accounting for 0.15%, 2.8%, 0.18% and 2.6% 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. In 2021, macrolides accounted for 8.5% (7.2 mg/PCU) of the total aggregated sales of antibiotic for food-producing animals. Ketolides are not authorised for use in animals.

When analysed by product form, 86.3% of aggregated sales (mg/PCU) corresponded to product forms predominantly used for group treatment: oral solutions (57.9%), premixes (21.8%) and oral powders (6.6%). On the other hand, product forms mainly intended for the treatment of individual animals presented 13.7% of total sales across all countries and included injectable products (12.6%), intramammary products (0.71%) and other forms such as oral pastes, boluses and intrauterine products (0.42%).

Sales trends of antibiotic VMPs from 2011 to 2021 for 25 countries

For the 25 countries that have provided sales data continuously between 2011 and 2021, aggregated sales (mg/PCU) declined by 46.5% over this period, i.e. from 161.2 mg/PCU in 2011 to 86.2 mg/PCU in 2021. During this same reference period, sales (in mg/PCU) decreased by more than 4% (decline in sales of between 4.4% and 65.4%) in 23 of these 25 countries, while in 2 countries sales increased by more than 5% (increase in sales between 34.5% and 39.0%).

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 2021, sales of 3rd- and 4th-generation cephalosporins decreased by 37.8% (from 0.24 mg/PCU to 0.15 mg/PCU), fluoroquinolones by 14.2% (from 2.5 mg/PCU to 2.2 mg/PCU), other quinolones by 83.1% (from 1.1 mg/PCU to 0.18 mg/PCU) and polymyxins by 79.5% (from 11.0 mg/PCU to 2.2 mg/PCU).

Sales trends of antibiotic veterinary medicinal product forms for food-producing animals have also changed between 2011 and 2021 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 (49.5%) than those product forms predominantly used for individual treatment (11.5%) between 2011 and 2021.

[15] 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 2021 the aggregated sales for the 27 EU Member States were 96.6 mg/PCU, in three years Member States have already reached approximately one third of the 50% reduction target set for 2030. Therefore, a maintained annual decrease of sales of approximately 8% over the remaining eight years would put Member States on track to reach the 2030 target.

Highlights of the twelfth ESVAC report:

Antibiotic VMP sales in 2021 (31 participating countries)

Primary indicator:

- Total sales 84.4 mg/PCU

Secondary indicators:

- Sales of 3rd- and 4th-generation cephalosporins = 0.15 mg/PCU
- Sales of quinolones = 2.5 mg/PCU
- Sales of fluoroquinolones = 93% of total sales of quinolones
- Sales of polymyxins = 2.2 mg/PCU

Trends from 2011 to 2021 in 25 ESVAC-participating countries:

Primary indicator:

↓ 46.5% total sales

Secondary indicators:

↓ 37.8% sales of 3rd- and 4th-generation cephalosporins
↓ 34.7% sales of all quinolones (↓ 83.1% for other quinolones and ↓ 14.2% for fluoroquinolones)
↓ 79.5% sales of polymyxins

Trends from 2017 to 2021 in 31 ESVAC-participating countries:

Primary indicator:

↓ 20.9% total sales

Secondary indicators:

↓ 19.9% sales of 3rd- and 4th-generation cephalosporins
↓ 8.5% sales of all quinolones (↓ 58.8% for other quinolones and ↑ 0.86% for fluoroquinolones)
↓ 39.0% 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 reduced by 18.3% in 2021 (96.6 mg/PCU), achieving approximately one third of the final 50% reduction target for overall aggregated sales of 59.2 mg/PCU in 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)[16], 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, comparability with the sale/use of antimicrobials in humans should be ensured.

About ESVAC activity

Through ESVAC activity, data on sales of antibiotic VMPs are collected at package level from the EU Member States, EEA countries, United Kingdom and Switzerland. Furthermore, in 2016, ESVAC established defined daily doses for animals (DDDvet) and defined course doses for animals (DCDvet) (EMA/224954/2016[17]). 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[18].

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 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:

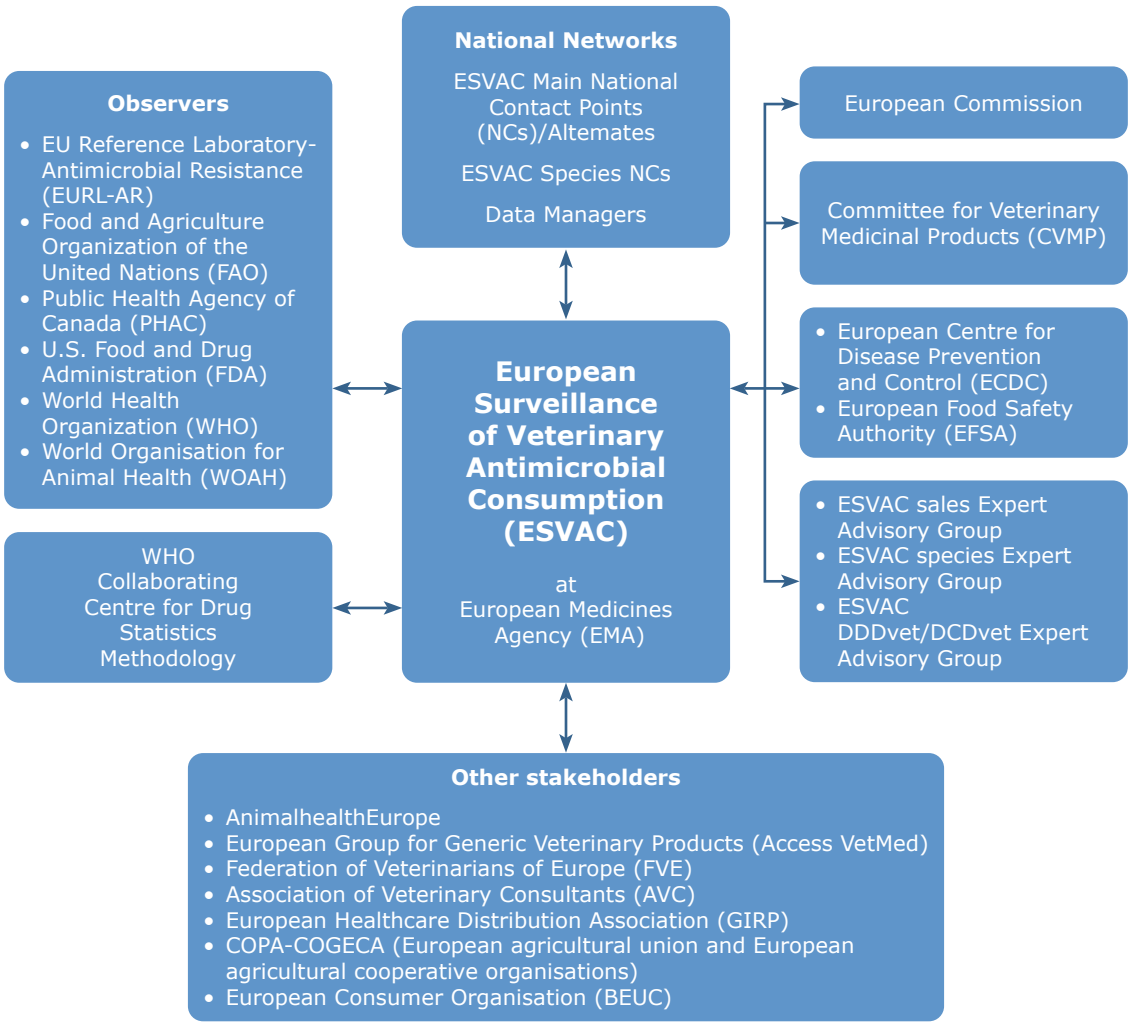
- provide sales data to the ESVAC team at EMA in response to annual data calls;
- revise the data in terms of quality and validity following requests from the ESVAC team;
- validate the animal population data used to calculate the PCU;
- provide comments on the annual ESVAC report.

[16] http://www.consilium.europa.eu/ueDocs/cms_Data/docs/pressData/en/lsa/101035.pdf
[17] Available on the EMA website (www.ema.europa.eu) via: Home > Veterinary regulatory > Antimicrobial resistance > European Surveillance of Veterinary Antimicrobial Consumption > Units of measurement.
[18] Available on the EMA website (www.ema.europa.eu) via Home > Veterinary regulatory > Antimicrobial resistance > European Surveillance of Veterinary Antimicrobial Consumption (ESVAC) > Reporting data by animal species: https://www.ema.europa.eu/en/documents/scientific-guideline/guidance-collection-provision-national-data-antimicrobial-use-animal-species/categories_en.pdf

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 surveillance of overall sales data of antibiotic VMPs, including 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.

Figure 1. Organisation of the ESVAC Network and Stakeholders



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)[19].

In 2023, the Agency will publish the last ESVAC report containing 2022 data submitted voluntarily by participating countries. 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.

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

1. Technical notes

1.1. 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 protocol[20] using ATCvet[21] 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) 2019/6[22]. Furthermore, data collected for ESVAC are also used for the JIACRA reports, where possible relationships between antimicrobial consumption and resistance are analysed between specific antibiotics and indicator bacteria, and the antiprotozoal activity of antimicrobials such as sulfonamides are not contemplated. 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) preparations. The contribution of these pharmaceutical forms to the total quantity of veterinary antibiotics sold, in tonnes of active substance, is considered to be negligible. The use of antimicrobial growth promoters is prohibited in the ESVAC-participating countries, and therefore they are not part of the data collection. Ionophore coccidiostat feed additives and veterinary medicines containing zinc oxide[23] 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 sales of VMPs 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 pharmaceutical form and 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

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

[21] Available on the WHO Collaborating Centre for Drug Statistics methodology ATCvet web page: www.whocc.no/atcvet/

[22] 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'.

[23] 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 to be administered orally to food-producing animals (https://ec.europa.eu/health/documents/community-register/2017/20170626136754/dec_136754_en.pdfl).

(for 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 protocol[24].

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 directly upload their data 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 strength of the antibiotic active substance per package unit, as described in the corresponding product information. 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 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 database[25] 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, 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)[26], 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.

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

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

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

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, inconsistencies in previously submitted datasets are identified during the data validation process due to reasons such as availability of new official statistics regarding animal population data or identification of a specific inaccuracy in data provided for a VMP presentation. 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.

Data in former 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 eleventh ESVAC report and during the validation process of 2021 data, the following historical sales updates were implemented and included in the results of this report:

- Bulgaria corrected the number of packs sold for several VMPs for 2020. During the preparation of the eleventh ESVAC report an overestimation due to double reporting of some VMPs by marketing authorisation holders (MAHs) and reporting of export sales not intended for the Bulgarian market were detected. These corrections resulted in a 27% reduction of sales in mg/PCU for 2020.
- Czechia corrected a reporting error for four products sold between 2013 and 2020, where pheneticillin was indicated as an ingredient instead of penethamate hydriodide (penethacillin). No significant changes were observed following this correction.
- Latvia corrected the number of packs sold in 2019 and 2020 for several VMPs, as trade movements had not been corrected previously in these years and sales of special licence products were missing. These changes resulted in a 31% and 4% reduction of mg/PCU values in 2019 and 2020, respectively.
- Poland corrected 2011 sales data by removing one product (containing natamycin as an active substance) that had been incorrectly reported to ESVAC (the use indication and administration fall outside the ESVAC scope). No significant changes were observed following this correction.

- Portugal corrected 2020 sales data by removing a second ingredient that had been erroneously reported for one product that contains only one active antibiotic ingredient. No significant changes were observed following this correction.
- United Kingdom corrected the number of packs sold for one product in 2020. No significant changes were observed following this correction.

1.5.2. Animal population data

The historical updates made to animal population data during this reporting cycle, included in the ESVAC database and in the results of this report, are:

- Cyprus changed the reporting of animal population figures to ESVAC concerning dairy cows and living sheep. Previously, figures were extracted from Eurostat as per ESVAC protocol. For 2021, the Veterinary Services of Cyprus collected animal figures representing the entire population of dairy cows and living sheep throughout the entire year and reported it to ESVAC. Corrected figures of dairy cows and living sheep for 2011–2020 were provided by the Veterinary Services of Cyprus to ESVAC so that country sales trends could be carried out. Additionally, Cyprus provided missing data on the biomass of farmed fish produced for the same period. These corrections resulted in increases in the PCU values that range from 14% to 31% and decreases of sales in mg/PCU ranging from 12% and 24%.
- Greece corrected the biomass of farmed fish produced from 2015 to 2019, resulting in minor PCU (decrease between 1.3–2.5%) and mg/PCU (increase between 2.0–2.7%) changes. For 2020, Greece updated the figures for biomass of farmed fish, dairy cows, living sows and living sheep, resulting in 8% decrease of PCU and 8% increase in mg/PCU.
- Hungary corrected the number of living sows, slaughtered bullocks and bulls, slaughtered heifers, slaughtered calves and young cattle, and biomass of farmed fish produced for 2019 and 2020. These corrections resulted in a PCU increase of 2.0% and 4.0% for 2019 and 2020, respectively.
- Portugal corrected the number of living horses from 2010 to 2020, resulting in minor PCU changes (increase between 0.8–2.0%).

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 jointly established by ECDC, EFSA and EMA primary and secondary outcome indicators of antibiotic consumption for 2021 and their trends between 2011 and 2021. 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.

For 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):

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

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 2021, sales of VMPs with these four substances accounted for 0.21% of the total tonnes sold for the 31 ESVAC-participating countries.

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 14 September 2022. 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.

Table 2. Summary of information on number of years of data collection, legal basis for data collection at national level, national data providers, sources for ESVAC data and characteristics of data, by country, for 2021

Country	Number of years of data collection	Legal basis	National data provider to ESVAC	Sources for ESVAC data (approx. number)	Sales data, prescription data or purchase data[1]	Sales between wholesalers and/or MAHs excluded (Yes/No)	Products sold on special licence included[2] (Yes/No)
Austria	>5 years	Mandatory to report	Austrian Agency for Health and Food Safety	MAHs (n=8) 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	Not mandatory	Bulgarian Food Safety Agency	Wholesalers (n=38)	Sales to veterinarians, farmers and pharmacies	Yes	No
Croatia	>5 years	Mandatory to report	Ministry of Agriculture, Veterinary Directorate	Wholesalers (n=15)	Sales to pharmacies and veterinarians	Yes	No
Cyprus	>5 years	Mandatory to report	Ministry of Agriculture, Rural Development and Environment – Veterinary Services	Wholesalers (n=26) Feed mills (n=22)	Sales by wholesalers to veterinarians and pharmacies; sales by feed mills to farmers	Yes	Yes (17.8%)
Czechia	>5 years	Mandatory to report	Institute for State Control of Veterinary Biologicals and Medicines	Wholesalers (n=95) Feed mills (n=41)	Sales by wholesalers to veterinarians and pharmacies; sales by feed mills to farmers	Yes	Yes (0.08%)
Denmark	>5 years	Mandatory to report	Danish Veterinary and Food Administration	VetStat (n=1) obtaining data from pharmacies (n=569) Feed mills (n=1)	Prescriptions data from pharmacies and feed mills	Yes	Yes (1.9%)
Estonia	>5 years	Mandatory to report	State Agency of Medicines	Wholesalers (n=9)	Sales to veterinarians and pharmacies	Yes	Yes (2.6%)
Finland	>5 years	Mandatory to report	Finnish Medicines Agency	Wholesalers (n=1) 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=63)	Sales to wholesalers	Yes	No
Germany	>5 years	Mandatory to report	Federal Office of Consumer Protection and Food Safety	MAHs (n=28) Wholesalers (n=11) PSURs[3] data for premixes	Sales to veterinarians	Yes	No

[1] Purchase/import data from e.g. pharmaceutical industry and/or from wholesalers in other countries.
[2] Antibiotic VMPs available through special licence/marketing authorisation or through parallel trade, i.e. obtained from another Member State and permitted to be marketed for specific animal species and indications, although the type of authorisation procedure used might differ among Member State. The % refers to such sales as a proportion of the total sales (in tonnes) reported for that year.
[3] PSURs = periodic safety update reports.

Country	Number of years of data collection	Legal basis	National data provider to ESVAC	Sources for ESVAC data (approx. number)	Sales data, prescription data or purchase data[1]	Sales between wholesalers and/or MAHs excluded (Yes/No)	Products sold on special licence included[2] (Yes/No)
Greece	>5 years	Mandatory to report	Greek National Organisation for Medicines	MAHs (n=64)[4]	Sales to pharmacies and veterinarians	Yes	No
Hungary	>5 years	Not mandatory	National Food Chain Safety Office Directorate of Veterinary Medicinal Products	Wholesalers (n=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 (15.5%)
Ireland	>5 years	Mandatory to report	Health Products Regulatory Authority	MAHs (n=60)	Sales to wholesalers, pharmacies, veterinarians and licensed merchants	Yes	No[5]
Italy	>5 years	Mandatory to report	Italian Ministry of Health	Italian Drug Traceability System (n=1) obtaining data from pharmacies (n=19,530) and wholesalers (n=220) MAHs (n=21)	Dispensed e-prescription from wholesalers and pharmacies to veterinarians, farmers and companion animal owners; sales of premixes from MAHs to wholesalers	Yes	Yes (<0.01%)
Latvia	>5 years	Mandatory to report	Food and Veterinary Service	Wholesalers (n=17)	Sales to pharmacies, veterinarians, veterinary clinics and farmers	Yes	Yes (3.4%)
Lithuania	>5 years	Mandatory to report	State Food and Veterinary Service	Wholesalers (n=45)	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	Not mandatory	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	No
Netherlands	>5 years	Not mandatory	Federation of the Dutch Veterinary Pharmaceutical Industry (FIDIN)	MAHs (n=17)	Sales to wholesalers and veterinarians	Yes	No

[4] Negligible sales from a few MAHs with a very small market share, and which do not have local representatives in Greece, are not included in the dataset.
[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.

Country	Number of years of data collection	Legal basis	National data provider to ESVAC	Sources for ESVAC data (approx. number)	Sales data, prescription data or purchase data[1]	Sales between wholesalers and/or MAHs excluded (Yes/No)	Products sold on special licence included[2] (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 (18.9%)
Poland	>5 years	Mandatory to report	Ministry of Agriculture and Rural Development	Wholesalers (n=127)	Sales to veterinarians	Yes	No
Portugal	>5 years	Mandatory to report	Directorate-General for Food and Veterinary	Wholesalers (n=80)	Sales to pharmacies and veterinarians	Yes	No
Romania	>5 years	Mandatory to report	Institute for Control of Biological Products and Veterinary Medicines	MAHs (n=86)[6]	Sales to wholesalers	Yes	No
Slovakia	>5 years	Mandatory to report	Institute for State Control of Veterinary Biologicals and Medicaments	Wholesalers (n=59)	Sales to pharmacies, military forces, State Veterinary and Food Administration, veterinarians, farmers and feed mills	Yes	No
Slovenia	>5 years	Mandatory to report	Administration of the Republic of Slovenia for Food Safety, Veterinary Sector and Plant Protection (AFSVSPP)	Wholesalers (n=10)	Sales to veterinarians	Yes	Yes (5%)
Spain	>5 years	Not mandatory	Spanish Agency for Medicines and Health Products	Retailers (n=689) Feed mills (n=19) Pharmacies (n=4,045)[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=1500)	Dispensed veterinary prescriptions and requisitions[8]	Yes	Yes (10.9%)
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=69)	Sales to wholesalers, veterinarians, feed mills and veterinary pharmacies	Yes	No

[6] For 2015–2020, 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. In 2021, two MAHs have not provided sales data for a small range of products. The contribution from these sources to the overall figure is likely to be very small.

