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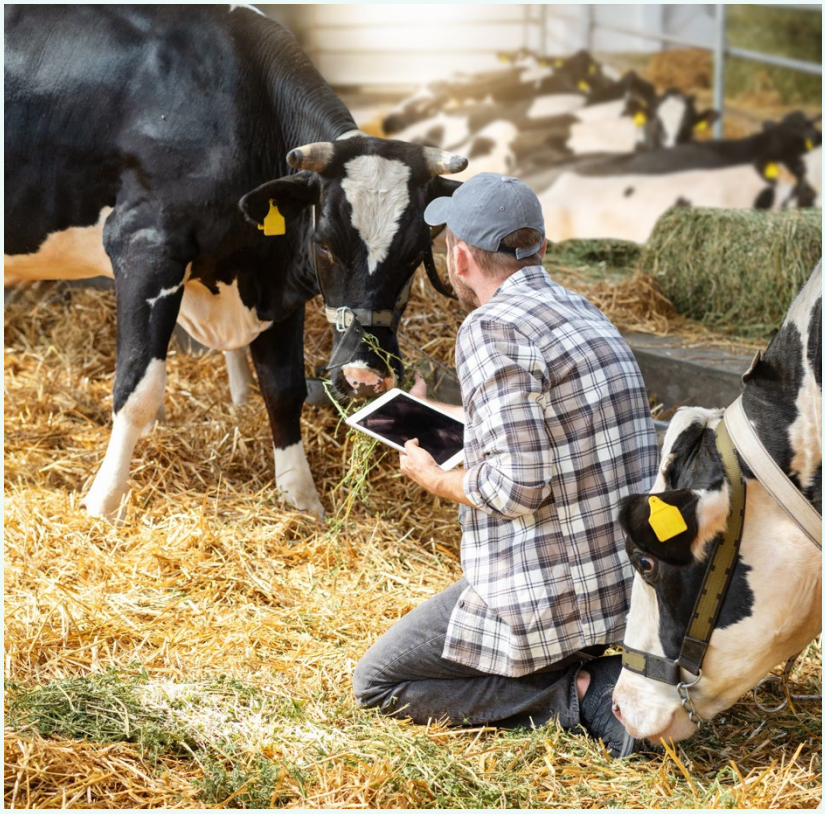

European sales and use of antimicrobials for veterinary medicine

Annual surveillance report for 2023

An agency of the European Union

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Foreword by Emer Cooke

EMA Executive Director

Welcome to the first report on the European Sales and Use of Antimicrobials, following a change in the legal framework governing veterinary medicines in the European Union (EU). I invite you to explore the wealth of information in the following pages, which details outcomes of the continued collaboration between EMA and the Member States in this important topic area.

The health challenges we face today affect more than humans and animals. One Health recognises the complex interplay between human, animal and plant health, food safety, the climate crisis and environmental sustainability. Implementing this approach across different sectors is key to making the EU and its Member States better equipped to prevent, predict, detect and respond to health threats. It can help to mitigate the impact and societal cost of such threats, or even prevent their emergence, while also helping to reduce human pressures on the environment and safeguarding key societal needs such as food security and access to clean air and water.

An important aspect of One Health is the development of antimicrobial resistance (AMR), which occurs when microorganisms develop resistance to antimicrobial medicines, making them less effective. AMR is one of the biggest health threats, estimated to cause 35,000 human deaths and 1.5 billion euros in healthcare costs and productivity losses in the EU every year. EMA plays a vital role in the global response to AMR and, in support of the One Health approach, promotes a close cooperation between the human and veterinary fields. The goal is to preserve the possibility of effective treatment of infections in humans and in animals.

The nature of AMR demands increased coordination in the EU and worldwide and a comprehensive response involving governments, civil society, international organisations, and the private sector. This report is testament to the continued close cooperation between EMA and the Member States. It demonstrates that we can achieve ambitious goals through collaboration and commitment.

The data in this report will also feed into the Joint Interagency Antimicrobial Consumption and Resistance Analysis (JIACRA) project in collaboration with other EU Health Agencies. This is the essence of a One Health approach: combining different approaches to address a common problem and including multiple stakeholders. We know from the work we are doing that the more we work together and collaborate, the more we can achieve.

Foreword by Ivo Claassen

Head of Veterinary Medicines Division
Deputy Executive Director

I am proud to present the first report on the European Sales and Use of Antimicrobials in veterinary medicines. We have a remarkable success story here.

A former voluntary initiative of the European regulatory network, the European Surveillance of Veterinary Antimicrobial Consumption (ESVAC) project has already been hugely successful in helping to reduce sales of veterinary antibiotics. The ESVAC reports, by providing detailed comparative information to policy makers and other interested parties, led to sales of veterinary antibiotics in Europe dropping by more than 50% over the course of 12 years. It was a concerted effort by farmers, veterinarians, and national authorities, which shows that we can reduce AMR through a combination of monitoring, collecting data and communication.

The principles of the ESVAC project are now embedded in EU legislation. Following the implementation of Regulation (EU) 2019/6 in 2022, the collection of data on sales and now also on use of veterinary antimicrobials is mandatory for all Member States. The scope of the data has been expanded to include more antimicrobial classes in comparison to ESVAC, addressing the increasing complexity of resistance across the EU.

In the spirit of establishing Europe as a best-practice region for surveillance, EMA launched the Antimicrobial Sales and Use (ASU) IT platform, which is a successor to the ESVAC database. The ASU platform is designed to standardise and streamline the collection of data from all Member States. It helps identify trends in antimicrobial consumption more accurately, to support better decision making towards the protection of animal and human health in Europe.

Data from this platform will help future monitoring of the effect of measures to reduce antimicrobial consumption in animals implemented at the national and EU levels. As data quality will improve over time, the data in ESUAvet reports will further enhance the EU's surveillance of antimicrobial consumption in animals and will support more in-depth analysis of potential relationships between antimicrobial consumption and AMR.

The continuous collection of antimicrobial sales and particularly of use data in animals requires significant effort. I would like to take this opportunity to thank all those involved in the different stages that led up to this publication for their dedicated work.

I encourage you to engage with this report and explore the valuable insights it offers. Policymakers, veterinarians, farmers, health professionals, patients, and both governmental and non-governmental organisations all have a role to play in addressing the public health threat of AMR. By working together as partners and stakeholders, we can make a significant difference in promoting responsible antimicrobial use and safeguarding both animal and public health in the EU.

Highlights

The first European Sales and Use of Antimicrobials for Veterinary Medicine (ESUAvet) annual surveillance report, featuring 2023 data, marks a significant milestone in the EU's efforts to monitor antimicrobial consumption in animals. For the first time, data collection and reporting of antimicrobial sales and use in animals were conducted under Article 57 of Regulation (EU) 2019/6. In 2024, 29 reporting countries — 27 EU countries, Iceland and Norway — reported 2023 data to the European Medicines Agency (hereinafter 'the Agency' or EMA) on the volume of sales of antimicrobial veterinary medicinal products (VMPs) and on the use of antimicrobial medicinal products in animals under this legal framework. It was also the first time countries reported antimicrobial use data to the Agency separately for cattle, pigs, chickens, and turkeys, marking a significant step towards obtaining more granular information on antimicrobial consumption by species.

Previously, the Agency published annual reports under the voluntary European Surveillance of Veterinary Antimicrobial Consumption (ESVAC) project, which ended with the publication of 2022 sales data from 31 European countries (United Kingdom and Switzerland do not report to ESUAvet).

New data collection systems

The new legal framework has broadened the surveillance scope of antimicrobial consumption in animals which, in additional to sales of antimicrobial VMPs, now covers the use of antimicrobial medicinal products in specified animal species. For some reporting countries, this has involved modifying existing or building new data collection systems to establish functional national systems for both sales and use data, in line with the defined legal and technical requirements.

EMA has developed and launched a new web interface, the Antimicrobial Sales and Use (ASU) Platform, in line with the legal requirements, to enable countries to report their collected data to the Agency. Starting with data from 2023, countries must complete the ASU sales and use templates — prefilled with VMP information from the Union Product Database (UPD) — with the number of packages sold or used per product presentation. Countries must also use this system to submit the animal population data required to normalise the sales and use data by the population at risk for being treated with antimicrobials. As with all new data collection and IT systems, extensive efforts were made (from the Agency and reporting countries) to ensure that the technical requirements and data quality standards were met. Consequently, data quality was a major focus during the 2023 data call and preparation of the first ESUAvet report.

New guideline on the reporting of antimicrobial sales and use data

In 2023, EMA published a guideline describing the methodology for calculating animal biomass denominators for presenting population-adjusted sales and use data in the ESUAvet reports. According to this document, the animal biomass for food-producing animals includes more species and categories, as well as different weights, than those used in ESVAC for calculating the Population Correction Unit, (PCU). The ESUAvet biomass of food-producing animals is considerably higher than the ESVAC PCU (Annex 5). Consequently, the sales indicator in ESUAvet reports is not directly comparable with the indicator values in previous ESVAC reports (mg/PCU). Additionally, the guideline introduces a biomass denominator for non-food-producing animals, enabling the reporting of normalised sales also for other animals kept or bred.

The main indicator for population-adjusted ESUAvet sales under the mandatory scope is **mg/kg animal biomass** (hereinafter '**mg/kg**').

Volume of sales of antimicrobial VMPs

The definition of antimicrobial in the veterinary medicines legislation covers antibiotics, antivirals, antifungals and antiprotozoals. The antimicrobial substances in VMPs that fall under the **mandatory scope** all have **antibiotic activity**. Overall EU sales in 2023 of antimicrobial VMPs in the mandatory scope, which covers the same antimicrobials as those included in the ESVAC scope, were 4,380.8 tonnes. Additionally, 17 countries also provided sales data under the voluntary scope (36.9 tonnes) that consisted of antibacterials for topical use, as well as antiprotozoals, antifungals and antiinfectives.

The results presented below are focused on sales data that fall under the mandatory scope.

Sales of antimicrobial VMPs for use in food-producing animals represented 98.4% of all reported sales in tonnes. A large difference is observed between countries with the highest and lowest sales, ranging from 6.0 mg/kg to 112.9 mg/kg, while the EU aggregated sales were 45.1 mg/kg.

The highest selling antimicrobial class for food-producing animals were penicillins (31.4%), followed by tetracyclines (21.6%) and sulfonamides (10.1%). In general, the sales patterns of the various antimicrobial classes varied substantially across the 27 EU countries. This was also the case for the antimicrobial classes included in AMEG category B, i.e. 3rd- and 4th-generation cephalosporins, fluoroquinolones, other quinolones and polymyxins. Regarding the distribution of sales per AMEG category, 65.3% of total EU sales for food-producing animals corresponded to substances that belong to category D (prudence), 29.3% to category C (caution) and 5.4% to category B (restrict).

Of aggregated sales for food-producing animals, 85.9% corresponded to product forms predominantly used for group treatment.

Sales of antimicrobial VMPs authorised solely for other animals kept or bred (mainly companion animals) represented 1.6% of all reported sales in tonnes. A large difference was also observed between countries with the highest and lowest sales, ranging from 12.5 mg/kg to 145.8 mg/kg, while the aggregated sales for the EU were 38.2 mg/kg. Tablets were the highest selling product form, accounting for 90.8% of the total antimicrobial VMP sales for other animals kept or bred.

The highest selling antimicrobial class for other animals kept or bred were penicillins accounting for 49.6% of overall sales, followed by 1st- and 2nd-generation cephalosporins (16.8%) and imidazole derivatives (11.4%). Categorised per AMEG category, 26.0% of total EU sales for other animals kept or bred corresponded to substances belonging to category D (prudence), 71.6% to category C (caution) and 2.4% to category B (restrict).

EU antimicrobial sales reduction target: 50% reduction of overall sales of antimicrobials for farmed animals and in aquaculture by 2030 in the EU

The European Commission (EC) has set targets as part of its actions against antimicrobial resistance (AMR). This European roadmap includes the aspirational target of 50% reduction in overall EU sales of antimicrobials for farmed animals and in aquaculture by 2030, with 2018 as the reference year.

The 2018 reference value (established with ESVAC data) for overall sales of antimicrobial VMPs in the EU is 118.3 mg/PCU, which sets the target for 2030 at 59.2 mg/PCU. In 2023, aggregated sales for the EU were 88.5 mg/PCU, meaning that approximately half of the 50% reduction target set for 2030 has already been achieved.

To attain the 2030 aspirational target, aggregated EU sales must continue to decline. Given the substantial reduction of antimicrobial VMP sales in many of the EU countries, there is likely a potential for reduction in other EU countries as well.

Use of antimicrobials in animals

For the first time, countries reported data to the Agency on the use of antimicrobials in cattle, pigs, chickens and turkeys, with data from 2023. All 29 countries reported use of antimicrobial medicinal products from the mandatory scope and 11 countries also provided use data from the voluntary scope. However, not all countries were able to report use data by animal species categories as required per legislation, and the accuracy and the coverage of the data varied greatly per species and between reporting countries.

Those countries that reported use data with 100% coverage accounted for only 22–50% of the biomass of cattle, pigs, chickens and turkeys. Given the variability in the completeness and granularity of the reported use data for 2023, quantitative use data are not presented in this report to prevent misleading interpretations and comparisons between animal sectors based on data with varying accuracy and coverage. Continued efforts will be necessary to improve the quality of use data to enable reporting of quantitative data, including trends.

Introduction

The Agency has been monitoring antimicrobial consumption in animals for more than a decade with the ESVAC project. Data collection of antimicrobial VMP sales began in 2010, with voluntary participation growing from 9 to 31 European countries over the years. As Regulation (EU) 2019/6 introduced a legal framework for collecting data on antimicrobial medicinal products used in animals, the ESVAC project concluded in November 2023 with the publication of its final annual report[2].

Voluntary surveillance of antimicrobial consumption in animals has changed to a legal obligation under Article 57 of Regulation (EU) 2019/6[3]. As of January 2024, all EU countries, Iceland and Norway must report data on the volume of sales of antimicrobial VMPs and on the use of antimicrobial medicinal products in animals to EMA. In turn, the Agency must analyse those data in cooperation with reporting countries and publish annual reports. Marking the transition to the new era of surveillance, the Agency's reports will be known as the ESUAvet Annual Surveillance Reports.

Legal framework

The legal framework behind the collection and publication of data on the volume of sales and on the use of antimicrobial medicinal products in animals can be found in three main legal acts:

- Article 57 of Regulation (EU) 2019/6 on veterinary medicinal products[3]
- Commission Delegated Regulation (EU) 2021/578[4]
- Commission Implementing Regulation (EU) 2022/209[5]

What is stated in Article 57 of Regulation (EU) 2019/6?

This article sets the obligation for Member States to collect and report data to the Agency on the volume of sales of veterinary medicinal products and the use of antimicrobial[6] medicinal products (both veterinary and human[7]) in animals, to enable the evaluation of the use of such products in food-producing animals. **This act has been incorporated into the European Economic Area Agreement and is also applicable to Iceland and Norway.** Therefore, the provisions described below apply to all ESUAvet reporting countries, i.e. the 27 EU countries, Iceland and Norway. The Agency will cooperate with ESUAvet reporting countries and other Union agencies and publish annual reports.

[2] Thirteenth ESVAC report
[3] 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.
[4] 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.
[5] 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.
[6] As per Article 4(12) of Regulation (EU) 2019/6, 'antimicrobials' are defined as any substance with a direct action on micro-organisms used for treatment or prevention of infections or infectious diseases, including antibiotics, antivirals, antifungals and antiprotozoals.
[7] If no authorised VMPs are available or authorised for a particular animal or disease in their country, under exceptional circumstances and in particular to avoid unacceptable suffering, the veterinarian is allowed to use the prescription 'cascade' subject to certain conditions. For more information, please refer to the Commission Implementing Regulation (EU) 2024/1973.

What is stated in Commission Delegated Regulation (EU) 2021/578?

This legal act outlines the requirements and timelines for reporting of both data on the volume of sales of antimicrobial VMPs and on the use of antimicrobial medicinal products in animals. Key points include:

- **Medicinal products data collection and reporting scopes**: specifying for which antimicrobial medicinal products Member States must collect and report sales (only VMPs) and use (both veterinary and human medicinal products) data to the Agency (refer to Annex 2 for more details).
- **Obligations of Member States and of the Agency**: detailing the responsibilities regarding quality assurance and data quality requirements.
- **Data collection and reporting methods**: describing the data requirements and methods for collecting and reporting data to the Agency.
- **Use data by animal species and categories**: defining the progressive stepwise approach for Member States to collect and report use data by animal species and categories. The three steps of this approach are outlined below, including the first year in which Member States must report the specified data to the Agency **for the preceding calendar year**:
    - **From 2024**, use data must be reported for cattle, pigs, chickens and turkeys.
    - **From 2027**, use data must be reported for other food-producing animal species: other poultry (duck and geese), sheep, goats, finfish (Atlantic salmon, Rainbow trout, Gilthead seabream, European seabass, Common carp), horses, rabbits, any other food-producing animals of relevance to the Member State.
    - **From 2030**, use data must be reported for other animals kept or bred: dogs, cats and fur animals (minks and foxes).
- **Annual reports and timelines**: specifying the data and analyses to be included in the Agency's annual reports and the timelines for its publication, including deadlines for Member States to submit their data.

What is stated in Commission Implementing Regulation (EU) 2022/209?

This legal act establishes the data format that Member States must use to report data to the Agency on antimicrobial VMP sales and on use of antimicrobials in animals. It also defines the specific variables that must be provided for each product presentation, enabling the Agency to calculate the quantity of antimicrobial active substance(s) in each product sold or used. Additionally, it requires that Member States provide animal population data in a specific format, allowing the Agency to adjust the data for the relevant animal populations for analysis purposes, as per Article 5.1 of this act.

EMA has published various manuals and guidelines to support countries to implement the legal requirements. Therefore, the legislation should be read in conjunction with the following materials[8]:

- Antimicrobial use data reporting per animal categories (numerator) - Manual for reporting the data to the Agency[9]

[8] For access to all ASU-related documentation published by the European Medicines Agency, please refer to the Antimicrobial Sales and Use Platform
[9] Antimicrobial use data reporting per animal categories (numerator) (EMA/757638/2021)

- Guideline on the reporting of antimicrobial sales and use in animals at the EU level – denominators and indicators[10]
- Antimicrobial Sales and Use (ASU) technical implementation protocol[11]
- Manual for Member States for establishing a data quality management plan for the collection of antimicrobial sales and use data under Regulation (EU) 2019/6 and its delegated and implementing regulations[12]

Aim and scope of the ESUAvet annual reports

The main aims of the Agency's annual reports are to document both at national and Union level:

- detailed and comparable data on the volume of sales of veterinary antimicrobials and of the use of antimicrobials in animals;
- changes in trends and patterns on the volume of sales of veterinary antimicrobials and of the use of antimicrobials in animals.

Which antimicrobial substances are covered by the ESUAvet reports?

The data that countries must collect and report is defined by legislation and is based on the World Health Organization (WHO) Anatomical Therapeutic Chemical (ATC) classification and the Anatomical Therapeutic Chemical veterinary (ATCvet) systems[13,14] .

The antimicrobial medicinal product's ATCvet (for VMPs) or ATC (for human medicinal products – HMPs) code determines if the sales or use data reported fall under either the **mandatory** or the **voluntary** data collection and reporting scope[15]:

- The antimicrobial substances in the medicinal products that fall under the **mandatory** scope are antibacterials, antiprotozoals with antibacterial effect[16], intramammary antimycobacterials, and antiinfective agents, all of which have antibiotic activity[17].
- The **voluntary** scope includes antivirals, antifungals, topical antibacterials, antiprotozoals and antiinfectives.

For a list of the ATCv(vet) codes that determine the antimicrobial medicinal products under surveillance please refer to Table 14 of Annex 2.

To harmonise the reporting of antimicrobial sales and use data in this report with the data on sales of antimicrobial substances used in human medicine, the data are presented according to the classes/subclasses referred in Annex 3, Table 16.

[10] Guideline on the reporting of antimicrobial sales and use in animals at the EU level – denominators and indicators (EMA/CVMP/882931/2022)
[11] Antimicrobial Sales and Use (ASU) technical implementation protocol (EMA/27838/2024)
[12] Manual for Member States for establishing a data quality management plan for the collection of antimicrobial sales and use data under Regulation (EU) 2019/6 and its delegated and implementing regulations (EMA/CVMP/ESUAVET/570091/2023)
[13] More information about the ATC code classification system is available at https://atcddd.fhi.no/
[14] More information about the ATCvet code classification system is available at https://atcddd.fhi.no/atcvet/
[15] According to Articles 1-4 of Commission Delegated Regulation (EU) 2021/578.
[16] Specifically concerns sulfonamides, which in the ATCvet system are classified as both antibacterial and antiprotozoal. In the context of these reports, sulfonamides are only presented under the class of 'antibacterials'.
[17] As per Article 4(12) of the Regulation (EU) 2019/6, 'antibiotic means any substance with a direct action on bacteria that is used for treatment or prevention of infections or infectious diseases'.

ASU Platform

This report is based on data reported by countries via the ASU Platform, the new IT system developed by the Agency to support the new data collection and reporting activities under Article 57 of Regulation (EU) 2019/6.

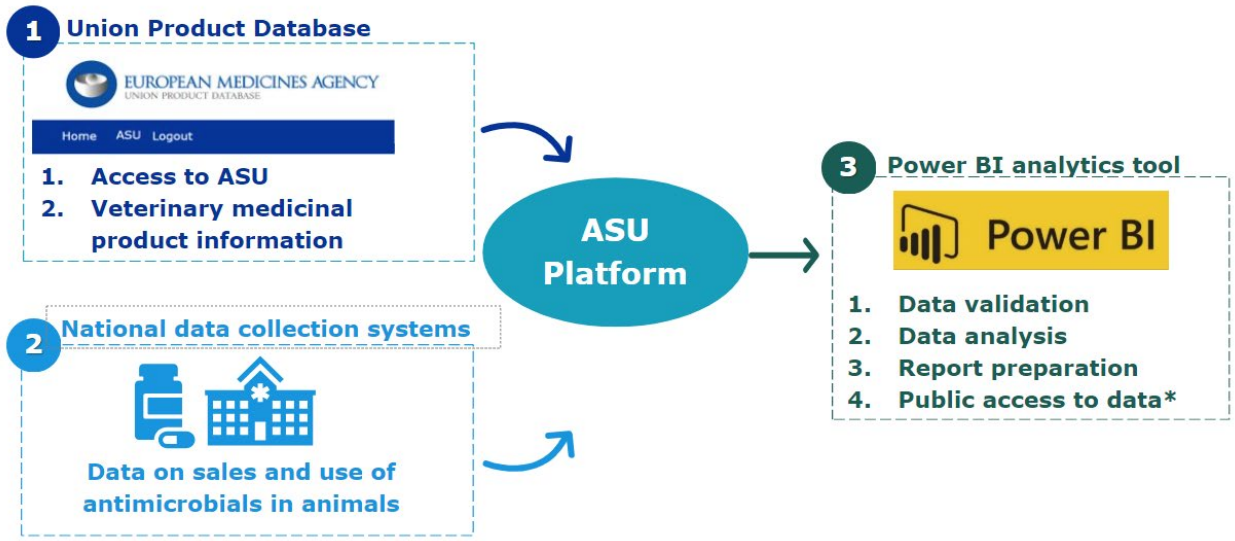
What is the ASU platform?

In essence, the ASU Platform is an IT system that enables the reporting, storage, analysis, and dissemination of data on the volume of sales of antimicrobial VMPs and the use of antimicrobial medicinal products in animals. Countries must also use this system to submit the animal population data required to normalise the sales and use data by the population at risk for being treated with antimicrobials.

The ASU Platform was developed in line with the legal requirements set out in the aforementioned legal acts superseding the ESVAC application, used until 2023 to collect sales data of antimicrobial VMP from ESVAC participating countries. All ESVAC data have been migrated to the ASU Platform for its preservation and use in potential trends analyses.

The ASU Platform has two components: the web interface for countries to submit their collected data and a Power BI application tool that enables data validation and analysis by reporting countries and the Agency. In the future, the ASU Power BI Application will be used to create dashboards to showcase aggregated data to the public (Figure 1). For more information on the methodology used in the ASU Power BI application to analyse the data please see Annex 2.

Figure 1. Components and functionalities of the ASU Platform



*Public Power BI dashboards have yet to be developed.

The ASU Platform is integrated with two other key EMA IT systems: the Substance, Product, Organisation and Reference (SPOR) data management services and the Union Product Database (UPD). SPOR acts as a source of substance, human medicinal product, organisation and other reference data. UPD primarily serves as the source of veterinary medicinal product information data used by the ASU Platform to prefill the sales and use templates for each country. These templates are then completed

by reporting countries with the number of packages sold or used per product presentation, allowing for the calculation of the antimicrobial active substance(s) content (in grams) per product presentation[18].

What added value does the ASU Platform bring?

The ASU Platform provides an environment for countries to submit sales, use and animal population data in a standardised format, supporting harmonisation and data quality. The integration with other EMA IT systems avoids duplication of data input across systems and ensures a single source of information which in turn reduces administrative burden compared to the previous ESVAC system. Finally, it also leverages the capabilities of the previous system by offering an improved user interface and enhanced data analysis functionalities.

About ESUAvet Working Group (WG) activities

The ESUAvet WG[19] was established in June 2023 to provide strategic guidance and recommendations to the Agency and its Committee for Veterinary Medicinal Products (CVMP) on matters related to Article 57 of Regulation (EU) 2019/6. This includes providing advice on collection and analysis of data, liaising with the relevant national bodies, and supporting the Agency in meeting its obligations regarding the surveillance of antimicrobial sales and use data in animals in the EU, including the preparation of the ESUAvet annual reports.

Furthermore, the ESUAvet WG serves as a forum for exchanging information on the collection, reporting and interpretation of the antimicrobial sales and use data, pooling knowledge and practices, and furthering cooperation between countries in this area. The working group comprises one member and one alternate from each of the 27 EU countries, Iceland and Norway, nominated by their country's national competent authorities.

In addition to the ESUAvet WG, the data reporting activities behind this report are also supported by a network of national contact points and ASU data managers responsible for reporting data to the Agency via the ASU Platform. Both national contact points and ASU data managers are nominated by national competent authorities or directly by the ESUAvet member of their country.

About this report

The first ESUAvet annual surveillance report presents data on the volume of sales of antimicrobial VMPS and use of antimicrobial medical products in animals in 2023 reported for the first time by countries following the entry into force of EU Regulation 2019/6. These data are provided in accordance with the legal requirements and the Agency's reporting protocols[20].

This report has the following two main result sections:

- **Volume of sales antimicrobial VMPs** (Section 1): presenting the data received from countries on the volume of sales of antimicrobial VMPs. The section starts with an overview of all antimicrobial VMP sales reported by countries to the Agency, from both the mandatory and voluntary reporting scope. Next, results are focused on the volume of sales for **antimicrobials in the mandatory scope**, presented separately for food-producing animals and other animals

[18] For further information on how the ASU templates should be completed by countries, please refer to the Antimicrobial Sales and Use (ASU) technical implementation protocol (EMA/27838/2024)
[19] More information available on the European Medicines Agency website here.
[20] Available on the European Medicines Agency website here.

kept or bred. An update on the progress made towards the EU antimicrobial sales reduction target is provided in Section 3.

- **Use of antimicrobial medicinal products in animals** (Section 2): presenting an overview of the first data countries reported on the use of antimicrobials in cattle, pigs, chickens and turkeys. This section also starts with an overview of all antimicrobial use reported to the Agency by countries from both the mandatory and voluntary scope. Next, a qualitative overview is provided on the data reported separately for each of the above-mentioned animal species.

This report also presents data as proportions of total antimicrobial sales, focusing on certain classes or subclasses of antimicrobials included in category B of the EMA's Antimicrobial Advice ad hoc Expert Group (AMEG) categorisation from 2019. The AMEG categories, available on the EMA website[21], consider the need for these antimicrobials in veterinary medicine, the probability of AMR transfer from animals to humans, and the WHO Critically Important Antimicrobial List for Human Medicine (6th revision)[22].

Further information on the methodology used to analyse the data (Annex 2), the list of substances for which sales data have been reported in 2023 (Annex 3), the data quality checks performed on the reported data (Annex 4), the transition from ESVAC to ESUAvet sales reporting (Annex 5), country trends from preceding years (Annex 6), among others, can be found in the corresponding annexes of this report.

The data and information included in this report have been reviewed and approved by the ESUAvet WG and adopted by CVMP prior to publication on the EMA website. The data were extracted from the ASU Platform on 7 January 2025, when all datasets were approved for publication.

[21] 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' EMA/CVMP/CHMP/682198/2017.
[22] This list has been revised and replaced by the WHO List of Medically Important Antimicrobials: a risk management tool for mitigating antimicrobial resistance due to non-human use.

1. Volume of sales of antimicrobial VMPs

In 2023, data on the volume of sales of antimicrobial VMPs were collected for the first time following EU regulation. This section presents the volume of sales of antimicrobial VMPs reported by the 29 ESUAvet-reporting countries (i.e. 27 EU countries, Iceland and Norway) for 2023.

Disclaimers for sales data:

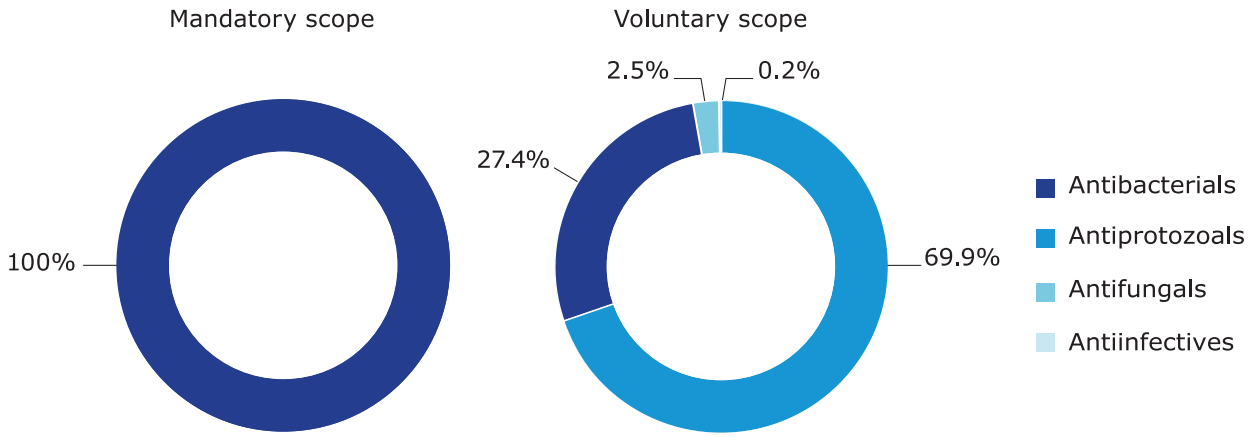
- In this report, data are mostly presented for the EU. Data for all reporting countries (EU countries, Iceland and Norway) are nearly identical in numerical values to the EU data and do not alter the distribution of data by class or product form. Notable deviations, if any, are highlighted in the text.
- Figures presenting sales within the voluntary scope should be considered with caution as no validation was performed and the coverage of the data under this scope is unknown.
- Volume of sales of antimicrobial VMPs are automatically assigned by the ASU system to sales for food-producing animals when the antimicrobial VMP has a withdrawal period. However, some products are marketed for both food-producing and other animals kept or bred. Consequently, sales for other animals kept or bred may be underestimated as some of the sales allocated to food-producing animals could be for other animals kept or bred.
- It is generally agreed that establishing a valid baseline for the sales data requires at least three to four years. Given the previous reporting period under the ESVAC project, ESUAvet participating countries have already been collecting sales data for longer than the estimated baseline formation period. However, a few countries have changed their methods of collecting sales data compared to the previous reporting period (Annex 6).
- Except for the sales data presented in Section 3 and Annex 6 for the purpose of monitoring the EU antimicrobial sales reduction target, sales data presented in the ESUAvet annual surveillance reports are not directly comparable with sales published in the ESVAC reports due methodological differences (please refer to Annex 5 for detailed information).
- The data presented in this report should not be used as a sole basis for setting management priorities as differences in animal demography, availability of VMPs across the EU and other factors such as disease incidence and outbreaks, types of animal production systems, national legislation and action plans should also be considered, among others. Moreover, as sales and use data collected at national level can be sourced from different providers, the **data presented in this report should also not be used for direct comparison between countries**.
- The data presented at country level may differ from those presented in national reports due to possible differences in the inclusion criteria of antimicrobials, methodology and type of analyses (e.g. indicators) used. Therefore, the **data presented in the ESUAVet annual surveillance report should not be directly compared to data presented in national reports**.