[7] Since 2017, data have been collected from retailers and pharmacies, but data from feed mills were used to verify the sales of medicated feed.

[8] Data represent veterinary prescriptions and requisitions dispensed by pharmacies for use in their own practice.

[9] No data provided by wholesalers or feed mills.

2. Results

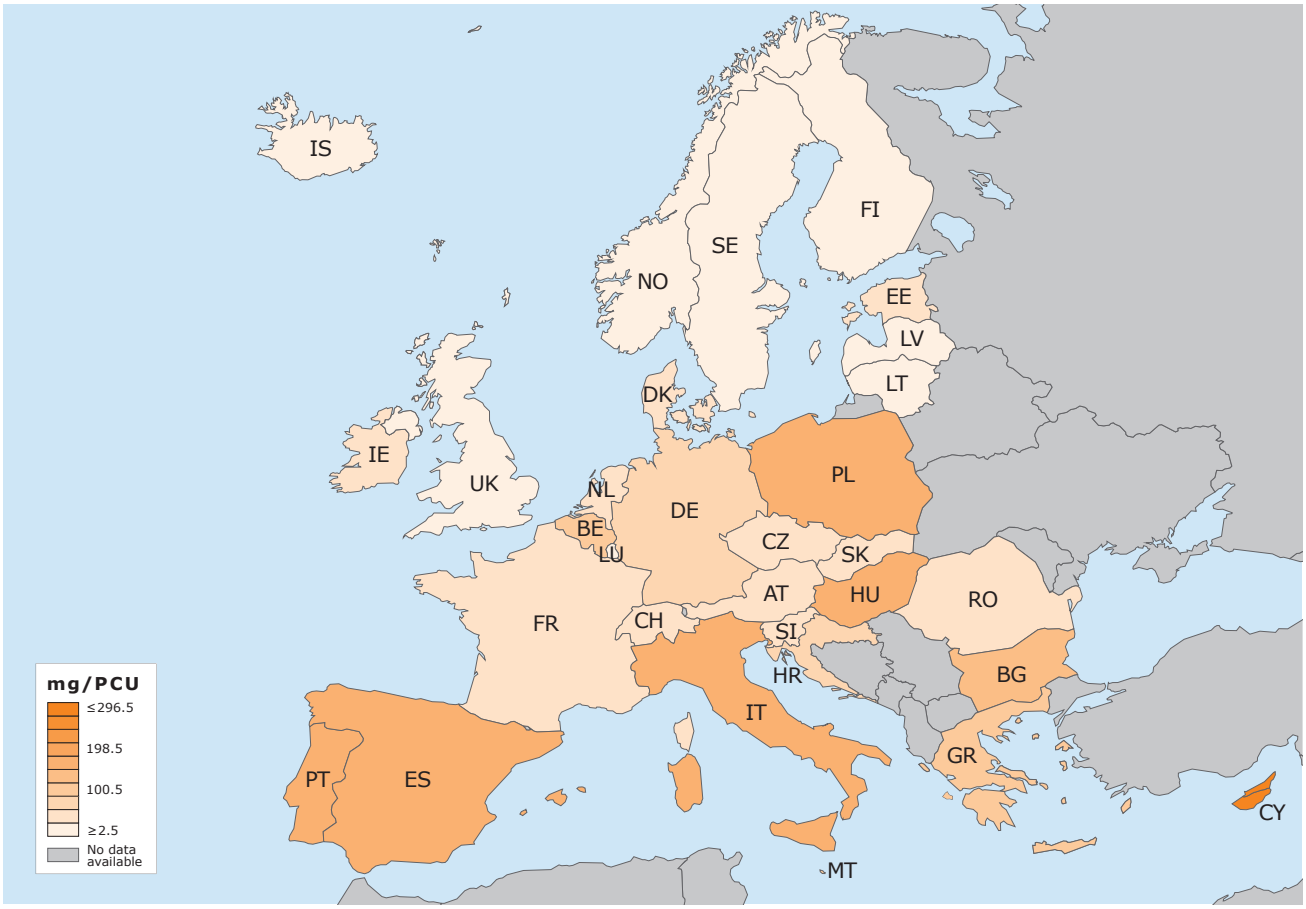
2.1. Sales of antibiotic VMPs for food-producing animals in 2021

2.1.1. Overall sales of antibiotic VMPs: primary outcome indicator

This section presents the 2021 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 horses[27]. 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 in terms of active substance. 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 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 2021.

Figure 2. Spatial distribution of overall sales, in mg/PCU, of antibiotic VMPs for food-producing animals in 31 European countries in 2021[1]



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

[27] 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 2021, sales of antibiotic VMPs for use in food-producing animals represented 98.6% of total sales (sales of tablets are described in Section 2.3) and ranged from 2.5 mg/PCU to 296.5 mg/PCU in the 31 participating countries (Figure 2). The total aggregated sales across all reporting countries were 84.4 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 factors such as data sources, animal demographics, types of animal production systems, selection of antibiotic agents and treatment protocols, among others.

Table 3. Sales in tonnes of active substance of antibiotic VMPs marketed mainly for food-producing animals[1], PCU in 1,000 tonnes and sales in mg/PCU in 31 European countries in 2021

Country	Sales (tonnes) for food-producing animals	PCU (1,000 tonnes)	mg/PCU
Austria	39.1	945.4	41.3
Belgium	168.6	1,769.5	95.3
Bulgaria	48.7	391.3	124.5
Croatia	20.7	330.8	62.7
Cyprus	45.1	152.0	296.5
Czechia	35.5	709.0	50.0
Denmark	81.9	2,452.1	33.4
Estonia	5.3	114.4	46.6
Finland	8.4	492.0	17.0
France	349.3	6,758.1	51.7
Germany	590.7	8,071.2	73.2
Greece	119.7	1,099.9	108.8
Hungary	131.6	845.8	155.6
Iceland	0.5	144.8	3.6
Ireland	93.2	2,196.1	42.4
Italy	661.7	3,812.6	173.5
Latvia	3.9	152.6	25.5
Lithuania	6.0	296.6	20.3
Luxembourg	1.5	54.2	27.1
Malta	1.6	14.8	110.5
Netherlands	147.2	3,091.9	47.6
Norway	5.5	2,196.9	2.5
Poland	775.1	4,417.2	175.5
Portugal	159.4	1,063.3	149.9
Romania	173.7	2,942.8	59.0
Slovakia	9.6	229.9	41.7
Slovenia	5.8	183.7	31.8
Spain	1,296.5	8,245.0	157.2
Sweden	8.6	787.6	10.9
Switzerland	25.9	809.8	32.0
United Kingdom	199.5	7,053.9	28.3
Total 31 countries	**5,219.6**	**61,825.1**	**84.4***

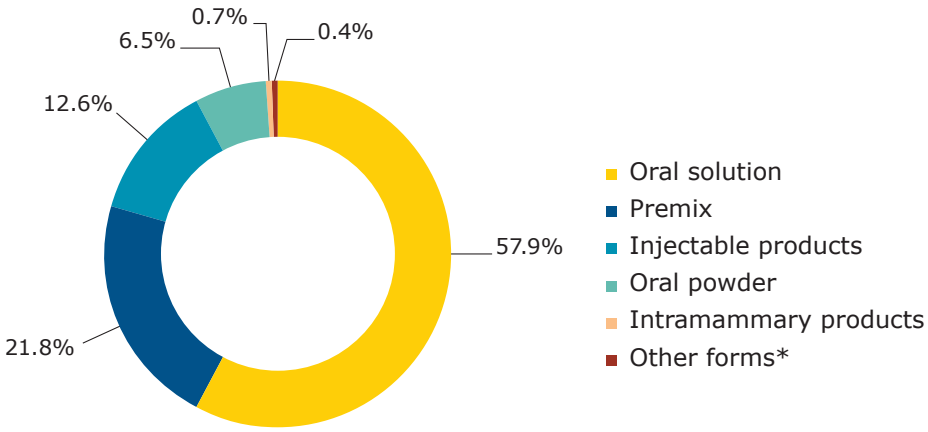
[1] Tablets are excluded as they are used almost exclusively in companion animals. On the contrary, sales of some injectable antibiotic VMPs and a few other products that are solely or also used in companion animals are included in the sales for food-producing animals given that their proportional use 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 57.9% of the total sales (mg/PCU) of antibiotic VMPs in the 31 countries, followed by premixes (21.8%), injectable products (12.6%), oral powders (6.6%), intramammary products (0.71%); the remaining sales (0.42%) 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 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/farm[28]. In 2021, 86.3% 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 2021 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 2021

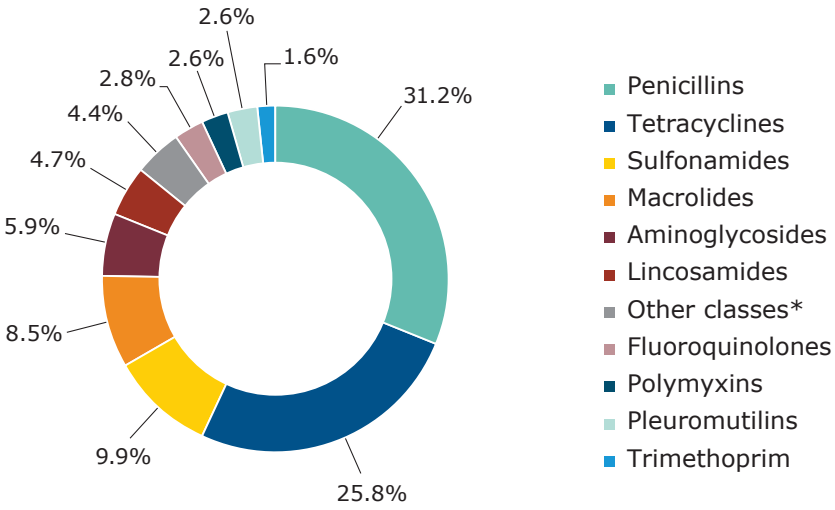


* 'Other forms' includes oral pastes, boluses and intrauterine products.

As shown in Figure 4, in 2021 the overall highest selling antibiotic classes were penicillins (31.2%), tetracyclines (25.8%) and sulfonamides (9.9%), accounting for 66.9% 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 0.14%, 0.18%, 2.8% and 0.21% of the overall sales in the 31 countries, respectively.

[28] Recently, 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 2021

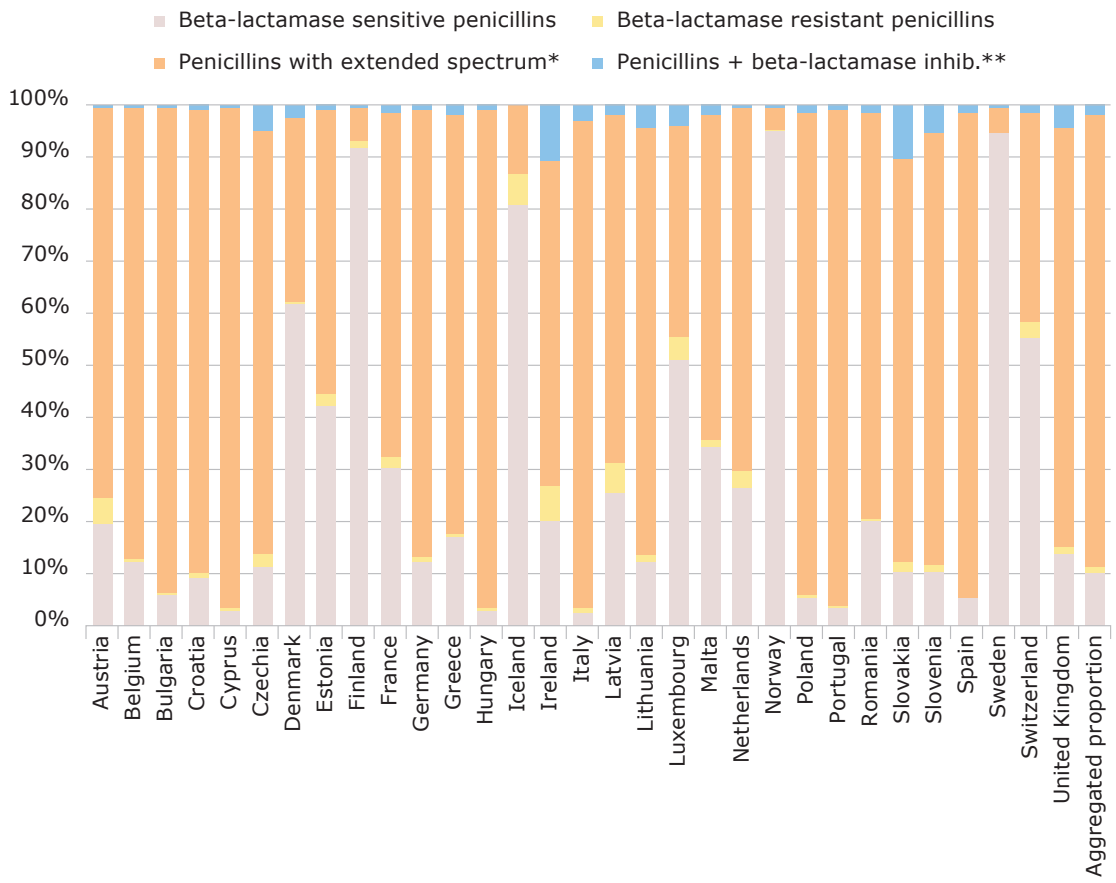


* 'Other classes' includes amphenicols, cephalosporins, other quinolones and 'Others'. The class 'Others' includes the following subclasses: imidazole derivatives (metronidazole), nitrofuran derivatives (furazolidone) and other antibacterials (bacitracin, furaltadone, novobiocin, rifaximin and spectinomycin). 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-lactamase-sensitive penicillins[29] were the highest selling penicillin subclass (representing between 62% and 96% of total penicillin sales). For the remaining countries, penicillins with extended spectrum (98.0% amoxicillin, 2.0% ampicillin and <0.01% metampicillin) accounted for the main proportion of penicillin sales. A small proportion of total penicillin sales for food-producing animals was represented by VMPs containing fixed combination of amoxicillin and beta-lactamase inhibitors (1.7% of penicillin sales for all 31 countries).

[29] Beta-lactamase-sensitive penicillins belong to ATCvet code QJ01CE and in 2021 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 2021[1]



* In 2021, 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 2021, 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 penicillins was the overall highest selling antibiotic class in 2021 (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 veterinarian prescribing habits, among other factors.

Table 4. Sales for food-producing animals, in mg/PCU, of the various antibiotic classes in 31 European countries in 2021[1]

Country	Tetracyclines	Amphenicols	Penicillins	1st- and 2nd-gen. cephalosporins	3rd- and 4th-gen. cephalosporins	Sulfonamides	Trimethoprim	Macrolides	Lincosamides	Fluoroquinolones	Other quinolones	Aminoglycosides	Polymyxins	Pleuromutilins	Others*	Total mg/PCU
Austria	20.4	0.4	8.8	0.1	0.2	3.9	0.8	2.6	0.2	0.5	0	1.4	1.6	0.3	0.2	41.3
Belgium	18.8	2.2	37.0	0.3	0.1	16.3	3.3	7.6	2.2	0.2	0.2	2.2	1.4	0.2	3.4	95.3
Bulgaria	60.5	4.4	25.2	0.02	0.2	6.7	0.9	9.2	4.9	3.9	0	4.1	3.1	1.0	0.5	124.5
Croatia	21.0	1.7	21.4	0.04	0.2	4.1	0.9	5.1	0.1	2.2	0	1.9	3.2	0.5	0.2	62.7
Cyprus	113.4	1.8	45.4	0.02	0.3	43.5	8.5	10.4	37.0	1.8	0.1	5.7	12.7	15.1	0.7	296.5
Czechia	12.8	0.3	17.4	0.1	0.5	7.6	0.9	2.5	0.1	1.6	0	2.7	0.5	2.6	0.3	50.0
Denmark	5.1	0.8	10.5	0.02	<0.01	2.8	0.6	5.0	0.8	<0.01	0.1	3.8	0	3.1	0.8	33.4
Estonia	13.5	0.4	11.5	0.1	0.5	2.9	0.6	0.9	0.5	0.9	0	3.1	0.2	10.6	0.9	46.6
Finland	3.6	0.3	8.7	<0.01	<0.01	3.3	0.7	0.4	0.04	0.1	0	0.1	0	0	0	17.0
France	16.6	0.8	8.5	0.2	0.02	10.6	1.7	3.8	0.4	0.1	0.2	6.5	1.3	0.4	0.6	51.7
Germany	15.5	0.7	28.4	0.1	0.1	7.9	1.1	6.1	1.5	0.7	0	2.5	6.3	1.0	1.3	73.2
Greece	57.3	0.9	16.7	0.01	0.2	9.7	1.2	5.3	0.7	2.6	0.6	9.9	1.7	1.3	0.6	108.8
Hungary	51.8	3.7	44.1	0.1	0.5	6.0	1.2	7.2	2.1	14.8	0	2.7	12.1	9.1	0.2	155.6
Iceland	0.5	0	2.4	0	<0.01	0.1	0.02	0	0	<0.01	0	0.6	0	0	0	3.6
Ireland[2]	17.2	1.3	9.3	0.6	0.2	7.2	0.5	2.4	0.1	0.4	0	2.6	0		0.6	42.4
Italy	40.3	5.9	58.0	0.2	0.1	23.9	2.4	10.8	15.3	1.2	0.7	7.5	0.6	4.6	2.2	173.5
Latvia	5.6	0.2	7.0	0.3	0.4	0.9	0.2	4.4	0.1	0.7	0	3.9	0.3	1.3	0.1	25.5
Lithuania	2.8	0.4	6.4	0.1	0.1	4.0	0.8	2.1	0.1	1.3	0	0.5	<0.01	1.4	0.2	20.3
Luxembourg	4.1	2.8	6.7	0.2	0.5	5.4	1.1	1.1	0.5	0.7	0	3.3	0.2	0.05	0.4	27.1
Malta[3]	34.4	1.7	9.6	0.05	0.3	21.4	3.8	11.8	0.4	8.5		7.1	0.3	6.4	4.7	110.5
Netherlands	16.2	1.4	10.8	0.04	<0.01	9.0	1.7	6.7	0.1	0.03	0.6	0.6	0.4	0.1	0.1	47.6
Norway	0.04	0.4	1.3	0	<0.01	0.6	0.1	<0.01	<0.01	<0.01	0.03	0.04	0	0.01	<0.01	2.5
Poland	36.9	2.4	63.3	0.2	0.4	7.7	1.5	22.6	2.7	12.7	0	7.4	8.1	7.6	2.0	175.5
Portugal	44.5	2.5	35.6	0.05	0.3	9.4	1.9	16.1	6.7	8.8	<0.01	7.6	6.1	10.2	0.3	149.9
Romania	15.6	2.6	11.1	<0.01	0.2	2.5	0.4	7.9	1.4	6.7	0.1	6.1	2.2	1.5	0.7	59.0
Slovakia	8.2	0.2	10.6	0.2	0.5	5.8	0.9	0.6	0.3	3.4	0.01	4.0	1.4	4.5	1.0	41.7
Slovenia	6.8	1.9	15.2	0.04	0.2	2.0	0.5	0.2	0.02	0.9	0	3.5	0.1	0.5	0.02	31.8
Spain	36.5	7.7	53.2	0.04	0.3	11.0	2.0	10.8	15.9	3.3	0.4	11.4	0.4	2.9	1.4	157.2
Sweden[4]	0.9		7.0		<0.01	1.6	0.3	0.4	0.05		0.1	0.4			0.1	10.9
Switzerland[5]	6.9	0.7	10.3	0.1	0.1	8.6	0.8	1.2		0.2	0	2.9	0.1		0.05	32.0
United Kingdom	9.6	0.6	7.6	0.1	0.02	2.6	0.5	2.7	0.5	0.1	0	2.6	0	0.9	0.5	28.3
Total sales[6] for 31 countries (mg/PCU)	**21.8**	**2.3**	**26.3**	**0.1**	**0.2**	**8.3**	**1.3**	**7.2**	**4.0**	**2.4**	**0.2**	**5.0**	**2.2**	**2.2**	**1.0**	**84.4**
Median[7] of 31 countries (mg/PCU)	**15.6**	**1.1**	**10.8**	**0.1**	**0.2**	**6.0**	**0.9**	**4.7**	**0.5**	**0.9**	**0.1**	**3.1**	**0.6**	**1.3**	**0.5**	**47.6**

* 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.