1.1. Overview of reported sales of antimicrobial VMPs

In 2023, a total of 4380.8 tonnes of antimicrobials from the mandatory scope were reported as sold across the EU, and 4386.5 when including Iceland and Norway. The sales reported under the mandatory scope consisted exclusively of antibacterials, all of which have antibiotic activity[23].

In total, 17 countries also reported sales data under the voluntary scope (36.9 tonnes), but coverage of the voluntary data reported is unknown. Within the EU, antiprotozoals (69.9%) accounted for the largest proportion of sales of antimicrobials in the voluntary scope, followed by topical antibacterials (27.4%), antifungals (2.5%) and antiinfectives (0.2%) (Figure 2, Table 1)[24].

Figure 2. Proportion of reported sales (in tonnes) of antimicrobial VMPs by antimicrobial category[1] and scope[2] in the EU in 2023[3]



[1] The ASU Platform groups antimicrobial substances in categories, classes and subclasses taking into account the ATCvet codes in the Annex to Commission Delegated Regulation (EU) 2021/578 and the ATC(vet) classification system (see Annex 3).
[2] Sales data subject to mandatory and voluntary reporting. In 2023, 17 countries reported sales data from the voluntary scope. Coverage of sales data reported under the voluntary scope is unknown.
[3] The mandatory scope only concerns substances with antibiotic activity. However, some ATCvet codes from the mandatory scope are for products that contain antiprotozoals without antibiotic effect in combination with sulfonamides (classified as antibacterials). As a result, sales of all substances in such products are assigned to the mandatory scope by default and in 2023 include a negligible amount (0.001%) of sales of antiprotozoals (diaveridine and ronidazole).

Table 1. Reported sales of antimicrobial VMPs, in tonnes, by antimicrobial category[1], reporting scope and country, for 2023

Country	Reporting scope[2]	Antimicrobial category (in tonnes)				
		Antibacterials	Antifungals	Antiinfectives	Antiprotozoals	Total reported
Austria	Mandatory	34.1	-	-	-	34.1
	Voluntary	*Not reported*				
Belgium	Mandatory	102.5	-	-	-	102.5
	Voluntary	*Not reported*				
Bulgaria	Mandatory	36.9	-	-	-	36.9

[23] 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'.
[24] No sales data were reported for antimycobacterial or antivirals in 2023.

Country	Reporting scope[2]	Antimicrobial category (in tonnes)				
		Antibacterials	Antifungals	Antiinfectives	Antiprotozoals	Total reported
	Voluntary	0.2	0.05	-	0.2	0.4
Croatia	Mandatory	13.1	-	-	-	13.1
	Voluntary	0.2	0.02	-	0.05	0.3
Cyprus	Mandatory	23.1	-	-	-	23.1
	Voluntary	0.06	0.02	-	0.09	0.2
Czechia	Mandatory	30.4	-	-	-	30.4
	Voluntary	*Not reported*				
Denmark	Mandatory	71.1	-	-	-	71.1
	Voluntary	*Not reported*				
Estonia	Mandatory	5.4	-	-	-	5.4
	Voluntary	0.1	<0.01	-	0.06	0.2
Finland	Mandatory	8.4	-	-	-	8.4
	Voluntary	0.02	0.05	-	0.1	0.2
France	Mandatory	271.9	-	-	-	271.9
	Voluntary	*Not reported*				
Germany[3]	Mandatory	529.8	-	-	-	529.8
	Voluntary	1.2	0.2	-	-	1.4
Greece	Mandatory	87.7	-	-	-	87.7
	Voluntary	*Not reported*				
Hungary	Mandatory	79.3	-	-	-	79.3
	Voluntary	0.6	0.04	-	0.3	0.9
Ireland	Mandatory	75.2	-	-	-	75.2
	Voluntary	*Not reported*				
Italy	Mandatory	658.0	-	-	<0.001*	658.0
	Voluntary	*Not reported*				
Latvia	Mandatory	3.7	-	-	-	3,7
	Voluntary	0.05	<0.01	-	0.04	0.1
Lithuania	Mandatory	13.5	-	-	-	13.5
	Voluntary	0.02	<0.01	-	2.3	2.3
Luxembourg	Mandatory	1.4	-	-	-	1.4
	Voluntary	0.02	<0.01	<0.01	<0.01	0.04
Malta	Mandatory	1.2	-	-	<0.001*	1.2
	Voluntary	<0.01	<0.001	-		<0.01
Netherlands	Mandatory	116.2	-	-	-	116.2
	Voluntary	0.4	0.09	-	-	0.5
Poland	Mandatory	691.6	-	-	-	691.6
	Voluntary	*Not reported*				
Portugal	Mandatory	141.5	-	-	-	141.5
	Voluntary	2.2	0.1	-	2.2	4.5
Romania	Mandatory	177.7	-	-	0.05*	177.8
	Voluntary	2.6	0.1	0.09	3.3	6.0
Slovakia	Mandatory	10.1	-	-	-	10.1

Country	Reporting scope[2]	Antimicrobial category (in tonnes)				
		Antibacterials	Antifungals	Antiinfectives	Antiprotozoals	Total reported
	Voluntary	0.3	0.03	-	0.09	0.4
Slovenia	Mandatory	4.5	-	-	-	4.5
	Voluntary	*Not reported*				
Spain	Mandatory	1183.2	-	-	-	1183.2
	Voluntary	2.1	0.1	-	17.1	19.3
Sweden	Mandatory	9.2	-	-	-	9.2
	Voluntary	*Not reported*				
EU	**Mandatory**	**4380.8**	**-**	**-**	**0.05***	**4380.8**
	Voluntary	**10.1**	**0.9**	**0.09**	**25.7**	**36.8**
Iceland	Mandatory	0.7	-	-	-	0.7
	Voluntary	<0.01	0.03	-	<0.01	0.04
Norway	Mandatory	5.0	-	-	-	5.0
	Voluntary	*Not reported*				
EU, IS and NO	**Mandatory**	**4386.5**	-	-	**0.05***	**4386.5**
	Voluntary	**10.1**	**0.9**	**0.09**	**25.8**	**36.9**

[1] The ASU Platform groups antimicrobial substances in categories, classes and subclasses taking into account the ATCvet codes in the Annex to Commission Delegated Regulation (EU) 2021/578 and the ATC(vet) classification system (see Annex 3). For 2023, no sales data were reported for antimycobacterials or antivirals.
[2] Coverage of sales data reported under the voluntary scope is unknown. In 2023, 17 countries reported sales data from the voluntary scope.
[3] According to the German Veterinary Medicines Act, only a few ATCvet codes, which are considered voluntary under European law, have to be reported.
* The mandatory scope only concerns substances with antibiotic activity. However, some ATCvet codes under the mandatory scope are for products that contain antiprotozoals without antibiotic effect in combination with sulfonamides (classified as antibacterials). As a result, sales of all substances in such products are assigned to the mandatory scope by default and in 2023, include a negligible amount (0.001%) of sales of antiprotozoals (diaveridine and ronidazole).

As per legislation[25], countries should consider and select data providers, as appropriate, to ensure that they obtain full coverage of the data: marketing authorisation holders (MAHs), retailers, feed mills, pharmacies or veterinarians. For 2023, wholesalers were the most common sales data sources and were selected in 20 reporting countries (Table 2), followed by MAHs (12 countries), feed mills (6 countries), pharmacies (3 countries), veterinarians (2 countries) and retailers (1 country). Coverage of sales data was estimated to be full for 25 countries, 90% for 1 country, incomplete for 2, and unknown for 1 (Table 2).

Table 2. Data providers and coverage of the data on the volume of sales of antimicrobial VMPs reported by countries to the Agency for 2023[1]

Country	Type of data provider(s)[1]	Coverage reported by countries[2]
Austria	MAH, wholesalers	Full
Belgium[a]	MAH, feed mills	Full
Bulgaria	MAH, wholesalers	Full
Croatia	MAH, wholesalers	Full
Cyprus	Wholesalers, feed mills	Full
Czechia	Wholesalers, feed mills	Full

[25] Article 11 of the Commission Delegated Regulation (EU) 2021/578.

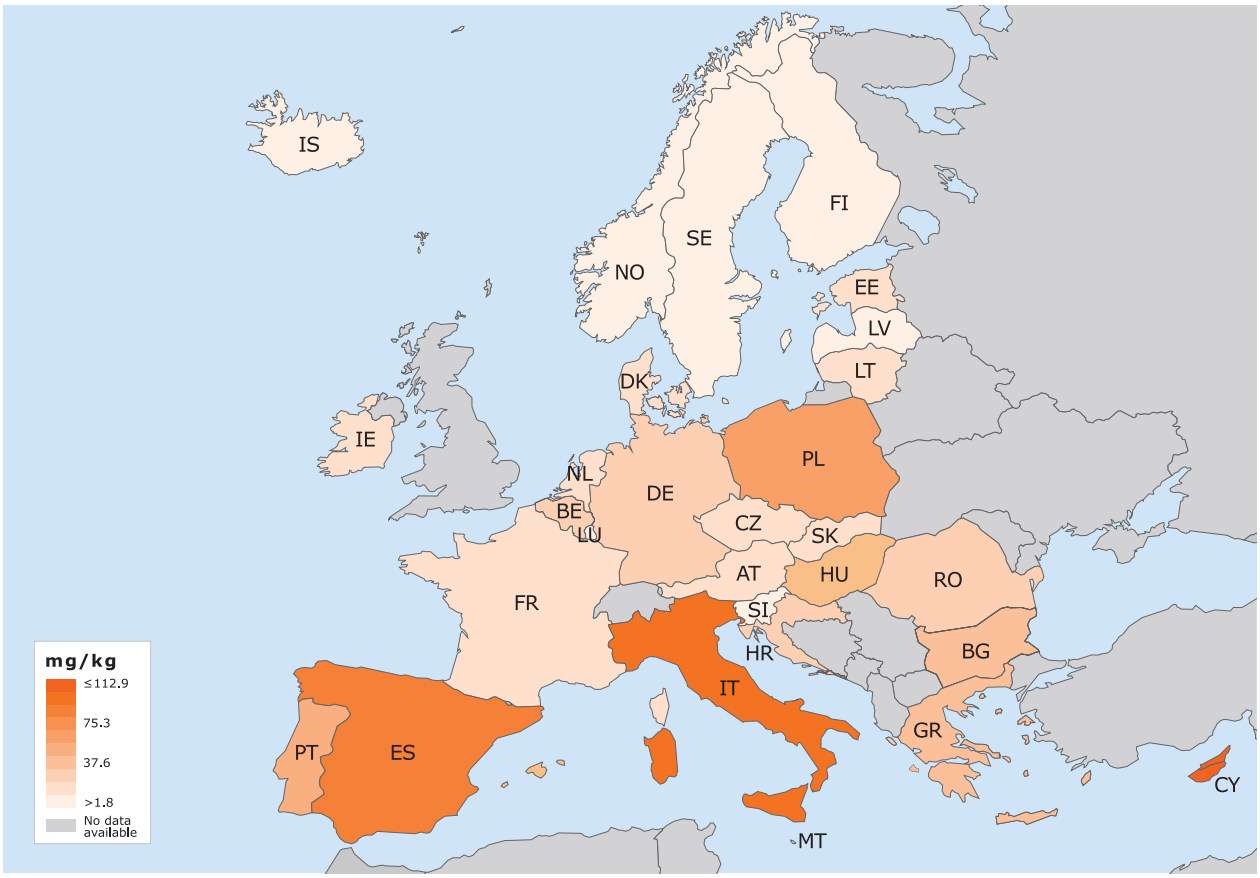
Country	Type of data provider(s)[1]	Coverage reported by countries[2]
Denmark	Pharmacies	Full
Estonia	Wholesalers	Full
Finland	Wholesalers	Full
France	MAH	Full
Germany	MAH, wholesalers	Full
Greece[b]	MAH, wholesalers	Incomplete
Hungary	Wholesalers	Full
Iceland	Wholesalers	Full
Ireland	MAH	Full
Italy	Retailers, feed mills, pharmacies	Full
Latvia	Wholesalers	Full
Lithuania	Wholesalers	Full
Luxembourg	Wholesalers	Full
Malta[c]	Wholesalers, feed mills and veterinarians	Incomplete
Netherlands[d]	MAH	Full
Norway	Wholesalers, feed mills	Full
Poland[e]	Wholesalers	Full
Portugal[f]	MAH, wholesalers	90%
Romania[g]	MAH	Unknown
Slovakia	Wholesalers	Full
Slovenia	Wholesalers	Full
Spain[h]	MAH	Full
Sweden	Pharmacies, veterinarians	Full

[1] In addition to reporting the volume of sales of antimicrobial VMPs, countries also have to submit additional information via the sales questionnaire to fulfil the requirements of Article 12(3) of Commission Delegated Regulation (EU) 2021/578, summarised in this table.
[2] As per Article 11(1) of Commission Delegated Regulation (EU) 2021/578.
[a)] In Belgium, the coverage presented concerns sales made in the country and not of sales bought in other Member States. The proportion of sales bought in other Member States is currently unknown. A project to collect sales data at the lowest level in the chain to address this gap is underway, with the first sales data expected in 2027.
[b)] For Greece, the volume of sales of antimicrobial VMPs was retrieved from the National Submission System in which both MAH and local representatives report sales. Full coverage was not achieved for 2023 data.
[c)] In Malta, veterinarians occasionally supply VMPs without the veterinary prescription when they administer the product themselves and/or give small amounts of VMPs to start the treatment right away. However, the veterinarian is not exempt from the record keeping requirements and since 10 February 2025 veterinarians must always issue a veterinary prescription when they administer antimicrobials VMPs.
[d)] In the Netherlands, the import of antimicrobial VMPs by wholesalers due to shortages are not collected by MAH and have a minor impact on the coverage of sales reported (approximately 1%).
[e)] In Poland, data on the volume of sales of veterinary antimicrobials are collected through an IT system. In accordance to the Regulation of the Minister of Agriculture and Rural Development of 16 December 2016, pharmaceutical wholesalers of VMPs submit quarterly reports containing data on the volume of sales of VMPs via this system.
[f)] In Portugal, medicated feed bought in other Member States is not captured in reported sales. The sales coverage reported in 2023 is similar to that of previous reporting period (i.e. ESVAC project).
[g)] For Romania, in 2023 the volume of sales of antimicrobial VMPs were obtained directly from national MAHs while for non-national MAHs data were derived from MAHs' submission to UPD. Of note, before 2023 sales from non-national MAHs were reported by their legal representatives in Romania, but only from what was sold from their deposit (the stock of medicinal products remaining was not reported as a sale). For 2023, non-Romanian MAHs reported everything that entered Romania as sales, while in previous years only what was sold.
[h)] In 2023, Spain changed the data providers from retailers, feed mills and pharmacies (use data) to MAHs (sales data).

1.2. Sales of antimicrobial VMPs (mandatory scope) for food-producing animals

All sales of antimicrobial VMPs under the mandatory scope for use in food-producing animals — including all horses[26] — are sales of VMPs with antibacterials substances, all of which have antibiotic activity[27]. In 2023, sales for food-producing animals represented 98.4% of total sales in tonnes (sales for other animals kept or bred are described in Section 1.3). Sales across reporting countries ranged from 1.8 mg/kg to 112.9 mg/kg (Figure 3), while the aggregated sales for the EU were 45.1 mg/kg (Table 3).

Figure 3. Sales of antimicrobial VMPs for food-producing animals (mg/kg) in the EU, IS and NO, in 2023[1,2]



[1] Sales data subject to mandatory reporting, which only concerns substances with antibiotic activity.
[2] Countries' codes according to ISO 3166 — Codes for the representation of names of countries and their subdivisions.

In 2023, the total estimated EU biomass for food-producing animals was 95.7 million tonnes, of which cattle, pigs and chickens accounted for 87.4%, with 38.7%, 30.3% and 18.5% respectively. Sheep contributed 5.7%, turkeys 2.4% and horses 2.3%. Other species (i.e. goats, other poultry, finfish and rabbits) accounted for the remaining 2.2% animal biomass (Figure 4). Animal biomass by food-producing animal species and country are shown in Annex 1 (Table 13, Figure 20).

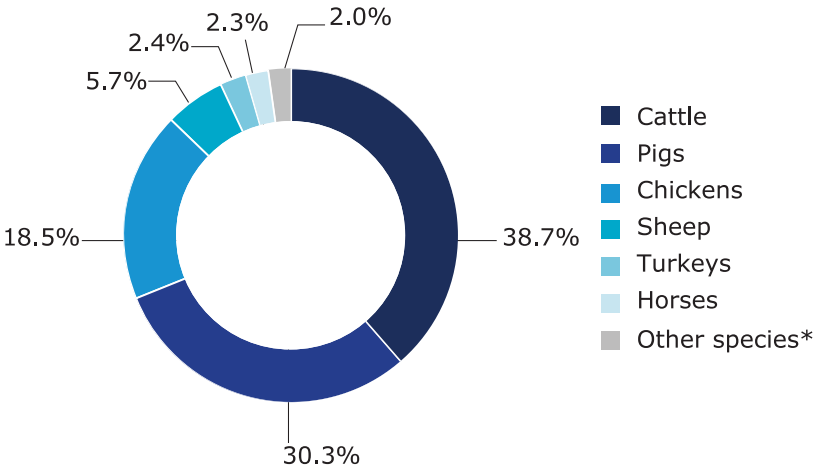
[26] Regulation (EC) No 854/2004 establishes that horses are considered to be food-producing animals. Typically, statistics on living horses cover both food-producing and non-food-producing horses. This implies that the use of medicines authorised for horses not intended for slaughter is also included in the surveillance.
[27] 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'.

Table 3. Sales for food-producing animals in tonnes of active substance of antimicrobial VMPs, animal biomass in 1,000 tonnes and sales in mg/kg per country in 2023[1]

Country	Sales for food-producing animals (tonnes) [2]	Animal biomass (1,000 tonnes)	mg/kg
Austria	33.6	1,767.1	19.0
Belgium	99.9	3,228.8	30.9
Bulgaria	36.6	741.8	49.3
Croatia	12.8	476.1	26.9
Cyprus	22.9	203.0	112.9
Czechia	28.8	1,514.9	19.0
Denmark	70.5	3,511.4	20.1
Estonia	5.2	260.5	20.0
Finland	7.5	874.7	8.6
France	253.9	15,639.0	16.2
Germany	520.2	13,892.9	37.4
Greece	87.3	2.311.0	37.8
Hungary	78.6	1,721.6	45.7
Ireland	74.3	4,448.3	16.7
Italy	651.2	6,218.2	104.7
Latvia	3.5	344.5	10.2
Lithuania	13.0	607.6	21.4
Luxembourg	1.3	129.2	10.0
Malta	1.0	27.6	38.0
Netherlands	113.1	5,137.0	22.0
Poland	688.4	10,007.6	68.8
Portugal	139.6	2,245.3	62.2
Romania	171.5	4,719.2	36.3
Slovakia	9.7	496.2	19.5
Slovenia	4.3	386.9	11.1
Spain	1,175.3	13,366.9	87.9
Sweden	8.6	1,439.4	6.0
EU	**4,312.6**	**95,716.9**	**45.1**
Iceland	0.6	174.2	3.5
Norway	4.6	2,626.6	1.8
EU, IS, NO	**4,317.8**	**98,517.7**	**43.8**

[1] Sales of antimicrobial VMPs subject to mandatory reporting, which only concerns substances with antibiotic activity. to food-producing animals could be for non-food-producing animals. The impact on the sales for food-producing animals is presumed to be minor.

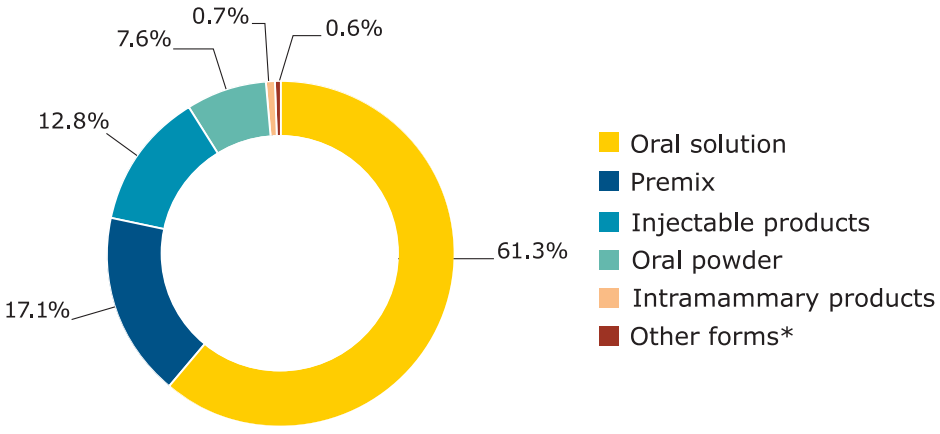
Figure 4. Calculated animal biomass (in 1,000 tonnes) of the food-producing animal species in the EU in 2023



* Other species are goats, other poultry, finfish and rabbits.

EU sales of antimicrobial VMPs for food-producing animals in 2023 stratified by product form are shown in Figure 5. In the EU, oral solutions were the highest selling product form, accounting for 61.2% of the total sales, followed by premixes (17.1%), injectable products (12.8%), oral powders[28] (7.6%), and intramammary products (0.7%); the remaining sales (0.6%) correspond to oral pastes, tablets, and intrauterine products[29]. Oral powders, oral solutions and premix sales combined provide a reasonable estimate of sales for group treatment, including groups kept per pen or at farm level. In 2023, 85.9% of total sales of antimicrobial VMPs for use in food-producing animals in the EU were of VMPs predominantly used for group treatment. Sales of antimicrobial VMPs for food-producing animals by product form by country are shown in Annex 1 (Figure 21).

Figure 5. Proportion of sales (in tonnes) of antimicrobial VMPs for food-producing animals by product form in the EU in 2023[1]



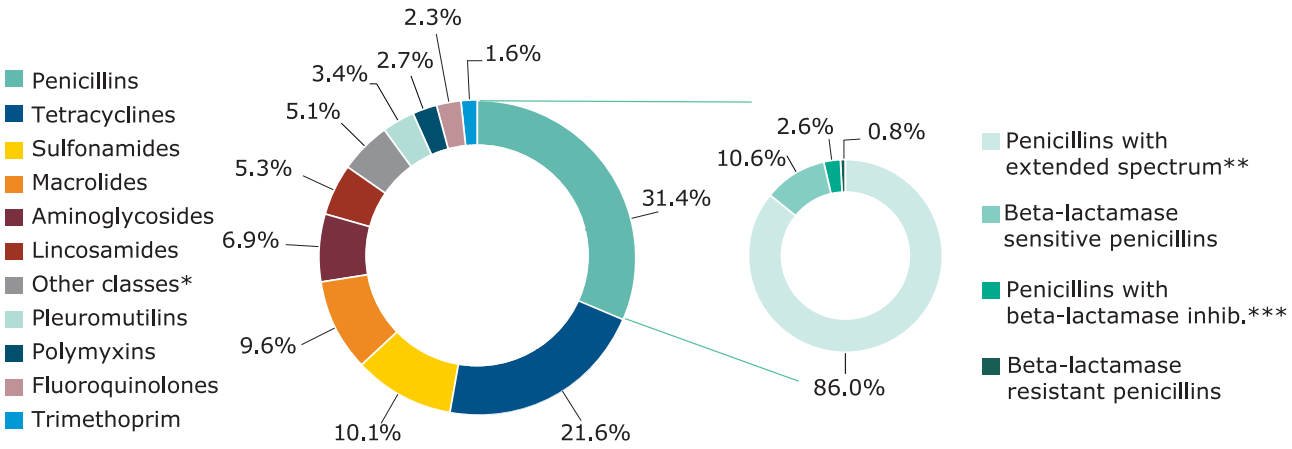
[1] Sales data subject to mandatory reporting, which only concerns substances with antibiotic activity.
* 'Other forms' includes oral pastes, tablets and intrauterine products.

[28] Oral powders that can be administered via feed or both feed and drinking water are reported as the product form 'oral powder'. The product form 'oral solution' refers to oral solutions and oral powders to be administered with drinking water, milk and/or milk replacer.
[29] A negligible proportion (0.03%) of all sales in the mandatory scope correspond to sales of topical dermatologic products due to a data quality issue.

As shown in Figure 6, in 2023 the highest selling antimicrobial classes were penicillins (31.4%), tetracyclines (21.6%) and sulfonamides (10.1%), accounting for 63.0% of the total sales of antimicrobial VMPs for food-producing animals. 'Other classes', i.e. 1st- and 2nd-generation cephalosporins, 3rd- and 4th-generation cephalosporins, amphenicols, other quinolones and other antibacterials accounted, respectively, for 0.2%, 0.2%, 3.1%, 0.2%, and 1.4% of the total sales in the EU.

Sales of antimicrobial VMPs for food-producing animals by antimicrobial class by country are shown in Annex 1 (Figure 22).

Figure 6. Proportion of sales (in tonnes) of antimicrobial VMPs for food-producing animals by antimicrobial class in the EU in 2023[1]



[1] Sales data subject to mandatory reporting, which only concerns substances with antibiotic activity.
* 'Other classes' includes amphenicols, cephalosporins, other quinolones and other antibacterials.
** In 2023, all penicillins included in this group were aminopenicillins (amoxicillin and ampicillin).
*** In the ATCvet system, these are classified as combinations of penicillins that include beta-lactamase inhibitors. In 2023, only combinations of amoxicillin with enzyme inhibitor were reported (Annex 3, Table 16).

At EU level, 86.0% of all penicillin sales were of penicillins with extended spectrum (98.0% amoxicillin, 2.0% ampicillin). Among all reporting countries, Denmark, Finland, Iceland, Norway and Sweden are the only ones where sales of beta-lactamase-sensitive penicillins[30] accounted for most penicillin sales, between 66.2% and 95.3% of those sales. A small proportion of the total penicillin sales for food-producing animals was represented by VMPs containing a fixed combination of amoxicillin and beta-lactamase inhibitors (2.6%).

Sales for food-producing animals were also analysed per AMEG categories[31]:

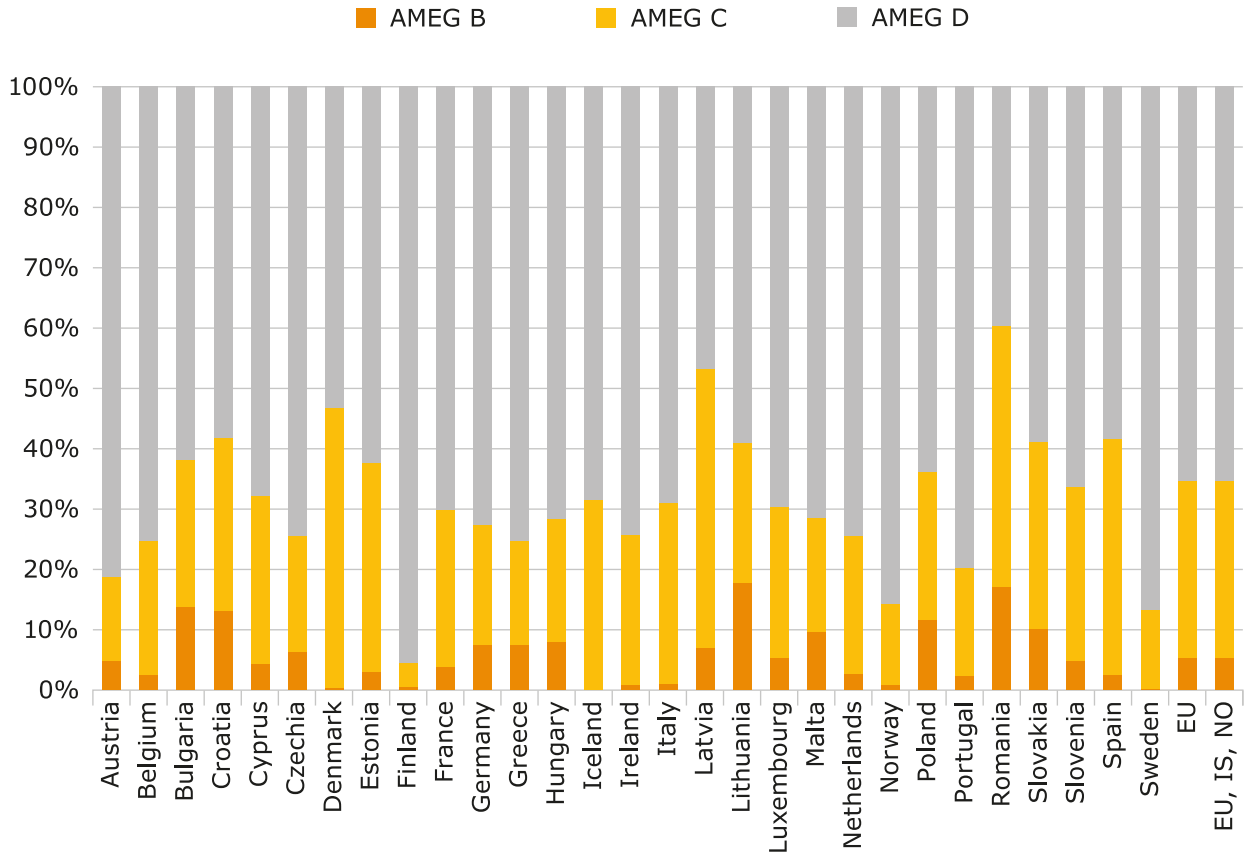
- AMEG category D (prudence) includes those antimicrobials that are recommended as first line treatments whenever possible. In the EU, sales of these antimicrobials accounted for 65.3% of total sales for food-producing animals. At country level, the proportion of these antimicrobials accounted for 39.7% to 95.4% of sales. (Figure 7).
- AMEG category C (caution) includes antimicrobials that should be considered only when there are no antimicrobials in category D that could be clinically effective. For antimicrobials in this category there are alternatives in human medicine but for some veterinary indications there are no alternatives belonging to category D. Sales of antimicrobial VMPs belonging to AMEG

[30] Beta-lactamase-sensitive penicillins belong to ATCvet code QJ01CE and, in 2023, procaine benzylpenicillin and phenoxymethylpenicillin were the two active substances from this penicillin subclass for which sales were reported.
[31] AMEG Infographic - Categorisation of antibiotics for use in animals for prudent and responsible use.

category C accounted for 29.3% in the EU and between 4.0% and 46.4% of total sales across reporting countries (Figure 7).

- AMEG category B (restrict) includes those veterinary antimicrobials for which the potential risk to public health is estimated to be higher than from other classes of antimicrobials. Fluoroquinolones, other quinolones, 3rd- and 4th-generation cephalosporins and polymyxins are included in this category. These antimicrobials are also classified as highest priority critically important antimicrobials for human medicine by WHO[32]. Sales of these antimicrobials in the EU represented 5.4% of the total sales. At country level, the proportion of these antimicrobials accounted for 0.08% to 17.8% of total sales; the proportion of AMEG B sales was higher than 10% for 6 reporting countries (Figure 7).
- AMEG category A (avoid) of the AMEG categorisation includes those antimicrobials that are not authorised as veterinary medicines in the EU and, consequently, should not be used in food-producing animals but may be given to companion animals under exceptional circumstances[33]. Therefore, there were no VMP sales for food-producing animals with antimicrobials included in category A.

Figure 7. Proportion of total sales (in tonnes) of antimicrobial VMPs[1] for food-producing animals by AMEG category[2] per country in 2023[1,2]

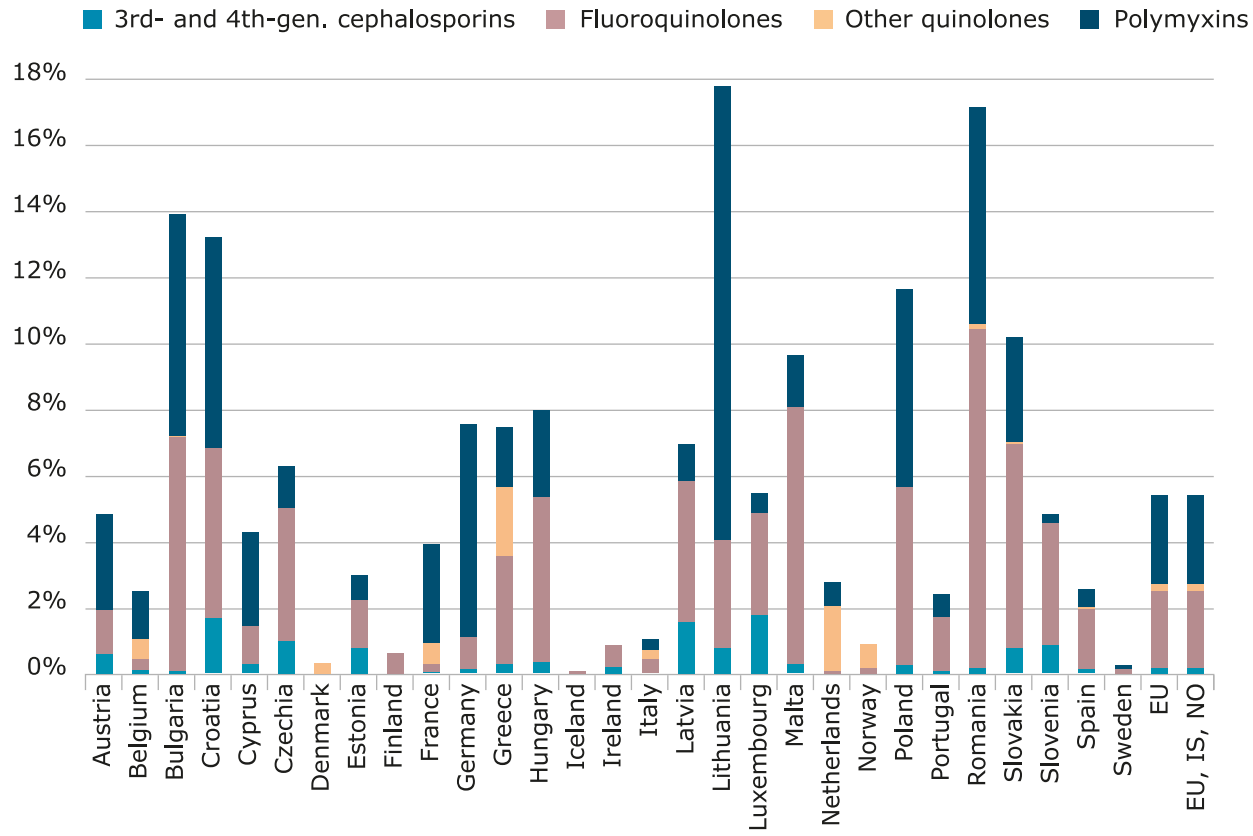


[1] Sales of antimicrobial VMPs subject to mandatory reporting, which only concerns substances with antibiotic activity.
[2] Novobiocin is not included in the AMEG categorisation and accounted for 0.001% of all EU sales.

[32] WHO List of Medically Important Antimicrobials: a risk management tool for mitigating antimicrobial resistance due to non-human use.
[33] Many substances from this category are included in the list of substances reserved for treatment of certain infections in humans, as per Commission Implementing Regulation (EU) 2022/1255.

In 2023, the proportion of sales corresponding to each of AMEG category B antimicrobials varied substantially between countries, ranging from 0% to 1.8% for 3rd- and 4th-generation cephalosporins, 0.01% to 10.3% for fluoroquinolones, 0% to 2.1% for other quinolones and 0% to 13.7% for polymyxins (Figure 8).

Figure 8. Proportion of total sales (in tonnes) of 3rd- and 4th-generation cephalosporins, fluoroquinolones, other quinolones and polymyxins of total antimicrobial VMP sales for food-producing animals, by country in 2023[1-5]



[1] Sales of antimicrobial VMPs subject to mandatory reporting, which only concerns substances with antibiotic activity.
[2] 3rd- and 4th-generation cephalosporins, fluoroquinolones, other quinolones and polymyxins belong to AMEG category B.
[3] No sales of 3rd- and 4th-generation cephalosporins reported for Finland and Iceland.
[4] No sales of other quinolones reported for Austria, Croatia, Cyprus, Czechia, Estonia, Finland, Germany, Hungary, Iceland, Ireland, Latvia, Lithuania, Luxembourg, Malta, Poland Portugal, Slovenia, and Sweden.
[5] No sales of polymyxins reported for Denmark, Finland, Iceland, Ireland, and Norway.

Sales of 3rd- and 4th-generation cephalosporins ranged from <0.001 mg/kg to 0.5 mg/kg between countries, with 2 countries not reporting any sales. Overall, sales of 3rd- and 4th-generation cephalosporins were 0.07 mg/kg accounted for 0.2% of the total EU sales (Figure 8, Table 4).

Sales of fluoroquinolones ranged from <0.01 mg/kg to 3.7 mg/kg between countries. Overall, sales of fluoroquinolones were 1.1 mg/kg and accounted for 2.3% of the total EU sales (Figure 8, Table 4).

Table 4. Range, median and aggregated sales of antimicrobial VMPs marketed for food-producing animals (mg/kg) in the EU in 2023[1,2]

Antimicrobial class	Antimicrobial VMP sales (mg/kg)		
	Range	**Median**	**Aggregated**
3rd- and 4th-generation cephalosporins[a3]	0–0.5	0.1	0.07
Fluoroquinolones	<0.01–3.7	0.4	1.1
Other quinolones[4]	0–0.8	0	0.09
Polymyxins[5]	0–4.1	0.5	1.2
Total sales (all classes)	6.0–112.9	22.0	45.1

[1] Sales data subject to mandatory reporting, which only concerns substances with antibiotic activity.
[2] 3rd- and 4th-generation cephalosporins, fluoroquinolones, other quinolones and polymyxins belong to AMEG category B.
[3] No sales of 3rd- and 4th-generation cephalosporins reported for Finland and Iceland.
[4] No sales of other quinolones reported for Austria, Croatia, Cyprus, Czechia, Estonia, Finland, Germany, Hungary, Iceland, Ireland, Latvia, Lithuania, Luxembourg, Malta, Poland, Portugal, Slovenia and Sweden.
[5] No sales of polymyxins reported for Denmark, Finland, Iceland, Ireland and Norway.

Sales of other quinolones ranged from <0.01 mg/kg to 0.8 mg/kg between countries, with 18 countries not reporting any sales. Overall, sales of other quinolones were 0.09 mg/kg and accounted for 0.2% of the total EU sales (Figure 8, Table 4).

Sales of polymyxins ranged <0.01 mg/kg to 4.1 mg/kg between countries, with 5 countries not reporting any sales. Overall, sales of polymyxins were 1.2 mg/kg and accounted for 2.7% of the total sales EU sales (Figure 8, Table 4).

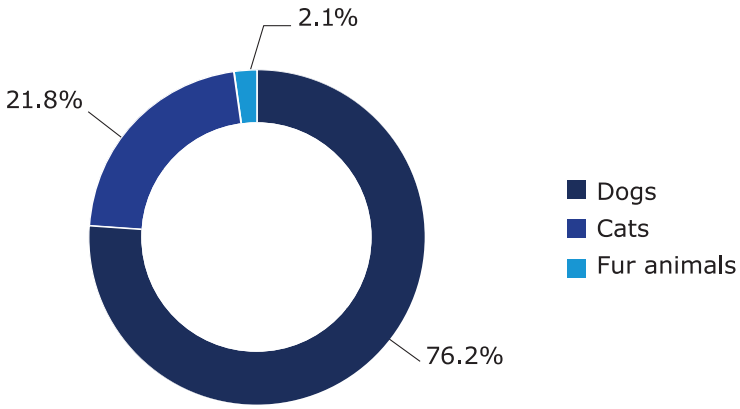
1.3. Sales of antimicrobial VMPs (mandatory scope) for other animals kept or bred

All sales of antimicrobial VMPs under the mandatory scope for other animals kept or bred — dogs, cats, fur animals (minks and foxes) and other non-food-producing animals such as exotic birds, pet rabbits and racing pigeons — were sales of VMPs with antibacterials substances, all of which have antibiotic activity[34]. In 2023, sales for this animal group accounted for 1.6% of all sales reported under the mandatory scope and ranged from 0.05 tonnes to 18.0 tonnes across reporting countries. The aggregated sales for the EU were 38.2 mg/kg (Table 5).

For 2023, the total estimated EU biomass for other animals kept or bred was 1.8 million tonnes, of which 76.2% corresponded to dogs, 21.8% to cats, 1.8% to minks and 0.3% to foxes (Figure 9)[35].

[34] 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'.
[35] The animal biomass denominator used to normalise the sales of VMPs for use in other animal kept or bred does not include all the animal species for which these VMPs may be authorised (e.g. exotic birds, racing pigeons and companion animals other than dogs and cats are not included).

Figure 9. Calculated animal biomass (in 1,000 tonnes) of the other animal species kept or bred in the EU in 2023[1,2]



[1] Animal population data for dogs and cats were not available for Malta for 2023.
[2] In 2023, fur animals (i.e. minks and/or foxes) were only kept or bred in 8 EU countries (Bulgaria, Finland, Greece, Latvia, Lithuania, Poland, Romania and Sweden). Minks and foxes accounted, respectively, for 1.8% and 0.3% of the EU biomass of other animals kept or bred.

Only 9 of all reporting countries, 8 of which are EU countries, indicated having fur animals in 2023 (as shown in Annex 1, Table 13). At EU level, the fur animal biomass represented only 2.1% of the total EU biomass of other animals kept or bred (Figure 9). At country level, the proportion of the fur animal biomass represented between 0.5% and 27.7% of the national biomass for animals kept or bred. Furthermore, only 20% of the sales of antimicrobial VMPs that include fur animals among the species for which they are authorised were assigned to other animals kept or bred. The remaining sales were allocated to sales for food-producing animals because the VMPs are also authorised for food-producing species[36]. Therefore, results shown in this section most likely represent sales of antimicrobial VMPs in companion animals. However, more accurate information on use of antimicrobials in other animals kept or bred will not be available until use data for dogs, cats and fur animals starts to be reported in 2030.

[36] The remaining 80% were of VMPs also authorised for use in food-producing animals in addition to fur animals. Given that sales of VMPs authorised for use in fur animals represent 0.3% of total EU sales under the mandatory scope, the impact of this can be considered minimal.

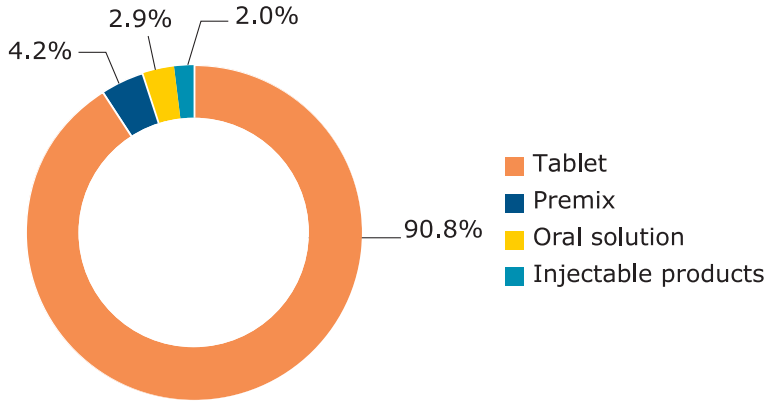
Table 5. Sales for other animals kept or bred in tonnes of active substance of antimicrobial VMPs, animal biomass in 1,000 tonnes and sales in mg/kg per country in 2023[1]

Country	Sales (tonnes) for other animals kept or bred	Biomass (1,000 tonnes)	mg/kg
Austria	0.6	25.6	22.2
Belgium	2.7	53.3	49.8
Bulgaria	0.3	19.4	15.0
Croatia	0.3	12.3	22.5
Cyprus	0.2	3.5	48.4
Czechia	1.6	51.0	31.8
Denmark	0.6	15.7	39.1
Estonia	0.2	6.2	36.2
Finland	0.9	24.1	36.0
France	18.0	253.8	70.9
Germany	9.6	288.0	33.5
Greece	0.4	22.4	19.4
Hungary	0.7	55.4	12.5
Ireland	0.9	11.7	78.6
Italy	6.8	226.2	29.9
Latvia	0.2	7.7	22.5
Lithuania	0.5	7.5	68.7
Luxembourg[2]	0.1	0.9	145.8
Malta[3]	0.1	0	n.a.
Netherlands	3.1	39.5	78.1
Poland	3.3	220.2	14.8
Portugal	1.9	61.1	30.5
Romania	6.2	107.1	58.2
Slovakia	0.4	21.0	19.3
Slovenia	0.2	7.3	32.9
Spain	7.9	215.6	36.6
Sweden	0.6	29.7	20.1
EU	**68.3**	**1785.9**	**38.2**
Iceland	0.05	1.0	47.4
Norway	0.4	13.8	27.0
EU, IS and NO	**68.7**	**1800.6**	**38.1**

[1] Sales data subject to mandatory reporting, which only concerns substances with antibiotic activity.
[2] Luxembourg's biomass of other animals kept or bred may be underestimated as no animal data was submitted for cats for 2023. Consequently, the mg/kg indicator might be overestimated.
[3] 'Other animal kept or bred' animal population data was not available for Malta and therefore mg/kg animal biomass cannot be calculated.

EU sales of antimicrobial VMPs for other animals kept or bred in 2023 stratified by product form are shown in Figure 10. In 2023, tablets were the highest selling product form, accounting for 90.8% of the total sales, followed by premixes[37] (4.2%), oral solutions (2.9%) and injectables (2.0%). The remaining sales (0.15%) corresponded to oral pastes and oral powders. Sales of antimicrobial VMPs for other animals kept or bred by product form by country are shown in Figure 23 of Annex 1.

Figure 10. Proportion of sales (in tonnes) of antimicrobial VMPs for other animals kept or bred by product form in the EU in 2023[1]

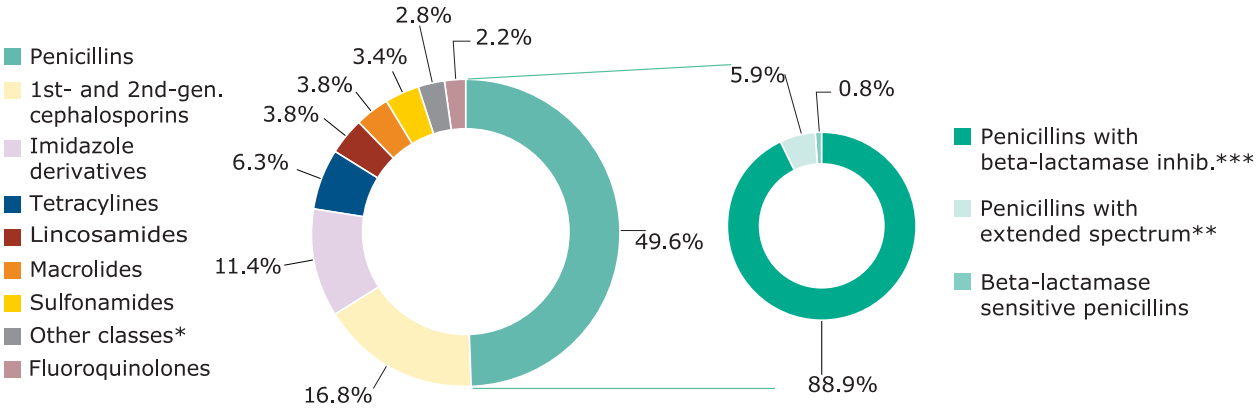


[1] Sales data subject to mandatory reporting, which only concerns substances with antibiotic activity.
* 'Other forms', which represented 0.2% of sales of antimicrobial VMPs for other animals kept or bred, include oral pastes and oral powders.

As shown in Figure 11, in 2023 the highest selling antimicrobial classes in the EU were penicillins (49.6%), 1st- and 2nd-generation cephalosporins (16.8%) and imidazole derivatives[38] (11.4%), accounting for 77.8% of total sales of antimicrobial VMPs for other animals kept or bred. 'Other classes' (i.e. nitrofuran derivatives, aminoglycosides, trimethoprim, amphenicols, 3rd- and 4th-generation cephalosporins, other antibacterials, pleuromutillins, other quinolones and polymyxins) accounted for 2.8% of the total sales in the EU[39]. Sales of antimicrobial VMPs for other animals kept or bred by antimicrobial class by country are shown in Figure 24 of Annex 1.

[37] All premix sales assigned to other animals kept or bred correspond to antimicrobial VMPs authorised for use in ornamental birds.
[38] In 2023, sales of imidazole derivatives under the mandatory scope for other animals kept or bred refer exclusively to metronidazole.
[39] The mandatory scope only concerns substances with antibiotic activity. However, some ATCvet codes from the mandatory scope are for products that contain antiprotozoals without antibiotic effect in combination with sulfonamides (classified as antibacterials). As a result, sales of all substances in such products are assigned to the mandatory scope by default and in 2023, include a negligible amount (0.08%) of sales of antiprotozoals (diaveridine and ronidazole) for other animals kept or bred.

Figure 11. Proportion of sales (in tonnes) of antimicrobials VMPs for other animals kept or bred in the EU by antimicrobial class in 2023[1,2]



[1] Sales data subject to mandatory reporting, which only concerns substances with antibiotic activity.
[2] Sales of imidazole derivatives, specifically of metronidazole, may be underestimated given that products containing this active substance fell under both the mandatory and the voluntary scope depending on the ATCvet code.
* Other classes include small quantities of nitrofuran derivatives, aminoglycosides, trimethoprim, amphenicols, 3rd- and 4th-generation cephalosporins, other antibacterials, pleuromutillins, other quinolones and polymyxins.
** In 2023, 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 2023, only combinations of amoxicillin with enzyme inhibitor were reported (Annex 3, Table 16).

At EU level, 88.9% of all penicillin sales were of combinations of penicillins with beta-lactamase inhibitors, representing the highest-selling penicillin subclass in all countries but one. The remaining penicillin sales were accounted for mainly by penicillins with extended spectrum (5.9%) and by beta-lactamase sensitive penicillins (0.8%).

Table 6. Range, median and aggregated sales of antimicrobial VMPs for other animals kept or bred (mg/kg) in 2023 in the EU[1,2]

AMEG category	VMP antimicrobial sales (mg/kg)		
	Range	**Median**	**Aggregated**
AMEG category B (restrict)	0.1-2.8	0.9	0.9
AMEG category C (caution)	7.5-116.6	26.6	27.4
AMEG category D (prudence)	1.4-46.2	4.9	9.9
Total sales (all classes)	12.5-145.8	33.2	38.2

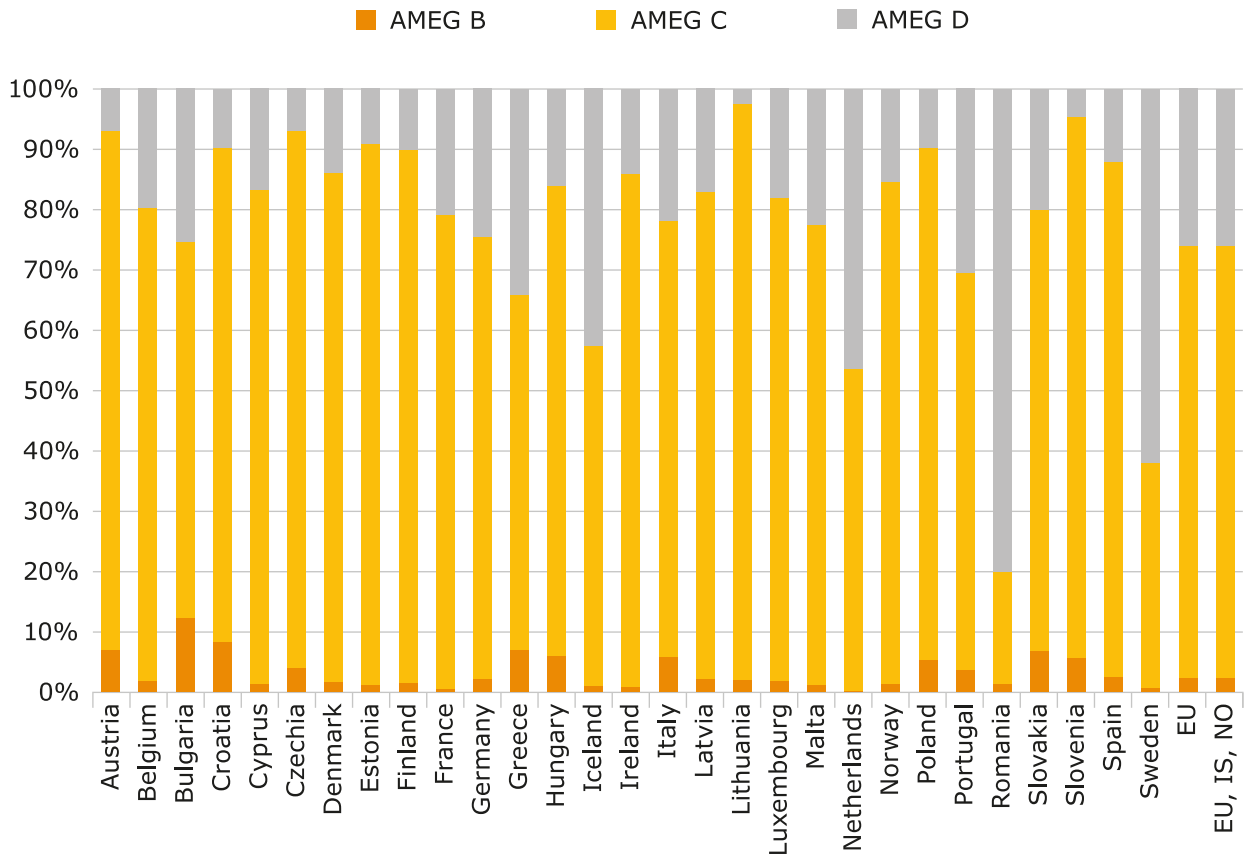
[1] Sales data subject to mandatory reporting, which only concerns substances with antibiotic activity.
[2] Malta's sales data are not included in this table because there is no animal population data available for other animals kept or bred and therefore the mg/kg indicator cannot be calculated for this country.

As described in the section 1.2 for food-producing animals, the proportion of antimicrobial VMP sales in 2023 per AMEG category were also analysed for other animals kept or bred:

- AMEG category D (prudence) accounted for 26.0% of total EU sales for other animals kept or bred. At country level, the proportion of these antimicrobials accounted for 2.5% to 80.0% of total sales (Table 6, Figure 12).

- AMEG category C (caution) accounted for 71.6% of total EU sales for other animals kept or bred. At country level, the proportion of these antimicrobials accounted for 18.7% to 95.5% of total sales (Table 6, Figure 12).
- AMEG category B (restrict) accounted for 2.4% of total EU sales for other animals kept or bred. At country level, the proportion of these antimicrobials accounted for 0.2% to 12.3% of total sales. Only in 9 countries were the proportion of sales of AMEG B higher than 5% (Table 6, Figure 12).
- AMEG category A (avoid) includes those antimicrobials that are not authorised as veterinary medicines in the EU. Therefore, there were no VMP sales for other animals kept or bred with antimicrobials included in category A.

Figure 12. Proportion of sales (in tonnes) of antimicrobial VMPs for other animals kept or bred per country by AMEG category in 2023[1]



[1] Sales data subject to mandatory reporting, which only concerns substances with antibiotic activity.

1.4. Discussion on sales of antimicrobial VMPs

First-time reporting of antimicrobial VMP sales via the ASU Platform

For the first time, the 27 EU countries, Iceland and Norway reported their antimicrobial VMP sales for 2023 to the Agency via the ASU Platform. The ASU Platform is the new IT system from EMA for countries to report their collated data under the legal framework of Regulation (EU) 2019/6. To do this, countries had to complete and submit the ASU templates for 2023, which included prefilled VMP data variables derived from UPD[40].

Data quality was a major focus during the call for 2023 data and preparation of this first ESUAvet report. Huge efforts by both EMA and reporting countries were made to ensure the VMP data variables were complete and accurate for at least the products under the mandatory scope (as described in Annex 4). Although most of the work was completed in 2024, improving and maintaining the quality of these data variables is a continuous process that should require less effort over time.

Sales of antimicrobial VMPs for food-producing animals (mandatory scope)

Sales for food-producing animals of antimicrobials under the mandatory scope represented 98.4% of all sales reported in tonnes for 2023. Sales ranged from 1.8 mg/kg to 112.9 mg/kg between countries, while the aggregated EU value was 45.1 mg/kg. The variation between countries could be explained, in part, by country-specific factors potentially affecting the sales of antimicrobial VMPs such as: differences in the composition of the animal population, disease incidence, production systems, animal husbandry practices, prescription practices, treatment guidelines, daily doses[41] used for the various antimicrobials and pharmaceutical forms, treatment duration, as well as availability of VMPs. In addition, differences in the selection of national sales data providers may also have an impact on the sales data. These and other potential country-specific factors must be taken into account when evaluating results on a country-by-country basis and comparisons between countries should be avoided.

Although direct comparisons between the ESUAvet and ESVAC sales indicators for food-producing animals are also discouraged due to methodological differences (Annex 5), it is still possible to follow ESVAC-based trends at the EU and country level in the ESUAvet reports (Section 3 and Annex 6, respectively). The main difference between the two indicators is the animal biomass denominator for food-producing animals, which is higher for ESUAvet. This is because additional animal species and categories are included in the calculations of animal biomass, and also because the principle used to calculate animal weights shifted from 'animal weights at the time of treatment' to 'animal live weights'[42]. This higher denominator results in a lower value for the ESUAvet sales indicator (mg/kg) compared to the ESVAC one (mg/PCU). However, the ESUAvet denominator methodology aligns more closely to the denominator method the World Organisation for Animal Health (WOAH) uses to report global data antimicrobial intended for use in animals[43]. This increased proximity between denominator

[40] The UPD provides the ASU Platform with all the VMP data variables required to prefill the ASU sales and use templates as described in the Annexes to the Commission Implementing Regulation (EU) No 2022/209.
[41] Available on the European Medicines Agency's website here.
[42] For detailed information of the animal species and categories used in the calculation of the animal biomass, including the weights, please refer to the Guideline on the reporting of antimicrobial sales and use in animals at the EU level – denominators and indicators (EMA/CVMP/882931/2022).
[43] For more information on WOAH's annual reporting of antimicrobial use in animals please visit: https://www.woah.org/en/article/animuse-monitoring-antimicrobial-use-in-animals/

methodologies will facilitate future global comparison, as per recital (7) of Commission Implementing Regulation (EU) 2022/209[44].

Despite the methodological difference mentioned above, the 2023 mandatory ESUAvet sales data covers the same ATCvet codes that ESVAC reported from 2010 to 2022. Even though some countries switched data providers between 2022 and 2023, the sales patterns for food-producing animals in 2023 closely resemble those of 2022. Penicillins, tetracyclines and sulfonamides continue to be the highest-selling antimicrobials, with oral solutions, premixes and injectable products remaining the most sold product forms.

Regarding product forms in 2023, 85.9% of sales corresponded to sales of oral powders, oral solutions and premixes. Sales of these product forms are considered to be reasonable estimates of sales of antimicrobial VMPs for group treatment. In veterinary medicine and in the context of food-producing animals, antimicrobials can be administered to animals for individual or group treatment. While administration of antimicrobials to individual animals aligns with principles of antimicrobial stewardship which aim to use antimicrobials responsibly to preserve their effectiveness by treating only those animals that need it, in agricultural settings this is not always feasible. In many agricultural operations animals are kept in large groups, such as herds of pigs or flocks of poultry for which group treatments may be necessary for practical reasons. Nevertheless, in accordance with the legal provisions of Regulation (EU) 2019/6 (Art. 107(3)) and Commission Delegated Regulation (EU) 2024/1159 (Article 6(2)), strict conditions of use exist for antimicrobials used prophylactically, as well as for antimicrobials administered orally via feed, including administration to individual animals and small animal groups. Therefore, the proportions observed for these product forms may change once the provisions concerning oral administrations of VMPs, as detailed in Commission Delegated Regulation (EU) 2024/1159[45], are fully implemented by countries. Specifically, that oral administration of antimicrobial VMPs via solid feed should be restricted to use in individual animals or a small group of animals where intake of the VMP by individual animals can be effectively controlled.

Sales patterns by AMEG categorisation varied significantly among reporting countries in 2023. In general, the high proportion of sales in category D (prudence) indicates strong adherence to prudent-use guidelines recommending these antimicrobials as first-line treatments. For most reporting countries, sales of these antimicrobials accounted for more than 50% of total tonnes sold and represented 65.3% of total sales at EU level in 2023. In contrast, the proportion of sales of category C and B antimicrobials varied more across countries, possibly reflecting the country-specific differences described above. Category C (caution) antimicrobials — which should only be considered when there are no clinically effective options from category D — accounted for 29.3% of total EU sales, with national sales ranging from 4.0% to 46.4%. Category B (restrict) antimicrobials, which may pose a potential higher risk to public health and include fluoroquinolones, other quinolones, 3rd- and 4th-generation cephalosporins, and polymyxins, represented 5.4% of total EU sales. Across countries, the proportion of these antimicrobials ranged from 0.08% to 17.8% of sales. The relatively low overall

[44] Recital 7: **"**To ensure that the data collected on the sales and the use of antimicrobials is comparable year-over-year within Member States and within the Union and that those data are adequately analysed, the format for reporting of the data should take into account the size of the animal population that is likely to be treated with antimicrobials. This should also facilitate the comparison of data reported at national level and at Union level with data available from non-Union countries and at global level. It is therefore important to define the format according to which the animal population data should be referred to. Any comparison of data across Member States should take into account the diversity of practices within the Union and the differences in national legal contexts.**"**

[45] Commission Delegated Regulation (EU) 2024/1159 of 7 February 2024 supplementing Regulation (EU) 2019/6 of the European Parliament and of the Council by laying down rules on appropriate measures to ensure the effective and safe use of veterinary medicinal products authorised and prescribed for oral administration via routes other than medicated feed and administered by the animal keeper to food-producing animals. The EC considered the European Medicines Agency's scientific advice on the effective and safe use of VMPs authorised and prescribed for oral administration via routes other than medicated feed.

sales of category B antimicrobials in the EU are encouraging, but higher sales in certain reporting countries indicate areas where further efforts may still be needed.