[1] 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.

[2] For commercial confidentiality reasons, pleuromutilins are aggregated with 'Others'.

[3] For commercial confidentiality reasons, other quinolones are aggregated with fluoroquinolones.

[4] For commercial confidentiality reasons, amphenicols, polymyxins and pleuromutilins are aggregated with 'Others', 1st- and 2nd-generation cephalosporins are aggregated with 3rd- and 4th-generation cephalosporins and fluoroquinolones are aggregated with other quinolones.

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

[6] Total 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.

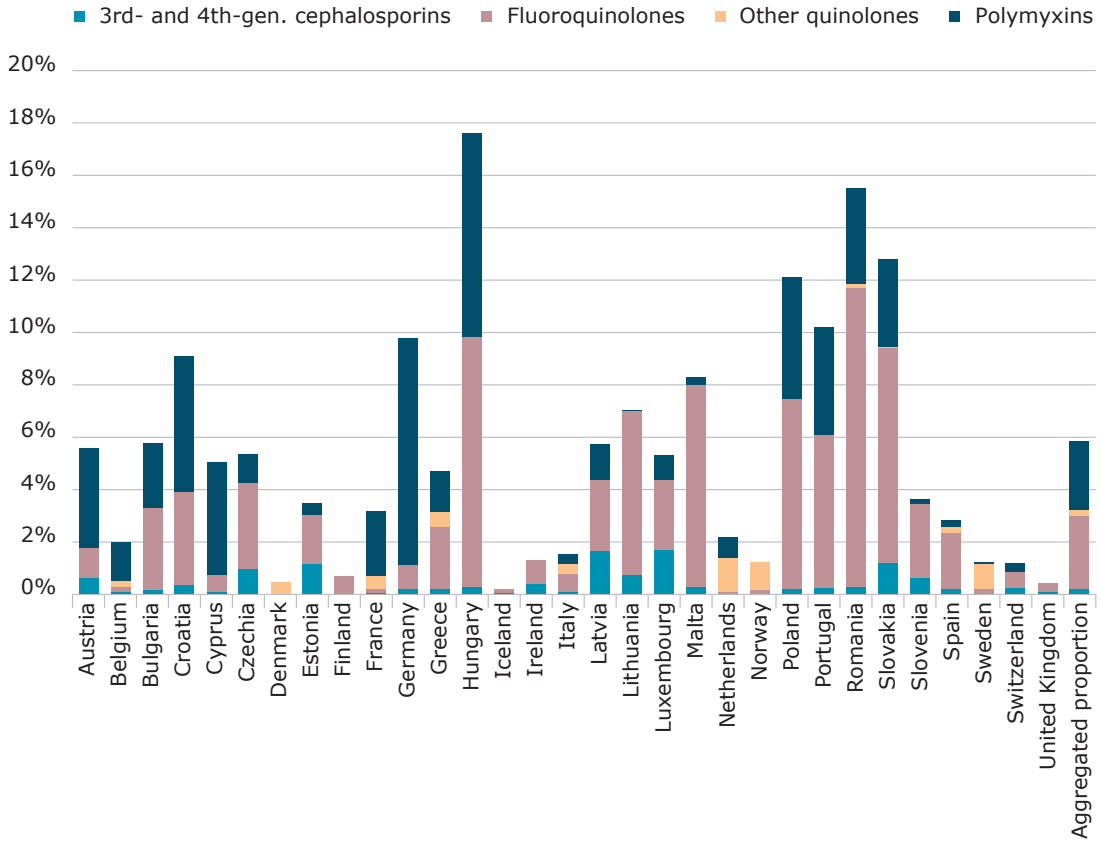
[7] Median shows the 16th value ranked from smallest to largest out of 31 observed values for each antibiotic class.

2.1.2. Sales of antibiotic VMPs: secondary outcome indicators

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

The proportion of total aggregated sales in 2021 corresponding to each of these antibiotic classes varied substantially between the 31 countries, ranging from <0.01% to 1.7% for 3rd- and 4th-generation cephalosporins, 0.01% to 11.4% for fluoroquinolones, 0% to 1.3% for other quinolones and 0% to 8.7% 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 2021[1,2,3,4]

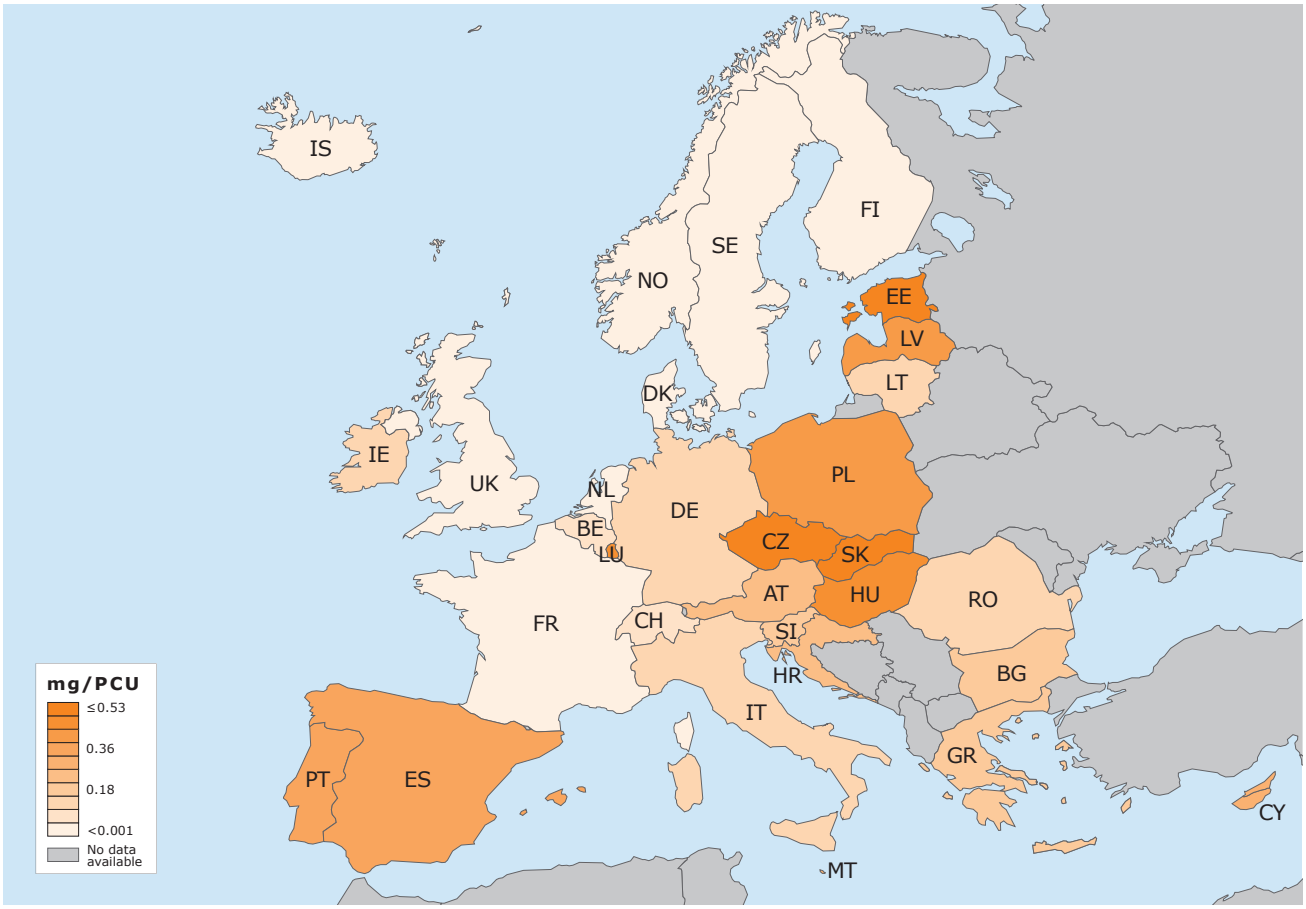


[1] Variations between the countries should be interpreted with great care due to the large differences in dosing schemes between these classes/subclasses of antibiotics.
[2] No sales of other quinolones were reported for Austria, Bulgaria, Croatia, Czechia, Estonia, Finland, Germany, Hungary, Iceland, Ireland, Latvia, Lithuania, Luxembourg, Malta, Poland, 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 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 0.53 mg/PCU (Table 4) between countries and presented aggregated sales of 0.15 mg/PCU accounting for 0.18% of total sales (Table 4 and Figure 4).

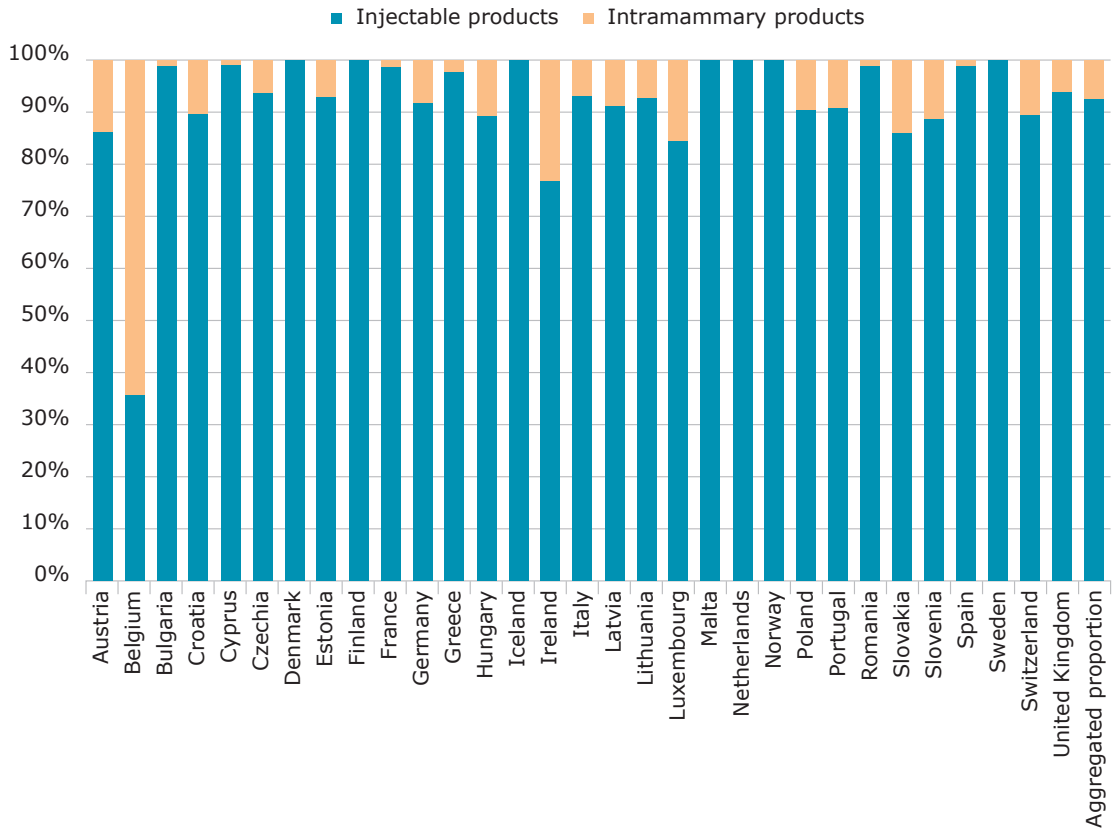
Figure 7. Spatial distribution of sales, in mg/PCU, of 3rd- and 4th-generation cephalosporins for food-producing animals in 31 European countries in 2021[1]



[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 2021[1,2,3,4]



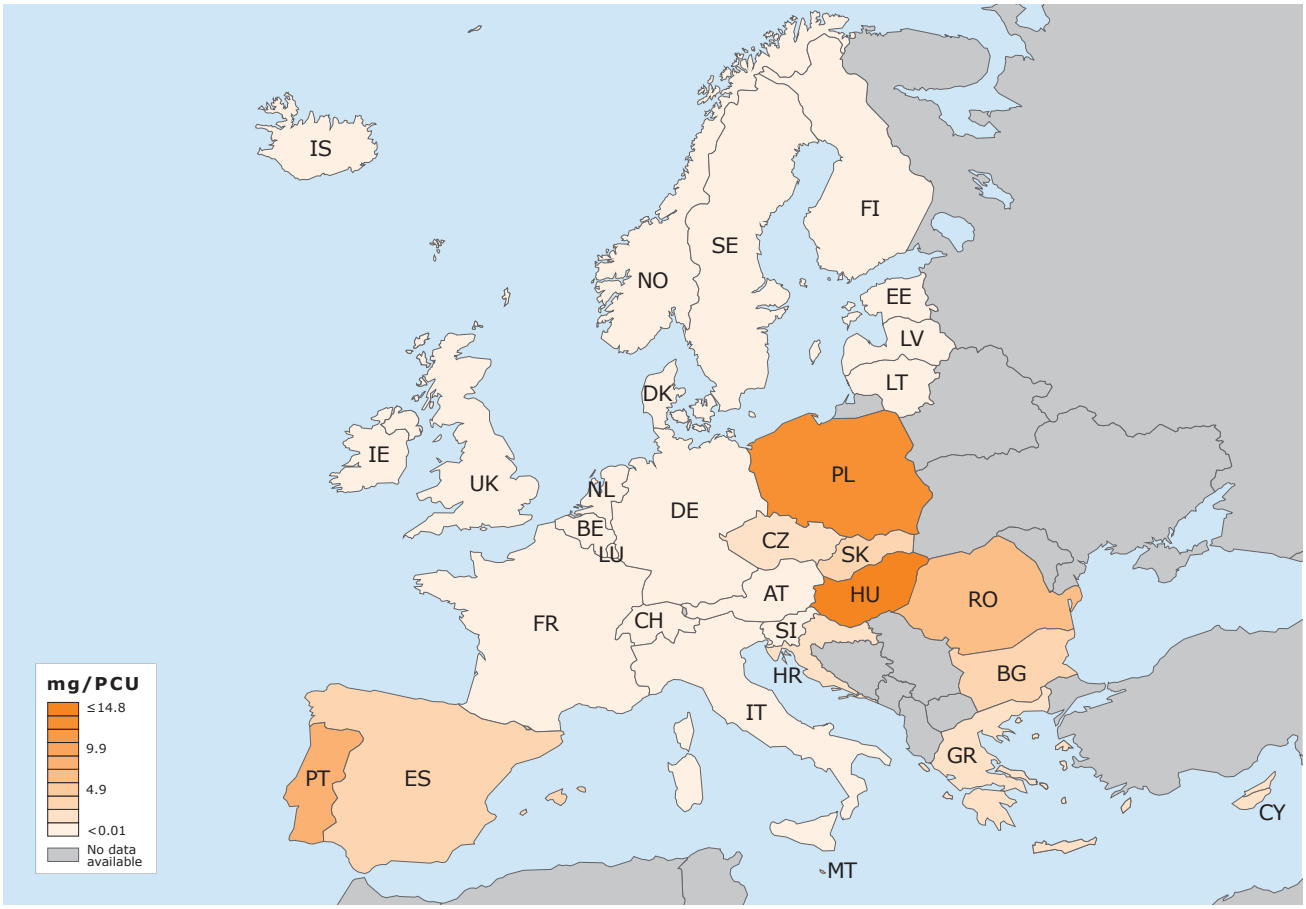
[1] Sales <1 kg in Finland, Iceland and Norway.
[2] No sales of intramammary products reported for Denmark, Finland, Iceland, Malta, the Netherlands, Norway and Sweden.
[3] For countries where injectable 3rd- and 4th-generation cephalosporins are solely or also marketed for dogs and cats, the data provide 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 14.8 mg/PCU between the 31 countries and presented aggregated sales of 2.5 mg/PCU, accounting for 3.0% of total sales (Table 4 and Figure 4).

Fluoroquinolones accounted for 92.9% of total quinolone sales, with this proportion varying between 1.6% 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 14.8 mg/PCU and presented aggregated sales of 2.4 mg/PCU, accounting for 2.8% of total (all antibiotics) aggregated sales (Table 4 and Figure 4).

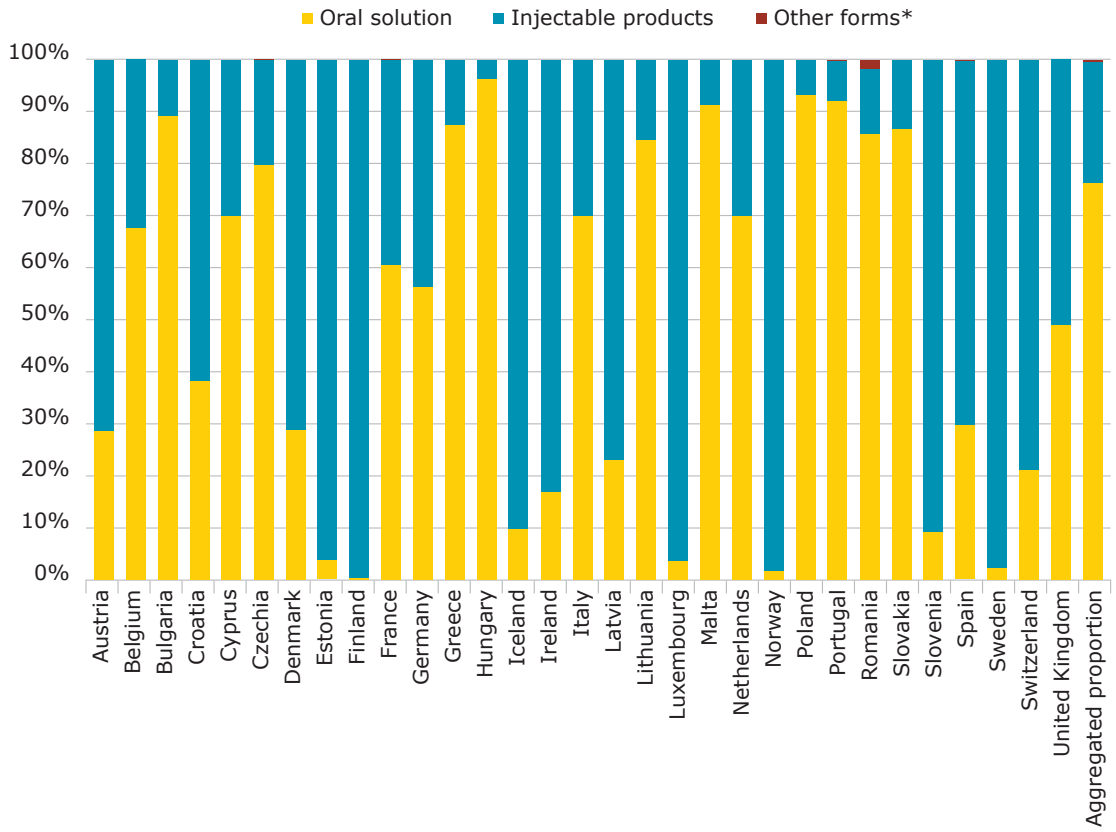
Figure 9. Spatial distribution of sales, in mg/PCU, of fluoroquinolones for food-producing animals in 31 European countries in 2021[1]



[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 16 of the participating countries; in the remaining 15 countries, injectables were the predominant product form. Aggregated for the 31 countries, 76.4% of total fluoroquinolone sales corresponded to oral solutions, 23.3% to injectable products and 0.24% to other product forms such as premixes, boluses and intrauterine preparations.

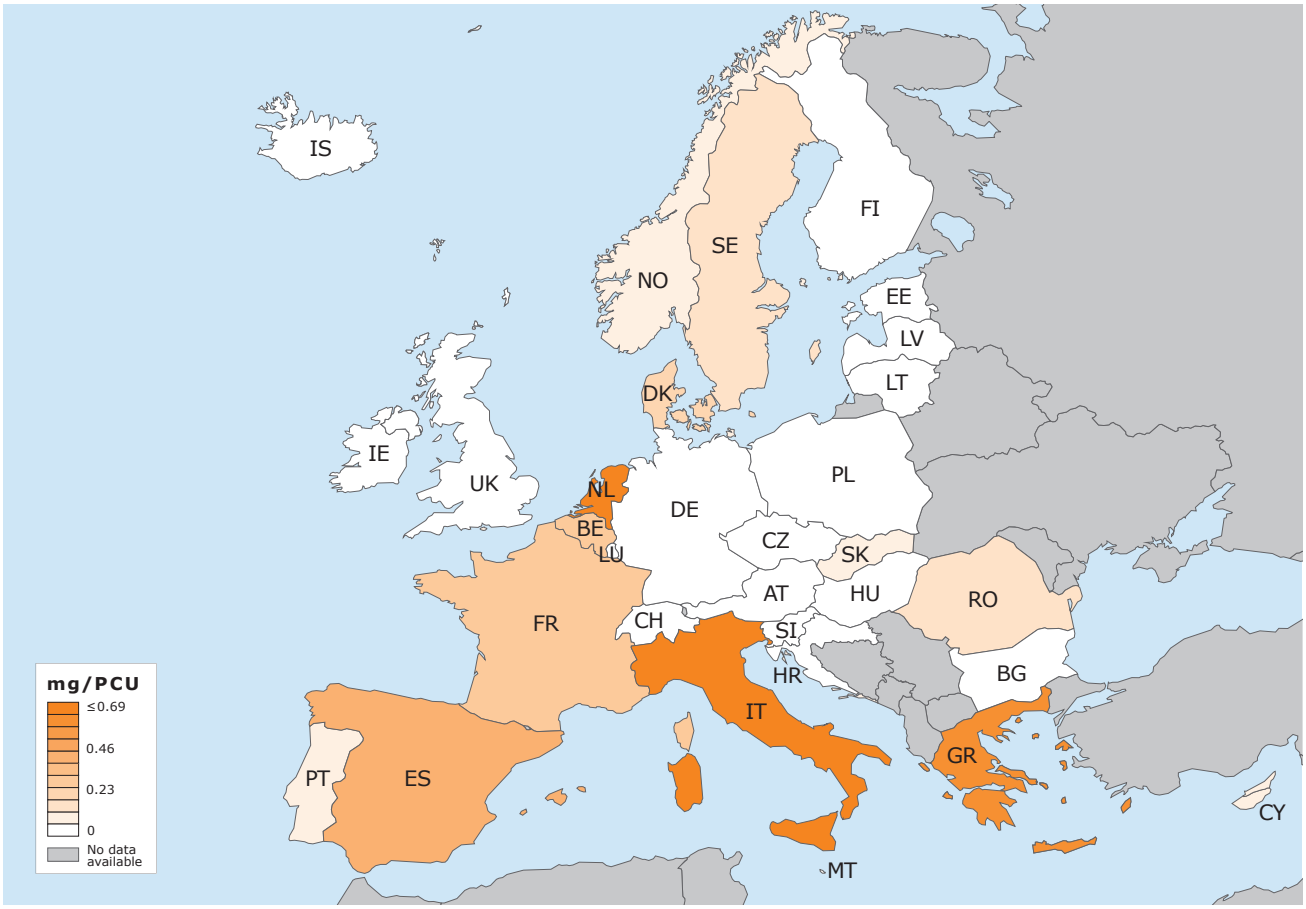
Figure 10. Proportion of sales, in mg/PCU, of fluoroquinolones for food-producing animals by product form in 31 European countries in 2021[1,2]



* '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 7.1% 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 0.69 mg/PCU (Table 4). Overall, the aggregated sales of other quinolones were 0.18 mg/PCU accounting for 0.21% of total sales (Table 4 and Figure 4).

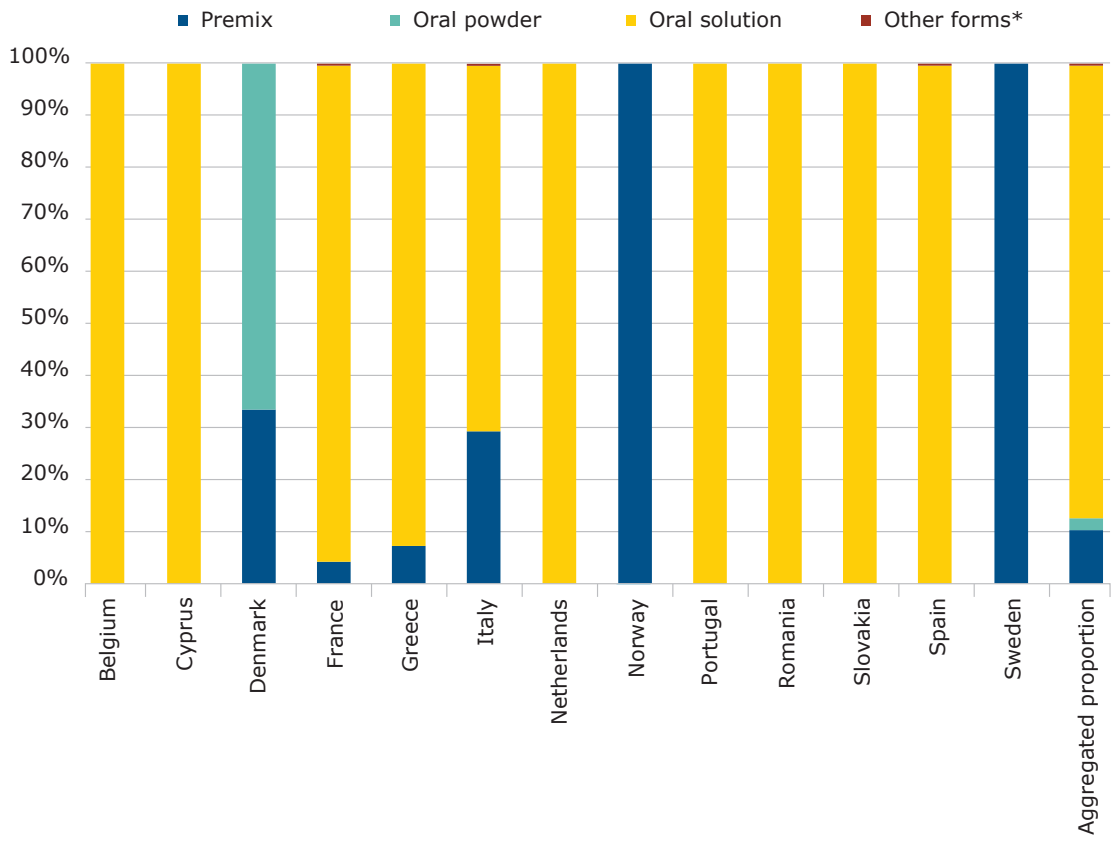
Figure 11. Spatial distribution of sales, in mg/PCU, of other quinolones for food-producing animals in 31 European countries in 2021[1,2]



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

The highest selling product form for other quinolones varied between the countries that reported sales of this antibiotic class in 2021 (Figure 12). In 2 countries other quinolones were sold exclusively as premixes, in 1 country predominantly as oral powders and in the remaining countries oral solutions accounted for at least 70% of the sales of this antibiotic class. Regarding the aggregated sales of other quinolones across the 31 countries, 87.2% corresponded to oral solutions, 10.4% to premixes, 2.2% to oral powders and the remaining <1% to other forms such as oral pastes, boluses or injectable products.

Figure 12. Proportion of sales, in mg/PCU, of other quinolones for food-producing animals by product form and by country in 2021[1,2]

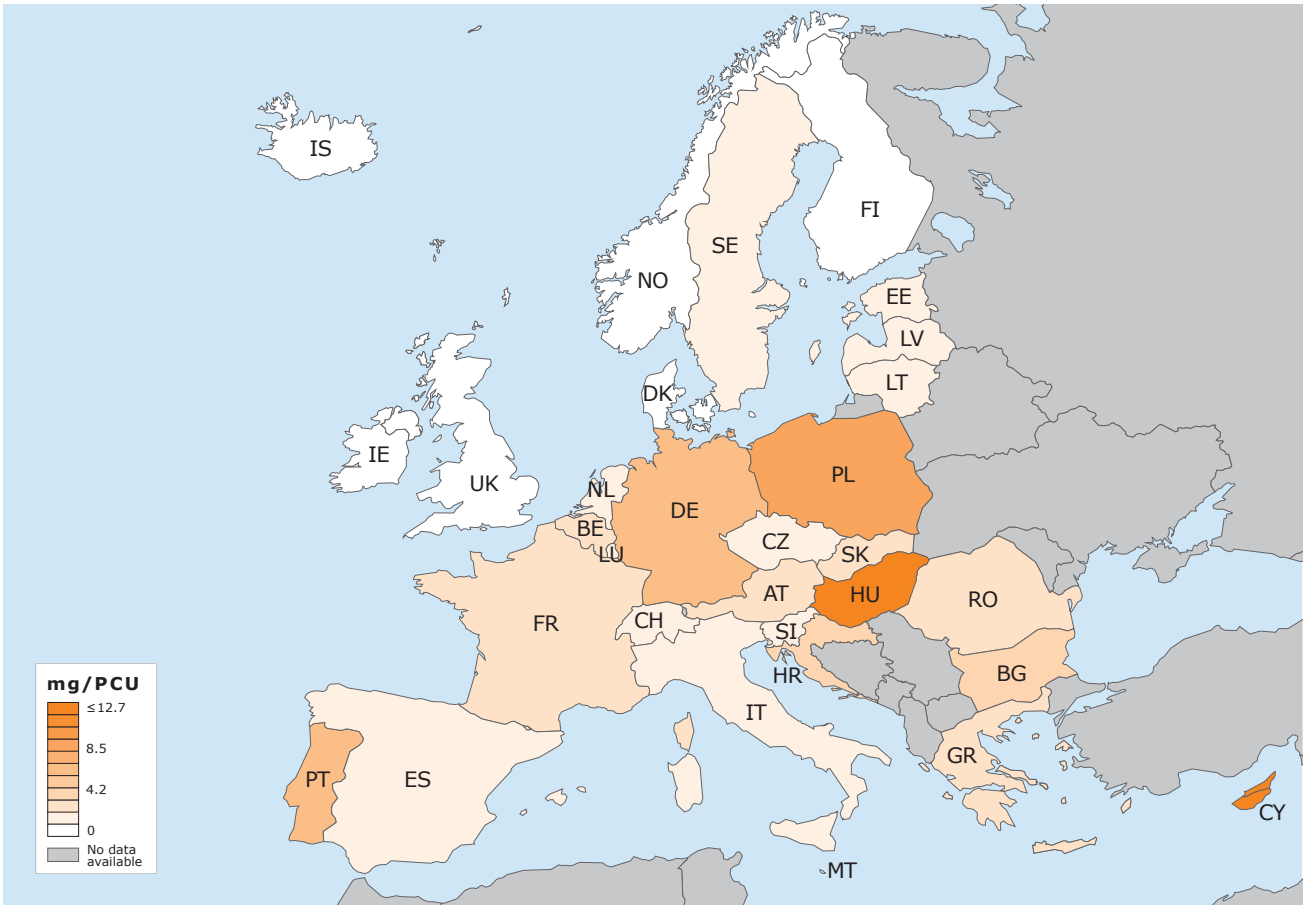


* 'Other forms' includes negligible quantities sold as injectable products, boluses and/or oral pastes in some countries.
[1] No sales of other quinolones reported in Austria, Bulgaria, Croatia, Czechia, Estonia, Finland, Germany, Hungary, Iceland, Ireland, Latvia, Lithuania, Luxembourg, Malta, Poland, 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 countries with sales of other quinolones in 2021.

2.1.2.3. Sales of polymyxins

Sales of polymyxins were also unevenly distributed across the 31 countries (Figure 13). Sales of this antibiotic class ranged between 0 mg/PCU and 12.7 mg/PCU over the different countries, with 6 not reporting any sales (Table 4). Overall, the aggregated sales of polymyxins were 2.2 mg/PCU accounting for 2.6% of total sales (Table 4 and Figure 4).

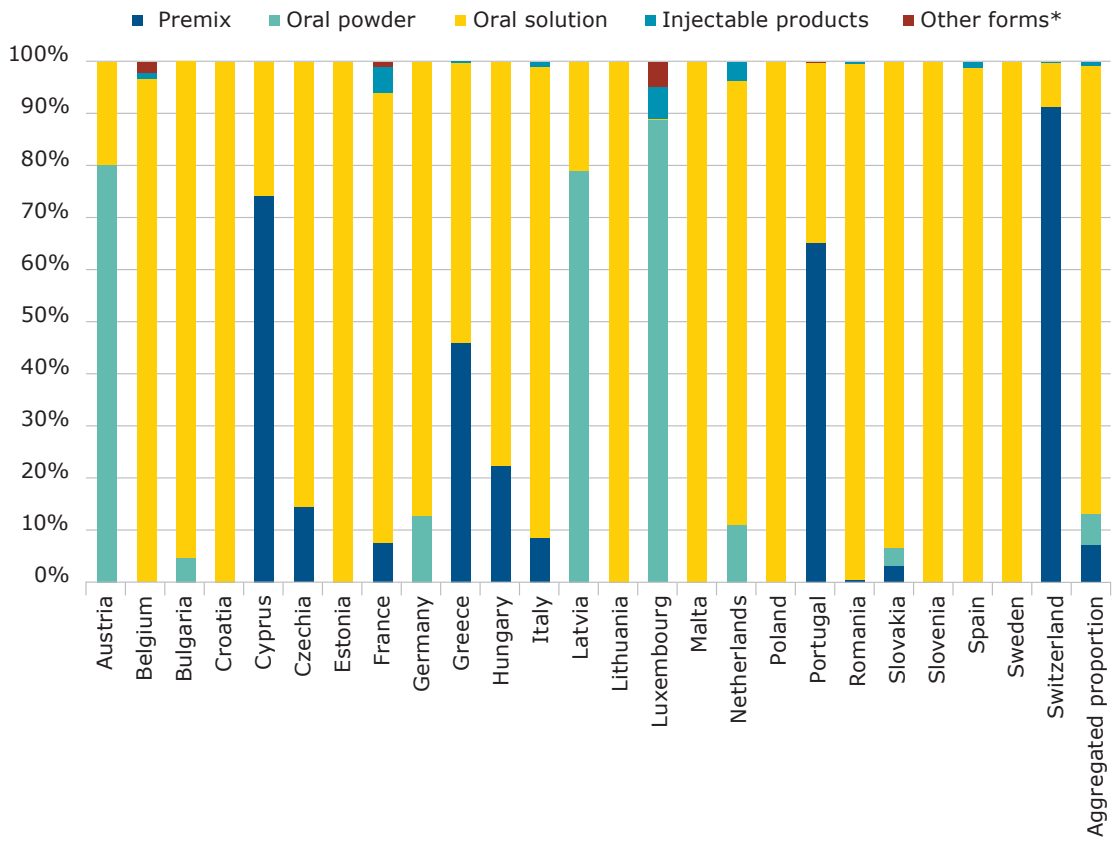
Figure 13. Spatial distribution of sales, in mg/PCU, of polymyxins for food-producing animals in 31 European countries in 2021[1,2]



[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 countries, polymyxins were predominantly sold as oral solutions (Figure 14). Of the aggregated sales of 31 countries, 86.3% corresponded to oral solutions, 7.2% to premixes, 5.8% to oral powders and the remaining <1% to injectable products and other forms such as boluses, intramammary products and oral pastes.

Figure 14. Distribution of sales, in mg/PCU, of polymyxins for food-producing animals by product form and by country, in 2021[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] Sales <1 kg in Lithuania.
[3] The aggregated proportion is based on the aggregated mg/PCU (total quantity of antibiotic active substance sold (mg) divided by total PCU (kg)) for all countries with sales of other quinolones in 2021.

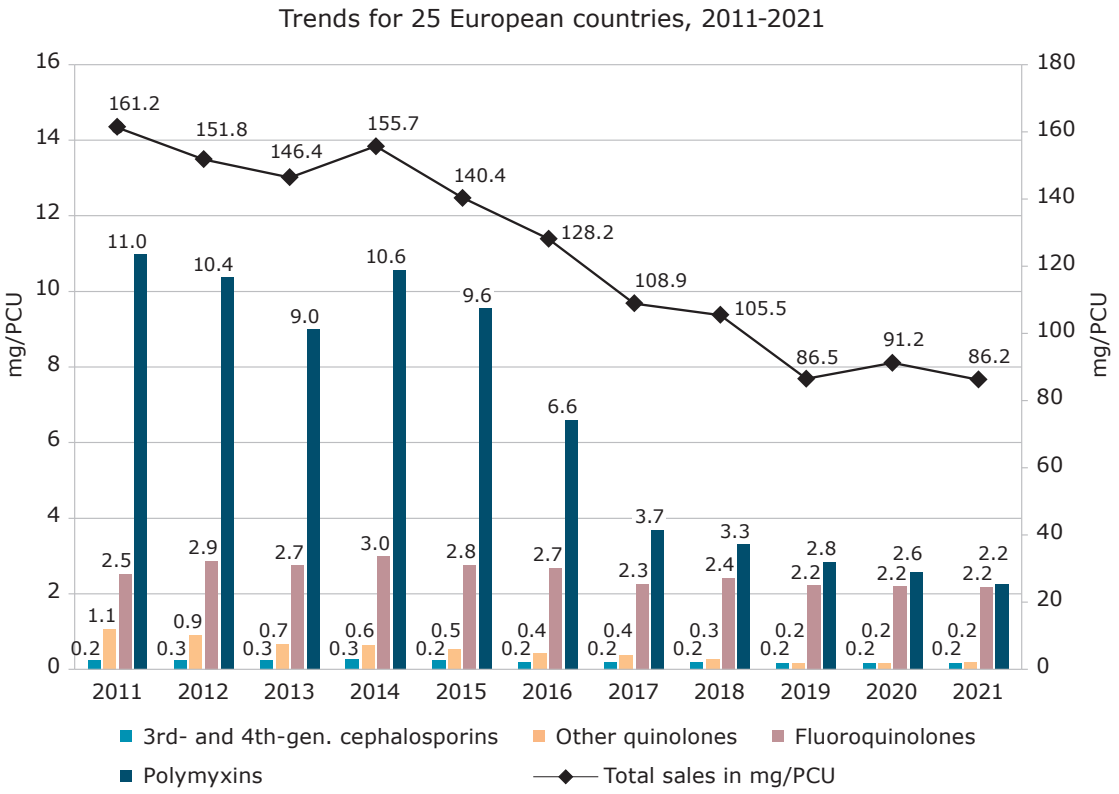
2.2. Sales trends of antibiotic VMPs for food-producing animals

This section is focused 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 from 2011 to date. 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 the current date. 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 at the end of this section in Tables 5 and 6.