Sales of antimicrobial VMPs for other animals kept or bred (mandatory scope)

Sales are assigned to this animal group if the products are not authorised for use in food-producing animals. Sales of antimicrobial VMPs for other animals kept or bred cover products for companion animals, fur animals and other non-food-producing animals such as exotic birds, pet rabbits and racing pigeons. However, because some products are authorised for use in both food-producing and non-food-producing animals, these sales are allocated to food-producing animals. For instance, approximately 80% of the sales of antimicrobial VMPs for fur animals — which accounted for only 0.3% of the total sales reported under the mandatory scope —, are allocated to the sales of food-producing animals because these products are also authorised for use in food-producing species. Consequently, the antimicrobial tonnes sold for other animals bred or kept may be underestimated.

The ESUAvet denominator for other animals kept or bred is the combined biomass of dogs, cats and fur animals. While this animal biomass may not cover all species for which these VMPs may be authorised (e.g. racing pigeons and companion animals other than dogs and cats such as pet rabbits, exotic birds, among others), it still offers a reasonable estimate of the non-food-producing animal population that could be treated with these antimicrobials. Considering the biomass per species represented in Figure 9 and that 20 reporting countries did not keep or breed fur animals in 2023, it is likely that most of the aggregated sales data for other animals kept or bred correspond to sales of antimicrobial VMPs for cats and dogs. However, more representative and informative data are expected when countries start reporting use data separately for dogs, cats and fur animals from 2030 (i.e. 2029 is the first year countries must start collecting these data).

2. Use of antimicrobial medicinal products in animals

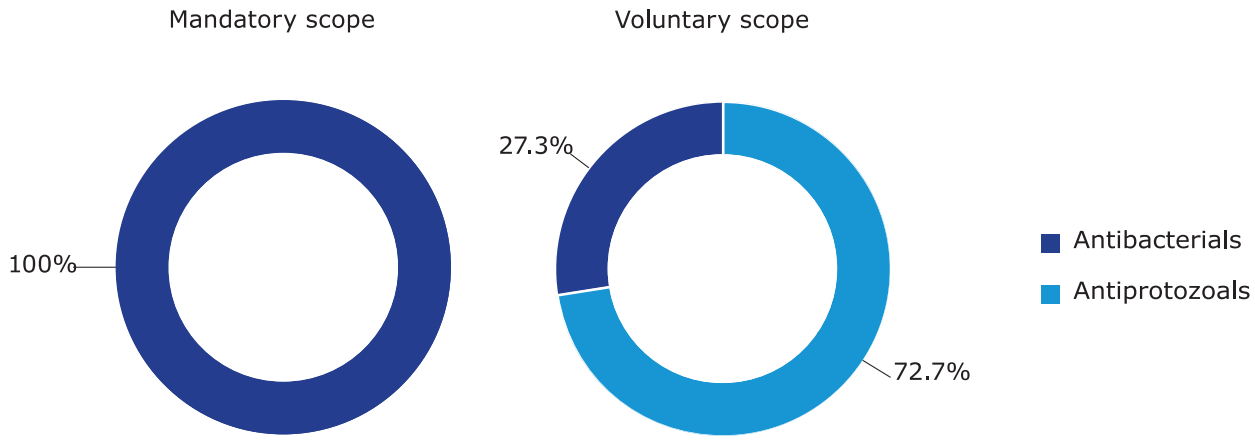
In 2023, data on the use of antimicrobials in animals were collected following EU regulation for the first time by the 29 ESUAvet-reporting countries (i.e. the 27 EU countries, Iceland and Norway). Many of these countries had no prior experience in antimicrobial use data collection by animal species. Following the stepwise approach outlined in the legislation, countries reported 2023 antimicrobial use data for four food-producing animal species: cattle, pigs, chickens and turkeys. Additionally, it was required for countries to specify use for the following animal categories: dairy cattle, beef cattle, other cattle, fattening pigs, laying hens, broilers, other chickens, fattening turkeys and other turkeys.

Not all countries provided use data to the Agency for each of these four animal species, and some did not report data at the category level for 2023. The coverage of these data, as interpreted and reported by each country, also varied significantly, ranging from 0% to 100%, partly due to non-harmonised interpretation of use data coverage. As a result, at the EU level, the 2023 use data are not representative of actual use. Therefore, **the section on use data for 2023 will only describe the data countries submitted to the Agency and does not provide a quantitative analysis of the data**.

2.1. Overview of reported use of antimicrobial medicinal products in animals

All 29 countries reported use of antimicrobial medicinal products under the mandatory scope for 2023 and 11 countries also provided use data from the voluntary scope (Figure 13, Table 7). Data were collected for four main food-producing animal species: **cattle, pigs, chickens and turkeys**. The reported coverage of the reported use data varied greatly across species and countries (Tables 9-12).

Figure 13. Proportion of reported use (in tonnes) of antimicrobial medicinal products by antimicrobial class in the EU in 2023[1-4]



[1] Use data subject to mandatory and voluntary reporting. In 2023, 11 countries reported use data under the voluntary scope.
[2] The ASU Platform groups antimicrobial substances in categories, classes and subclasses taking into account the ATCvet codes in the Annex to Commission Delegated Regulation (EU) 2021/578 and the ATC(vet) classification system (see Annex 3).
[3] Under the voluntary scope, use of antifungals and antiinfectives represented less than 0.02% and 0.03%, respectively.
[4] Coverage of use data subject to mandatory reporting is described per species in Tables 9 to 12. Coverage of use data subject to voluntary reporting is unknown.

All use data reported under the mandatory scope corresponded to substances with antibacterial effect, whereas most of the reported use belonging to the voluntary scope corresponded to antiprotozoals, just under a quarter to topical antibacterials and a very small percentage to antifungals and antiinfectives (Figure 13, Table 7).

Table 7. Reported use of antimicrobial medicinal products, by antimicrobial category, in cattle, pigs, chickens and turkeys per country for 2023[1-4]

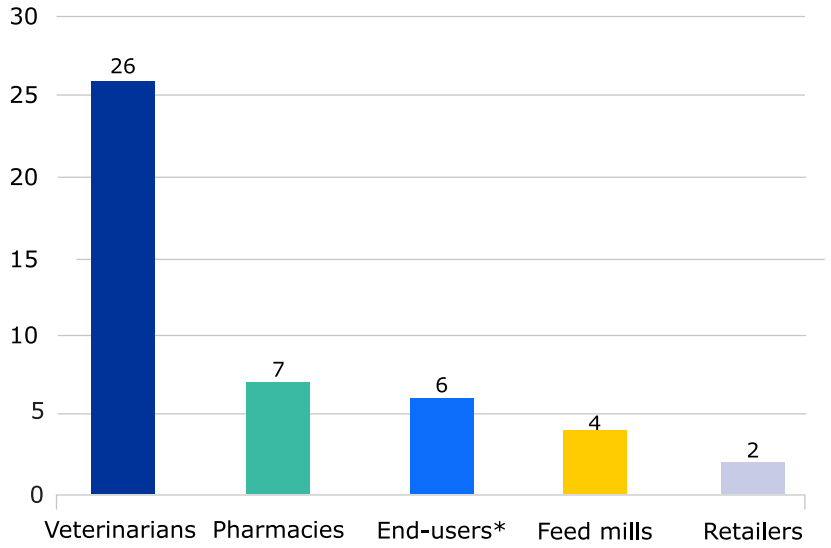
Country	Mandatory scope	Voluntary scope
Austria	Antibacterials	Not reported
Belgium	Antibacterials	Not reported
Bulgaria	Antibacterials	Antibacterials, antiprotozoals, antifungals
Croatia	Antibacterials	Antibacterials, antiprotozoals
Cyprus	Antibacterials	Not reported
Czechia	Antibacterials	Not reported
Denmark	Antibacterials	Not reported
Estonia	Antibacterials	Not reported
Finland	Antibacterials	Not reported
France	Antibacterials	Not reported
Germany	Antibacterials	Antibacterials
Greece	Antibacterials	Not reported
Hungary	Antibacterials	Antibacterials, antiprotozoals, antifungals
Iceland	Antibacterials	Antibacterials, antiprotozoals
Ireland	Antibacterials	Not reported
Italy	Antibacterials	Not reported
Latvia	Antibacterials	Not reported
Lithuania	Antibacterials	Antibacterials, antiprotozoals
Luxembourg	Antibacterials	Not reported
Malta	Antibacterials	Antibacterials, antiprotozoals
Netherlands	Antibacterials	Antibacterials, antiprotozoals
Norway	Antibacterials	Not reported
Poland	Antibacterials	Not reported
Portugal	Antibacterials	Antibacterials, antiprotozoals
Romania	Antibacterials	Antibacterials, antiprotozoals, antiinfectives
Slovakia	Antibacterials	Antibacterials, antiprotozoals, antifungals
Slovenia	Antibacterials	Not reported
Spain	Antibacterials	Antibacterials, antiprotozoals, antifungals
Sweden	Antibacterials	Not reported

[1] Use data subject to mandatory and voluntary reporting.
[2] The ASU Platform groups antimicrobial substances in categories, classes and subclasses taking into account the ATCvet codes in the Annex to Commission Delegated Regulation (EU) 2021/578 and the ATC(vet) classification system (see Annex 3).
[3] For 2023, no data were reported for substances that belong to the following antimicrobial categories: antimycobacterials or antivirals.
[4] Antibacterials from the voluntary scope correspond to topical antibacterials.

As national use data collection systems can vary considerably, countries had to select one or more data providers and data sources from those listed in the legislation[46]. For more information about the use data collection systems set up in each country, see Annex 7.

Veterinarians were the most selected providers of use data in 2023 and were chosen by all but 3 of the 29 reporting countries (Figure 14, Table 8). Furthermore, veterinarians were the sole data providers selected by 16 countries while for the remaining 13, other providers were also used including pharmacies (7), end users (including farmers or breeders) (6), feed mills (4), and retailers (2).

Figure 14. Number of countries that used each type of use data provider to collect use data for cattle, pigs, chickens and turkeys in 2023[1,2]

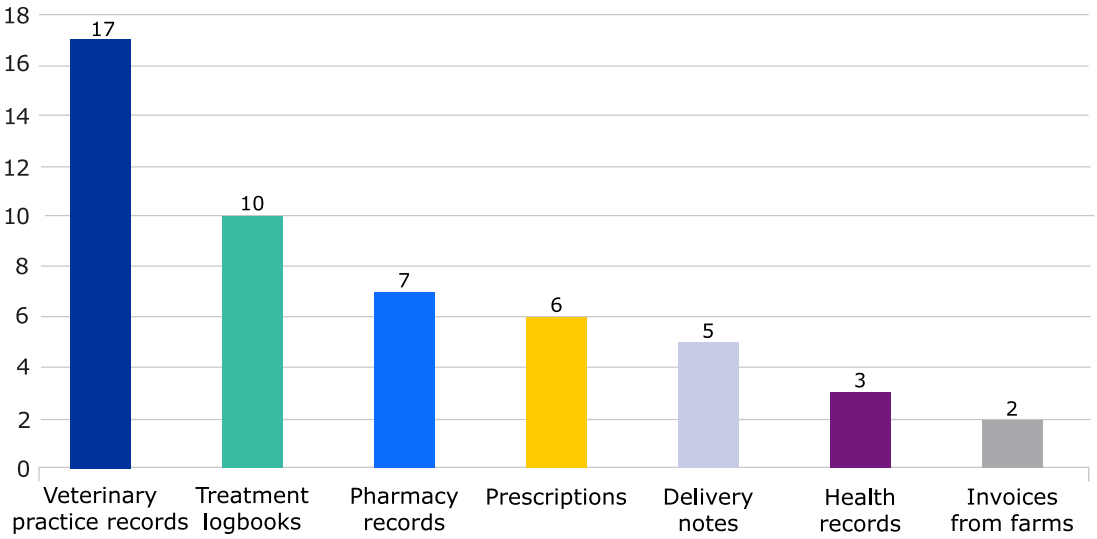


[1] As per Article 13(1a) of Commission Delegated Regulation (EU) 2021/578 and Annex II to Commission Implementing Regulation (EU) 2022/209.
[2] Some countries selected more than one data provider.
* End users include farmers or breeders.

Regarding use data sources, in 2023 the most frequently used data source were veterinary practice records (17 countries), followed by treatment logbooks (10), pharmacy records (7), prescriptions (6), delivery notes (5), health records (3) and invoices from farms (2) (Figure 15, Table 8).

[46] As per Article 13 of Commission Delegated Regulation (EU) 2021/578.

Figure 15. Number of countries that used each type of use data source to collect use data for cattle, pigs, chickens and turkeys in 2023[1,2]



[1] As per Article 13(1)(b) of Commission Delegated Regulation (EU) 2021/578 and Annex II to Commission Implementing Regulation (EU) 2022/209.
[2] Some countries selected more than one data source.

Table 8. Data providers and data sources used to collect data on the use of antimicrobial medicinal products in cattle, pigs, chickens and turkeys per country in 2023

Country	Type of data provider(s)[1]	Data sources[1]
Austria	Veterinarians	Veterinary practice records
Belgium	Veterinarians	Veterinary practice records
Bulgaria	Veterinarians	Veterinary practice records
Croatia	Veterinarians	Veterinary practice records
Cyprus	Veterinarians, Retailers	Delivery notes, Invoices from farms, Veterinary practice records
Czechia	Veterinarians	Delivery notes
Denmark	Veterinarians, Pharmacies, Feed mills	Pharmacy records, Veterinary practice records
Estonia	Veterinarians	Veterinary practice records
Finland	Veterinarians	Veterinary practice records
France	Veterinarians, Pharmacies, Feed mills	Delivery notes, Prescriptions, Veterinary practice records
Germany	Veterinarians	Veterinary practice records
Greece	End-users (including farmers or breeders)	Treatment logbooks
Hungary	Veterinarians	Treatment logbooks
Iceland	Veterinarians, End-users (including farmers or breeders)	Treatment logbooks
Ireland	Veterinarians, End-users (including farmers or breeders)	Health records, Prescriptions, Veterinary practice records
Italy	Veterinarians, End-users (including farmers or breeders)	Treatment logbooks

Country	Type of data provider(s)[1]	Data sources[1]
Latvia	Veterinarians	Health records, Treatment logbooks, Veterinary practice records
Lithuania	Veterinarians	Treatment logbooks
Luxembourg	Veterinarians	Treatment logbooks, Delivery notes
Malta	Veterinarians, Pharmacies, Feed mills	Prescriptions, Pharmacy records
Netherlands	Veterinarians	Prescriptions, Treatment logbooks, Veterinary practice records
Norway	Veterinarians, Pharmacies	Pharmacy records, Veterinary practice records
Poland	End-users (including farmers or breeders)	Health records, Treatment logbooks
Portugal	Veterinarians	Prescriptions
Romania	Veterinarians, Pharmacies, End-users (including farmers or breeders)	Treatment logbooks, Invoices from farms, Prescriptions, Pharmacy records, Veterinary practice records
Slovakia	Veterinarians	Treatment logbooks
Slovenia	Veterinarians	Veterinary practice records
Spain[2]	Retailers, Pharmacies	Pharmacy records
Sweden	Veterinarians, Pharmacies	Pharmacy records, Veterinary practice records

[1] As per Article 13(1) of Commission Delegated Regulation (EU) 2021/578 and Annex II to Commission Implementing Regulation (EU) 2022/209.
[2] Spain also used retail sale of prescribed antimicrobials as a use data source.

2.2. Cattle: reported use of antimicrobial medicinal products (mandatory scope)

EU countries, Iceland and Norway had to collect data on antimicrobial use for cattle distinguishing between the following categories: dairy cattle, beef cattle, beef cattle under one year of age and other cattle[47]. For 2023, 26 countries submitted use data for the cattle species while 3 did not submit any data. Of the 26 countries that submitted data, all but one reported use data at category level and 13 reported use data for beef cattle under one year of age[47, 48] (Table 9). The coverage of use data reported for cattle varied greatly across reporting countries: 7 countries reported 98%–100% coverage, 5 reported 70%–98% coverage, 2 reported 50%–70% coverage, 2 reported 35% or lower coverage, and 10 indicated incomplete coverage (Table 9).

[47] As per Article 15(1)(a) of Commission Delegated Regulation (EU) 2021/578 and described in further detail in Antimicrobial use data reporting per animal categories (numerator) - Manual for reporting the data to the Agency (EMA/757638/2021).
[48] Based on the data available in the Eurostat database Slaughtering in slaughterhouses - annual data, at least 8 countries had a production of beef cattle under one year of age higher than 10,000 tonnes in 2023 and, therefore, had to and reported use data in this category separately from use data reported in the beef cattle category: Belgium, Denmark, France, Germany, Italy, the Netherlands, Portugal and Spain.

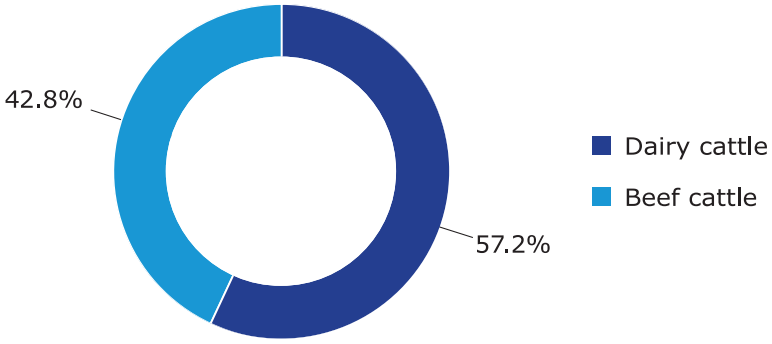
Table 9. Overview of antimicrobial use data reported for **cattle** per country in 2023[1]

Country	Use data submitted for cattle	Data reported by category	Data reported for Beef cattle <1 year of age[2]	Coverage reported by countries
Austria	Yes	Yes	No	70–90%
Belgium	Yes	Yes	Yes	Incomplete
Bulgaria	Yes	Yes	No	35%*
Croatia	Yes	Yes	Yes	100%
Cyprus	Yes	No	-	Incomplete
Czechia	Yes	Yes	No	>98%
Denmark	Yes	Yes	Yes	100%
Estonia	Yes	Yes	No	Incomplete
Finland	Yes	Yes	No	Incomplete
France	Yes	Yes	Yes	10%
Germany	Yes	Yes	Yes	Incomplete
Greece	No	-	-	-
Hungary	Yes	Yes	No	70%
Iceland	Yes	Yes	No	Incomplete
Ireland	No	-	-	-
Italy	Yes	Yes	Yes	100%
Latvia	No	-	-	-
Lithuania	Yes	Yes	Yes	60–70%*
Luxembourg	Yes	Yes	No	Incomplete
Malta	Yes	Yes	No	Incomplete
Netherlands	Yes	Yes	Yes	100%
Norway	Yes	Yes	No	85%*
Poland	Yes	Yes	No	Incomplete
Portugal	Yes	Yes	Yes	70%*
Romania	Yes	Yes	Yes	Incomplete
Slovakia	Yes	Yes	Yes	71%*
Slovenia	Yes	Yes	Yes	100%
Spain	Yes	Yes	Yes	100%
Sweden	Yes	Yes	No	55–70%

[1] Use data subject to mandatory reporting, which only concerns substances with antibiotic activity.
[2] Countries in which production of beef cattle under one year of age year exceeds 10,000 tonnes per year are obliged to report use data in this category separately. Other countries can report the use separately but are not obliged to. In 2023, at least 8 countries had to and reported use data for this category (underlined above): Belgium, Denmark, France, Germany, Italy, the Netherlands, Portugal and Spain.
* Coverage provided for all use data in general and not specified per animal species.

In 2023, the total EU biomass for cattle was 37.0 million tonnes, of which 57.2% corresponded to dairy cattle and 42.8% beef cattle (Figure 16). Of the 15.8 million tonnes of beef cattle biomass, around 11.6% corresponded to beef cattle under one year of age[49]. The 7 EU countries that submitted use data for cattle with 98%–100% coverage accounted for only 22% of the total EU cattle biomass. For this reason, the use data submitted for this animal species was not further analysed.

Figure 16. Calculated **cattle** biomass (in 1,000 tonnes) and proportion by animal species category in the EU in 2023[1]



[1] Beef cattle biomass includes biomass beef cattle <1 year of age.

2.3. Pigs: reported use of antimicrobial medicinal products (mandatory scope)

EU countries, Iceland and Norway had to collect data on antimicrobial use for pigs distinguishing between the following categories: fattening pigs and other pigs[50]. For 2023, all reporting countries except one submitted use data for the pig species. Of those that submitted data, all but two reported data at category level. The coverage of use data reported for pigs varied greatly across countries: 9 countries reported 98%–100% coverage, 6 reported 71%–98% coverage, 2 reported 60%–70% coverage, 2 reported 35% or lower coverage, and 9 reported incomplete coverage (Table 10).

Table 10. Overview of antimicrobial use data reported for **pigs** per country in 2023[1]

Country	Use data submitted for pigs	Data reported by category	Coverage reported by countries
Austria	Yes	Yes	80-95%
Belgium	Yes	Yes	100%
Bulgaria	Yes	Yes	35%*
Croatia	Yes	Yes	100%
Cyprus	Yes	No	Incomplete
Czechia	Yes	Yes	>98%
Denmark	Yes	Yes	100%
Estonia	Yes	Yes	Incomplete
Finland	Yes	Yes	Incomplete
France	Yes	Yes	16%

[49] The 'Other cattle' category does not have an assigned animal biomass as described in the Guideline on reporting antimicrobial sales and use in animals at the EU level – denominators and indicators (EMA/CVMP/882931/2022)
[50] As per Article 15(1)(b) of Commission Delegated Regulation (EU) 2021/578 and described in further detail in Antimicrobial use data reporting per animal categories (numerator) - Manual for reporting the data to the Agency (EMA/757638/2021)

Country	Use data submitted for pigs	Data reported by category	Coverage reported by countries
Germany	Yes	Yes	Incomplete
Greece	Yes	Yes	Incomplete
Hungary	Yes	Yes	80%
Iceland	Yes	Yes	100%
Ireland	Yes	No	>90%
Italy	Yes	Yes	100%
Latvia	No	-	-
Lithuania	Yes	Yes	60–70%*
Luxembourg	Yes	Yes	Incomplete
Malta	Yes	Yes	Incomplete
Netherlands	Yes	Yes	100%
Norway	Yes	Yes	85%*
Poland	Yes	Yes	Incomplete
Portugal	Yes	Yes	70%*
Romania	Yes	Yes	Incomplete
Slovakia	Yes	Yes	71%*
Slovenia	Yes	Yes	100%
Spain	Yes	Yes	100%
Sweden	Yes	Yes	>90%

[1] Use data subject to mandatory reporting, which only concerns substances with antibiotic activity.
* Coverage provided for all use data in general and not specified per animal species.

In 2023, the total EU biomass for pigs was 28.9 million tonnes, all of which corresponded to fattening pigs[51]. The 8 EU countries that submitted use data for pigs with 98%–100% coverage accounted for only 51% of the total pig biomass. For this reason, the use data submitted for this animal species was not further analysed.

2.4. Chickens: use of antimicrobial medicinal products (mandatory scope)

EU countries, Iceland and Norway had to collect data on antimicrobial use for chickens distinguishing between the following categories: laying hens, broilers and other chickens[52]. For 2023, all 29 countries submitted use data for the chicken species and of these, all but two countries reported data at category level. The coverage of use data reported for chickens varied greatly across countries: 12 reported 98%–100% coverage, 4 reported 71–98% coverage, 2 reported 60–70% coverage, 2 reported 35% or lower coverage, and 9 reported incomplete coverage (Table 11).

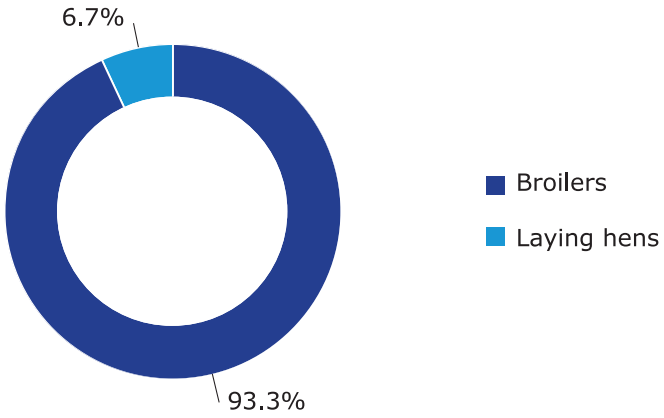
[51] The 'Other pigs' category does not have an assigned animal biomass as described in the Guideline on reporting antimicrobial sales and use in animals at the EU level – denominators and indicators (EMA/CVMP/882931/2022).
[52] As per Article 15(1)(c) of Commission Delegated Regulation (EU) 2021/578 and described in further detail in Antimicrobial use data reporting per animal categories (numerator) - Manual for reporting the data to the Agency EMA/757638/2021).

Table 11. Overview of antimicrobial use data reported for **chickens** per country in 2023[1]

Country	Chickens use data submitted	Data reported by category	Coverage reported by countries
Austria	Yes	Yes	100%
Belgium	Yes	Yes	100%
Bulgaria	Yes	Yes	35%*
Croatia	Yes	Yes	100%
Cyprus	Yes	No	Incomplete
Czechia	Yes	Yes	>98%
Denmark	Yes	Yes	100%
Estonia	Yes	Yes	Incomplete
Finland	Yes	Yes	100%
France	Yes	Yes	27%
Germany	Yes	Yes	Incomplete
Greece	Yes	Yes	Incomplete
Hungary	Yes	Yes	Incomplete
Iceland	Yes	Yes	100%
Ireland	Yes	No	>90%
Italy	Yes	Yes	100%
Latvia	Yes	Yes	100%
Lithuania	Yes	Yes	60-70%*
Luxembourg	Yes	Yes	Incomplete
Malta	Yes	Yes	Incomplete
Netherlands	Yes	Yes	100%
Norway	Yes	Yes	85%*
Poland	Yes	Yes	Incomplete
Portugal	Yes	Yes	70%*
Romania	Yes	Yes	Incomplete
Slovakia	Yes	Yes	71%*
Slovenia	Yes	Yes	100%
Spain	Yes	Yes	100%
Sweden	Yes	Yes	>95%

[1] Use data subject to mandatory reporting, which only concerns substances with antibiotic activity.
* Coverage provided for all use data in general and not specified per animal species.

Figure 17. Calculated chicken biomass denominator (in 1,000 tonnes) and proportion by animal species category in the EU in 2023



In 2023, the total EU biomass for chickens was 17.7 million tonnes, of which 93.3% corresponded to broilers and 6.7% to laying hens (Figure 17)[53]. The 11 EU countries that submitted use data for chickens with 98%–100% coverage accounted for only 35% of the total EU chicken biomass. For this reason, the use data submitted for this animal species was not further analysed.

2.5. Turkeys: use of antimicrobial medicinal products (mandatory scope)

EU countries, Iceland and Norway had to collect data on antimicrobial use for turkeys distinguishing between the following categories: fattening turkeys and other turkeys[54]. For 2023, 27 countries submitted use data for the turkey species while 2 countries did not submit any data. Of the countries that submitted data, all but 2 reported data at category level. The coverage of use data reported for turkeys varied greatly across countries: 15 reported 98%–100% coverage, 4 reported 70%–97% coverage, 2 reported 35%, and 6 reported incomplete coverage (Table 12).

Table 12. Overview of antimicrobial use data reported for **turkeys** per country in 2023[1]

Country	Turkeys use data submitted	Data reported by category	Coverage reported by countries
Austria	Yes	Yes	100%
Belgium	Yes	Yes	Incomplete
Bulgaria	Yes	Yes	35%*
Croatia	Yes	Yes	100%
Cyprus	Yes	No	Incomplete
Czechia	Yes	Yes	>98%
Denmark	Yes	Yes	100%
Estonia	Yes	Yes	100%
Finland	Yes	Yes	100%
France	Yes	Yes	36%
Germany	Yes	Yes	Incomplete
Greece	No	-	-

[53] The 'Other chickens' category does not have an assigned animal biomass as described in the Guideline on reporting antimicrobial sales and use in animals at the EU level – denominators and indicators (EMA/CVMP/882931/2022)
[54] As per Article 15(1)(d) of Commission Delegated Regulation (EU) 2021/578 and described in further detail in Antimicrobial use data reporting per animal categories (numerator) - Manual for reporting the data to the Agency (EMA/757638/2021).

Country	Turkeys use data submitted	Data reported by category	Coverage reported by countries
Hungary	Yes	Yes	Incomplete
Iceland	Yes	Yes	100%
Ireland	Yes	No	>70%
Italy	Yes	Yes	100%
Latvia	Yes	Yes	100%
Lithuania	No	-	-
Luxembourg	Yes	-	100%
Malta	Yes	-	100%
Netherlands	Yes	Yes	100%
Norway	Yes	Yes	85%*
Poland	Yes	Yes	Incomplete
Portugal	Yes	Yes	70%*
Romania	Yes	Yes	Incomplete
Slovakia	Yes	Yes	71%*
Slovenia	Yes	Yes	100%
Spain	Yes	Yes	100%
Sweden	Yes	Yes	100%

[1] Use data subject to mandatory reporting, which only concerns substances with antibiotic activity.
* Coverage provided for all use data in general and not specified per animal species.

In 2023, the total EU biomass for turkeys was 2.3 million tonnes, all of which corresponded to fattening turkeys[55]. The 14 EU countries that submitted use data for turkeys with 98%–100% coverage accounted for only 34% of the total EU turkey biomass. For this reason, the use data submitted for this animal species was not further analysed.

2.6. Discussion on the reported data of antimicrobial medicinal product use in animals

First year of use data collection and associated challenges

In 2023, data on the use of antimicrobials in animals had to be collected for the first time at the EU level. As can be expected, this huge endeavour did not come without its challenges.

Firstly, countries had to work against an ambitious timeline to adapt their existing use data collection systems or to establish new ones to comply with Article 57 of Regulation (EU) 2019/6. Secondly, setting up or improving data collection systems is resource intensive as it requires involving and coordinating between the relevant National Competent Authorities and the selected data providers. Some countries had limited financial and human resources available to dedicate to this task. The EC provided funding opportunities to support the competent authorities of the EU countries in setting up or improving their national data collections systems.

Finally, many of the countries did not yet have any experience in antimicrobial use data collection prior to the implementation of this new legislation. However, to overcome this challenge, countries with such experience offered guidance and support, fostering a productive and international collaborative

[55] The 'Other turkeys' category does not have an assigned animal biomass as described in the Guideline on reporting antimicrobial sales and use in animals at the EU level – denominators and indicators (EMA/CVMP/882931/2022).

environment. Furthermore, EMA also provided written guidance, dedicated trainings and other support to help countries prepare for this new legal responsibility.

Despite these challenges, by the legal deadline for use data submission on 30 September 2024, all 29 reporting countries had submitted antimicrobial use data from the mandatory scope and 11 also provided data from the voluntary scope for 2023, marking a milestone in surveillance of antimicrobial consumption in animals in the EU.

Use data reported in 2023

Following the stepwise approach outlined in the legislation, countries reported antimicrobial use data for four food-producing animal species: cattle, pigs, chickens and turkeys. Additionally, it was required for countries to specify use for the following animal categories: dairy cattle, beef cattle, other cattle, fattening pigs, laying hens, broilers, other chickens, fattening turkeys and other turkeys. Overall, 26 countries provided use data for cattle, 28 for pigs, 29 for chickens and 27 for turkeys. Not all countries were able to provide use data at category level for some of the species.

The coverage of the reported use data, as interpreted and reported by each country, varied greatly across countries and species, ranging from 10 to 100%. This was probably also true for the data reported per use category, although no specific information was provided at this level. Those countries that were able to report use data with 100% coverage accounted for only 22%–50% of the biomass of the four food-producing animal species. Therefore, given the variability in the completeness and granularity of the reported 2023 use data, quantitative analyses were avoided to prevent misleading interpretations and incorrect comparisons between animal sectors.

Improvements needed for future use data collection and reporting

First and foremost, one of the main priorities is for countries to finish consolidating their use data collection systems and to increase the accuracy and coverage of their reported use data at both species and category level. Moreover, a more harmonised understanding of what these parameters refer to will help with data comparability. On the one hand, accuracy can refer to any of the different characteristics of the data (e.g. product data variables, number of packs used) provided at any of the different entry points (e.g. original data source, national data collection system, ASU Platform). On the other hand, coverage can refer to various different concepts such as the number of available data providers that actually provided data, the number of prescribed antimicrobial treatments that were reported or even how many of the sold antimicrobial medicinal products were actually used, among others.

Another important point for improvement is ensuring the quality of the antimicrobial product data used in the ASU Platform. For this report, focus was placed on products with reported **sales** from the mandatory scope which covered approximately 85% of the products with reported **use** from the mandatory scope. Future checks need to include:

- the remaining 15% of products with reported use in 2023;
- any other products that may have reported data in the future;
- and all products from the entire voluntary scope.

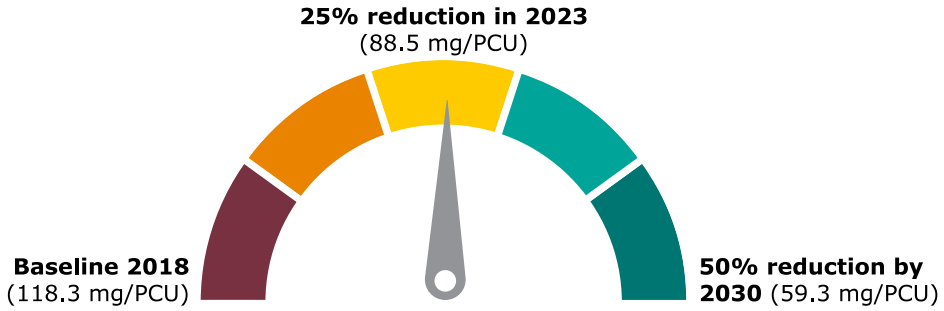
These points and potential others will need to be worked on in order for all countries to fully achieve their legal obligations and for it to be possible to perform quantitative assessment on the reported use data.

3. Farm to Fork Strategy antimicrobial sales reduction target: to reduce overall EU sales of antimicrobials for farmed animals and in aquaculture by 50% by 2030

Recognising that AMR is a One Health problem affecting both human and animal health, the EC is taking action to contribute to the aspirational target of reducing overall EU sales of antimicrobials for farmed animals and aquaculture by 50% by 2030[56,57]. The 2018 reference value for overall sales of antibiotic VMPs in the EU was 118.3 mg/PCU setting the 2030 target at 59.2 mg/PCU. For the purpose of monitoring the progress towards the target, sales data reported by the 27 EU countries to the ASU Platform were analysed using the ESVAC methodology to ensure data comparability. For more information on the ESVAC methodology please refer to Annex 5. For sales trends per country since 2018 (also for Iceland and Norway), see Annex 6.

In 2023, the aggregated sales for the EU were 88.5 mg/PCU, a reduction of 29.8 mg/PCU (25.2%) in comparison to the 2018 reference value (Figure 18). The 2023 value represents a slight increase (4.3%) compared to 2022 (84.8 mg/PCU), which could be explained by some countries changing sales data providers or detecting underreporting in previous years (for more detailed information, see Annex 6). Data for the next years are necessary to assess whether the EU tendency continues to decline towards the target.

Figure 18. EU's progress towards 50% reduction of overall antimicrobial sales for farmed animals and in aquaculture by 2030[1]

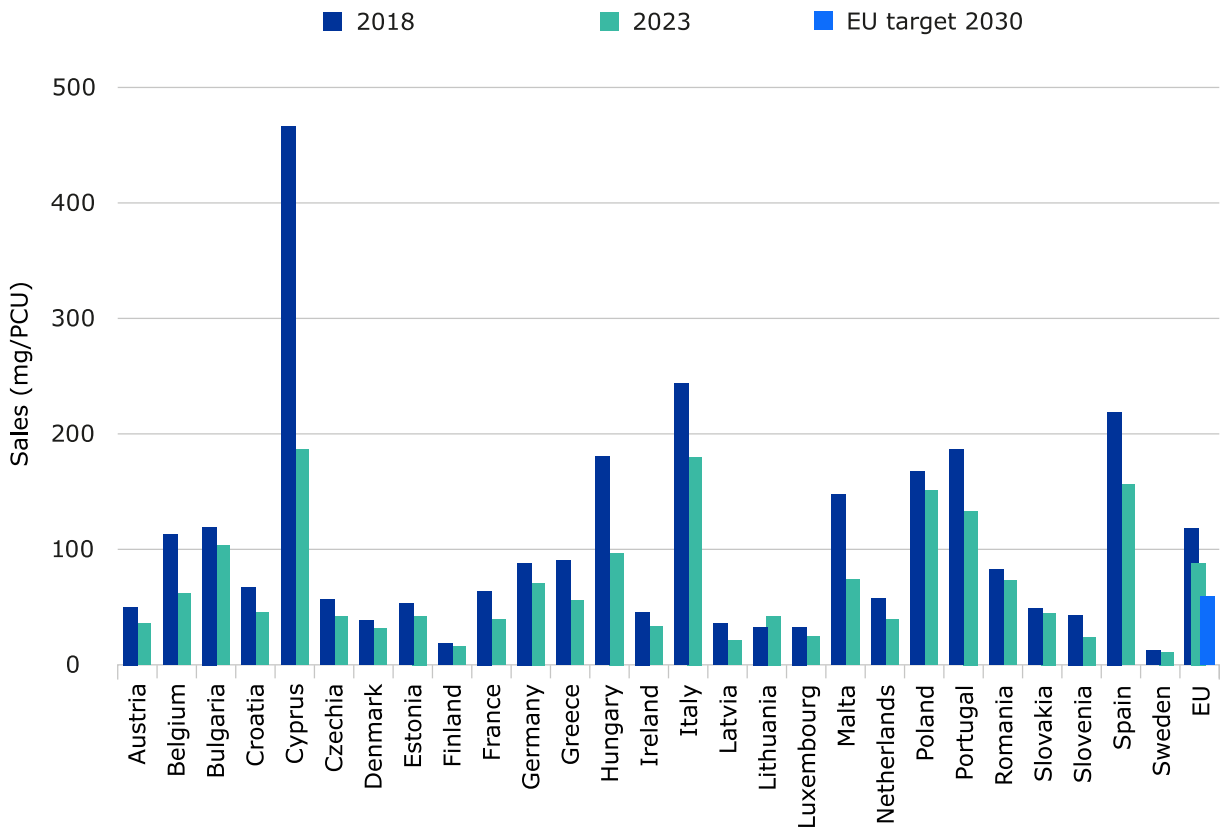


[1] EU sales (in mg/PCU) are aggregated sales for the 27 EU countries.

Although the reduction target is an EU objective, all EU countries have decreased their sales over the past five years compared to their individual 2018 baselines (Figure 19)[58]. The extent of the decrease in sales has varied between countries. Some started at very low levels of antimicrobial consumption which are difficult to reduce further without compromising animal welfare and production, while others with higher initial levels have more room for implementing changes. Nevertheless, it is a joint effort of all EU countries to continue improving or maintaining the appropriate use of antimicrobials in animals to meet the common 2030 reduction goal.

[56] Farm to Fork Strategy: https://food.ec.europa.eu/horizontal-topics/farm-fork-strategy_en.
[57] European Commission: Recommendations to EU countries as regards their strategic plan for the Common Agricultural Policy (COM/2020/846 final).
[58] The only exception would appear to be Lithuania however, as corrections to sales data were made for 2019–2021 during the preparation of the 13th ESVAC report that did not cover the baseline Farm to Fork year of 2018. It is therefore advisable to exercise caution when interpreting trends and drawing conclusions from data for Lithuania before 2019, as it was not feasible to verify their accuracy or completeness.

Figure 19. EU countries progress in reducing antimicrobial sales (mg/PCU) for farmed animals and in aquaculture from 2018 to 2023



As it stands, EU countries have already achieved more than half of the reduction target set for 2030 within the first five years of the twelve-year period between 2018 and 2030. However, EU countries will need to continue taking action to achieve the target by further reducing aggregated sales of antimicrobials by another 29.3 mg/PCU within the next seven years.

4. Concluding remarks

The collection and reporting of 2023 data on sales of antimicrobial VMPs and use of antimicrobials per animal species marked a significant milestone in the EU's efforts to monitor antimicrobial consumption in animals. Despite the challenges, including tight timelines, resource constraints, and varying levels of experience between countries, the collaborative efforts of the EMA and reporting countries resulted in the successful submission of data within the legal deadlines.

For over a decade, sales data of antimicrobial VMPs have served as a reliable proxy for estimating antimicrobial consumption in animals in the EU. This approach remains essential for monitoring antimicrobial consumption in the animal sector and accommodates the need for more time to enhance the quality and reliability of antimicrobial use data by species. However, sales data have inherent limitations one of the main ones being not knowing in which species a product was finally used when it is authorised for use in more than one species. Antimicrobial use data per species can bridge these gaps, providing more granular data of antimicrobial consumption across the EU.

The ultimate goal of use data is to support informed, data-driven decision making. In turn, such data can:

- guide the review of AMR action plans (both at EU and national level);
- help identify and implement concrete and targeted actions and measures against AMR;
- promote appropriate antimicrobial use, guide policy making related to AMR and monitor the effect of implemented measures, among many others.

In conclusion, collection of antimicrobial use data for 2023 marked the start of a new era of surveillance of antimicrobial consumption in animals at the EU level. Each year, improvements in accuracy and coverage of use data are expected, thereby enhancing our understanding of antimicrobial consumption across different animal species in the EU and enabling trend monitoring over time.

Annex 1: Additional figures and tables regarding 2023 data

Table 13. Calculated animal biomass (1,000 tonnes) of the food-producing and other animals kept or bred per country in 2023

Country	Cattle	Pigs	Chickens	Turkeys	Other poultry	Sheep	Goats	Finfish	Horses	Rabbits	Total food-producing animals	Dogs	Cats	Fur animals	Total other animals kept or bred
Austria	870.6	559.5	220.6	22.0	2.1	37.4	8.1	2.3	44.7	<0.001	1767.1	15.3	10.2	0	25.6
Belgium	1080.1	1265.7	722.5	13.4	0.1	16.3	6.4	0	120.0	4.3	3228.8	40.6	12.7	0	53.3
Bulgaria	289.4	166.7	137.4	0.2	30.6	84.9	11.4	9.0	12.2	<0.01	741.8	15.0	4.1	0.3	19.4
Croatia	126.8	141.1	107.5	13.4	0.2	47.6	4.9	20.8	13.8	0.01	476.1	10.0	2.3	0	12.3
Cyprus	50.1	68.3	34.4	0.2	0	27.2	15.2	5.6	1.9	0.1	203.0	3.4	0.1	0	3.5
Czechia	778.5	304.5	320.9	10.6	16.8	14.0	1.9	16.3	41.9	9.4	1514.9	44.2	6.8	0	51.0
Denmark	685.7	2392.3	301.8	6.8	0.2	13.1	0.6	36.9	74.0	0	3511.4	12	3.3	0	15.7
Estonia	150.3	64.4	34.8	0.01	0.01	4.5	0.2	0.8	5.5	<0.01	260.5	4.7	1.5	0	6.2
Finland	373.5	226.7	208.2	11.6	0	10.4	0.4	15.3	28.6	0	874.7	15.6	4.9	3.6	24.1
France	9057.2	2849.9	2020.5	393.2	185.5	596.1	96.1	42.7	361.0	37.0	15639.0	175.0	78.8	0	253.8
Germany	5537.8	5271.4	2015.5	333.9	51.1	140.2	11.0	11.7	520.0	0.4	13892.9	212.0	76.0	0	288.0
Greece	254.1	160.0	412.5	5.1	0.04	1061.5	283.7	128.6	3.8	1.8	2311.0	13.1	3.0	6.2	22.4
Hungary	400.1	551.6	427.2	95.2	126.6	79.9	2.1	17.5	14.8	6.5	1721.6	43.4	11.9	0	55.4
Iceland	38.8	9.4	14.4	0.8	0	38.7	0.1	44.0	28.0	0	174.2	0.8	0.2	0.02	1.0

Country	Cattle	Pigs	Chickens	Turkeys	Other poultry	Sheep	Goats	Finfish	Horses	Rabbits	Total food-producing animals	Dogs	Cats	Fur animals	Total other animals kept or bred
Ireland	3229.3	468.2	243.5	20.4	8.3	368.2	0.5	9.9	100.0	0	4448.3	9.9	1.8	0	11.7
Italy	2280.7	1291.1	1456.8	314.5	4.9	527.3	67.2	47.8	189.9	38.0	6218.2	175.1	51.1	0	226.2
Latvia	209.4	60.3	63.1	0.02	<0.01	6.5	0.7	0.6	3.6	0.2	344.5	5.4	2.1	0.3	7.7
Lithuania	323.0	116.5	145.0	5.4	0.01	9.8	1.0	2.4	4.7	0.03	607.6	5.6	0.7	1.2	7.5
Luxembourg	109.8	15.3	1.4	0	0	0.7	0.3	0	1.7	0	129.2	0.9	0	0	0.9
Malta	6.6	6.3	8.1	0	0	1.1	0.5	2.2	2.7	0.1	27.6	0	0	0	0
Netherlands	1829.8	2299.9	828.8	14.5	18.2	65.4	41.0	0	38.9	0.5	5137.0	30.0	9.5	0	39.5
Norway	475.2	200.1	182.7	12.1	1.6	95.6	5.5	1603.9	50.0	0	2626.6	9.9	3.9	0	13.8
Poland	3225.6	2197.9	3736.6	539.9	166.1	23.0	4.5	37.5	76.0	0.7	10007.6	160.4	35.6	24.2	220.2
Portugal	766.8	598.0	559.2	50.5	20.2	180.8	22.9	5.2	36.0	5.7	2245.3	52.1	9.0	0	61.1
Romania	1885.8	427.0	1342.8	29.5	1.8	858.6	94.5	6.2	73.1	<0.01	4719.2	83.9	21.9	1.4	107.1
Slovakia	249.6	82.6	123.4	4.4	0.2	24.7	1.2	3.3	6.8	<0.01	496.2	18.3	2.7	0	21.0
Slovenia	219.2	31.3	106.7	6.7	0	9.3	1.8	0.9	11.0	0.03	386.9	5.0	2.3	0	7.3
Spain	2380.0	7007.4	1828.1	371.0	7.6	1238.1	173.6	47.5	254.0	59.6	13366.9	186.3	29.3	0	215.6
Sweden	641.2	333.7	274.8	6.9	0.2	30.9	1.3	8.2	142.2	0	1439.4	22.5	7.0	0.1	29.7

Figure 20. Proportion of animal biomass (in tonnes) of the food-producing animal species per country in 2023

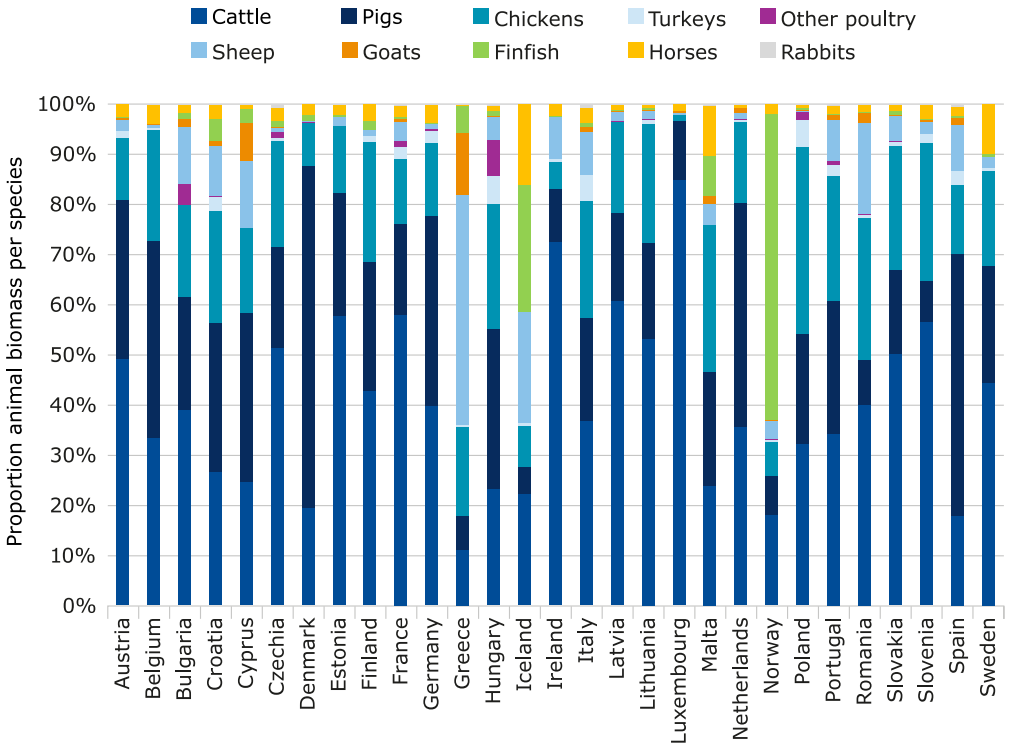
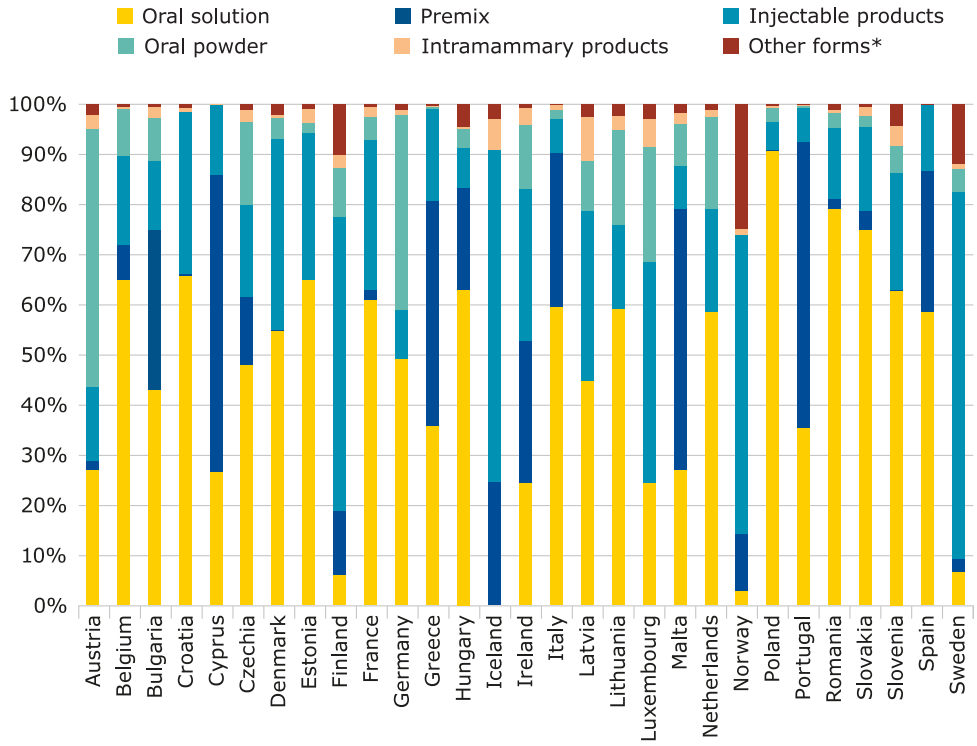
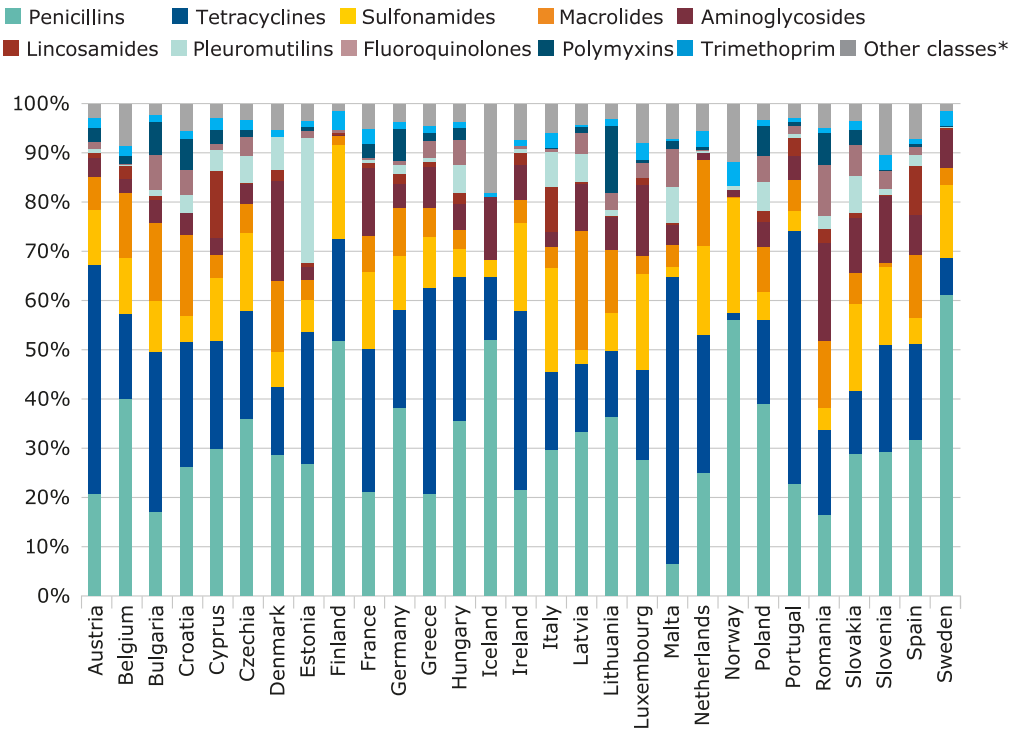


Figure 21. Proportion of sales (in tonnes) of antimicrobial VMPs for food-producing animals by product form per country in 2023[1]



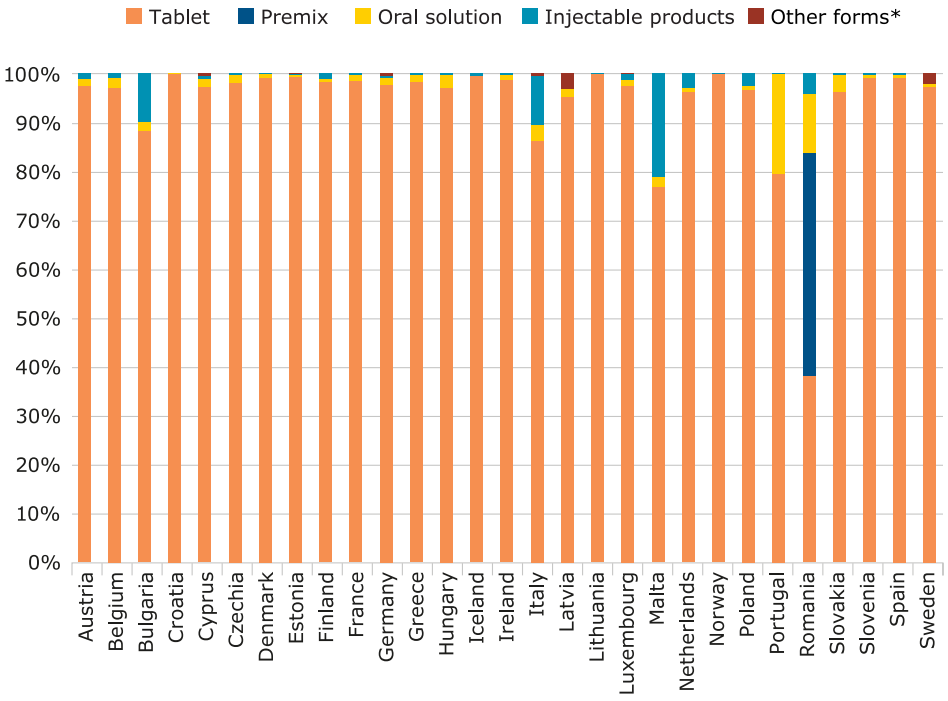
[1] Sales data subject to mandatory reporting, which only concerns substances with antibiotic activity.
* 'Other forms' includes oral pastes, tablets and intrauterine products.

Figure 22. Proportion of sales (in tonnes) of antimicrobial VMPs for food-producing animals by antimicrobial class per country in 2023[1]



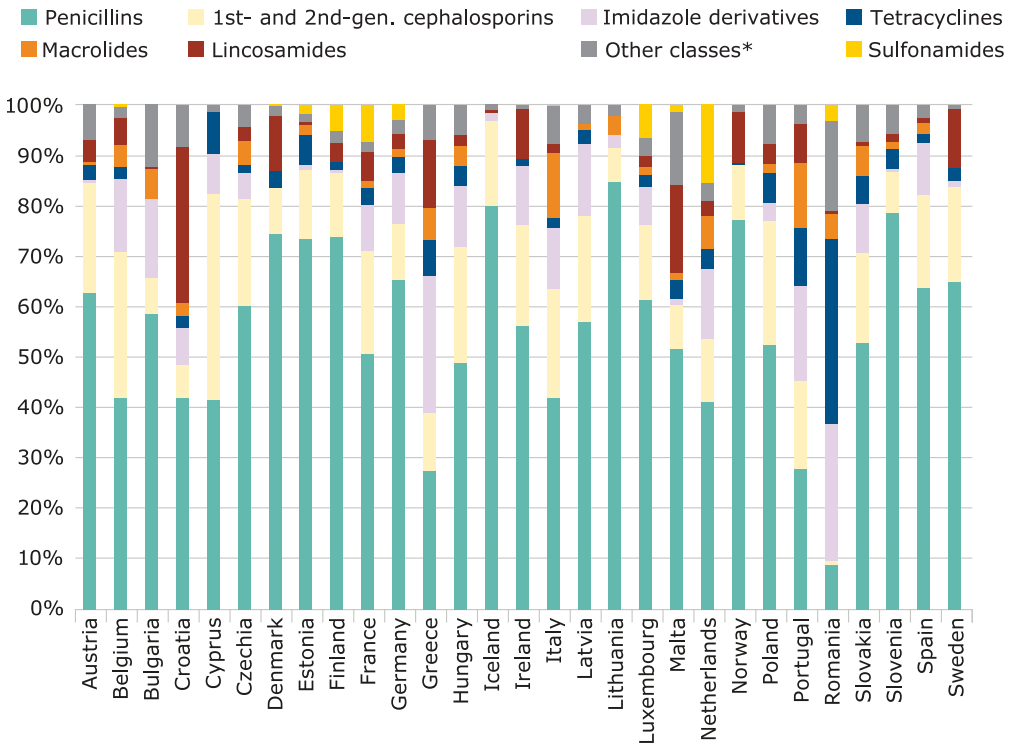
[1] Sales data subject to mandatory reporting, which only concerns substances with antibiotic activity.
* 'Other classes' includes amphenicols, cephalosporins, other quinolones, and other antibacterials.

Figure 23. Proportion of sales (in tonnes) of antimicrobial VMPs for other animals kept or bred by product form per country in 2023[1]



[1] Sales data subject to mandatory reporting, which only concerns substances with antibiotic activity.
* 'Other forms' include oral pastes and oral powders.

Figure 24. Proportion of sales (in tonnes) of antimicrobial VMPs for other animals kept or bred by antimicrobial class per country in 2023[1]



[1] Sales data subject to mandatory reporting, which only concerns substances with antibiotic activity.
* 'Other classes' includes fluoroquinolones, nitrofuran derivatives, aminoglycosides, trimethoprim, amphenicols, 3rd- and 4th-generation cephalosporins, other antibacterials, pleuromutillins, antiprotozoals, other quinolones and polymyxins.

Annex 2: Technical notes

Antimicrobials to be included in sales and use datasets (scope)

The ATC and ATCvet systems[59,60] are used to classify substances in human and veterinary medicines according to their main therapeutic use. In the context of ESUAvet-ASU activities, the ATC(vet) codes are used to identify those antimicrobial medicinal products for which data collection and reporting to the Agency is mandatory or voluntary[61]. The ATC(vet) codes that determine the antimicrobials under surveillance are summarised in Table 14.

Table 14. Antimicrobial reporting scope as per Articles 1 to 4 of Commission Delegated Regulation (EU) 2021/578

Scope	Groups of antimicrobial substances	ATCvet[1] codes	ATC[2] codes
Mandatory	Antidiarrheals, intestinal anti-inflammatory and antiinfective agents	QA07AA, QA07AB, QA07AX03, QA07AX04	A07AA, A07AB, A07AX03, A07AX04
Mandatory	Gynaecological antiinfectives and antiseptics	QG01AA, QG01AE, QG01BA, QG01BE	G01AA, G01AE, G01BA, G01BE
Mandatory	Antiinfectives and antiseptics for intrauterine use	QG51AA, QG51AG	-
Mandatory	Antibacterials for systemic use	QJ01	J01
Mandatory	Antibacterials for intramammary use	QJ51	-
Mandatory	Antiprotozoals (with antibacterial effect)	QP51AG	-
Mandatory	Antimycobacterials for intramammary use	QJ54 (voluntary for use)	-
Voluntary	Antiprotozoals (other than QP51AG)	QP51	P01
Voluntary	Antifungals for topical use	QD01A	D01A
Voluntary	Antifungals for systemic use	QD01B	D01B
Voluntary	Antimycotics for systemic use	QJ02	J02
Voluntary	Antimycobacterials	QJ04	J04
Voluntary	Antivirals for systemic use	QJ05	J05
Voluntary	Antibiotics and chemotherapeutics for dermatological use	QD06	D06
Voluntary	Other nasal preparations	QR01AX06, QR01AX08	R01AX06, R01AX08
Voluntary	Ophthalmological antiinfectives	QS01AA, QS01AB, QS01AD, QS01AE, QS01CA, QS01CC	S01AA, S01AB, S01AD, S01AE, S01CA, S01CC
Voluntary	Otological antiinfectives	QS02AA, QS02CA, QS03AA, QS03CA	S02AA, S02CA, S03AA, S03CA

[1] ATCvet codes define the reporting scope of both sales and use of antimicrobial VMPs. The ATCvet codes that also fell under ESVAC reporting scope are underlined.
[2] ATC codes define the reporting scope of use of antimicrobial HMPs in animals.