2.2.1. Sales (mg/PCU) trends from 2011 to 2021, 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 2021, having declined 46.5% since 2011 (from 161.2 mg/PCU to 86.2 mg/PCU). In comparison to 2020 (91.2 mg/PCU), sales in 2021 decreased by 5.5% (Figure 15). During the period 2011–2021, sales (mg/PCU) decreased by more than 4% (a decline in sales of between 4.4% and 65.4%) in 23 of the 25 countries, and in the remaining 2 countries sales increased by more than 5% (between 34.5% and 39.0%) (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 countries[1] reporting data for ESVAC from 2011 to 2021 (note the different scales of the two y-axes)

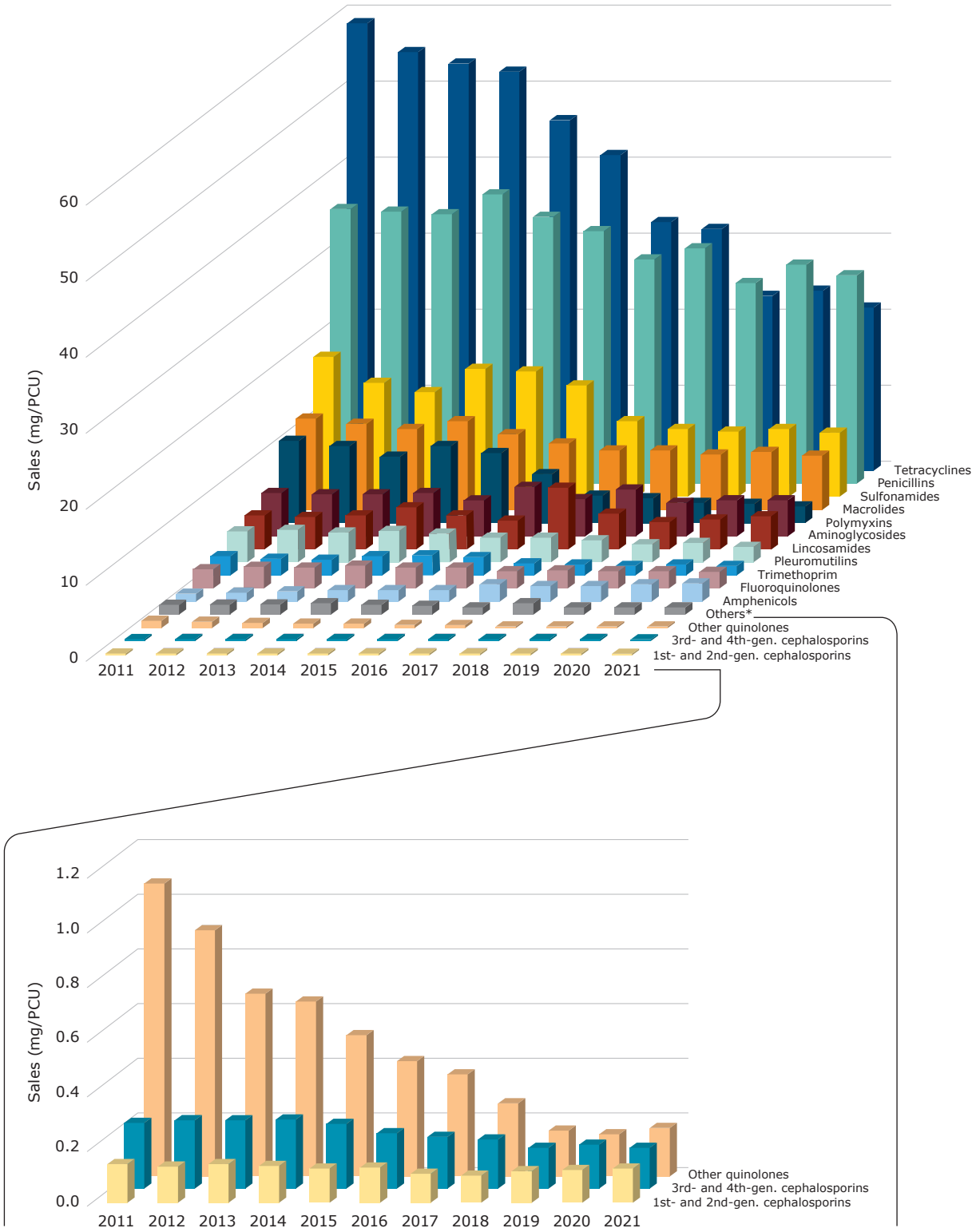


[1] Austria, Belgium, Bulgaria, Cyprus, Czechia, Denmark, Estonia, Finland, France, Germany, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, the Netherlands, Norway, Poland, Portugal, Slovakia, Slovenia, Spain, Sweden and the United Kingdom.

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 2021, sales of 3rd- and 4th-generation cephalosporins decreased by 37.8% (from 0.24 mg/PCU to 0.15 mg/PCU), sales of fluoroquinolones decreased by 14.2% (from 2.5 mg/PCU to 2.2 mg/PCU), sales of other quinolones decreased by 83.1% (from 1.1 mg/PCU to 0.18 mg/PCU) and sales of polymyxins decreased by 79.5% (from 11.0 mg/PCU to 2.2 mg/PCU) (Figure 15).

With the exception of amphenicols, for which sales have increased from 1.0 mg/PCU in 2011 to 2.4 mg/PCU in 2021, sales of the other antibiotic classes have decreased since 2011, albeit with some fluctuations for some classes. Tetracyclines was the highest selling class up until 2019, after which penicillins started accounting for the majority of the aggregated sales for the 25 countries. Nonetheless, tetracyclines, penicillins and sulfonamides have always been the top three highest selling antibiotic classes between 2011 and 2021. Overall, the sales of these three classes declined by 63.4% (from 59.2 mg/PCU to 21.7 mg/PCU), 24.1% (from 36.3 mg/PCU to 27.6 mg/PCU) and 53.8% (18.7 mg/PCU to 8.6 mg/PCU), respectively. Sales of 1st- and 2nd-generation cephalosporins have remained relatively stable, constituting the lowest selling antibiotic class throughout the entire period. Sales of macrolides, classified as critically important antimicrobials (CIAs) with the highest priority for human medicine by WHO, have declined by 40.4% (from 12.2 mg/PCU to 7.3 mg/PCU) (Figure 16).

Figure 16. Trends of aggregated sales (mg/PCU) by antibiotic class in 25 European countries[1], from 2011 to 2021[2]

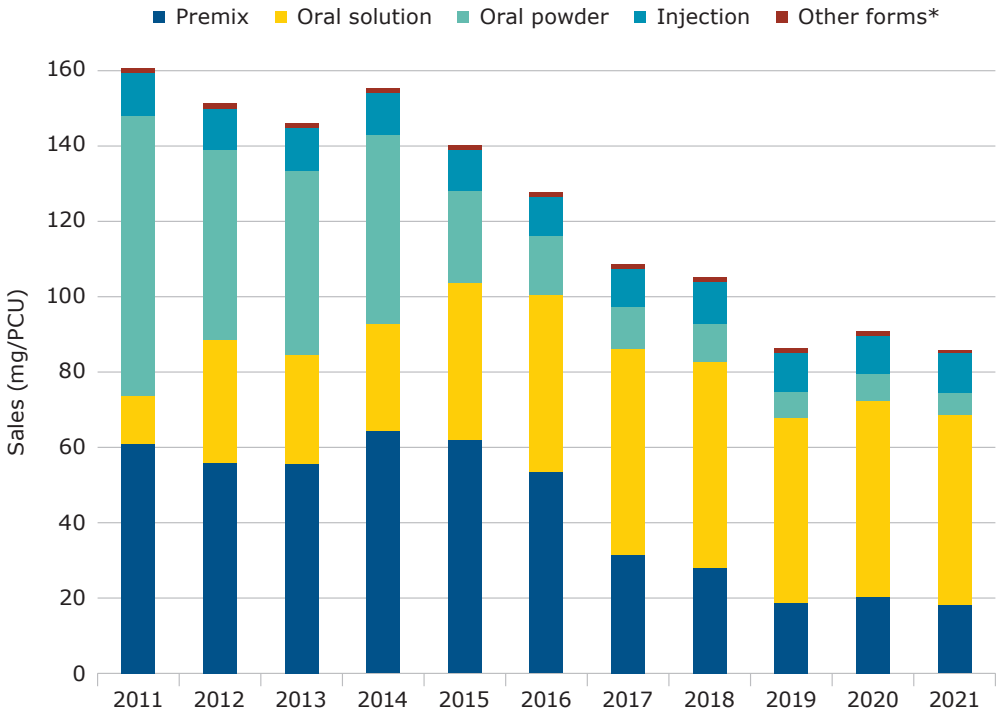


[1] Austria, Belgium, Bulgaria, Cyprus, Czechia, Denmark, Estonia, Finland, France, Germany, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, the Netherlands, Norway, Poland, Portugal, Slovakia, Slovenia, Spain, Sweden and the United Kingdom.
[2] Antibiotic classes are sorted from highest to lowest 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 from 2011 to 2021 in the 25 countries (Figure 17). While sales of oral solutions have increased over the years (from 12.8 mg/PCU to 50.3 mg/PCU), sales have declined for all other product forms: oral powders (from 74.3 mg/PCU to 6.1 mg/PCU), premixes (from 61.3 mg/PCU to 18.6 mg/PCU), injectables (from 11.3 mg/PCU to 10.3 mg/PCU) and other forms including intrauterine preparations, intramammary products, oral pastes and boluses (from 1.4 mg/PCU to 0.94 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 49.5% in the period 2011–2021 (from 148.5 mg/PCU to 74.9 mg/PCU), they still accounted for the majority of sales in 2021 (86.9% of total sales) with oral solutions representing 58.3% of sales, premixes 21.6% and oral powders 7.0%. Sales of product forms predominantly used for individual treatment also declined by 11.7% between 2011 and 2021 (from 12.7 mg/PCU to 11.3 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 countries[1] from 2011 to 2021

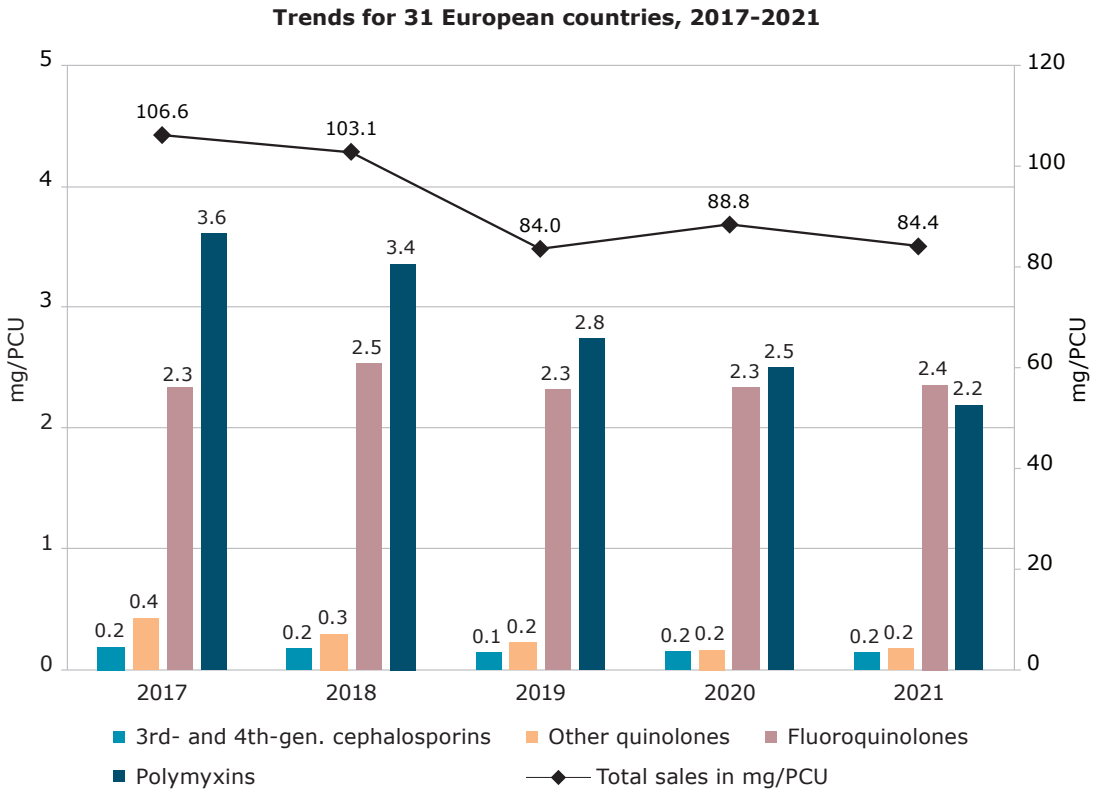


* Other forms include oral pastes, boluses, and intrauterine and intramammary products.
[1] Austria, Belgium, Bulgaria, Cyprus, Czechia, Denmark, Estonia, Finland, France, Germany, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, the Netherlands, Norway, Poland, Portugal, Slovakia, Slovenia, Spain,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

2.2.2. Sales (mg/PCU) trends from 2017 to 2021, 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 20.8% until 2021 (from 106.6 mg/PCU to 84.4 mg/PCU), as shown in Figure 18. During this five-year period, sales (in mg/PCU) decreased in 28 of the 31 countries (by between 3.5% and 40.8%) and increased in 3 countries (by between 7.1% and 13.7%) (Table 5). When compared to 2020 (88.8 mg/PCU), sales in 2021 decreased by 4.9% and reached similar levels to those registered in 2019 (84.0 mg/PCU).

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 2021 (note the different scales of the two y-axes)



For the AMEG Category B antibiotics, sales have also decreased between 2017 and 2021. The most noticeable changes were observed for other quinolones and polymyxins, which showed a 58.8% (from 0.44 mg/PCU to 0.18 mg/PCU) and a 39.0% (sales reduced from 3.6 mg/PCU to 2.2 mg/PCU) decrease in sales, respectively. The decrease in sales was more modest for 3rd- and 4th-generation cephalosporins (a reduction of 19.9% from 0.19 mg/PCU to 0.15 mg/PCU) while sales of fluoroquinolones remained relatively stable (increase from 2.3 mg/PCU to 2.4 mg/PCU) (Figure 18).

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

For the years that the various European countries have reported sales to ESVAC, the overall sales (in mg/PCU) decreased by more than 4% (a decline in sales of between 4.4% and 65.4%) in 28 of the 31 countries, while in 3 countries sales increased by more than 5% (an increase in sales of between 34.5% and 87.0%) (Table 5).

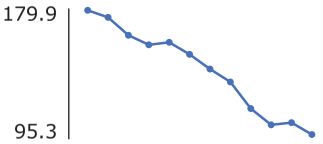
The values presented in Table 5 may differ from those published in previous ESVAC reports, due to corrections of historical data of sales and of animal population data for the calculation of the PCU (Section 1.5). Considerable differences can be found for Cyprus PCU due to historical animal population data corrections for dairy cows and living sheep made for all previous reporting years (2011–2020). Additionally, Cyprus provided missing data on the biomass of farmed fish produced for the same period. These corrections resulted in PCU increases ranging from 14% to 31%. In comparison with the historical data published in the 2019 and 2020 ESVAC reports, overall sales (mg/PCU) in Cyprus decreased between 12% and 24%.

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

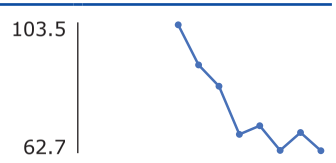
The main indicator used in this report expresses the consumption of antibiotics in food-producing animals by normalising the sales of active substance in mg (numerator) by the PCU in kg (denominator). Table 6 offers an overview of trends for both numerator (in tonnes) and denominator (in 1,000 tonnes) and an overall trendline for the numerator for all 31 participating countries from their first reporting year until 2021.

Sales of active substances (in tonnes) have declined for most countries, while for others they have fluctuated or increased. The PCU (in 1,000 tonnes) varied between a 9.6% decrease and 9.4% increase for 21 countries, declined by more than 10% for 3 countries, and increased by more than 10% for 7 countries.

Table 5. Sales trends for food-producing animals (mg/PCU), including horses and farmed fish, per country[1,2,3] from 2010 to 2021

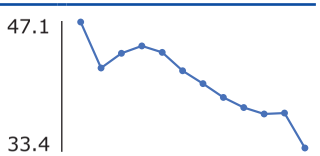
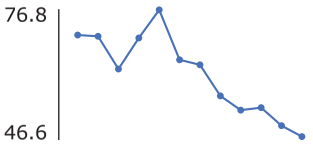
Country		2010	2011	2012	2013	2014	2015	2016	2017	2018	2019	2020	2021	Trends 2010-2021
Austria	**Overall sales**	62.9	54.4	54.8	57.2	56.3	50.7	46.1	46.7	50.2	42.6	46.3	41.3	
	3rd- and 4th-gen. cephalosporins	0.30	0.33	0.33	0.35	0.18	0.21	0.22	0.23	0.23	0.23	0.24	0.24	
	Quinolones (% fluroquinolones)	0.60 (100%)	0.59 (100%)	0.52 (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%)	
	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	
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	
	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	
	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%)	
	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	
Bulgaria[4]	**Overall sales**		92.6	98.9	116.1	82.9	121.8	155.2	129.8	119.6	112.7	120.9	124.5	
	3rd- and 4th-gen. cephalosporins		0.05	0.03	0.12	0.06	0.20	0.10	0.09	0.09	0.09	0.11	0.18	
	Quinolones (% fluroquinolones)		5.4 (92%)	6.5 (95%)	6.9 (98%)	1.8 (100%)	5.7 (94%)	5.2 (93%)	6.1 (92%)	6.0 (100%)	4.1 (100%)	3.7 (100%)	3.9 (100%)	
	Polymyxins		3.2	3.8	2.7	0.53	3.6	2.3	2.9	3.7	1.6	5.2	3.1	

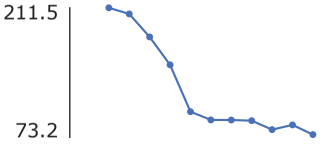
[1] Updates to sales data or PCU data as published in the ESVAC 2021 report are described in Section 1.5.
[2] Strength was reported as the active moiety for the large majority of antibiotic VMPs from 2019 onwards.
[3] For countries where injectable 3rd- and 4th-generation cephalosporins are solely or also marketed for dogs and cats, the data provide a considerable overestimate for food-producing animals.
[4] For Bulgaria, 2011, 2012, 2014 and 2015 are underestimates, as several wholesalers failed to report data.

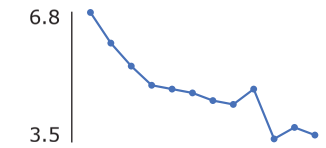
Country		2010	2011	2012	2013	2014	2015	2016	2017	2018	2019	2020	2021	Trends 2010-2021
Croatia	**Overall sales**					103.5	90.5	83.6	68.0	70.8	62.8	68.6	62.7	
	3rd- and 4th-gen. cephalosporins					0.12	0.19	0.16	0.20	0.33	0.29	0.22	0.22	
	Quinolones (% fluroquinolones)					4.0 (84%)	3.8 (82%)	3.0 (85%)	2.4 (75%)	3.1 (72%)	2.0 (97%)	2.4 (89%)	2.2 (100%)	
	Polymyxins					3.6	2.3	3.4	3.0	2.6	1.5	2.7	3.2	
Cyprus[5]	**Overall sales**		332.3	301.9	333.4	317.0	350.2	346.4	335.2	392.3	350.0	344.2	296.5	
	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	
	Quinolones (% fluroquinolones)		1.7 (26%)	2.8 (21%)	0.9 (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%)	
	Polymyxins		6.6	6.2	6.6	9.0	10.0	8.5	8.3	10.8	12.3	13.9	12.7	
Czechia[6]	**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	
	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	
	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 (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	

[5] For Cyprus, corrections were made to the animal population data (dairy cows and living sheep) in all reporting years (2011–2020). Missing data on the biomass of farmed fish produced was also reported for the same period. Consequently, the mg/PCU figures published in previous ESVAC reports are 12% to 24% higher.