These codes are important for the ASU Platform to identify all products that should appear in the sales and use templates. Therefore, the scope is assigned at product level depending on the ATC or ATCvet code(s) and substances in a product will have the same scope as the product. If a product has more

[59] More information about the ATC code classification system is available here.
[60] More information about the ATCvet code classification system is available here.
[61] As per Articles 1 to 4 of Commission Delegated Regulation (EU) 2021/578.

than one ATC or ATCvet code falling under both the mandatory and the voluntary scope, the product is assigned to the mandatory scope.

Reporting of sales and use data by countries

Each calendar year, countries must report the number of packages sold or used per package presentation[62] for the antimicrobial medicinal products within the scopes mentioned above.

For sales of antimicrobial VMPs, countries must also confirm whether the product is authorised for food-producing animals or exclusively for other animals kept or bred (i.e. companion animals and fur animals). In the ASU Platform, by default, sales of VMPs with a withdrawal period indicated in the UPD are classified as for food-producing animals and those without one are assigned to other animals kept or bred. If there is no withdrawal period indicated in the UPD, countries must verify this information against the relevant section of the Summary of Product Characteristics to ensure that the product is not authorised for use in any food-producing animals, including all horses[63]. If it is authorised, countries must update the ASU sales template accordingly.

For use data, countries must report the number of packages used of each VMP/HMP per animal species and animal species category[64] within their territory, following the stepwise approach as per Article 15 of Commission Delegated Regulation (EU) 2021/578.

Calculation of sales and use data (numerator)

The quantity of antimicrobial active substance sold or used is calculated for each antimicrobial medicinal product presentation (and use species or category in the case of use data) by multiplying:

- the number of packages sold or used;
- the strength given in the corresponding product information;
- the pack size.

For fixed combination antimicrobial medicinal products, the quantity of each antimicrobial active substance is calculated separately.

These calculations are performed automatically in a standardised and harmonised manner by the ASU Power BI application, 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 antimicrobial active moiety in mg when the strength is reported as the derivative strength. The ASU Power BI application uses all IU and derivative conversion factors available in EMA's Substance Management Service (unpublished). The conversion factors common with ESVAC are listed in the ASU Technical Implementation Protocol[65].

[62] Packaged veterinary or human antimicrobial medicinal product approved for marketing as provided in the relevant section of the corresponding Summary of Product Characteristics SPC. Each product presentation is distinguished by the name, package ID, strength, form, pack size and packaging material.
[63] 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.
[64] For more information on the instructions to countries for collecting and reporting antimicrobial use data for each animal species and category please refer to Antimicrobial use data reporting per animal categories (numerator) - Manual for reporting the data to the Agency (EMA/757638/2021).
[65] For more information on the methodology followed to calculate the quantity of antimicrobial active substance sold or used per antimicrobial medicinal product presentation and on the conversion factors, please refer to Antimicrobial Sales and Use (ASU) technical implementation protocol (EMA/27838/2024).

Animal population data and biomass (denominator)

What are denominators?

To ensure comparability of the reported data and to allow monitoring of trends – both on the volume of sales of antimicrobial VMPs and on the use of antimicrobial medicinal products in animals – it is necessary to evaluate these data in the context of the associated animal populations, which vary in size and composition across countries.

For the purpose of these reports, denominators are used as a proxy for the animal population likely to be treated with antimicrobials within a reporting year and expressed as animal biomass (kg) per year. They are calculated by multiplying standardised animal weights by the total number of animals slaughtered or by the number of live animals present in a country during the data collection period[66]. In the context of intra-EU trade, the biomass of animals sent to or brought from other countries are subtracted and added, respectively, from the domestic animal biomass so that only animals raised in the country during the time at which they could have been treated with antimicrobials are considered.

For presenting data in this report, the following animal biomass sales denominators were used:

- **Denominator for food-producing animals**: the biomass of cattle, pigs, chickens, turkeys, other poultry (ducks and geese), sheep, goats, finfish, horses and rabbits are used as the denominator of sales assigned to food-producing animals.
- **Denominator for other animals kept or bred**: the biomass of dogs, cats and fur animals are used as the denominator of sales assigned to other animals kept or bred.
- **PCU:** the ESVAC denominator[67] that has been in place for several years for reporting the sales of antimicrobial VMPs is used in this report solely for the purpose of monitoring the progress towards the EU antimicrobial sales reduction target (Section 3 and Annex 6).

What animal population data are used for the calculation of the denominators?

The food-producing animal population data used in this report come mainly from two reference data sources:

- the European Statistical Office (Eurostat) for the numbers of livestock and slaughtered food-producing animals;
- the Trade control and Expert System (TRACES) for numbers of animals moved between the EU countries, Iceland and Norway for fattening or slaughter.

For certain animal species, such as rabbits, geese, horses and farmed fish, dogs, cats, minks and foxes, data are not available in Eurostat, and national statistics, when available, have to be used instead. As many countries do not collect data or have data with low coverage for cats and dogs, figures published in the annual reports of the European Pet Food Industry (FEDIAF)[68] have been used as reference data to calculate the biomass for these species[69].

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[66] For more information on how these denominators are calculated please refer to the Guideline on reporting antimicrobial sales and use in animals at the EU level – denominators and indicators (EMA/CVMP/882931/2022)
[67] For more information please refer to the European Surveillance of Veterinary Antimicrobial Consumption (ESVAC) Sales Data and Animal Population Data Reporting Protocol (EMA/210691/2015-Rev.4) and the 13th ESVAC report (EMA/299538/2023).
[68] FEDIAF: https://europeanpetfood.org/
[69] For more information what animal population data is used please refer to the Guideline on reporting antimicrobial sales and use in animals at the EU level – denominators and indicators (EMA/CVMP/882931/2022).

Countries have verified and validated all animal population data, amending them when necessary[70]. Each country is responsible for the quality of the data it delivers to EMA.

Data presentation and indicators

The quantities of antimicrobial active substance sold or used are expressed using the following metrics[71]:

- Tonnes sold (expressed in mg when used as numerator).
- As proportion of total sales or use (in tonnes). For use, only Figure 13.
- Milligrams sold per kilogram of animal biomass (mg/kg). This indicator is to be used for all ESUAvet sales data collected under Article 57 of Regulation (EU) 2019/6.

$$\frac{\text{Quantity antimicrobial active substance in mg}}{\text{Animal biomass in kg}}$$

- Milligrams sold per kilogram of PCU (mg/PCU). This indicator is only used for the analysis of sales data for monitoring the progress towards the EU antimicrobial sales reduction target and is different from the previous one in that it follows the ESVAC methodology for analysing sales data (see Annex 5).

The quantities of antimicrobial active substance sold are presented in this report in the following ways:

- Aggregated at EU level (27 EU countries), or per country. Data aggregated for all 29 reporting countries (27 EU countries, Iceland and Norway) are only shown in tables or when there are significant differences with the EU aggregated data. When presented in mg/kg, the aggregated data is the total quantity of antimicrobial active substance (mg) divided by the total relevant animal biomass (kg).
- Per product form, which are specific groupings of authorised pharmaceutical forms that take into consideration the route of administration and the intended site of action. The product forms used in this report are listed in Table 15[72].
- Per antimicrobial class. The antimicrobial classes used in this report and the basis of the classification used are explained in Annex 3.

Table 15. Product forms reported per antimicrobial VMP presentation

Product form	Description
INJ	Injectable products
INTRAMAM-LC	Intramammary products for lactating animals or for both lactating and drying-off animals.
INTRAMAM-DO	Intramammary products only for drying-off animals.
ORAL SOLU	Oral solutions and powders to be administered with drinking water, milk and/or milk replacer

[70] As per Article 16(5) of Commission Delegated Regulation (EU) 2021/578.
[71] For more detailed information on the indicators used in this report, please refer to the Guideline on reporting antimicrobial sales and use in animals at the EU level – denominators and indicators (EMA/CVMP/882931/2022).
[72] For more information on product forms, please refer to the ASU technical implementation protocol (EMA/27838/2024).

Product form	Description
ORAL PASTE	Oral pastes
ORAL POWD	Oral powders to be administered in feed or in drinking water and feed
PREMIX	Premixes
TABL	Capsules, tablets, boluses and other similar oral pharmaceutical forms
INTRAUT	Intrauterine products
TOPICAL_DERM	Topical dermatological products
TOPICAL_OPHTHALM	Topical ophthalmological products
TOPICAL_OTOLOG	Topical otological products
TOPICAL_NASAL	Topical nasal products
OTHER	Other forms when none of the previous product forms apply

Annex 3: List of antimicrobial substances reported in the ESUAvet reports

The classification of antimicrobial substance in the context of the ASU Platform corresponds to the classes and subclasses defined in the ATC and ATCvet classification 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). Substances are assigned to a single class irrespective of whether the medicinal product sold or used is a single or a fixed-combination product. Exceptions to this are penicillin and beta-lactamase inhibitor combinations, as in Figures 6 and 11.

Table 16 includes all the substances for which sales were reported under the mandatory scope in 2023, their assigned class and AMEG category. Some of these substances are only authorised for use in companion animals and indications have been added to those substances for which maximum residue limits (MRLs) have not been established or that are prohibited for use in any food-producing animals as per Tables 1 and 2 of the Annex to Commission Regulation (EU) No 37/2010.

Table 16. Substances for which sales were reported under the mandatory scope in 2023[1]

Antimicrobial category	Antimicrobial class	Antimicrobial subclass	Substances*	AMEG category
Antiprotozoals	Antiprotozoals	Nitroimidazole derivatives	Ronidazole	n.a.
		Other antiprotozoal agents	Diaveridine	n.a.
Antibacterials	1-2 gen. cephalosporins	First-generation cephalosporins	Cefacetrile, Cefadroxil[2], Cefalexin, Cefalonium, Cefapirin, Cefazolin	C
	3-4 gen. cephalosporins	Third-generation cephalosporins	Cefoperazone, Cefovecin[2], Ceftiofur	B
		Fourth-generation cephalosporins	Cefquinome	B
	Aminoglycosides	Other aminoglycosides	Amikacin[2], Apramycin, Framycetin, Gentamicin, Kanamycin, Neomycin, Paromomycin	C
		Streptomycins	Dihydrostreptomycin, Streptomycin	C
	Amphenicols	Amphenicols	Chloramphenicol[3], Florfenicol, Thiamphenicol	C
	Fluoroquinolones	Fluoroquinolones	Danofloxacin, Difloxacin, Enrofloxacin, Marbofloxacin, Norfloxacin[2], Pradofloxacin[2]	B

Antimicrobial category	Antimicrobial class	Antimicrobial subclass	Substances*	AMEG category
	Imidazole derivatives	Imidazole derivatives	Metronidazole[3]	D
	Lincosamides	Lincosamides	Clindamycin[2], Lincomycin, Pirlimycin	C
	Macrolides	Macrolides	Erythromycin, Gamithromycin, Spiramycin, Tildipirosin, Tilmicosin, Tulathromycin, Tylosin, Tylvalosin	C
	Nitrofuran derivatives	Nitrofuran derivatives	Furazolidone[3]	D
	Other antibacterials	Other antibacterials	Bacitracin, Furaltadone[3], Nitroxoline[2], Novobiocin, Rifaximin, Spectinomycin	D (except Nitroxoline and Novobiocin which aren't categorised and rifaximin which is category C)
	Other quinolones	Other quinolones	Flumequine, Oxolinic acid	B
	Penicillins	Beta-lactamase resistant penicillins	Cloxacillin, Dicloxacillin, Nafcillin	D
		Beta-lactamase sensitive penicillins	Benzylpenicillin, Phenoxymethylpenicillin	D
		Combinations of penicillins, incl. beta-lactamase inhibitors	Amoxicillin	C
		Penicillins with extended spectrum	Amoxicillin, Ampicillin	D
	Pleuromutilins	Pleuromutilins	Tiamulin, Valnemulin	C
	Polymyxins	Polymyxins	Colistin	B
	Sulfonamides	Sulfonamides	Sulfacetamide, Sulfachlorpyrazine, Sulfachlorpyridazine, Sulfaclozine, Sulfadiazine, Sulfadimethoxine, Sulfadimidine, Sulfadoxine, Sulfaguanidine, Sulfamerazine, Sulfamethoxazole, Sulfamethoxypyridazine, Sulfamonomethoxine,	D

Antimicrobial category	Antimicrobial class	Antimicrobial subclass	Substances*	AMEG category
			Sulfapyridine, Sulfaquinoxaline, Sulfathiazole	
	Tetracyclines	Tetracyclines	Chlortetracycline, Doxycycline, Oxytetracycline, Tetracycline	D
	Trimethoprim	Trimethoprim	Trimethoprim	D

[1] The ASU Platform groups antimicrobial substances in categories, classes and subclasses taking into account the ATCvet codes in the Annex to Commission Delegated Regulation (EU) 2021/578 and the ATC(vet) classification system.
[2] MRLs not established for any food-producing animals.
[3] Included in Table 2 (prohibited substances) of the Annex to Commission Regulation (EU) No 37/2010.

Annex 4: Data Quality

Different efforts and measures have been made to ensure the best possible quality of the data presented in this report. This includes the antimicrobial medicinal product data used to calculate the total amount of antimicrobial active substance(s) per product presentation, as well as the reported sales data and use data. Each country is responsible for the quality of the data it delivers to EMA and is assisted by EMA with data validation.

Medicinal product data quality

One of the main benefits of the ASU Platform is its integration with other EMA IT systems, such as SPOR and UPD. This avoids duplication of data input across systems and ensures a single source of information. However, this setup also presented challenges for the first data call as the data quality and the integration between systems needed to be verified and validated.

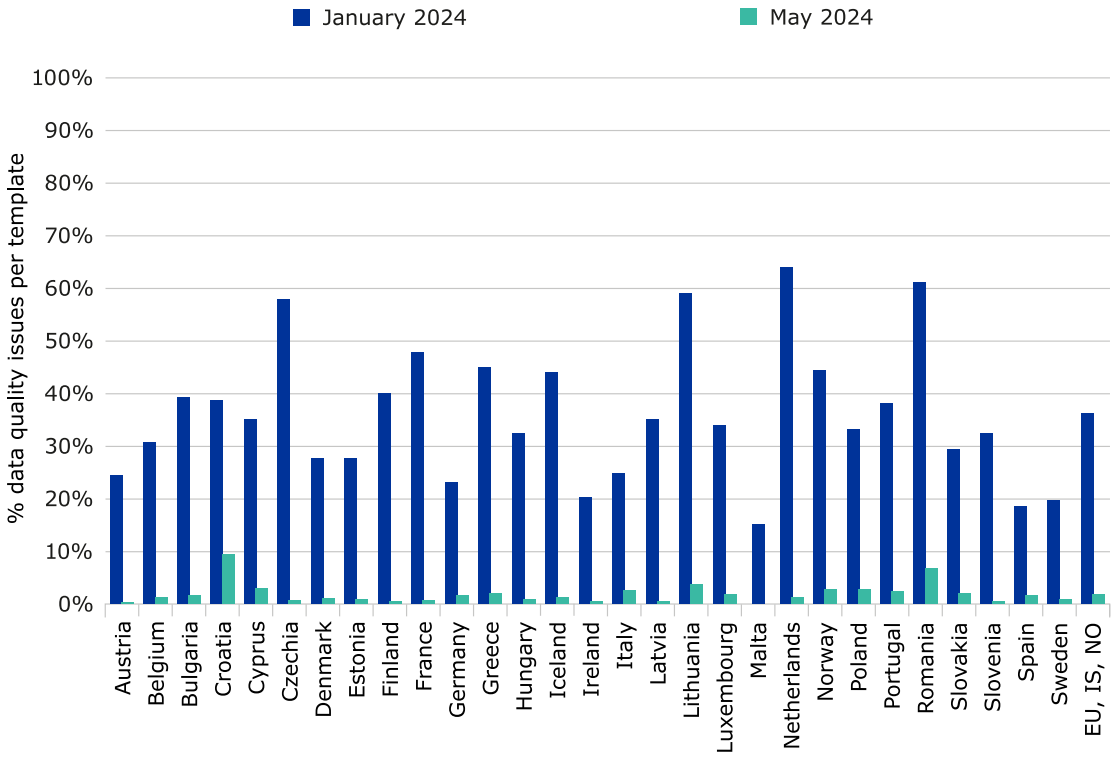
The UPD provides the ASU Platform with all the data variables for each VMP presentation required to prefill the ASU sales and use templates as described in the Annexes to the Commission Implementing Regulation (EU) No 2022/209[73]. These product data variables serve mainly three functions: 1) to help countries identify the products for which sales and use data should be reported, 2) to standardise data variables for those products that are authorised in more than one country, and 3) to calculate the amount of antimicrobial active substance sold or used per product presentation.

At the start of 2024, EMA estimated that approximately 40% of the antimicrobial VMP presentations in the ASU sales templates had incomplete or inaccurate data variables due to product data being entered incorrectly in UPD. Consequently, quality of product data variables needed to greatly improve before countries could start submitting their 2023 data via the ASU Platform and this required cooperation between different national organisations and countries.

Given the scale and the complexity of the situation, a two-stage 'data quality clean-up' campaign was organised focusing on all antimicrobial VMPs under the mandatory scope. The first stage, from January to May 2024, targeted 'machine-detectable' issues such as blank fields in the ASU sales templates that would prevent the ASU Power BI application from calculating the amount of antimicrobial active substance sold or used per product presentation. By the end of this stage, the total percentage of product presentations with data quality issues had declined from 40% to approximately 2% (Figure 25).

[73] For more information on the ASU data variables and the connection with the UPD, please refer to the Antimicrobial Sales and Use (ASU) technical implementation protocol (EMA/27838/2024).

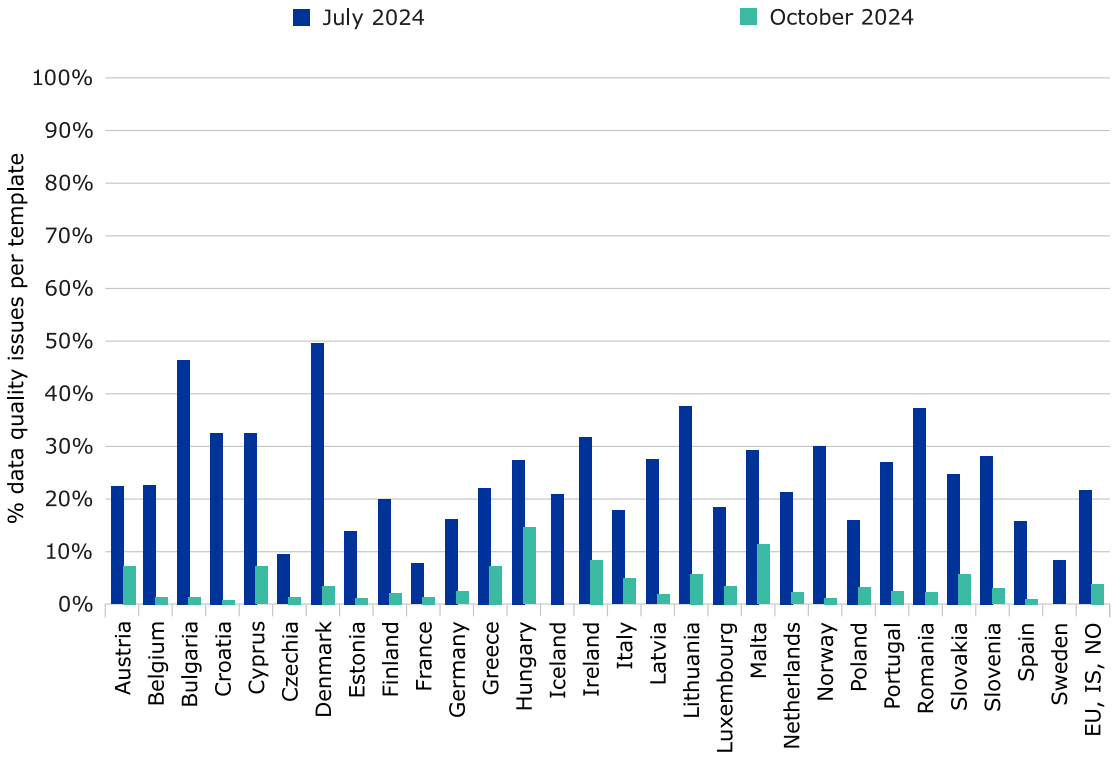
Figure 25. Percentage of machine-detectable data quality issues on VMP data variables per ASU country sales templates at the beginning and end of the first stage (January to May 2024) of the data quality clean-up campaign[1]



[1] For each country, the percentage is derived from the number of VMP presentations that have machine-detectable data quality issues with regards to the total number of VMP presentations that fall under the mandatory scope from their ASU sales data template.

The second stage of the data quality clean-up campaign took place between 1 July and 31 of October 2024 and was focused on 'human-detectable' issues, i.e. incorrect product data variables that would affect data analysis. For this stage, EMA and countries compared the product data in the ASU sales templates with that available in official documents, primarily the Summary of Product Characteristics, for all products from the mandatory reporting scope for which countries had submitted 2023 sales data. All the identified human-detectable issues found were then grouped per responsible country for their resolution. By the end of this stage, the percentage of products with human-detectable data quality issues declined from 21% to just below 4% (Figure 26).

Figure 26. Percentage of human-detectable data quality issues on VMP data variables per ASU country sales templates at the beginning and end of the second stage (July to October 2024) of the data quality clean-up campaign[1]



[1] For each country, the percentage is derived from the number of VMP presentations that have human-detectable data quality issues with regards to the total number of VMP presentations that fall under the mandatory scope and that have reported sales for 2023 in their ASU sales data template.

At the end of the data quality clean-up campaign, EMA estimated the impact of the unresolved data quality issues on the total reported sales falling under the mandatory scope by calculating what the total amount of antimicrobial active substance sold would have been if the product information were correct. In this manner, total sales (in tonnes) aggregated for all reporting countries were 0.08% lower than they should have been. At country level the impact ranged between -3.1% and 1.3% but was below 0.5% for 25 out of 29 countries.

The hard work and extraordinary cooperation between countries, UPD contact points and EMA, enabled this remarkable improvement in antimicrobial VMP data variable quality and stopped it from being an impediment for the reporting and analysis of 2023 antimicrobial sales data. Furthermore, because of the integration between ASU and UPD, these corrections are permanent unless the product information is purposefully changed. Therefore, it is estimated that most of the work needed to improve the quality of product data variables has been done during the 2023 data call. However, future data quality clean-up campaigns will be required to cover products that were not validated during the 2023 ASU data call[74].

[74] This includes 11% of the VMPs from the mandatory scope for which 2023 use data were reported, all products from the voluntary scope for which 2023 data were reported and any unvalidated VMP or HMP for which data may be reported in the future.

Sales data quality

Sales data quality refers here to compliance with the legal requirements and to the accuracy and coverage of the antimicrobial VMP sales data submitted via the ASU sales templates as indicated in the ASU sales questionnaire. Each country defines and sets up their quality control measures, including assessment of data coverage and accuracy, considering the distinctive characteristics of their national data collection systems. Consequently, quality control measures are not harmonised across reporting countries and the answers given in the questionnaire and presented in this report should be interpreted with care. Of note, at the beginning of 2024, ESUAvet guidance was published to advise countries on how to establish a data quality management plan for the collection of antimicrobial sales and use data[75]. Further efforts will be made to harmonise how reporting countries measure these data quality parameters.

In addition to estimating coverage and accuracy of their sales data, countries also had to meet a series of data quality requirements that are listed in the legislation[76]. Fulfilment of these requirements and the estimated coverage and accuracy of the sales data were communicated to EMA via the ASU sales data questionnaire. The following points summarise countries' compliance with the data quality requirements for 2023 data:

- Full coverage of sales data was achieved for all but four countries (for more information see Table 2 of Section 1.1).
- All countries indicated that actions were taken to avoid double reporting of sales data, if applicable.
- All countries except one confirmed that their sales data were corrected for movements of products across their borders as part of parallel trade, if applicable.
- All countries but one confirmed that data were validated and reported according to the standards specified in the latest reporting protocols and templates made available by the Agency.
- All countries but one confirmed that data were amended in case gaps, errors or inconsistencies were identified.
- All countries confirmed that data on the volume of sales covered all sales in their territory of at least the antimicrobials listed as part of the mandatory reporting scope.
- Six countries reported sales of 15 products via the ASU sales questionnaire because these were not available in the ASU templates due to withdrawn authorisation status, data quality issues or import from third countries. The sales of these products were excluded from the sales results presented in this report.

After submission, data were further validated by countries and EMA using the ASU Power BI Data Validation reports to detect potential outliers in the submitted datasets. This was done by analysing total sales (in tonnes), by product form and antimicrobial class against those from the previous reporting period (using the subset of 2023 data that falls in the ESVAC scope, see Annex 5). Inconsistencies or outliers were then followed up by countries. For more information on how 2023

[75] Manual for Member States for establishing a data quality management plan for the collection of antimicrobial sales and use data under Regulation (EU) 2019/6 and its delegated and implementing regulations (EMA/CVMP/ESUAVET/570091/2023)
[76] As per Article 6 of the Commission Delegated Regulation (EU) 2021/578.

sales data may compare to that from the previous reporting period (ESVAC) and the justifications provided by countries for significant changes in trends please refer to Annex 6.

Use data quality

Use data quality refers here to compliance with the legal requirements[77] and to the accuracy and coverage of the data on use of antimicrobial medicinal products in animals submitted via the ASU use templates as indicated in the ASU use questionnaire. As with sales data, use data quality control measures, including assessment of data coverage and accuracy, are defined and set up by each country individually, considering the distinctive aspects of each country's data collection system, which in this case can also vary per animal species.

It is important to note that 2023 was the first year that use data had to be collected by the 27 EU countries, Iceland and Norway for cattle, pigs, chickens and turkeys. This required in many cases the establishment of new national use data collection systems and as a result, the quality of the reported 2023 data varied greatly across countries. Continued efforts are needed to improve the completeness and quality of these data in the upcoming years.

The following points summarise countries' compliance with the data quality requirements in 2023:

- Accuracy and coverage varied greatly across countries and species. For more information on the coverage reported per country and animal species, please refer to Tables 9 to 12 of Sections 2.2 to 2.5.
- All countries took actions to avoid double reporting of use data, if applicable.
- All countries except four confirmed that data were validated and reported according to the standards specified in the latest reporting protocols and templates made available by the Agency.
- All countries except four confirmed that data were amended in case gaps, errors or inconsistencies were identified.
- Twenty-three countries provided use data of at least the antimicrobials from the mandatory scope for all animal species and categories or stages, referred to in Article 15(1) of Commission Regulation (EU) 2021/578. Six countries did not provide data for at least one of the animal species, and two countries only provided data at species and not category level.
- Seven countries reported use of 54 products via the ASU use data questionnaire because these products were not available in the ASU templates due to withdrawn authorisation status, data quality issues, import from third countries or because they were human medicinal products. Therefore, the use of these products was excluded from the results presented in this report.

In addition to the actions taken by countries, EMA also validated the submitted use data by ensuring that the responses countries provided via the ASU use data questionnaire were adequate and complete. Given the wide coverage and accuracy range of the submitted use data, no further quantitative validations were performed using the ASU Power BI Data Validation reports.

[77] As per Article 6 of the Commission Delegated Regulation (EU) 2021/578.

Annex 5: Transition from ESVAC to ESUAvet sales reporting

For both the ESVAC project (concluded in 2023) and the ESUAvet reporting (started in 2024), identification of antimicrobial VMPs for which sales must be reported is done based on the products' ATCvet codes. The ESUAvet sales mandatory scope incudes three additional ATCvet codes compared to the ESVAC scope (Table 14, Annex 2). However, no sales of products with these ATCvet codes (QA07AX03, QA07AX04, QJ54) were reported in 2023 – i.e. the ESUAvet mandatory data covers the same ATCvet codes as for ESVAC during the period 2010-2022.

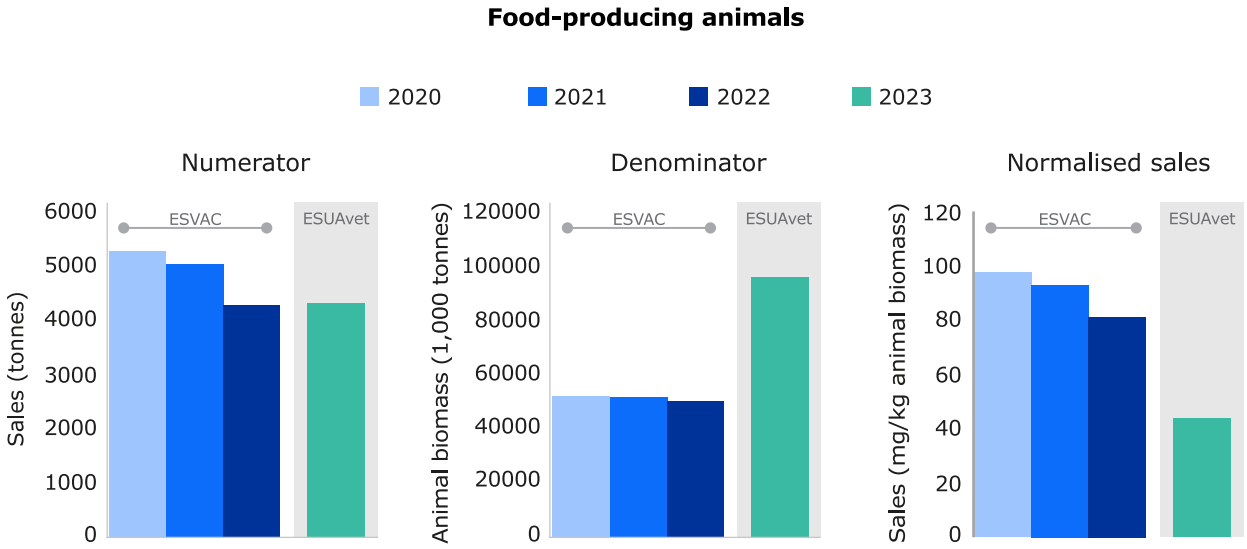
In this section, any mention of ESUAvet sales refers solely to mandatory sales.

Food-producing animals

Sales numerator

One of the main differences between ESUAvet and ESVAC sales is how reported sales are assigned to different animal groups. For ESVAC, sales were assigned to food-producing animals based on the VMP product form, excluding tablets as these are almost exclusively used in companion animals. In contrast, for ESUAvet, sales are assigned to food-producing animals whenever a product has a withdrawal period,[78]. For food-producing animals, data from the ESVAC project for the years 2020, 2021, and 2022 are presented next to 2023 ESUAvet sales data in Figure 27. This exercise shows that 2022 (ESVAC) and 2023 (ESUAvet) sales are in the same range. In the context of the declining trend of sales reported to ESVAC between 2011-2022, fluctuations have been observed in some of the years which suggests that the impact of this change in methodology is low concerning the sales numerator for food-producing animals (Figure 27, left).