[6] For Czechia, strength was reported as the active moiety for most VMPs for 2011–2012; for 2013–2018, strength reported as on the VMPs' labels; since 2019, strength was reported as in the VMPs' Summary of Product Characteristics.

Country		2010	2011	2012	2013	2014	2015	2016	2017	2018	2019	2020	2021	Trends 2010-2021
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	
	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	
	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%)	
	Polymyxins	0.26	0.22	0.25	0.25	0.42	0.53	0.54	0.20	<0.01	<0.01	<0.01	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	
	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	
	Quinolones (% fluroquinolones)	2.7 (95%)	2.3 (100%)	1.1 (100%)	1.7 (100%)	1.6 (100%)	1.8 (100%)	1.3 (100%)	1.3 (100%)	1.2 (100%)	1.1 (100%)	1.1 (100%)	0.88 (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	
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	
	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	
	Quinolones (% fluroquinolones)	0.15 (100%)	0.16 (100%)	0.16 (100%)	0.16 (100%)	0.18 (100%)	0.14 (100%)	0.15 (100%)	0.12 (100%)	0.13 (100%)	0.10 (100%)	0.11 (100%)	0.11 (100%)	
	Polymyxins	0	0	0	0	0	0	0	0	0	0	0	0	

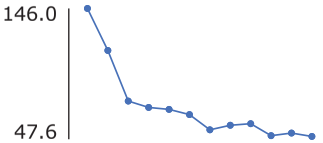
Country		2010	2011	2012	2013	2014	2015	2016	2017	2018	2019	2020	2021	Trends 2010-2021
France	**Overall sales**	133.6	114.3	101.1	93.9	105.8	69.4	71.2	68.0	64.2	58.3	56.6	51.7	
	3rd- and 4th-gen. cephalosporins	0.30	0.30	0.31	0.29	0.28	0.21	0.06	0.02	0.02	0.02	0.02	0.02	
	Quinolones (% fluroquinolones)	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%)	
	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	
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	
	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	
	Quinolones (% fluroquinolones)		0.91 (100%)	1.2 (100%)	1.4 (100%)	1.4 (100%)	1.1 (100%)	1.0 (100%)	1.1 (100%)	0.88 (100%)	0.70 (100%)	0.76 (100%)	0.67 (100%)	
	Polymyxins		14.8	14.8	14.6	12.2	9.2	7.9	8.5	8.6	7.9	7.3	6.3	
Greece	**Overall sales**						58.2	64.8	95.7	93.6	84.8	96.4	108.8	
	3rd- and 4th-gen. cephalosporins						0.09	0.10	0.11	0.13	0.08	0.20	0.21	
	Quinolones (% fluroquinolones)						4.4 (39%)	7.1 (32%)	6.7 (41%)	4.9 (46%)	5.0 (33%)	3.4 (65%)	3.2 (81%)	
	Polymyxins						3.4	1.1	1.3	1.6	1.5	2.0	1.7	

Country		2010	2011	2012	2013	2014	2015	2016	2017	2018	2019	2020	2021	Trends 2010-2021
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	
	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	
	Quinolones (% fluroquinolones)	9.1 (97%)	6.9 (97%)	11.2 (98%)	9.4 (99%)	9.4 (97%)	9.7 (97%)	9.8 (98%)	9.0 (99%)	10.9 (99%)	11.9 (99%)	11.2 (100%)	14.8 (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	
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	
	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	
	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%)	
	Polymyxins	0	0	0	0	0	0	0	0	0	0	0	0	
Ireland[7]	**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	
	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	
	Quinolones (% fluroquinolones)	0.38 (100%)	0.40 (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%)	
	Polymyxins	0	<0.1	>0.1	<0.1	<0.1	<0.1	<0.1	<0.1	<0.1	<0.01	<0.01	0	

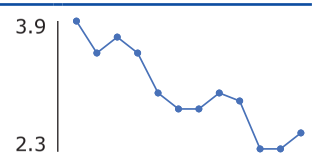
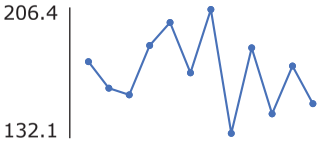
[7] For Ireland, due to commercial confidentiality reasons, exact sales figures of polymyxins are not included in this table.

Country		2010	2011	2012	2013	2014	2015	2016	2017	2018	2019	2020	2021	Trends 2010-2021
Italy[8]	**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	
	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	
	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%)	
	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	
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	
	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	
	Quinolones (% fluroquinolones)	4.1 (100%)	2.2 (100%)	1.7 (100%)	2.1 (100%)	1.6 (99%)	1.1 (99%)	0.85 (99%)	1.1 (99%)	0.93 (99%)	0.58 (100%)	0.88 (100%)	0.69 (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	
Lithuania	**Overall sales**	48.2	41.1	39.1	29.0	35.5	35.0	37.4	34.2	32.7	20.8	20.5	20.3	
	3rd- and 4th-gen. cephalosporins	0.02	0.04	0.05	0.17	0.18	0.05	0.13	0.17	0.32	0.19	0.14	0.14	
	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%)	1.5 (100%)	1.3 (100%)	1.3 (100%)	
	Polymyxins	1.7	1.4	1.3	0.11	0.12	0.61	0.97	0.65	0.24	0.65	<0.01	<0.01	

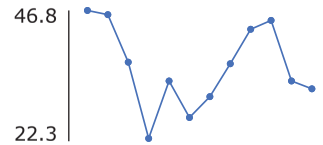
[8] For Italy, sales data represent sales from MAH to wholesalers and feed mills for 2010–2019. Since 2020 they represent sales of premixes from MAHs to wholesalers and dispensed e-prescription for all other pharmaceutical forms obtained from wholesalers, pharmacies and others to veterinarians, farmers and companion animal owners.

Country		2010	2011	2012	2013	2014	2015	2016	2017	2018	2019	2020	2021	Trends 2010-2021
Luxembourg	**Overall sales**			43.2	52.1	40.6	34.5	35.4	35.1	33.6	29.0	29.0	27.1	
	3rd- and 4th-gen. cephalosporins			0.68	0.68	0.63	0.62	0.73	0.59	0.59	0.55	0.52	0.46	
	Quinolones (% fluroquinolones)			0.68 (97%)	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%)	
	Polymyxins			1.7	3.1	2.4	1.5	1.0	0.99	0.59	0.41	0.37	0.25	
Malta	**Overall sales**								129.3	153.4	110.3	116.1	110.5	
	3rd- and 4th-gen. cephalosporins								0.26	0.20	0.27	0.35	0.28	
	Quinolones (% fluroquinolones)								16.3 (93%)	4.6 (99%)	8.5 (99%)	4.4 (100%)	8.5 (100%)	
	Polymyxins								4.9	1.9	0.08	0.52	0.32	
Netherlands[9]	**Overall sales**	146.0	113.7	74.8	69.9	68.4	64.4	52.7	56.2	57.4	48.2	50.2	47.6	
	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	
	Quinolones (% fluroquinolones)	2.1 (26%)	1.6 (28%)	0.93 (26%)	0.88 (14%)	1.2 (11%)	1.3 (9%)	0.98 (9%)	1.0 (7%)	1.2 (6%)	0.84 (7%)	0.85 (5%)	0.66 (5%)	
	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	

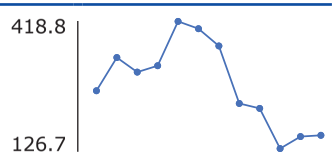
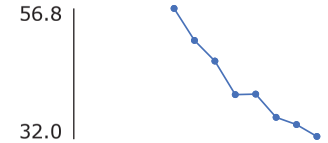
[9] For the Netherlands, strength was reported as the active moiety for some VMPs for 2011–2012; for 2013–2018, strength was reported as on the labels of the VMPs; since 2019, strength was reported as in the VMPs' Summary of Product Characteristics.

Country		2010	2011	2012	2013	2014	2015	2016	2017	2018	2019	2020	2021	Trends 2010-2021
Norway	**Overall sales**	3.9	3.5	3.7	3.5	3.0	2.8	2.8	3.0	2.9	2.3	2.3	2.5	
	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	
	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%)	
	Polymyxins	0	0	0	0	0	0	0	0	0	0	0	0	
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	
	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	
	Quinolones (% fluroquinolones)		7.2 (99%)	8.3 (99%)	8.8 (99%)	9.0 (99%)	8.5 (100%)	9.6 (100%)	11.0 (100%)	10.9 (100%)	13.2 (100%)	12.9 (100%)	12.7 (100%)	
	Polymyxins		4.1	4.0	4.4	5.0	5.9	5.6	7.4	7.4	10.6	9.1	8.1	
Portugal[10]	**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	
	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	
	Quinolones (% fluroquinolones)	6.1 (89%)	8.7 (95%)	9.5 (98%)	8.3 (98%)	11.4 (98%)	8.8 (98%)	8.9 (99%)	3.5 (100%)	7.5 (100%)	6.1 (100%)	7.2 (100%)	8.8 (100%)	
	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	

[10] For Portugal, 2010–2014, 2017 and 2019 sales are underestimates, due to underreporting.

Country		2010	2011	2012	2013	2014	2015	2016	2017	2018	2019	2020	2021	Trends 2010-2021
Romania	**Overall sales**					109.0	100.5	85.2	90.1	82.7	53.9	57.8	59.0	
	3rd- and 4th-gen. cephalosporins					0.05	0.04	0.08	0.16	0.19	0.10	0.18	0.16	
	Quinolones (% fluroquinolones)					5.5 (96%)	6.3 (97%)	3.5 (94%)	4.5 (96%)	6.0 (100%)	5.3 (99%)	5.7 (99%)	6.8 (99%)	
	Polymyxins					6.5	7.4	5.6	4.1	6.4	2.5	2.2	2.2	
Slovakia[11]	**Overall sales**		43.6	43.3	59.2	65.6	50.8	50.3	61.8	49.2	42.3	51.9	41.7	
	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	
	Quinolones (% fluroquinolones)		3.3 (90%)	3.2 (100%)	2.9 (96%)	4.2 (99%)	2.9 (99%)	3.6 (99%)	3.4 (99%)	3.0 (99%)	3.2 (99%)	3.4 (99%)	3.4 (100%)	
	Polymyxins		1.2	2.1	1.1	1.5	1.1	1.2	1.7	1.4	1.3	2.0	1.4	
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	
	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	
	Quinolones (% fluroquinolones)	2.7 (95%)	6.0 (99%)	4.1 (100%)	1.8 (99%)	4.0 (100%)	3.1 (100%)	2.9 (99%)	2.9 (100%)	2.8 (100%)	1.8 (100%)	0.99 (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	

[11] 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	Trends 2010-2021
Spain[12]	**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	
	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	
	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%)	5.6 (100%)	3.6 (100%)	3.7 (100%)	3.7 (90%)	
	Polymyxins	33.0	33.5	29.4	21.5	36.1	34.9	22.0	4.4	3.3	0.90	0.43	0.39	
Sweden[13]	**Overall sales**	14.7	13.1	13.0	12.2	11.1	11.4	11.7	11.3	12.1	11.1	11.1	10.9	
	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	
	Quinolones (% fluroquinolones)	0.13 (99%)	0.10 (99%)	0.10 (100%)	0.05 (79%)	0.03 (99%)	0.02 (100%)	0.07 (33%)	0.05 (40%)	0.12 (24%)	0.06 (31%)	0.10 (26%)	0.12 (14%)	
	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	
Switzerland	**Overall sales**					56.8	50.6	46.6	40.1	40.2	35.7	34.3	32.0	
	3rd- and 4th-gen. cephalosporins					0.22	0.20	0.16	0.17	0.15	0.09	0.07	0.07	
	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%)	
	Polymyxins					0.95	0.62	0.46	0.41	0.29	0.25	0.18	0.11	

[12] For Spain, 2010–2013 sales are underestimates due to underreporting. Since 2017, retailers have been the sales data providers (previously MAHs).
[13] For Sweden, there was no reporting of sales for use in farmed fish in 2012 and there was underreporting in 2017. For reasons of commercial confidentiality, exact sales figures of 3rd- and 4th-generation cephalosporins and polymyxins are not included in this table.

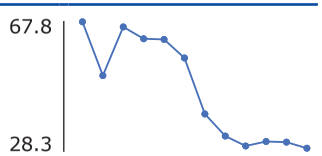
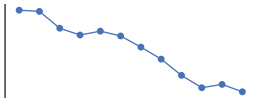
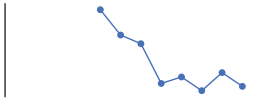
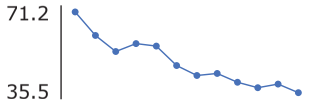
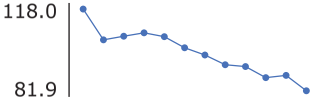
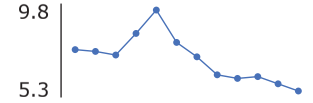
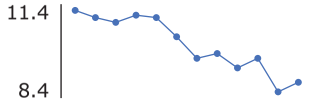
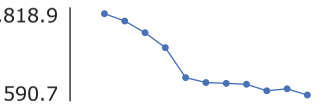
Country		2010	2011	2012	2013	2014	2015	2016	2017	2018	2019	2020	2021	Trends 2010-2021
United Kingdom	**Overall sales**	67.8	51.0	66.2	62.5	62.3	56.5	39.0	32.1	29.0	30.4	30.2	28.3	
	3rd- and 4th-gen. cephalosporins	0.21	0.17	0.20	0.18	0.19	0.17	0.14	0.11	0.06	0.03	0.04	0.02	
	Quinolones (% fluroquinolones)	0.30 (100%)	0.28 (100%)	0.33 (100%)	0.36 (100%)	0.35 (100%)	0.35 (100%)	0.23 (100%)	0.15 (100%)	0.15 (100%)	0.13 (100%)	0.10 (100%)	0.10 (100%)	
	Polymyxins	0.12	0.13	0.09	0.11	0.12	0.12	0.02	<0.01	<0.01	<0.01	<0.01	0	

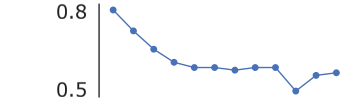
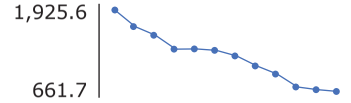
Table 6. Trends in sales of all antibiotic active substances (tonnes) for food-producing animals and PCU (in 1,000 tonnes) by country from 2010 to 2021[1,2]

Country		2010	2011	2012	2013	2014	2015	2016	2017	2018	2019	2020	2021	Active substance sales trends (in tonnes) 2010–2021
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	
	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	
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	
	PCU (1,000 tonnes)	1,660.5	1,695.3	1,658.3	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	
Bulgaria[3]	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	
	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	
Croatia	Tonnes active substance					31.3	27.8	26.6	21.1	22.0	20.1	22.6	20.7	
	PCU (1,000 tonnes)					302.3	307.4	317.7	310.4	311.1	319.4	328.9	330.8	
Cyprus[4]	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	
	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	

[1] Updates to sales or PCU data as published in the ESVAC 2021 report are described in Section 1.5.
[2] Strength was reported as the active moiety for the large majority of the antibiotic VMPs from 2019 onwards.
[3] For Bulgaria, 2011, 2012, 2014 and 2015 are underestimates as several wholesalers failed to report data.
[4] For Cyprus, extensive corrections were made to their animal population data in all reporting years (2011–2020). Consequently the PCU figures published in previous ESVAC reports are 14% to 31% higher.

Country		2010	2011	2012	2013	2014	2015	2016	2017	2018	2019	2020	2021	Active substance sales trends (in tonnes) 2010–2021
Czechia[5]	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	
	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	
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	
	PCU (1,000 tonnes)	2,503.3	2,478.7	2,424.3	2,417.2	2,415.3	2,415.4	2,419.7	2,397.6	2,446.7	2,362.4	2,384.7	2,452.1	
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	
	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	
Finland	Tonnes active substance	11.4	11.1	10.9	11.2	11.1	10.3	9.4	9.6	9.0	9.4	8.0	8.4	
	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	
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	
	PCU (1,000 tonnes)	7,478.8	7,784.8	7,529.5	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	
Germany	Tonnes active substance		1,818.9	1,708.0	1,531.9	1,305.9	853.7	779.4	766.8	753.1	654.5	684.6	590.7	
	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	8,517.6	8,327.2	8,172.8	8,071.2	

[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 as in the VMPs' Summary of Product Characteristics.

Country		2010	2011	2012	2013	2014	2015	2016	2017	2018	2019	2020	2021	Active substance sales trends (in tonnes) 2010–2021
Greece	Tonnes active substance						72.6	79.9	116.6	112.9	99.8	108.4	119.7	
	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	
Hungary	Tonnes active substance	207.4	147.5	178.6	176.0	150.4	176.0	155.5	147.2	150.1	152.1	136.1	131.6	
	PCU (1,000 tonnes)	768.4	766.5	727.0	763.1	779.1	832.5	831.7	770.9	831.8	823.1	833.0	845.8	
Iceland	Tonnes active substance	0.77	0.69	0.62	0.57	0.55	0.55	0.54	0.55	0.55	0.46	0.52	0.53	
	PCU (1,000 tonnes)	112.7	113.5	115.7	115.2	115.8	116.4	120.1	125.1	116.4	131.3	135.3	144.8	
Ireland	Tonnes active substance	91.3	82.0	94.5	98.1	88.6	96.1	102.0	98.2	98.3	87.5	102.9	93.2	
	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	
Italy[6]	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	
	PCU (1,000 tonnes)	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	3,827.5	3,790.4	3,812.6	

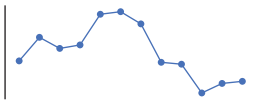
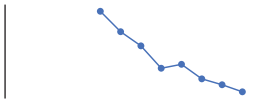
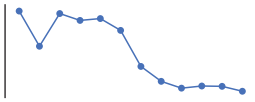
[6] For Italy, sales data represent sales from MAH to wholesalers and feed mills for 2010–2019. Since 2020, they represent sales of premixes from MAHs to wholesalers and dispensed e-prescription for all other pharmaceutical forms obtained from wholesalers, pharmacies and others to veterinarians, farmers and companion animal owners.

Country		2010	2011	2012	2013	2014	2015	2016	2017	2018	2019	2020	2021	Active substance sales trends (in tonnes) 2010–2021
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	
	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	
Lithuania	Tonnes active substance	16.5	13.8	13.3	9.9	11.9	11.9	12.7	11.5	10.7	6.5	6.2	6.0	
	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	
Luxembourg	Tonnes active substance			2.2	2.7	2.1	1.8	1.9	1.9	1.8	1.6	1.6	1.5	
	PCU (1,000 tonnes)			50.4	51.0	52.0	52.8	54.6	54.7	54.7	53.8	54.4	54.2	
Malta	Tonnes active substance								1.8	2.1	1.5	1.7	1.6	
	PCU (1,000 tonnes)								13.7	14.0	13.8	14.7	14.8	
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	
	PCU (1,000 tonnes)	3,155.3	3,185.9	3,279.1	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	

[7] 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.