Figure 27. ESVAC and ESUAvet (mandatory scope) numerator, denominator and indicator for sales of antimicrobial VMPs for food-producing animals in the EU, IS and NO



Other changes may also affect the ESUAvet sales numerator. For instance, some countries changed data providers between 2022 and 2023, resulting in a sales increase, while other countries identified underreporting in previous years (see Annex 6). Moreover, while the methodology used to calculate

[78] There were 66.8 tonnes of tablet sales in 2022 (ESVAC) and 68.6 tonnes with all the product forms for other animals kept or bred in 2023 (ESUAvet). For more information on how ESUAvet sales are assigned to animal groups, please refer to the ASU Implementation protocol (EMA/27838/2024).

the quantities of antimicrobial active substances in each VMP for ESVAC and ESUAvet is the same, the ASU Platform uses derivative conversion factors available in EMA's integrated systems when the substance strength in UPD is given for the derivate (strength of the active moiety not available). On the other hand, ESVAC only used a pre-defined list of 8 derivative conversion factors[79]. It is estimated, however, that the impact of analysing sales data with conversion factors for additional derivatives compared to ESVAC is minimal for ESUAvet sales both at the country and the EU levels (2.6%).

Nonetheless, it is advised to avoid making direct comparisons between the ESVAC and ESUAvet sales numerator for food-producing animals.

Sales denominator

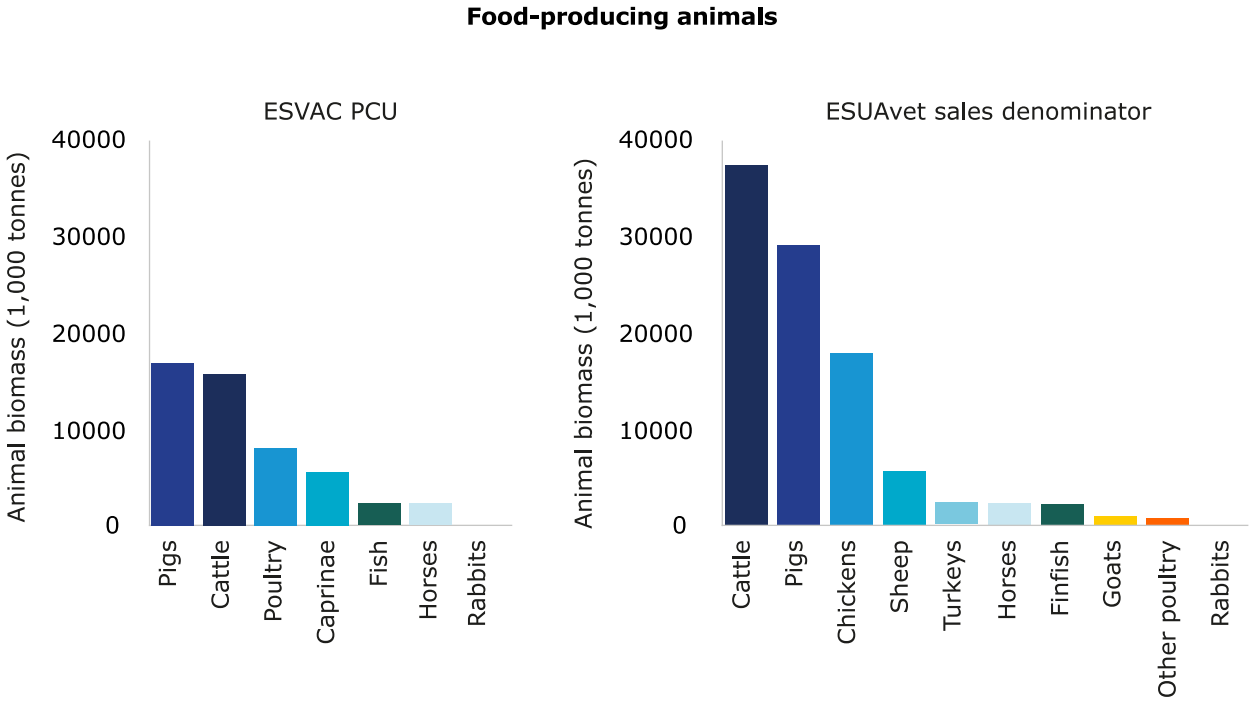
The animal biomass denominators are used to normalise antimicrobial VMP sales data. These are proxies for the animal population likely to be treated with antimicrobials within a reporting year. For the ESVAC project, the PCU was used to normalise the sales for food-producing animals, where 1 PCU = 1 kg animal biomass. The ESUAvet sales denominator for food-producing animals and the PCU cannot be directly compared because the animal population categories and the standard animal weights used to calculate the animal biomass are different[80]. Figure 27 (middle) illustrates the impact of these differences between the two denominators. Consequently, normalised sales figures derived from these two denominators should also not be compared directly as it can lead to misinterpretations of data and trends. Understanding the differences between these denominators is essential for accurate data interpretation.

In 2023, the animal biomass denominator for ESUAvet sales for food-producing animals (Figure 28) was, on average, 1.9 times higher than the PCU for all reporting countries. The fold difference between countries varied from 1.2 to 2.5.

In terms of composition of the ESUAvet sales denominators for food-producing animals more than 80% of the total biomass is composed of cattle (38.1%), pigs (29.6%) and chickens (18.1%). The remaining biomass is composed of sheep (2.7%), turkeys (2.3%), horses (2.3%), finfish (2.2%), goats (0.9%), other poultry (0.7%) and rabbits (0.2%). For the PCU, 80.0% of the animal biomass is accounted for by pigs (33.2%), cattle (31.0%) and poultry (15.8%), followed by sheep and goats (10.9%), farmed fish produced (4.4%), horses (4.4%) and rabbits (0.2%). Although the species contribution to the total biomass of both denominators remains relatively similar (aggregated for all countries), the impact at the country level (fold increase between 1.2 and 2.5) is highly dependent on the predominant productions in each country.

[79] More information on the methodology can be found in the European Surveillance of Veterinary Antimicrobial Consumption (ESVAC) Sales Data and Animal Population Data Reporting Protocol(version 4) (EMA/210691/2015)
[80] New animal species, categories, and average animal body weights have been introduced into the ESUAvet denominator for food-producing animals. For more details, please refer to Annex 1 of the Guideline on the reporting of antimicrobial sales and use in animals at the EU level – denominators and indicators (EMA/CVMP/882931/2022)

Figure 28. Composition of the food-producing animal denominators for reporting ESVAC and ESUAvet sales in the EU, IS and NO in 2023[1]



1 For ESVAC, the denominator for reporting the sales data for food-producing animals was referred to as PCU (population correction unit), where 1 PCU = 1 kg of animal biomass. For 2023, the PCU was calculated using the animal population data submitted to the ASU Platform according to ESVAC methodology.

In conclusion, while the ESUAvet and PCU denominators both serve to normalise antimicrobial sales for food-producing animals, they are not directly comparable. The PCU served its purpose during the ESVAC project[81] and will continue to be used in the context of monitoring the progress towards the EU antimicrobial sales reduction target, as the EU baseline and targets were calculated using the PCU. On the other hand, the ESUAvet sales denominator for food-producing animals[82] will be the primary denominator for normalising sales in the ESUAvet reports.

Sales indicator

The main measurement unit used to express consumption of antimicrobial VMPs in food-producing animals is sales (in mg of active substance) divided by the estimated animal population biomass (kg) that could be treated with antimicrobials within a reporting year (Figure 27, right).

As concluded separately for the numerator and denominators, comparisons between ESVAC and ESUAvet sales indicators should not be performed. Methodologically, only the EU antimicrobial sales reduction target sections of the ESUAvet and ESVAC reports can be compared. For this purpose, the ESVAC methodology will be followed when analysing sales data to continue measuring the overall progress towards the target. This entails including only those antimicrobial VMPs with the ATCvet codes specified in the ESVAC protocol[83], calculating the PCU as for ESVAC (i.e. using the same animal

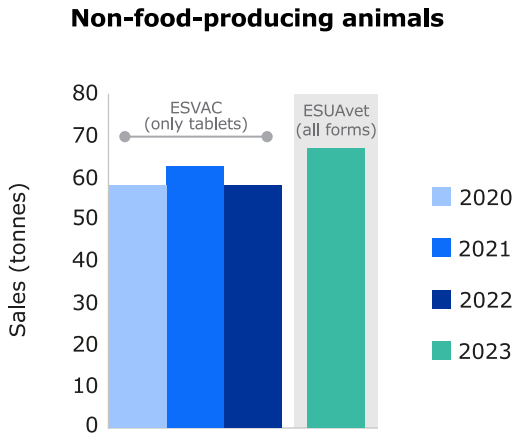
[81] More information on the methodology can be found in the European Surveillance of Veterinary Antimicrobial Consumption (ESVAC) Sales Data and Animal Population Data Reporting Protocol(version 4) (EMA/210691/2015)
[82] For more details, please refer the Guideline on the reporting of antimicrobial sales and use in animals at the EU level – denominators and indicators (EMA/CVMP/882931/2022)
[83] European Surveillance of Veterinary Antimicrobial Consumption (ESVAC) Sales Data and Animal Population Data Reporting Protocol(version 4) (EMA/210691/2015).

categories and weights used to calculate PCU for the ESVAC reports), and excluding tablets from the data sets before the normalisation of sales by the PCU.

Non-food-producing animals

For the ESVAC project, sales for non-food-producing animals were presented as sales for companion animals. These sales were assigned based on product form, with all tablet sales attributed to companion animals, as tablets are almost exclusively used in this animal group. All other product forms were designated for food-producing animals[84]. In contrast, the ESUAvet sales are assigned to other animals kept or bred when VMPs are exclusively authorised for use in companion and fur animals (i.e. whenever a product does not have a withdrawal period), regardless of product form[85]. Figure 29 presents the two sales numerators for non-food-producing animals (companion animals for ESVAC and other animals kept or bred for ESUAvet), which despite the different methodology, appear to be of similar magnitude.

Figure 29. Numerator for sales of antimicrobial VMPs (in tonnes) for companion animals (ESVAC) and other animals kept or bred (ESUAvet) in the EU, IS and NO



ESUAvet sales for other animals kept or bred are also presented normalised by the estimated relevant animal biomass. Animal population data of companion animals such as dogs and cats were not available for most ESVAC participating countries, therefore ESVAC did not use a denominator for sales of companion animals, presenting them exclusively in tonnes. On the other hand, ESUAvet has developed a denominator for other animals kept or bred, comprised of the biomass of dogs, cats, minks and foxes, which will allow presenting sales for this animal group in mg/kg (as for food-producing animals)[86]. Still today there are several countries that do not have in place a system for collecting complete data on the population of dogs and cats in their territory. Until this is the case, figures published in the European Pet Food Industry Federation (FEDIAF) annual reports[87] can be used as reference data to estimate the biomass for dogs and cats.

[84] This approach did not include sales of those products (e.g. injectable products) frequently marketed for both food-producing and companion animals, which would be included in the statistics of food-producing animals and considered to be minor. Also, some tablet formulations for companion animals are also authorised for use in food-producing or fur animals, and those sales would be presented as part of sales for companion animals.
[85] Sales of antimicrobial VMPs that are authorised for companion (or fur animals) but also any food-producing animal species will be presented as part of sales for food-producing animals.
[86] For more details, please refer to the Guideline on the reporting of antimicrobial sales and use in animals at the EU level – denominators and indicators (EMA/CVMP/882931/2022)
[87] FEDIAF: https://europeanpetfood.org/

Annex 6: Country trends from preceding reporting periods (ESVAC)

To compare ESUAvet sales data with preceding reporting periods, Table 17 presents published ESVAC data from 2018[88] to 2022 for EU countries, Iceland and Norway. Data from 2023 onwards (reported to the ASU Platform) are analysed according to ESVAC methodology to monitor the progress towards the EU antimicrobial sales reduction target (Section 3).

Table 17. Sales trends for food-producing animals, including horses and farmed fish, per country, in mg/PCU, from 2018 to 2023

Country	2018	2019	2020	2021	2022	2023	Trends 2018-2023
Austria[a]	50.2	42.6	46.3	41.3	36.2	36.0	
Belgium[b]	113.0	101.9	103.4	95.3	73.5	61.8	
Bulgaria[c]	119.6	112.7	120.9	124.5	103.2	103.6	
Croatia[d]	70.8	62.8	68.6	62.7	56.2	45.4	
Cyprus	392.3	350.0	344.2	296.5	254.7	186.6	
Czechia	56.9	53.8	56.2	50.0	46.4	42.2	
Denmark	37.8	37.1	37.2	33.4	34.1	31.9	
Estonia	52.9	53.5	49.2	46.6	45.8	42.5	
Finland	18.2	19.1	16.2	17.0	14.9	16.1	
France	64.2	58.3	56.6	51.7	38.9	39.5	

[88] Baseline for the EU antimicrobial sales reduction target.

Country	2018	2019	2020	2021	2022	2023	Trends 2018-2023
Germany[e]	88.4	78.6	83.8	73.2	69.9	71.1	
Greece[f]	93.6	84.8	96.4	108.8	89.0	56.0	
Hungary	180.5	184.8	163.4	155.6	111.2	97.1	
Iceland	4.8	3.5	3.8	3.6	4.4	4.3	
Ireland	45.9	40.8	47.0	42.4	33.6	33.4	
Italy[g]	244.0	191.1	181.8	173.5	157.5	180.3	
Latvia	35.9	28.2	29.6	25.5	20.8	21.5	
Lithuania[h]	32.7	65.6	60.2	71.2	48.2	42.5	
Luxembourg	33.6	29.0	29.0	27.1	25.1	24.7	
Malta[i]	153.4	110.3	116.1	110.5	74.4	74.2	
Netherlands[j]	57.4	48.2	50.2	47.6	37.0	39.4	
Norway	2.9	2.3	2.3	2.3	2.1	2.1	
Poland[k]	168.3	185.2	187.9	175.5	196.0	150.9	

Country	2018	2019	2020	2021	2022	2023	Trends 2018-2023
Portugal[l]	183.4	143.8	172.5	149.9	77.1	133.4	
Romania[m]	82.7	53.9	57.8	59.0	48.8	73.0	
Slovakia	49.2	42.3	51.9	41.7	41.1	45.0	
Slovenia	43.2	44.9	33.3	31.8	25.7	24.3	
Spain[n]	219.0	126.7	154.3	157.2	127.4	156.6	
Sweden	12.1	11.4	12.2	12.1	10.6	11.2	
EU	118.3	95.6	101.5	96.9	84.8	88.5	
EU, IS, NO	113.9	92.0	97.5	92.8	81.2	84.6	

[a)] For Austria, VMPs bought in other Member States (under the cascade use) are included for the first time in 2023; the impact on previous years is expected to be minor, estimated at less than 5%.
[b)] For Belgium, the data reported concerns sales made in the country and does not include sales of VMPs bought in other Member States. The proportion of sales bought in other Member States is currently unknown. A project to collect sales data at the lowest level in the chain to address this gap is underway, with the first sales data expected in 2027. In 2023, Belgium also changed the data providers from wholesalers and feed mills to MAHs and feed mills.
[c)] Bulgaria changed data providers from wholesalers to wholesalers and MAHs in 2023.
[d)] Croatia changed data providers from wholesalers to wholesalers and MAHs in 2023.
[e)] Due to legal changes since the collection year 2023, Germany has an extended group of recipients for which data must be reported. For the first time, the quantities of antibiotic VMPs dispensed to pharmacies, for example, were also recorded. Furthermore, data are now collected according to specific ATCvet codes. This leads to slight shifts for certain VMPs.
[f)] For Greece, in 2023 the volume of sales of antimicrobial VMPs were retrieved from the National Submission System in which both MAH and local representatives report sales data. Full coverage in 2023 has not been achieved.
[g)] For Italy, sales data represent sales from MAHs to wholesalers and feed mills for 2018–2019. 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. In 2023, Italy changed the data provider of premixes, from MAHs to feed mills. 2022 sales are underestimated due to underreporting.
[h)] For Lithuania, corrections to sales data were made for 2019–2021 during the preparation of the 13th ESVAC report. It is advisable to exercise caution when interpreting trends and drawing conclusions from data for Lithuania up to 2019, as it was not feasible to verify their accuracy or completeness.
[i)] In Malta, veterinarians occasionally supply VMPs without the veterinary prescription when they administer the product themselves and/or give small amounts of VMPs to start the treatment right away. However, the veterinarian is not exempt from the record keeping requirements and since 10 February 2025 veterinarians must always issue a veterinary prescription when they administer antimicrobials VMP.
[j)] For the Netherlands in 2023, the import of antimicrobial VMPs by wholesalers due to shortages - sales which are not collected by MAH – has a minor impact on the coverage of sales reported (app. 1%).
[k)] For Poland, sales prior to 2023 are likely an overestimation due to an error in reporting pack sizes.

[l)] For Portugal, medicated feed bought in other Member States is not captured in the reported sales (app. 10% of all sales). The sales coverage reported in 2023 is similar to that of previous reporting period (i.e. ESVAC project). 2019 and 2022 sales are underestimates, due to underreporting. In 2023, Portugal changed data providers from wholesalers to MAHs and wholesalers.
[m)] For Romania, in 2023 the volume of sales of antimicrobial VMPs were obtained directly from national MAHs while for non-national MAHs data were derived from MAHs' submission to UPD. Of note, before 2023 sales from non-national MAHs were reported by their legal representatives in Romania, but only from what was sold from their deposit (the stock of medicinal products remaining was not reported as a sale). For 2023, non-Romanian MAHs reported everything that entered Romania as sales, while in previous years only what was sold to the end-user.
[n)] Spain changed the data providers from retailers, feed mills and pharmacies (use data) to MAHs (sales data) in 2023.

Annex 7. Distribution of VMPs, antimicrobial use data collection systems, and AMR policy initiatives at country level

ESUAvet reporting countries are responsible for the information provided in this annex.

Austria

National distribution system for VMPs

In Austria, all VMPs containing antimicrobial substances are prescription-only medicines and in principle may only be distributed by pharmaceutical companies (e.g. marketing authorisation holders) or wholesalers to public pharmacies, veterinary pharmacies and pharmacies of academic training centres for veterinary medicine. Prescription-only VMPs may only be dispensed to animal owners/farmers by veterinarians holding a veterinary pharmacy or by public pharmacies based on a veterinarian's prescription. Veterinarians must record any dispensing of VMPs for food-producing animals to the animal keeper, the records must be kept at least for seven years. Antimicrobial VMPs for intramammary use, for systemic use (injection) or premixes can be dispensed to livestock owners/farmers only if they are members of the Austrian Animal Health Service and undergo regular training.

National system for collection of data on use of antimicrobial medicinal products in animals

Since 2015, veterinarians operating a pharmacy must report their dispensing data for veterinary antimicrobials to a national database, in compliance with the 'Veterinär-Antibiotika-MengenströmeVO' legislation. This dataset includes details such as animal species, category, farm ID, and the quantity of VMP dispensed. Since 2023, on a voluntary basis for the first year, the database also allows for direct reporting of administered VMP amounts by veterinarians. Use data is collected in predefined units for each VMP (e.g. ml, mg, piece) and is converted to the smallest pack size for ASU reporting. Further, ATCvet-relevant VMPs bought under the cascade use in other Member States (therefore, not authorised in Austria, but in another EU/EEA country) must be reported to the authority and are added to the use dataset.

National antimicrobial resistance policies and initiatives

In Austria, a national action plan for the reduction of antimicrobial resistance was implemented in 2013 and is updated regularly (last update in 2021). One of the main goals of the plan is to improve the monitoring system of antimicrobial consumption in veterinary medicines. As a result, a new method for sales data collection was implemented in 2014. Wholesalers and MAHs are required to upload their sales data directly into a database, which has led to an improvement in data quality. In addition, veterinary pharmacies must also report their dispensing of AM-VMPs to livestock holdings (including species information). These results are published in the national report each year and individual reports (benchmarking) are provided for veterinarians and farmers. Furthermore, different research projects (in cooperation with the Federal Ministry of Social Affairs, Health, Care and Consumer Protection, AGES and vetmeduni) concerning antimicrobial usage in poultry, pigs and cattle are currently ongoing. Prudent use campaigns have been implemented together with the animal health services. In addition, guidelines for the prudent use of antimicrobials, which are binding for veterinarians and regulate the selection and use of antibiotics/antibiotic classes, are applicable since 2018. Since 2014 the legal basis for the monitoring of sales and use of antimicrobial VMPs in Austria is the Veterinär-Antibiotika-Mengenströme-Verordnung BGBl. II Nr. 83/2014 as amended.

The national action plan and resistance report can be found here.

Belgium

National distribution system for VMPs

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

VMPs are distributed through manufacturers or importers (e.g. MAHs) or through wholesalers to veterinarians and pharmacists. Wholesalers obtain the VMPs from manufacturers or importers (e.g. MAHs). Antimicrobial VMPs are only available to animal owners from pharmacies, on veterinary prescription, or directly from the veterinarian.

Premixes are distributed directly through manufacturers or importers (e.g. MAHs) to manufacturers of medicated feed or through wholesalers. Farmers are the sole recipients of medicated feed from manufacturers. Medicated feed is only distributed on veterinary prescription.

Until 2022, sales data were collected from wholesalers (then still wholesaler-distributors) and manufacturers of medicated feed. The new Veterinary Medicinal Products Regulation (Regulation (EU) 2019/6) allows veterinarians to purchase directly from a MAH (with the appropriate authorisation) and the veterinarians no longer have to go through a wholesaler. Sales data are now collected at MAH and manufacturers of medicated feed level. The Federal Agency for Medicines and Health Products (FAMHP) is currently developing the VAM-Reg, with the support from the EC (SMP-FOOD-2022-AMRtool-AG-IBA grant), which aim will be to collect sales data at veterinarians and pharmacies level. The first sales data are expected in 2027 (sales data collection in 2026).

National system for collection of data on use of antimicrobial medicinal products in animals

Antibiotic use in cattle (including veal calves), pigs, poultry (chickens and turkeys) needs to be reported in the Belgian Sanitel-Med data collection system of the FAMHP. The veterinarian is responsible for completeness, accuracy and timely submission of data in Sanitel-Med, directly or via third parties. The farmer can validate these data or request the veterinarian to correct mistakes. If the farmer does not validate, the data is automatically validated.

There are no important differences in the use data collection systems between the different use species (cattle, pigs, chickens, turkeys).

In Sanitel-Med, use data can be introduced as package or as unit. In case of indication of a unit, it is afterwards calculated in packages.

National antimicrobial resistance policies and initiatives

In Belgium, awareness campaigns on antibiotic use and the emergence of resistance are primarily based on the national reports BelVet-SAC on antibiotic sales (all species) and use (in pigs, poultry and veal calves) and BELMAP.

It is mandatory, by royal decree, to support the use of critical antibiotics (quinolones and third- and fourth-generation cephalosporins) with an antibiotic susceptibility test. In 2016 the first of two 'Antibiotics Covenants' on the responsible use of antibiotics in animals was signed by the competent authorities and their Minister, the knowledge center on antibiotic use and resistance in animals in Belgium (AMCRA) and partners from all sectors and contained very ambitious targets to reduce the use

of antibiotics in animals. A third covenant is foreseen to be agreed upon for the coming 4 years. These objectives and planned actions are since 2021 included in a One Health National Action Plan on Antimicrobial Resistance (OH NAP AMR). The aim was to coordinate all human medicine, veterinary medicine and environment AMR-related actions. The competent authorities and the sectoral partners are currently working on a new OH NAP AMR for 2025-2029.

Awareness-raising initiatives (e.g. on antimicrobial stewardship and infection prevention and control), communication and enforcement of the legislation by the competent authorities and individual benchmarking reports of both veterinarians and farmers remain the cornerstones of the national AMR policy.

The AMCRA Vision 2024 was developed in 2019 following the end of the first reduction plan in 2020. The goal was to reduce antibiotic use in all animal species and by all veterinarians to a minimum. To this end, the limits of what constitutes responsible use have been defined. This vision is followed by the Vision 2030, defining the objectives and actions for sustainable and rational use of antibiotics in Belgium until 2030, starting from a 'One World, One Health, One Welfare' approach.

Bulgaria

National distribution system for VMPs

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

National system for collection of data on use of antimicrobial medicinal products in animals

A new web-based system has been developed – AMRTool – for the collection of antimicrobials sales and use data. The use data providers are the veterinary practitioners working at veterinary practices, being the only professionals in Bulgaria allowed to use and prescribe antimicrobials in animals. Such single data source prevents the risk of double reporting of the antimicrobial used data. There are no differences in the use data collection systems between the different use species. For this reason, the same use data coverage is estimated for cattle, pigs, chickens and turkeys. All use data have been collected as packages used at veterinary practitioners level.

National antimicrobial resistance policies and initiatives

In Bulgaria, under the One Health approach, a National Program for Action against Antimicrobial Resistance for the period 2023-2027 has been prepared and is still waiting approval by the Council of Ministers. The Program is based on the EU One Health Action plan and the applicable guidelines for responsible use of antimicrobials, within the context of the WHO One Health approach. The programme is addressing the interconnected problems in human and animal health, and environmental protection. In this context, the Bulgarian Food Safety Agency (BFSA) carries out surveillance of resistance, consumption and control of antibiotic sales in animals and prepares annual reports to the European Food Safety Authority (EFSA) and the European Medicines Agency (EMA). A council of Experts has been established in the BFSA to coordinate the implementation of the action plan in the veterinary and

food sectors. Periodical meetings with representatives of the veterinary pharmaceutical industry, farmers organisations and the Bulgarian Veterinary Union are organised and held by the BFSA, where issues related to the risks and responsibilities related to AMR are discussed. In the meetings/trainings of the inspectors from the BFSA, responsible for the control of the sales and use of VMPs, topics related to the risks of AMR and the rules for the legal and prudent use of antimicrobial products are always included. The Veterinary activity law was amended in 2024 in order to allow proper implementation of Regulation (EU) 2019/6.

Croatia

National distribution system for VMPs

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 and from veterinary pharmacies.

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

National system for collection of data on use of antimicrobial medicinal products in animals

Veterinarian organisations and veterinarians from clinics and stations report data to the national competent authority. The same system is used to collect use data for the different animal species and categories, with data collected at the package level.

National antimicrobial resistance policies and initiatives

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. Sales data for veterinary antimicrobial agents are obtained each year from the authorised wholesalers. All veterinary organisations receive a call for data on the use of antimicrobials. Deadlines and templates are respected and only EMA guidance and national requirements are followed. Frequent trainings for veterinarians and farmers are carried out at all levels. It is done in accordance with AMR national plan of Ministry of Health.

Cyprus

National distribution system for VMPs

In Cyprus, all VMPs containing antimicrobials are prescription-only medicines and are dispensed exclusively through pharmacies or veterinary clinics. Veterinarians are permitted to administer VMPs only to animals under their direct personal responsibility. The supply of VMPs to pharmacies and veterinary clinics is managed by authorised wholesalers.

Medicated feeding stuffs containing antimicrobials are produced strictly on a prescription basis and may only be manufactured by authorised feed mills. Whether produced domestically or imported, these feeding stuffs are distributed by approved suppliers and can only be administered under a veterinarian's prescription.

National system for collection of data on use of antimicrobial medicinal products in animals

As Cyprus' electronic prescription system is not yet fully operational, data on the use of antimicrobial medicinal products in animals is currently collected from retailers and veterinary records. However, due to the system's limitations, data cannot yet be categorised by specific animal species. Additionally, usage data is collected only in terms of antimicrobial product packages.

National antimicrobial resistance policies and initiatives

A farm incentive program to reduce antibiotic use was first introduced for pig farming and is planned to expand to poultry. Under Cyprus' Strategic Plan for the Common Agricultural Policy (CAP) 2023–2027, subsidies are provided to pig farmers to lower antimicrobial use. Approved by the European Commission on December 8, 2022, the plan launched Intervention A.A.1.5 in 2023, attracting significant interest. This three-year program (2023–2025) promotes biosecurity, disease prevention, and alternative treatments to reduce antimicrobial dependence.

A new national AMR plan is being developed by a specialised committee within the Veterinary Services of the Ministry of Agriculture, with completion expected in 2025. The existing AMR plan, first approved in 2018, will be revised in 2025. This five-year plan includes:

- Awareness campaigns
- Infection prevention measures in food-producing animals
- Controls on critically important antimicrobials for human medicine
- Recommendations for responsible antimicrobial use, aligned with guidance from the European Commission.

Recent measures and the AMR action plan have contributed to a steady decline in both antimicrobial sales and usage in recent years.

Cyprus' National Strategic Plan to Combat Antimicrobial Resistance was published in December 2012 by the Ministry of Health, following the One Health approach. Managed by the National Committee on Antibiotics, the plan primarily focuses on human health but includes veterinary measures such as improving antibiotic diagnostics and promoting prudent use in animals. The plan is currently under revision, with a stronger emphasis expected on the veterinary sector.

Parallel updates and improvements will continue in alignment with EU and WOAH guidelines.

Czechia

National distribution system for VMPs

In Czechia, all VMPs containing antimicrobial agents are prescription-only medicines. This includes medicated feeding stuffs manufactured mostly from medicated premixes containing antimicrobials or, since 2022, other VMPs as indicated by the Regulation (EU) 2016/4. Wholesalers can sell antimicrobial VMPs to five different groups/recipients: 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 Czech 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 Medicines.

National system for collection of data on use of antimicrobial medicinal products in animals

Delivery notes are used as data source for antimicrobial use data collection for the species in the first step of the stepwise approach as per legislation (i.e. cattle, pigs, chickens, turkeys). Veterinarians indicate the exact species and category for which the VMP is intended to be used in their practices when ordering the VMPs. Delivery notes are sent to the national competent authority for completing of the national statistics and validation.

National antimicrobial resistance policies and initiatives

In Czechia, by working with the sales data at national level until end of 2023, a multifaceted approach has been established consisting of: a) the National Action plans on AMR (1st, 2nd, and drafted 3rd – including setting targets considering datasets collected via ESVAC (until 2022) and via ASU methodologies (recently); b) the long term National policy on AMR; c) the amendment of national legislative – Act on pharmaceuticals; d) specific measures tailored for individual sectors, e.g. an improved vaccination programme in pigs, farm software of diseases/use of VMPs (not only antimicrobial) in cattle; e) pig, poultry, cattle: guidelines on 1st, 2nd, 3rd choice of antimicrobials, considering AMEG classification.

Use data collection started in 2023 and allows the setting of more detailed targets for major food-producing species, especially for AMEG B antimicrobials within the 3rd National Action plan on AMR. Use data allows monitoring of trends in antimicrobials use in correlation with improved vaccination programmes in the pig sector. New and more precise use data in cattle categories allows better monitoring of antimicrobial trends, especially intramammary and injectable products used mainly in dairy cattle comparing for example to the total sales of non-antimicrobial teat sealants and vaccines covering mastitis indication. It is expected, together with the new scoring system for DC treatment (dairy cattle), to help further reduce and work on qualitative parameters of antimicrobial use in dairy sector.