Country		2010	2011	2012	2013	2014	2015	2016	2017	2018	2019	2020	2021	Active substance sales trends (in tonnes) 2010–2021
Norway	Tonnes active substance	6.2	6.0	6.9	6.4	5.6	5.4	5.4	5.6	5.5	4.7	4.7	5.5	
	PCU (1,000 tonnes)	1,572.4	1,715.3	1,886.5	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	
Poland	Tonnes active substance		500.3	528.5	576.6	578.4	582.6	570.3	749.5	786.5	840.6	853.2	775.1	
	PCU (1,000 tonnes)		3,962.8	3,941.1	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	
Portugal[8]	Tonnes active substance	181.5	164.5	156.6	179.4	190.0	169.8	211.0	135.1	191.8	149.5	177.9	159.4	
	PCU (1,000 tonnes)	1,036.6	1,033.1	1,009.3	971.0	957.0	1,008.3	1,022.1	1,023.2	1,046.1	1,039.8	1,031.2	1,063.3	
Romania	Tonnes active substance					272.8	257.2	265.4	262.9	230.6	169.0	173.7	173.7	
	PCU (1,000 tonnes)					2,501.8	2,558.6	3,116.1	2,916.2	2,788.2	3,134.6	3,003.7	2,942.8	
Slovakia[9]	Tonnes active substance		10.8	10.2	14.6	16.3	12.6	12.2	13.9	12.1	10.2	11.8	9.6	
	PCU (1,000 tonnes)		248.2	236.0	247.2	249.2	247.3	242.6	224.9	246.6	241.8	228.3	229.9	
Slovenia	Tonnes active substance	8.4	8.4	6.8	4.0	5.7	4.6	5.4	6.7	7.8	7.9	5.9	5.8	
	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	

[8] For Portugal, 2010–2014, 2017 and 2019 sales are underestimates due to underreporting.
[9] 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	Active substance sales trends (in tonnes) 2010–2021
Spain[10]	Tonnes active substance	1,804.6	2,390.7	2,115.1	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	
	PCU (1,000 tonnes)	6,955.1	7,120.2	6,996.1	6,943.6	7,077.1	7,531.8	7,517.7	7,684.5	7,865.4	7,950.0	8,067.5	8,245.0	
Sweden[11]	Tonnes active substance	12.2	10.9	10.2	9.7	9.0	9.2	9.4	9.1	9.4	8.6	8.7	8.6	
	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	
Switzerland	Tonnes active substance					46.4	41.2	37.6	31.9	32.9	29.2	27.7	25.9	
	PCU (1,000 tonnes)					818.0	814.4	805.8	795.9	818.5	817.4	806.1	809.8	
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	
	PCU (1,000 tonnes)	6,714.0	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	

[10]For Spain, 2010–2013 sales are underestimates due to underreporting. Since 2017, retailers have been the sales data providers (previously MAHs).
[11]For Sweden, there was no reporting of sales for use in farmed fish in 2012 and there was underreporting in 2017.

2.3. Sales of tablet antibiotic VMPs for companion animals in 2021

This section presents overall tablets 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.

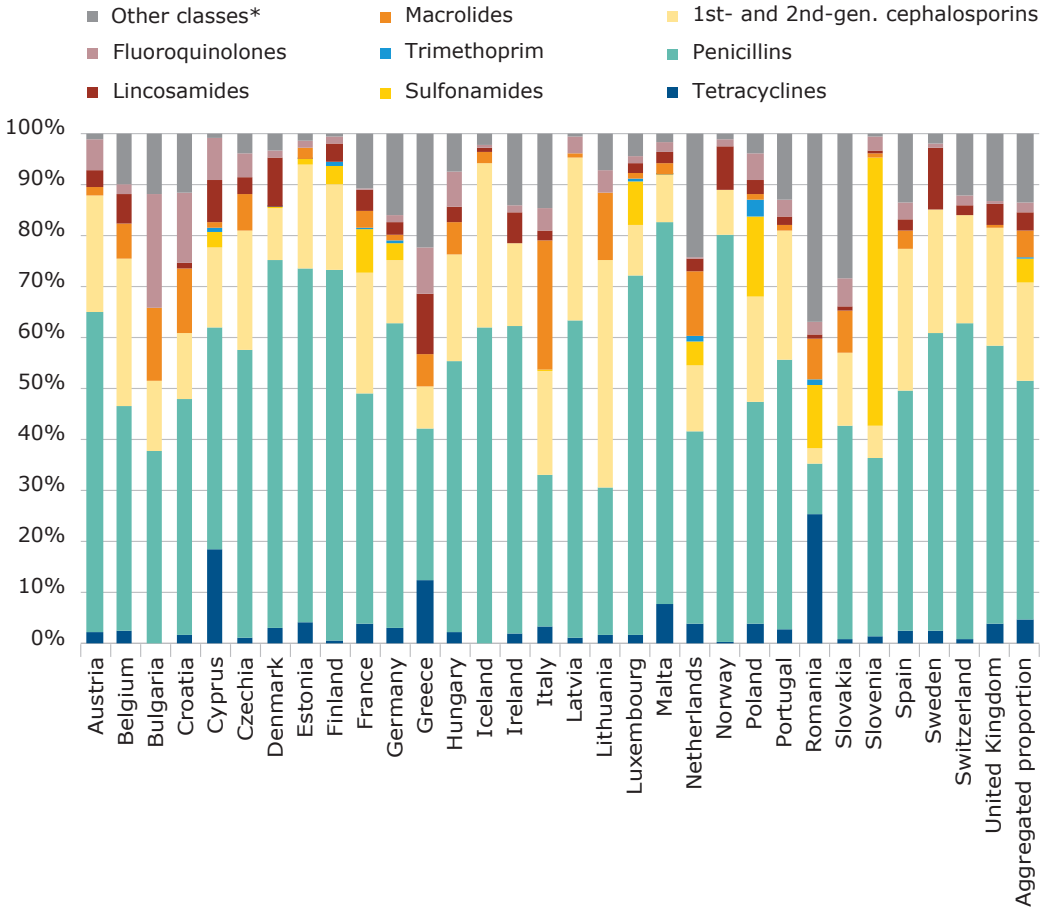
Table 7. Overall sales, in tonnes of active substance, split by tablets (used mainly in companion animals) and all other product forms (used mainly in food-producing animals), by country, in 2021

Country	Tablets		All other products forms		Total tonnes
	Tonnes	% of overall sales	Tonnes	% of overall sales	
Austria	0.59	1.5%	39.1	98.5%	39.7
Belgium	2.4	1.4%	168.6	98.6%	171.0
Bulgaria	0.14	0.29%	48.7	99.7%	48.9
Croatia	0.17	0.82%	20.7	99.2%	20.9
Cyprus	0.07	0.15%	45.1	99.8%	45.1
Czechia	1.2	3.2%	35.5	96.8%	36.6
Denmark	0.75	0.91%	81.9	99.1%	82.6
Estonia	0.18	3.2%	5.3	96.8%	5.5
Finland	1.0	10.6%	8.4	89.4%	9.4
France	17.9	4.9%	349.3	95.1%	367.3
Germany	11.4	1.9%	590.7	98.1%	602.2
Greece	0.55	0.46%	119.7	99.5%	120.2
Hungary	0.63	0.47%	131.6	99.5%	132.2
Iceland	0.05	8.1%	0.53	91.9%	0.57
Ireland	1.0	1.1%	93.2	98.9%	94.2
Italy	7.5	1.1%	661.7	98.9%	669.1
Latvia	0.14	3.4%	3.9	96.6%	4.0
Lithuania	0.09	1.4%	6.0	98.6%	6.1
Luxembourg	0.14	8.5%	1.5	91.5%	1.6
Malta	0.10	5.8%	1.6	94.2%	1.7
Netherlands	3.3	2.2%	147.2	97.8%	150.5
Norway	0.38	6.5%	5.5	93.5%	5.8
Poland	3.7	0.47%	775.1	99.5%	778.7
Portugal	1.3	0.79%	159.4	99.2%	160.6
Romania	4.0	2.3%	173.7	97.7%	177.7
Slovakia	0.43	4.3%	9.6	95.7%	10.0
Slovenia	0.48	7.6%	5.8	92.4%	6.3
Spain	2.3	0.17%	1,296.5	99.8%	1,298.7
Sweden	0.66	7.1%	8.6	92.9%	9.3
Switzerland	0.77	2.9%	25.9	97.1%	26.7
United Kingdom	12.9	6.1%	199.5	93.9%	212.4
Total 31 countries	**76.2**	**1.4%**	**5,219.6**	**98.6%**	**5,295.8**

In 2021, tablet sales accounted for a minor proportion (1.4%) 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 0.2% and 10.6% of total sales and in 8 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 2021. Although tablet sales patterns varied substantially between countries, penicillins constituted the highest selling tablet antibiotic class in 27 countries. Aggregated by the 31 countries, penicillins accounted for 47.0% (35.8 tonnes) of all tablets sales, followed by 1st- and 2nd-generation cephalosporins with 19.5% (14.8 tonnes), and by tetracyclines and sulfonamides, each representing 4.5% of tablet sales (3.4 tonnes) (Figure 19).

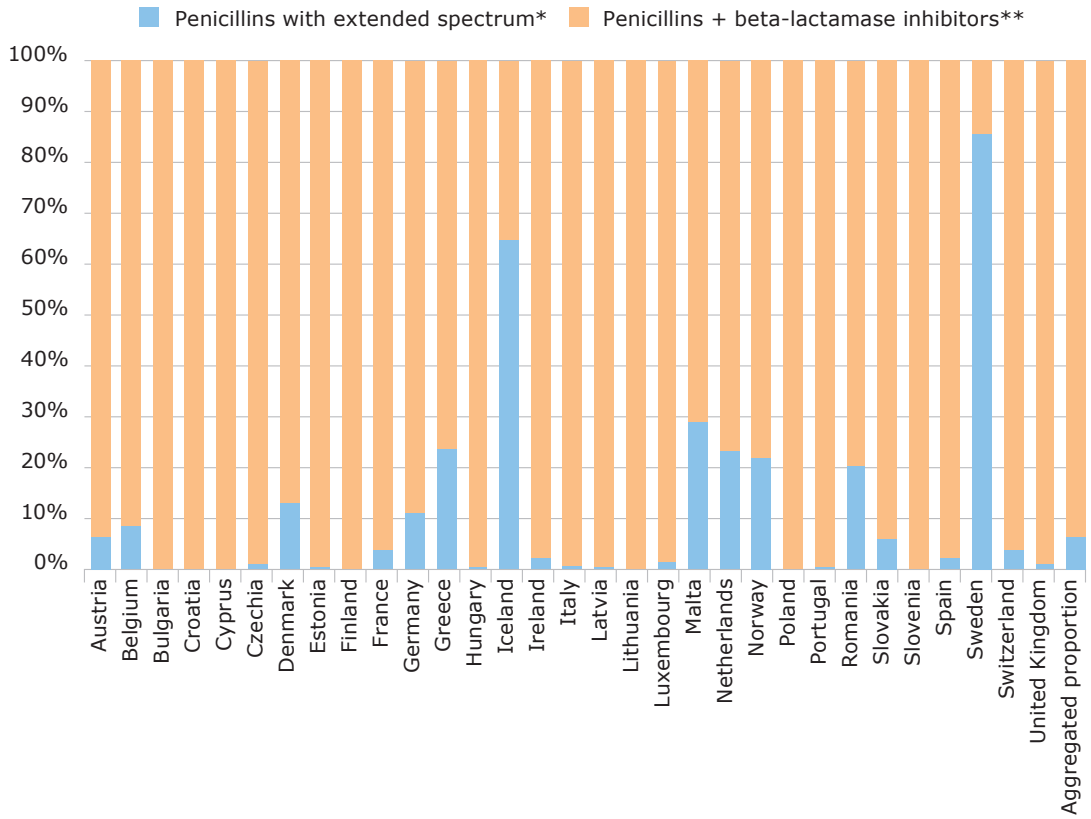
Figure 19. Proportion of tablet sales, in tonnes of active substance, by antibiotic class (reported according to the ATCvet hierarchical system) in 31 European countries in 2021[1,2,3]



* 'Other classes' includes small quantities of aminoglycosides (0.86%), amphenicols (0.04%), pleuromutilins (<0.001%), polymyxins (<0.001%) and 'Others' (12.6%).
[1] Some tablet formulations are authorised for use in food-producing, fur and companion animals.
[2] In Romania, 27.0% (1.1 tonnes) of tablets sold were indicated for food-producing or non-food-producing birds.
[3] Average proportion of tablet sales per antibiotic class (tonnes) divided by the total sales of tablets (tonnes) for 31 countries.

The sales patterns of penicillins as tablets did not differ substantially between the 31 countries with regards to their various subclasses (Figure 20). For 29 countries, sales of penicillins in combination with beta-lactamase inhibitors accounted for 70–100% of all penicillin tablet sales and for the remaining 2 countries accounted less than 40%. Overall, sales of penicillins with beta-lactamase inhibitors aggregated by the 31 countries represented 93.6% of all penicillin tablet sales with the remaining 6.4% of 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 2021[1,2,3]



* In 2021, 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 2021, 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, Lithuania and Slovenia.
[3] Average of tablet sales containing penicillins per subclass (tonnes) divided by the total sales of tablets containing penicillins (tonnes) for 31 countries.

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

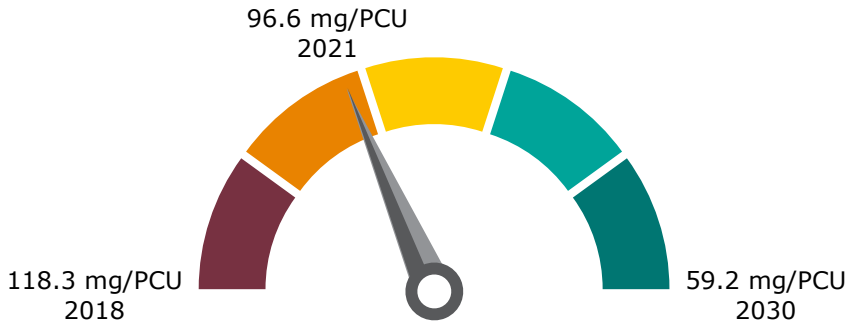
The EU Farm to Fork Strategy[30,31] aims to accelerate the transition to a sustainable food system at the EU level that is fairer, healthier and more environmentally friendly. Sitting at the heart of the European Green Deal[32], focused on the transformation of the EU into a modern, resource-efficient 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 33,000 human deaths every year in the EU/EEA alone[33]. 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 humans[34].

[30] Farm to Fork Strategy web page: https://food.ec.europa.eu/horizontal-topics/farm-fork-strategy_en
[31] Farm to Fork Strategy action plan: https://food.ec.europa.eu/system/files/2020-05/f2f_action-plan_2020_strategy-info_en.pdf
[32] European Green Deal web page: https://ec.europa.eu/info/strategy/priorities-2019-2024/european-green-deal_en
[33] Cassini et al. (2019), 'Attributable deaths and disability-adjusted life-years caused by infections with antibiotic-resistant bacteria in the EU and the European Economic Area in 2015: a population-level modelling analysis', in Lancet Infect Dis. Vol. 19 (1), pp. 55–56.
[34] Available on the EMA website (www.ema.europa.eu) via: Home > Veterinary regulatory > Antimicrobial resistance > Analysis of consumption and resistance (JIACRA) > Report on 2016-2018 (new): https://www.ema.europa.eu/en/documents/report/ema/ecdc/efsa-third-joint-report-integrated-analysis-consumption-antimicrobial-agents-occurrence_en.pdf

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 States[35]. 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 (118.3 mg/PCU) in the 27 EU Member States sets the 2030 target at 59.2 mg/PCU[36] (Figure 21).

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



In 2021, the aggregated sales for the 27 EU Member States were 96.6 mg/PCU, which corresponds to a reduction of 21.7 mg/PCU (18.3%) in comparison to the 2018 reference value. Hence, Member States have already reached approximately one third of the 50% reduction target set for 2030 in only the first three 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 37.4 mg/PCU within the next nine years.

[35] 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

[36] 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 reports 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 products[37], 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 11 of Directive 2001/82/EC (and as of 28 January 2022 according to Articles 107, 112, 113 and 114 of Regulation (EU) 2019/6[38]). 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 of the scope of the ESVAC protocol.

In 2021, 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 <0.01% to 18.9% of total sales.

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 thought to be 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 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.

In the current report, data presented on sales of antibiotic VMPs for companion animals solely represent 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 generally limited to hospitalised animals or perioperative treatments. For instance, data from Denmark for 2021 showed that approximately 1.5% the injectable antimicrobial VMPs sold were used for dogs and cats (L. Mie Jensen, unpublished data). In this report sales of injectable antibiotic VMPs are assumed to be for the 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.

[37] 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: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex%3A32001L0082

[38] 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, 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 in these and those displayed in the interactive database.

Twelfth ESVAC report — main results

For the 25 European countries that continuously reported data to ESVAC between 2011 and 2021, overall sales decreased 46.5%, from 161.2 mg/PCU to 86.2 mg/PCU, showing a clear decline throughout this period despite a modest increase of sales in 2014 and 2020 and more moderate reductions in recent years. 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 37.8%, 14.2%, 83.1% and 79.5%, respectively. The overall decrease of polymyxin sales is aligned to the Agency's recommendation for Member States to reduce the use of colistin in animals[39], with most countries (16 out of 31) presenting polymyxin sales between 0 and 1.0 mg/PCU and only 5 higher than 5 mg/PCU in 2021. Furthermore, the sales of most antibiotic classes have reduced significantly for the 25 countries since 2011, with the decline in sales of the three highest selling antibiotic classes — tetracyclines (63.4%), penicillins (24.1%) and sulfonamides (53.8%) — 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. However, 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 feed[40]. Although aggregated sales for the 25 countries of product forms predominantly destined for group treatment have declined by 49.5% between 2011 and 2021, they still accounted for the majority of sales in 2021 (87% 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 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 could mean that animal exposure times to antibiotics are reducing. The aggregated PCU of those species most exposed to group treatment, i.e. poultry, pigs and farmed fish, has remained quite stable over the reporting period for the 25 countries, suggesting that the reduction in sales have not been heavily influenced by changes in the animal population.

Total sales and trends vary between the different reporting countries. For instance, in 2021, total sales of antibiotic VMPs for food-producing animals ranged from 2.5 mg/PCU to 296.5 mg/PCU across the 31 countries reporting data to ESVAC. The variation between countries can be explained by, in part, to 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[41]. In addition, differences among countries in the

[39] 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: https://www.ema.europa.eu/en/documents/scientific-guideline/updated-advice-use-colistin-products-animals-within-european-union-development-resistance-possible_en-0.pdf

[40] Recently, 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 (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.

[41] Available on the European Medicines Agency website (www.ema.europa.eu) via Home > Veterinary regulatory > Antimicrobial resistance (https://www.ema.europa.eu/en/veterinary-regulatory/overview/antimicrobial-resistance/european-surveillance-veterinary-antimicrobial-consumption/standardised-units-measurement-veterinary-antimicrobials)

selection of sales data providers may also have an impact on sales data, although this is thought to be minor. In summary, 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.

In the eleventh ESVAC report with data from 2019 and 2020, the downward trend in the overall sales of veterinary antibiotics for food-producing animals was temporarily inverted between these two reporting years. In 2020, the overall sales (mg/PCU) for the 25 countries participating in ESVAC since 2011 showed a 5.5% increase in comparison to 2019. Tentative explanations given to justify this increase in sales in 2020 included an over-purchasing of VMPs due to the uncertainty surrounding the medicines' market situation because of the COVID-19 pandemic and Brexit combined with an overestimation of sales in some countries due to double reporting. On the other hand, the decrease in sales observed in 2019 was partly explained by under-reporting, shortages, changes in data-collection systems or decreases in sales for specific antibiotic classes. In 2021, the increase in sales was reversed and overall sales reached lower levels than those registered for 2019. It is possible that the COVID-19 pandemic may have influenced in a country-specific manner the increase of sales in 2020, which is still observed despite historical corrections of double reporting. For example, various ESVAC-reporting countries indicated that pandemic-related stockpiling events could be responsible for the increase in sales in 2020 and the posterior decrease in 2021.

Farm to Fork Strategy in 27 EU Member States

In May 2020, the EC adopted the Farm to Fork Strategy[42,43] 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 Deal[44] and monitored under the EU Zero Pollution Action plan[45,46]. 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 27 EU Member States to set the targeted consumption levels at 59.2 mg/PCU by 2030[47]. Already after three years, the 27 EU Member States have attained approximately one-third of this targeted reduction, with the pointer currently sitting at 96.6 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 nine years.

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

Regulation (EU) 2019/6[48] 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 people 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.

With regards to veterinary antimicrobial consumption surveillance, Article 57 of Regulation (EU) 2019/6 introduces the mandatory collection and reporting of data by Member States 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 at farm level. In comparison to the ESVAC project, 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 the Agency with antimicrobial

[42] Farm to Fork Strategy web page: https://food.ec.europa.eu/horizontal-topics/farm-fork-strategy_en
[43] Farm to Fork Strategy action plan: https://food.ec.europa.eu/system/files/2020-05/f2f_action-plan_2020_strategy-info_en.pdf
[44] European Green Deal web page: https://ec.europa.eu/info/strategy/priorities-2019-2024/european-green-deal_en
[45] Zero pollution action plan web page: https://environment.ec.europa.eu/strategy/zero-pollution-action-plan_en
[46] 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' (https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A52021DC0400).
[47] 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.
[48] 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

use data by animal species in a stepwise approach, starting with data from 2023 for the main food-producing animal species. Submission of data via an online application will enable only standardised and harmonised data to be uploaded, facilitating validation and automated data analyses. The Commission Delegated Regulation (EU) 2021/578 of 29 January 2021[49] and the Commission Implementing Regulation (EU) 2022/209 of 16 February 2022[50] 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.

[49] 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: http://data.europa.eu/eli/reg_del/2021/578/oj

[50] 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: https://eur-lex.europa.eu/eli/reg_impl/2022/209/oj

4. Concluding remarks

The 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 2021. 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 just three years, approximately one third of the target 50% reduction of veterinary antimicrobial sales for 2030, established by the EC in the Farm to Fork Strategy, has 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 antimicrobials to be achieved by 2030.

Last but not least, the voluntary reporting of veterinary antibiotic sales data by European countries for ESVAC serves as an important leverage point for countries to comply with the new EU legislative obligation to collect and report data, not only on the sales of veterinary antimicrobials but also on the use of antimicrobials in animals in the upcoming years. In 2023, the Agency will publish the last ESVAC report containing 2022 data submitted voluntarily by participating countries. In turn, the Agency will publish a new series of annual reports with data on sales of veterinary antimicrobials and on the use of antimicrobials in animals starting in 2025 with data from 2023.

Annex 1. Additional tables regarding 2021 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 2021 (tablets not included)

Country	Tetracyclines	Amphenicols	Penicillins	1st- and 2nd-gen. cephalosporins	3rd- and 4th-gen. cephalosporins[1]	Sulfonamides	Trimethoprim	Macrolides	Lincosamides	Fluoroquinolones	Other quinolones	Aminoglycosides	Polymyxins	Pleuromutilins	Others[2]	Total tonnes
Austria	19.3	0.4	8.3	0.1	0.2	3.7	0.7	2.5	0.2	0.5	0	1.3	1.5	0.3	0.2	39.1
Belgium	33.2	3.8	65.4	0.6	0.1	28.8	5.8	13.5	3.9	0.3	0.4	3.9	2.5	0.4	6.0	168.6
Bulgaria	23.7	1.7	9.9	<0.01	0.1	2.6	0.3	3.6	1.9	1.5	0	1.6	1.2	0.4	0.2	48.7
Croatia	7.0	0.6	7.1	0.01	0.1	1.4	0.3	1.7	0.04	0.7	0	0.6	1.1	0.2	0.1	20.7
Cyprus	17.2	0.3	6.9	<0.01	0.05	6.6	1.3	1.6	5.6	0.3	<0.01	0.9	1.9	2.3	0.1	45.1
Czechia	9.1	0.2	12.4	0.1	0.3	5.4	0.6	1.8	0.1	1.2	0	1.9	0.4	1.8	0.2	35.5
Denmark	12.4	2.0	25.7	0.04	<0.01	6.8	1.4	12.3	2.0	<0.01	0.4	9.2	0	7.6	2.0	81.9
Estonia	1.5	0.04	1.3	0.01	0.1	0.3	0.1	0.1	0.1	0.1	0	0.4	0.02	1.2	0.1	5.3
Finland	1.8	0.1	4.3	<0.01	<0.01	1.6	0.3	0.2	0.02	0.1	0	0.03	0	0	0	8.4
France	112.3	5.5	57.6	1.2	0.1	71.6	11.5	25.8	2.5	0.7	1.6	43.6	8.7	2.9	3.8	349.3
Germany	124.9	5.7	229.2	0.7	1.2	63.4	9.0	49.2	11.9	5.4	0	20.3	51.2	8.1	10.6	590.7
Greece	63.0	1.0	18.4	0.01	0.2	10.7	1.3	5.8	0.8	2.8	0.7	10.9	1.9	1.4	0.7	119.7
Hungary	43.8	3.1	37.3	0.1	0.4	5.0	1.0	6.1	1.8	12.5	0	2.3	10.2	7.7	0.2	131.6
Iceland	0.1	0	0.4	0	<0.01	0.01	<0.01	0	0	<0.01	0	0.1	0	0	0	0.5
Ireland[3]	37.8	2.9	20.5	1.2	0.3	15.9	1.1	5.4	0.2	0.8	0	5.6	0		1.3	93.2
Italy	153.7	22.4	221.1	0.6	0.5	91.0	9.0	41.1	58.3	4.5	2.6	28.5	2.5	17.5	8.4	661.7
Latvia	0.9	0.02	1.1	0.04	0.1	0.1	0.03	0.7	0.02	0.1	0	0.6	0.1	0.2	0.02	3.9
Lithuania	0.8	0.1	1.9	0.04	0.04	1.2	0.3	0.6	0.04	0.4	0	0.2	<0.01	0.4	0.1	6.0
Luxembourg	0.2	0.2	0.4	0.01	0.02	0.3	0.1	0.1	0.03	0.04	0	0.2	0.01	<0.01	0.02	1.5
Malta[4]	0.5	0.03	0.1	<0.01	<0.01	0.3	0.1	0.2	<0.01	0.1		0.1	<0.01	0.1	0.1	1.6
Netherlands	50.1	4.3	33.2	0.1	<0.01	27.7	5.1	20.8	0.3	0.1	1.9	1.9	1.2	0.2	0.2	147.2
Norway	0.1	0.9	2.8	0	<0.01	1.2	0.2	<0.01	<0.01	<0.01	0.1	0.1	0	0.03	<0.01	5.5
Poland	162.8	10.5	279.7	0.8	1.7	33.9	6.7	100.0	12.1	56.0	0	32.5	35.9	33.7	8.9	775.1
Portugal	47.3	2.7	37.8	0.05	0.4	10.0	2.0	17.1	7.1	9.3	<0.01	8.1	6.5	10.8	0.3	159.4
Romania	45.9	7.6	32.7	0.02	0.5	7.4	1.3	23.2	4.1	19.8	0.2	18.0	6.3	4.5	2.0	173.7
Slovakia	1.9	0.1	2.4	0.1	0.1	1.3	0.2	0.1	0.1	0.8	<0.01	0.9	0.3	1.0	0.2	9.6
Slovenia	1.3	0.3	2.8	<0.01	0.04	0.4	0.1	0.04	<0.01	0.2	0	0.6	<0.01	0.1	<0.01	5.8
Spain	301.1	63.6	438.3	0.4	2.7	91.0	16.8	88.8	131.0	27.4	3.2	94.1	3.2	23.6	11.3	1296.5
Sweden[5]	0.7		5.5		<0.01	1.3	0.2	0.3	0.04		0.1	0.3			0.1	8.6
Switzerland[6]	5.6	0.6	8.3	0.1	0.1	7.0	0.7	1.0		0.2	0	2.4	0.1		0.04	25.9
United Kingdom	67.6	4.3	53.7	1.0	0.1	18.1	3.6	18.8	3.8	0.7	0	18.2	0	6.4	3.3	199.5
Total 31 countries	**1,347.5**	**145.1**	**1,626.3**	**7.2**	**9.4**	**516.0**	**81.0**	**442.2**	**247.9**	**146.4**	**11.1**	**309.5**	**136.5**	**134.2**	**59.1**	**5,219.5**

[1] For the countries where injectable 3rd- and 4th-generation cephalosporins are solely or almost solely marketed for dogs and cats, the data provide a considerable overestimate for food-producing animals.
[2] 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.
[3] Pleuromutilins are aggregated with 'Others' for commercial confidentiality reasons.
[4] Fluoroquinolones and other quinolones are aggregated for commercial confidentiality reasons.
[5] For commercial confidentiality reasons, amphenicols, polymyxins and pleuromutilins are aggregated with 'Others', 1st- and 2nd-generation cephalosporins are aggregated with 3rd- and 4th-generation cephalosporins, and fluoroquinolones are grouped with other quinolones.
[6] For reasons of commercial confidentiality, pleuromutilins are grouped with 'Others' and lincosamides are grouped with macrolides.

Table A2. Estimated PCU (in 1,000 tonnes) of the population of food-producing animals[1], by country, in 2021

Country	Cattle	Pigs	Poultry	Sheep and goats	Fish	Rabbits	Horses	Total
Austria	420	358	91	37	0	0	39	945
Belgium	473	867	283	19	0	4	123	1,770
Bulgaria	111	93	51	104	13	<0.01	19	391
Croatia	96	98	49	49	27	0.01	12	331
Cyprus	29	46	13	54	8	0.1	2	152
Czechia	290	202	135	14	21	7	40	709
Denmark	378	1,826	121	11	45	0	70	2,452
Estonia	58	43	2	5	1	<0.01	5	114
Finland	203	148	87	11	14	0	30	492
France	2,961	1,774	1,055	627	45	39	258	6,758
Germany	2,838	3,545	992	134	18	23	520	8,071
Greece	74	101	146	661	113	2	2	1,100
Hungary	191	340	190	74	21	5	24	846
Iceland	19	6	6	39	53	<0.01	22	145
Ireland	1,298	296	106	354	43	0	100	2,196
Italy	1,469	803	759	550	62	29	141	3,813
Latvia	85	33	23	7	0	0.03	3	153
Lithuania	154	73	51	11	2	0.04	6	297
Luxembourg	42	10	0.4	1	0	0	2	54
Malta	4	4	2	1	0	0.1	2	15
Netherlands	1,079	1,544	350	74	5	0.4	39	3,092
Norway	215	118	74	95	1,646	0	50	2,197
Poland	1,538	1,387	1,302	22	45	2	120	4,417
Portugal	212	375	236	183	17	6	35	1,063
Romania	733	707	537	864	7	<0.01	95	2,943
Slovakia	83	60	49	28	4	0.2	6	230
Slovenia	100	19	43	9	2	0.01	11	184
Spain	1,009	4,391	869	1,351	313	54	258	8,245
Sweden	284	201	119	31	10	0	142	788
Switzerland	460	192	80	32	0	1	45	810
United Kingdom	1,716	809	1,255	2,731	204	0	339	7,054
Total 31 countries	**18,623**	**20,469**	**9,078**	**8,185**	**2,740**	**172**	**2,558**	**61,825**

[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 presentations[1] sold as premixes, oral powders and oral solutions containing 1, 2 and 3 active substances, by country, in 2021[2]

	1 substance		2 substances		3 substances		Total tonnes (premixes, oral powders and oral solutions)
Country	**Tonnes**	**%**	**Tonnes**	**%**	**Tonnes**	**%**	
Austria	28.6	90%	3.3	10%			31.9
Belgium	107.4	73%	39.9	27%			147.2
Bulgaria	40.5	93%	3.0	7%			43.5
Croatia	15.0	95%	0.9	5%			15.9
Cyprus	30.9	72%	12.1	28%			42.9
Czechia	23.0	82%	4.6	17%	0.3	1%	27.9
Denmark	40.0	91%	3.9	9%			43.9
Estonia	2.9	87%	0.4	13%			3.3
Finland	1.6	60%	1.1	40%			2.6
France	182.9	70%	80.0	30%			262.9
Germany	462.0	89%	57.2	11%			519.2
Greece	92.3	92%	8.0	8%			100.3
Hungary	117.1	94%	6.9	6%			124.0
Iceland	0.03	100%					0.03
Ireland	54.1	89%	7.0	11%			61.1
Italy	424.8	70%	171.4	28%	7.2	1%	603.6
Latvia	1.9	97%	0.1	3%			2.0
Lithuania	2.8	71%	1.1	29%			3.9
Luxembourg	0.5	64%	0.3	36%			0.7
Malta	1.0	71%	0.4	26%	0.03	3%	1.4
Netherlands	92.4	79%	24.1	21%			116.5
Norway	1.1	100%	<0.01	0.1%			1.1
Poland	668.1	93%	51.5	7%			719.6
Portugal	137.1	92%	12.2	8%			149.3
Romania	123.5	93%	8.6	6%	0.9	1%	133.0
Slovakia	6.1	81%	1.4	18%	0.1	1%	7.6
Slovenia	3.9	93%	0.3	7%			4.2
Spain	1,069.9	91%	100.7	9%			1,170.6
Sweden	0.8	100%					0.8
Switzerland	5.7	39%	4.0	27%	5.0	34%	14.7
United Kingdom	126.9	85%	23.1	15%			149.9
Total 31 countries	**3,864.5**	**85.8%**	**627.1**	**13.9%**	**13.6**	**0.3%**	**4,505.5**

[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.

Table A4. List of substances reported sold in ESVAC, 2010–2021[1]

Class	Subclass	Substances
Tetracyclines		Chlortetracycline Doxycycline Oxytetracycline Tetracycline
Amphenicols		Chloramphenicol[2] Florfenicol Thiamphenicol
Penicillins	*Beta-lactamase-sensitive penicillins*	Benzathine benzylpenicillin Benzathine phenoxymethylpenicillin Benzylpenicillin Penethamate hydriodide Phenoxymethylpenicillin Procaine benzylpenicillin
	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
Cephalosporins[4]	*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 Sulfamonomethoxine Sulfadimethoxine Sulfadimidine Sulfadoxine

Class	Subclass	Substances
		Sulfafurazole Sulfaguanidine Sulfalene Sulfamerazine Sulfamethizole Sulfamethoxazole Sulfamethoxypyridazine Sulfanilamide Sulfapyridine Sulfaquinoxaline Sulfathiazole Sulfazuinoxaline
	Trimethoprim and derivatives	Trimethoprim
Macrolides and lincosamides	*Macrolides*	Erythromycin Gamithromycin Oleandomycin Spiramycin Tildipirosin Tilmicosin Tulathromycin Tylosin Tylvalosin
	Lincosamides	Clindamycin[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] Previous 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 (https://ec.europa.eu/health/documents/community-register/html/vo22101.htm), 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: BGBl. II Nr. 83/2014 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, farms and pharmacists; the wholesalers acquire the VMPs from another wholesaler or the authorised manufacturer. Antimicrobial VMPs are only available to animal owners by delivery from a pharmacy or wholesaler, on veterinary prescription or directly from the veterinarian. Premixes are distributed through wholesalers directly to feed mills. Only farmers receive feed from feed mills. Medicated feed is 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 either through pharmacies or via a small number of dispensing companies approved by the Danish Medicines Agency to dispense VMPs on the same legal terms as those 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. Veterinarians 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

The collection of sales data from pharmaceutical companies and wholesalers is based on the German Medicinal Products Act and is further specified in a specific regulation.

Data sources

Sales data for antimicrobial VMPs that were 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. 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 2020, sales of veterinary antimicrobial agents were reported to ESVAC for the sixth time. Data were provided by 68 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. 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

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

Data sources

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

Iceland

Distribution of veterinary medicines

In Iceland, all antimicrobial VMPs and almost all other VMPs are prescription-only medicines. They must be dispensed to animal owners by veterinarians (or used by the veterinarians in their practices), or 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, as a result of 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

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

Data sources

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

Malta

Distribution of veterinary medicines

All VMPs that contain antimicrobials are registered as prescription-only medicines. In accordance with Regulation 58 of Subsidiary Legislation 437.47, distribution of VMPs is subject to the holding of an authorisation. In accordance with Regulation 60 of Subsidiary Legislation 437.47, a veterinary prescription is required for 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

There is no legal basis for the reporting of veterinary antimicrobial sales data in Malta and monitoring is done on a voluntary basis by the Veterinary Medicines Section, which falls under the administration of the Ministry for Agriculture, Fisheries, Food and Animal Rights.

Data sources

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

Netherlands

Distribution of veterinary medicines

In the Netherlands, antimicrobial VMPs are available on prescription-only. Veterinarians purchase approximately 40% of their VMPs directly from manufacturers and approximately 60% through wholesalers. About 98% of the total volume of antimicrobial VMPs is dispensed by MAHs who are either direct members of the Dutch federation of the veterinary pharmaceutical industry (FIDIN) or are represented by FIDIN members. An estimated 2% are sold by authorisation holders not associated with FIDIN. Veterinarians sell the products directly to animal owners. Pharmacies dispense only minor quantities of VMPs, but no antimicrobial VMPs.

Legal basis for the monitoring of sales

Since January 2022, the legal basis for the mandatory reporting of sales data is found in the VMP-Reg EU 2019/6; in previous years monitoring of sales took place voluntarily, including 2021.

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.

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. However, before purchase, medicated feed producers must obtain confirmation from the district veterinary officer.

Legal basis for the monitoring of sales

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

Data sources

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

Portugal

Distribution of veterinary medicines

In Portugal, all VMPs containing antimicrobial agents are prescription-only medicines. This includes medicated premixes containing pharmaceutically active substances, 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. Only farmers are receivers from feed mills. Medicated feeds containing antimicrobial premixes must also be prescribed by a veterinarian and can only be manufactured by officially authorised feed mills.

Legal basis for the monitoring of sales

The collection of sales data is based on 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 on 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 the distributors of VMPs, while the monitoring of sales by MAHs takes place voluntarily.

Data sources

For 2017–2020, 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

It needs to be highlighted that since 1 January 2019, the regulatory framework for data collection in Switzerland has been governed by 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 no prescription figures are currently available at national level, sales figures cannot be validated further. Veterinarians may import VMPs for companion and food-producing animals, including products containing antimicrobial agents, based on a single authorisation valid for one year and delivered by Swissmedic, the Swiss Agency for Therapeutic Products. As MAHs or wholesalers in Switzerland do not sell these products, and since these single authorisations are not given for defined quantities, these products cannot be monitored and are therefore not included in the statistics.

United Kingdom

Distribution of veterinary medicines

In the United Kingdom, antimicrobial VMPs may only be supplied on prescription. The products can be dispensed either by the veterinarian or by a veterinary pharmacist, and 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.

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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 2021

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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.

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- Iva Gruden Zdunic
- Katariina Kivilahti-Mäntylä
- Laura Mie Jensen
- Lucie Pokludová
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