As noted above, targets based on ASU data have been set for the National AMR Strategy (enforced by the 3rd National Action plan on AMR). Legislation e.g. Act on Pharmaceuticals (in the wording of 314/2022 Col.) enforces national rules for 'prudent use regimen' for VMPs containing fluoroquinolones, 3rd- and 4th-generation cephalosporins, rifaximin, and selected aminoglycosides (according to the Art. 107(7) of Regulation (EU) 2019/6 on VMPs). Use per species/categories datasets also helps to create: a) better tailored risk assessment for the plan of residue monitoring; b) targeted trainings and workshops for veterinarians and agriculture specialists (pre- and post-graduate), farmers and other professionals in the animal sector (e.g. dairy sector and beef meat production sector); d) planning and execution of projects targeted to environmental studies of fate of antimicrobials and AMR; d) One Health information campaigns for professionals and the general public together with communication with the press that ensure exchange of more specific information and awareness building.

Denmark

National distribution system for VMPs

The VMPs are sold by MAHs to wholesalers that may also import and export VMPs. All antimicrobial VMPs exit the distribution system through pharmacies as they are all subject to prescription.

Pharmacies may sell premixes to producers of medicated feed. This sale is also considered an exit from the distribution system even though there is one final sale of the finished medicated feed to the farmer – the sale of a premix to a producer of medicated feed requires a prescription by a veterinarian. The prescription should specify the animal stock in which the medicated feed must be used.

National system for collection of data on use of antimicrobial medicinal products in animals

Since 2000 VetStat has been collected use data based on sales from pharmacy for use in practice and farms as well as sales from feed mills for use on farms, and from veterinarians for use in practice on production animals. These data combined result in the data reported to ASU. VetStat collects data based on the information given on prescription and reported based on legal obligations. This includes information like product ID, Vet ID, Pharmacy/feed mill ID, receiver information, animal species and age group, as well as disease code. The reported use data is collected from approximately 470 veterinarians treating production animals, and approximately 580 pharmacies. Data collected in VetStat do not support the data reporting to ASU without minor modelling. Data modelling includes mapping between Nordic Product ID and UPD-ID and re-grouping of data reported to VetStat on age groups to correspond with ASU animal group based on farm production information collected in our Central Husbandry Register (CHR) system.

National antimicrobial resistance policies and initiatives

There are no initiatives specifically targeting the sale of antimicrobial VMPs. The products may be distributed and sold only by authorised companies, the antimicrobial products are all subject to prescription, and all pharmacies (the only entities authorised to sell antimicrobial VMPs) are subject to the requirement of reporting on the volume of sales to the Danish Health Data Authority that is responsible for national statistics of sales of medicinal products in Denmark.

In order to promote prudent and reduced use of antimicrobials in animals the Danish Veterinary and Food Administration (DVFA) has produced guidelines for use of antimicrobials in pigs and cattle. Furthermore, the Yellow Card initiative has been in place since 2011, sanctioning pig producers with high antimicrobial usage. Universities and the national Medical Institute collaborate with the DVFA to monitor antimicrobial use, which results in political decisions e.g. an AMR action plan and working towards an 8% reduction in antimicrobial usage for pigs.

More information (currently only available in Danish) on the yellow card initiative and the National Action Plan Against Antimicrobial Resistance in Animals and Food can be found here.

Estonia

National distribution system for VMPs

In Estonia, antimicrobial VMPs are prescription-only medicines. VMPs are supplied by wholesalers and must be dispensed through pharmacies (general and veterinary) and veterinarians. The sales data is collected in packages by the State Agency of Medicines. In order to avoid double reporting, only sales from wholesalers to the general public, hospitals, veterinary pharmacies and veterinarians are taken into account.

National system for collection of data on use of antimicrobial medicinal products in animals

A veterinary database for veterinarians to report their use of all antimicrobials was created by the Agriculture and Food Board. The use data collection system is the same for all species. The use data is collected in units (ml, g etc) and then calculated to packages.

The sales data is collected in packages by the State Agency of Medicines.

National antimicrobial resistance policies and initiatives

The national action plan for the reduction of antimicrobial resistance is updated regularly. The current AMR action plan is effective for 2024-2030. Since 2021, the use of antimicrobials is regulated with strong recommendations to avoid 3rd-and 4th-generation cephalosporins for the treatment of food-producing animals, and antimicrobial sensitivity testing prior to use is mandatory.

In Estonia, all wholesalers are required to report the sales of human and VMPs to the State Agency of Medicines under the Medicinal Products Act of 2005. Since 2006 the Estonian State Agency of Medicines has been collecting drug use data nationally for human and veterinary medicines at package level, covering 100% of the market. The data is analysed according to the WHO ATC/ DDD and ATCvet methodology, as well as mg/PCU-methodology for veterinary medicines. The results are published on the website and in the Statistical Yearbook of the Estonian State Agency of Medicines each year.

Finland

National distribution system for VMPs

In Finland antimicrobial VMPs 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 and always require a prescription from a veterinarian.

National system for collection of data on use of antimicrobial medicinal products in animals

Most part of the data is transferred directly from the veterinary practise management systems. Around 10-15 % of the data is recorded by the veterinarians into their user interface, made available by the Finnish Food Authority.

National antimicrobial resistance policies and initiatives

The use of antimicrobials has always been relatively low in Finland. This is due to several historical reasons and political decisions. An overview of the major strategic actions implemented since 1949 is available on the Finnish Food Authority website.

For decades, the key policy objective in Finland has been to reduce the need for antibiotic treatment in animals by eradicating animal diseases, using biosecurity measures and efficient herd health programmes to achieve good animal health. If antibiotics are needed, they should be used prudently, in accordance with the national prudent use guidelines. Old narrow spectrum antibiotics for individual patients is at the heart of these principles.

A new strategic part of AMR national action plan for 2024-2028 was published in 2024 in which recommendations for the use of antimicrobials in animals are under revision. The recommendations

were published for the first time in 1996 and this will be the fourth edition. Special legislation on the use of antimicrobials in animals is in place e.g. the use of certain critically important antimicrobials in animals is restricted. The prudent use of antimicrobials is included in veterinary education.

France

National distribution system for VMPs

In France, all antimicrobial VMPs are only available on prescription, either from pharmacies or directly from veterinarians. Pharmacies and veterinarians are supplied by wholesalers. Medicated feed is produced by feed mills and requires a prescription from a veterinarian.

National system for collection of data on use of antimicrobial medicinal products in animals

An IT system called Calypso was launched in March 2023 to connect veterinarians to the French ministry of agriculture. One of the aims is to collect antimicrobial medicines prescription/delivery data from veterinarians, pharmacists, and feed-mill manufacturers. The data collection covers all animal species from 2023. Since 4 April 2023, veterinarians have been able to transmit data on antimicrobial use via a data flow between their management software and Calypso, provided that the management software used supports this feature (automatic transmission of data to Calypso is only possible with approved software). Several software packages are approved, and approval is under way for others. Feed mills have the possibility to report their data on antimicrobial use by uploading a pre-formatted Excel spreadsheet to the Calypso application, or by using the application to declare no sales. As some veterinarians and pharmacists have no prescription or sales management software, a module for manual entry of antimicrobial prescriptions and deliveries was developed and has been available since October 2023. Deconditioning of antimicrobial VMPs has been managed at package level. The quantity of antimicrobials used in medicated feed was converted into the number of premix packages.

National antimicrobial resistance policies and initiatives

The large decrease in antibiotics used in animals in France is the result of collective action by all stakeholders. The decrease began with the implementation of the first French action plan 'EcoAntibio' in 2011. A decree was published in 2016 to regulate prescribing of 3rd- and 4th generation cephalosporins and fluoroquinolones. The second action plan set the goal of a 50% reduction in exposure to colistin in the cattle, pig and poultry sectors over 5 years. Various factors have contributed to the remarkable reductions of antibiotic sales compared to 2011 (in mg/PCU): -65% for the overall sales and reductions of between 83% and 95% for classes in AMEG category B 'restrict'. The entry into force of the European Regulation in January 2022 had an important impact on the sales of antimicrobials in France. Between 2021 and 2022, sales of antibiotic VMPs decreased by 25%. In 2021, premixes accounted for 28.0% of the total sales in France, whereas in 2022 premix sales accounted for 6.7%. Sales of antibiotic VMPs increased by 1.5% between 2022 and 2023, with sales of powders and oral solutions increasing.

Since 2011, thanks to the strong involvement of stakeholders in France, the objectives of the two Ecoantibio action plans have been largely achieved. The main actions of the plans were aimed at developing measures to prevent infectious diseases and facilitate the use of alternative treatments; communicating and training on the challenges of combating antibiotic resistance and on the prudent prescription of antibiotics. Several treatment guidelines have been regularly updated, addressing treatment of both food-producing and companion animals. Launched in November 2023, Écoantibio 3 action plan aims to maintain current good levels of exposure of farm animals to antibiotics and to

reduce the exposure of dogs and cats by 15% within five years. It also promotes the rational use of other antimicrobials and antiparasitics. In September 2024 a new Interministerial roadmap was published, which aims to structure existing resources in order to take greater account of and implement a One Health approach.

Germany

National distribution system for VMPs

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

National system for collection of data on use of antimicrobial medicinal products in animals

In Germany, data on the use, supply and prescription of antimicrobial medicinal products in animals are reported by practising veterinarians. This is regulated and laid down in national legislation by the Law on VMPs of 27 September 2021, as amended by Article 1 of the Ordinance of 14 March 2024. An existing software system — comprising frontend, database, APIs and business logic — deriving from the previous national benchmarking system for antibiotic use was extended for the collection of use data. This system has been in use since 2014 and has been adapted to the new requirements. Reports are based on the records kept by the veterinarians and have to be submitted electronically. It is possible to enter data into the system manually by means of web-based forms supported by drop-down menus for usage of controlled vocabulary, to transfer data directly from the practice management software to the database using the provided APIs, or to upload data as csv files in defined formatting. The latter option was implemented by software manufacturers during the reporting phase and is not yet available for all practice management software. The reports from the veterinarians contain information at treatment-level and have to be assigned to an animal category, a half-year, a product and a pack size. The amount of used product is reported in ml, l, mg, g, kg, tablet or piece (syringes e.g.) and is converted to number of packs by BVL, the data processing authority, based on data provided by the German medicinal product database.

National antimicrobial resistance policies and initiatives

An important component related to AMR topic is the German Antibiotic Resistance Strategy “DART 2030”. It was adopted in April 2023 and is intended to build on the results of the previous strategy "DART 2020" in six fields of action. As a national action plan, DART supports the Global Action Plan on AMR which was launched by the WHO and was developed back in 2008. Germany supports the EU's efforts to becoming a best-practice region.

Article 57 of Regulation (EU) 2019/6 is being implemented in conjunction with the national Veterinary Medicinal Products Act (Tierarzneimittelgesetz TAMG). It regulates the collection of sales data (§ 45 para. 6 TAMG) and use data (§ 56 TAMG) as well as a benchmarking system (§§ 57-59 TAMG). The collection and reporting of sales data have been implemented at national level in Germany since 2011. A benchmarking system for the recording of use of antibiotic VMPs in fattening animals was established in 2014. In 2023 it was extended to cover other food-producing animals like laying hens and dairy cows (§ 57 veterinary medicinal products act). Since 2023, use data is also collected for farm animals.

There are further regulations for veterinarians to promote proper use and to limit unnecessary use of antibiotics. On 1 March 2018, the 2nd Amendment of the Veterinary Pharmacies Prescription Regulation came into force. It aims at addressing the issue of antimicrobial resistance by optimising therapy. Among other things, susceptibility testing was made mandatory for the use of 3rd and 4th generation cephalosporins and fluoroquinolones.

In addition to the legal requirements, efforts are being made to raise awareness of AMR in Germany. For example, the Federal Association of Practicing Veterinarians has published guidelines on the responsible use of antibiotics, and awareness campaigns are in place.

Greece

National distribution system for VMPs

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

National system for collection of data on use of antimicrobial medicinal products in animals

The electronic system for veterinary e-prescribing is operational since 1 January 2025. Until then the data was collected from the farm treatment registers.

National antimicrobial resistance policies and initiatives

The antimicrobial sales and use data monitoring has improved surveillance of AMR, while the annual reports are useful tools for public policy making. Consequently actions should be taken towards a more harmonised approach to secure the quality of data in all Member States, engaging all stakeholders.

Greece operates an AMR surveillance framework, engaged on developing public policies and actions towards the reduced consumption of antibiotics, enhanced awareness and the development of alternative therapeutic methods for microbial infections. The main partners of the framework are the Ministry of Health, the Ministry of Agriculture, the Greek National Organization for Medicines, the National Public Health Organization and academic institutes.

National action plans regarding AMR are published towards a versatile One Health approach, including actions in both veterinary and human medicine sectors. Some of the actions described in the national action plan on antimicrobial resistance are implemented, such as strict prescription for all drugs. There is also a strict legislative framework for the supply and use of antibiotics in food-producing animals. There are guidelines for the prudent use in animals and the restriction of antibiotics of critical importance to humans. With the implementation of the electronic prescription of veterinary medicines, it is expected that the surveillance of antibiotic sales and use will be significantly enhanced towards a more efficient controlling of AMR.

Hungary

National distribution system for VMPs

In Hungary, all VMPs that contain antimicrobials are prescription-only medicines. All VMPs must be dispensed through authorised retailers, which are only supplied by authorised wholesalers. Wholesalers

are authorised by the county government office; retailers are authorised by the district government office.

Antimicrobial VMPs can be bought from a wholesaler by other wholesalers, retailers, veterinarians, farmers or feed mills. Animal farms can only be supplied by retailers. All VMPs must be tracked and documented in order 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, in the same way as nationally produced medicated feeds. The import of medicated feeds is supervised by the office that authorises importers and distributors.

National system for collection of data on use of antimicrobial medicinal products in animals

The national data collection system at the main website of the Hungarian National Food Chain Safety Office (Nébih/NFCSO) is linked to the national product database (daily synchronisation). Veterinarians can use their personal account to log in. They report use data monthly. It is also possible to send data via API connection from farm management software.

National antimicrobial resistance policies and initiatives

In Hungary a legislation amendment was passed (in 2021) by the Agricultural Ministry to encourage the prudent use of antimicrobials in food-producing animals.

Since 1st of January 2024 veterinarians can prescribe antibiotics to food-producing animals only with a specific certificate. They should complete a 2-day training and pass an exam to acquire a 5-year legitimacy for prescription. Antimicrobial VMPs can only be prescribed for food-producing animals for a maximum of 7 days if the product is administered by the animals' owner / keeper. Farm level resistance examinations are mandatory if the use of any AMEG B category antibiotics is planned. The efficacy of any antibiotic treatment administered to food-producing animals should be checked by the responsible veterinarian during an on-site clinical examination. Common agricultural policy (CAP) funds are also available in Hungary to support the examinations. The prophylactic use of VMPs containing 3rd- and 4th-generation cephalosporins, fluoroquinolones and colistin is prohibited for food-producing animals.

Every large farm needs to perform a 'Plan for reduction of antibiotic use', which must be reviewed annually. On-site targeted inspections have been performed annually since 2023 at randomly selected livestock farms. Treatment logbooks and the 'Plan for reduction of antibiotic use' are checked during inspections.

The experts of the national competent authority make efforts to give presentations about the reporting system and the prudent use of antibiotics to farmers and veterinarians at professional forums. Online trainings are organised annually to help wholesalers to report sales data and a functional e-mail address is available for related questions.

Iceland

National distribution system for VMPs

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. Wholesalers in Iceland are mandated to provide sales statistics for both human and VMPs, as well as for medicated feeding stuffs, to the Icelandic Medicines Agency. The data on sales of veterinary antimicrobial agents at package level are provided by wholesalers in Iceland, of which there are only two that sell VMPs.

National system for collection of data on use of antimicrobial medicinal products in animals

For pigs, chickens and turkeys there is no electronic system to collect the data. In those animal species the number of farms is small and there are few veterinarians servicing those farms. To acquire information on use of antimicrobial medicinal products for pigs the veterinarians who are servicing the pig farms are contacted each year and asked to report on the use of antimicrobial medicinal products for pigs. In the case of chickens and turkeys the farmers are contacted each year and asked to confirm that there has been no use of antimicrobial medicinal products for chicken and turkeys, or to report the use if there has been any. For cattle there is a database where veterinarians register the use of medicines for cattle. Farmers have access to this information for their farm in their electronic herd book systems, where they also register their own use of medicines.

National antimicrobial resistance policies and initiatives

In recent years the use of antimicrobials in Iceland has been low. This is due to multiple factors, including good animal health status in Iceland. Also factoring in is the 2001 medicinal policy of the Icelandic veterinary association which includes prudent selection of antimicrobials, emphasis on preventive measures other than medicinal use and the diagnosis by veterinarians before the use of antimicrobials. Rules stating that antimicrobials can only be used when a veterinarian has made a diagnosis were set in Iceland in the year 2000. In recent years general awareness on AMR and the importance of prudent use has grown which is probably a factor of general reduction in sales of antimicrobials. Aquaculture has increased a lot in recent years, with biomass increasing nine-fold between 2011 and 2023, which affects the mg/kg animal analysis. Over the same period there were no antimicrobials used in aquaculture until the fall of 2021 and the following years in one fish farm, which contributed to an overall increase of antimicrobial use in Iceland.

A proposal for a cross-sectional, One Health approach AMR NAP with budget estimation is available. Currently, the budget estimate is under evaluation and the NAP will be published in 2025. A monitoring and evaluation plan is under development.

Ireland

National distribution system for VMPs

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 (DFAM). The products can be dispensed by either a veterinarian or a pharmacist, with the exception of intramammary antimicrobial substances, which can be dispensed by licensed retailers. Medicated feeds containing antimicrobials are prepared from authorised premixes, under veterinary prescription. They are incorporated into the feed by licenced feed mills or on-farm mixers. 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.

National system for collection of data on use of antimicrobial medicinal products in animals

The current sources of data are collected from the pig and poultry sector. The pig usage data is collected from end user data from the national pig AMU database, which all farmers are requested to submit on a quarterly basis. The poultry data is supplied by a small number of veterinary practices providing services to the poultry industry. DAFM receives anonymised, bulk data which is then re-formatted into the ASU template.

National antimicrobial resistance policies and initiatives

The establishment in 2019 of a national database to record farm level antibiotic usage on commercial pig farms (AMU pig) has allowed farmers to benchmark their antimicrobial use (AMU) against the national average and coupled with the legislative changes brought about under EU 2019/6 and 2019/4, has helped drive behavioural change and a reduction in the volume of antibiotics used in the pig sector, in particular premixes delivered in feed. Similarly, the national mastitis control programme Cellcheck has prompted an overall improvement in udder health in recent years and promoted a move towards selective dry cow strategies with a knock-on reduction in the sales and use of dry cow intramammary tubes. There are many other initiatives at national level which focus on the control and eradication of diseases such as BVD, IBR, Salmonella and Johnes and improved animal welfare, with enhanced benefits in terms of improved animal health and a reduction in AMU. National policies such as the National Farmed Animal Biosecurity Strategy and Food Vision 2030 and the National Farmed Animal Biosecurity Strategy (2021-2024) also promote improved animal health and reduced AMU levels. Communication, education and awareness resources aimed at farmers and practicing veterinarians focusing on the issue of reducing HPCIA use have been of benefit, based on year-on-year sales trends.

Ireland's second One Health National Action Plan on AMR 2021-2025 (INAP2) is currently in place building on Ireland's first NAP on AMR which ran from 2017-2020. INAP has fostered collaboration between stakeholders from across the Agrifood sector through the establishment of an Animal Health Implementation Committee which oversees the delivery of all actions under the 5 WHO strategic objectives. These centre around raising knowledge and awareness of AMR, improving Surveillance of AMR/AMU, reducing Disease and improving animal health, optimising the use of antimicrobials and promoting research and new innovations to tackle AMR.

Italy

National distribution system for VMPs

In Italy, antimicrobial agents for use in animals are prescription-only medicines. Since April 2019, electronic veterinary prescriptions are mandatory. The sale of veterinary medicines (including antimicrobial agents) on Italian territory may take place as described below.

Direct sale of VMPs

Holders of authorised wholesale veterinary medicine storage premises may, with additional authorisation from the local competent authority, also sell VMPs to veterinarians and veterinary care facilities, breeders and pet owners. This category of transaction also includes the sale of premixes for medicated feed by MAHs, wholesalers 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 only by electronic veterinary prescription.

Retailing of VMPs

The retail sale of VMPs containing antibiotics can only take place at pharmacies, upon presentation of an electronic veterinary prescription, and 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 of AMEG category B and antibiotics in the form of medicated feed or veterinary drugs administered in feed, water or liquid feed, except for small quantities which must not exceed a treatment period of five 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.

National system for collection of data on use of antimicrobial medicinal products in animals

The national IT system for VMP traceability enables the tracking of the quantities of medicines administered to all food-producing animals, including those in medicated feed. Since 2022, it has been mandatory to electronically record all medicines administered to animals intended for food production. The use data have been collected as units of antibiotics used and then calculated to packages.

National antimicrobial resistance policies and initiatives

Since 2019, Italy has implemented a mandatory computerised system for the traceability of VMPs and medicated feed, which includes electronic veterinary prescriptions and electronic records maintained by owners and keepers of food-producing animals. This initiative has contributed to a significant decrease in sales. However, the 2023 data do not show the same trend of reduction, and some errors and quality issues are being addressed.

The AMR National Plan, which fully integrates the veterinary strategy, includes guidelines on the prudent use of antimicrobials for rabbits, pigs, cattle, and companion animals, with ongoing work for poultry and aquaculture. Additionally, the national IT system for VMP traceability continues to support efforts, alongside training and communication campaigns on antimicrobial resistance (AMR) and the prudent use of antimicrobial.

The national action plan can be found here.

The national report can be found here.

Latvia

National distribution system for VMPs

VMPs in Latvia are distributed by manufacturers and importers of VMPs, wholesalers, pharmacies and veterinary pharmacies and veterinary practices. Veterinary practices, pharmacies and licenced farms purchase VMPs from wholesalers while other consumers (natural and legal persons) can only purchase them from pharmacies and/or veterinary practices. VMPs for licensed farms must be ordered by a veterinarian contracted to provide routine healthcare services. Other institutions (educational, scientific and research institutions, competent state institutions) purchase VMPs from wholesalers. Distribution

or any kind of operations with veterinary narcotic and psychotropic medicines is determined as a special condition that is permitted only by special licences issued by the State Agency of Medicines (Agency in charge of human medicines). VMPs from a country that is not a member of the EU or a country of the EEA may be imported by a merchant who has received a special permit (license) issued by the Food and Veterinary Service.

National system for collection of data on use of antimicrobial medicinal products in animals

The development of the Veterinary Health Information System (eVETIS) for the national data collection of antimicrobial use in Latvia begun in 2021 (no historical data or system available before). A number of different challenges have affected the progress of this work: dealing with technical errors due to data transmission between the national system and the UPD; the data connectivity and compatibility between different IT systems; and, essentially, the adaptation of national legislation. The current status of the eVETIS is in the pilot stage, which means that the system was tested by a small number of main users (veterinarians) and feedback from pilot participants regarding system functionality and usability has been gathered. It is intended that eVETIS will start to collect use data on a larger scale when the national legislation will be adopted. Meanwhile Latvia is facing difficulties in obtaining data for 2023 and is anticipating similar problems for the antimicrobial use data of 2024 as the national regulation is still under development. After carefully assessing limitations of capacity and timing for the veterinarians to report data and ability to process and validate, a shared decision guided by the Ministry of Agriculture of the Republic of Latvia was made to fulfil the data reporting requirements in regard to antimicrobial use data at least for two animal species – chickens and turkeys. Using specifically designed MS Excel forms, veterinarians assigned to animal care at each chicken/turkey facility have provided compiled information about the use of antimicrobial VMPs under their care (at package level). This information has been compared and validated with sales data of 2023 submitted by the wholesalers. Only large and significant chicken or turkey facilities (with total number of animal population) were included in the data collection exercise where the owner handles over 120 broilers or over 500 laying hens.

National antimicrobial resistance policies and initiatives

The Latvian Antimicrobial Resistance Limitation and Precautionary Antibiotic Use Plan 'One Health' (2023–2027) was developed and approved. This plan includes activities such as training of veterinarians and animal owners on AMR issues, expanding AMR monitoring in animals, carrying out regular monitoring of AMR of microorganisms, development of fully automated continuous data collection system for VMPs (including antimicrobial VMPs) used in animals, etc. There are various risk assessment projects underway, for example, a study on the spread of antibacterial agent residues in meat of Latvian origin (2018-2023) and on antimicrobial resistance of zoonotic agents and indicator bacteria in cattle and pig farms in Latvia, etc. The Nord-Balt project BALTOHOP on antimicrobial resistance is ongoing.

Lithuania

National distribution system for VMPs

Wholesalers sell VMPs to veterinarians or veterinary pharmacies. A veterinarian can prescribe and sell a VMP to the animal owner for the course of the treatment.

National system for collection of data on use of antimicrobial medicinal products in animals

A national system for collecting data on the use of antimicrobial medicinal products in animals is in place, but it is not yet fully functional for performing all necessary tasks. While the system can collect some data, further development is required to ensure it meets the full requirements for comprehensive monitoring and reporting.

National antimicrobial resistance policies and initiatives

Key initiatives include:

- National surveillance programs: enhanced surveillance systems have been established to monitor antibiotic use and resistance patterns in food-producing animals and foodstuffs. The data collected help inform policy decisions and progress tracking.
- Veterinarian training: comprehensive training programs for farmers and veterinarians on the risks of AMR and best practices for antibiotic use. Education efforts focus on the importance of adhering to guidelines and exploring non-antibiotic alternatives.
- Education and public awareness campaigns: efforts to raise awareness among consumers about the importance of responsible antibiotic use in agriculture and its impact on public health. Informed consumers can drive demand for antibiotic-free and responsibly produced food. Training programs for stakeholders in agriculture and veterinary medicine on the risks of AMR and strategies for effective antibiotic management
- Promoting antibiotic stewardship: encouraging responsible antibiotic use through guidelines and best practices for farmers and veterinarians. Emphasis on alternatives to antibiotics, such as improved hygiene, vaccination, and biosecurity measures.
- Technological innovation: adoption of IT solutions like precision farming technologies and electronic prescription systems to optimise antibiotic use and enhance farm management practices.
- Regulatory control: strict regulations are in place for governing the prescription and administration of antimicrobials, limiting their use to veterinary supervision.
- International cooperation: Lithuania participates in global efforts, aligning its policy with EU regulations and the World Health Organisation's action plans on antimicrobial resistance.

Luxembourg

National distribution system for VMPs

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.

National system for collection of data on use of antimicrobial medicinal products in animals

Veterinarians report the use of antibiotics by animal species via a web application developed and provided by the Ministry of Agriculture, Viticulture and Rural Development. The data was collected in the corresponding unit, calculated into packages, and then transferred into the appropriate templates.

National antimicrobial resistance policies and initiatives

Luxembourg, although small, faces challenges regarding the use of veterinary antimicrobials. More than 400 antimicrobial medicines are used without a Luxembourgish marketing authorisation, being registered in neighbouring countries. These medicines circulate freely and are commonly imported by veterinarians. Additionally, many veterinarians not registered in Luxembourg cross the border to treat animals with these antimicrobials. This situation complicates the collection of accurate data on actual antimicrobial use, which could lead to an underestimation of their consumption, with a significant portion coming from purchases made abroad.

The Luxembourg National Antibiotics Plan (PNA), in force from 2018 to 2022, aims to reduce antibiotic resistance through a 'One Health' approach. The main actions taken are:

- The establishment of a governance mechanism: setting up a sustainable framework to coordinate efforts against antibiotic resistance, involving actors from human health, animal health and the environment.
- Monitoring and evaluation: creation of a national system for monitoring antibiotic consumption, with performance indicators to assess the effectiveness of the actions taken.
- Partnerships: development of sustainable partnerships with national, European and international organizations to ensure coordination of actions.
- Education and awareness: conducting awareness campaigns on the appropriate use of antibiotics, aimed at informing the general public and health professionals.
- Treatment recommendations: development of recommendations based on a surveillance system to guide veterinarians in the use of antibiotics.
- Training and technical support: creation of working groups to provide technical support in the implementation of PNA activities.
- External evaluation: provision for an external evaluation at the end of the implementation period to measure the results and impact of the actions.

These actions aim to strengthen the fight against antibiotic resistance in Luxembourg and improve public and animal health.

Malta

National distribution system for VMPs

In accordance with Regulation 23 of the Subsidiary Legislation (S.L.) 437.115, VMPs can only be distributed when a wholesale distribution authorisation is acquired from the competent authority. All VMPs that contain antimicrobials are registered as prescription-only medicines. As per Regulation 18 of S.L. 437.115, distribution of VMPs is subject to the holding of an authorisation. As per Regulation 18 of S.L. 437.115, 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 rule 5 of S.L. 437.114 on the Manufacture, Placing on the Market and use of Medicated feed. Authorised medicated feed mills and authorised feed business operators can distribute the finished medicated feed directly to farms.

National system for collection of data on use of antimicrobial medicinal products in animals

Use data is collected from electronic prescriptions but also from paper prescriptions issued by veterinarians. There are no differences in how use data is collected for different use species. However, in some instances use data is collected in different units and then calculated into packages.

National antimicrobial resistance policies and initiatives

- More rigorous data collection on the use and sales of antimicrobials carried out by dedicated staff.
- Extensive information campaigns to stakeholders including farmers, veterinarians and pharmacists.
- Several objectives are in place with regards to the 'Strategy and Action Plan for the Prevention and Containment of Antimicrobial Resistance in Malta 2020 – 2028'. These include changes in legislation/infrastructure, stewardship, surveillance, infection prevention and control, continuous professional development and education, research and performance measurements, international partnerships and collaboration, as well as relevant reporting.

Netherlands

National distribution system for VMPs

In the Netherlands, antimicrobial VMPs are only available on prescription. 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. Veterinarians sell the products directly to animal owners.

National system for collection of data on use of antimicrobial medicinal products in animals

In the Netherlands veterinarians must record antibiotic prescriptions in government assigned databases. Annually, the Netherlands Veterinary Medicines Institute (SDa) receives AM use data from these databases. The data are analysed and described in the SDa reports: https://www.autoriteitdiergeneesmiddelen.nl/en. More information can be found on the SDa Standard Operating Procedure here.

National antimicrobial resistance policies and initiatives

The SDa establishes benchmark values for farmers and veterinarians. Since 2011, antibiotic use (AMU) by livestock farms in the Netherlands has been monitored using the indicator number of defined daily doses animal (DDDA) per animal-year. Farms and veterinarians with AMU or Veterinary Benchmark Indicator (VBI) above the action level benchmark-value are obliged to adapt their use or prescription patterns. Specific studies, per livestock sector, were undertaken to identify critical success factors to guide farmers and veterinarians. The number of monitored sectors is gradually increasing. In 2023, the following sectors were included: dairy cattle, veal calves, other cattle, pigs, broilers, turkeys, laying hens, poultry parents/grandparents, rabbits and goats. The Netherlands have a national antibiotic

policy for animals since 2008 and the latest national action plan was published in June 2024. Every year the government reports to the parliament about the outcomes of the antibiotic policy.

The new national action plan was published in 2024 (in Dutch) here.

Norway

Distribution system for medicinal products

In Norway, all medicinal products for use in animals are prescription-only (except some antiparasitics against ectoparasites in small animals) and are issued by veterinarians and/or by fish health biologists for farmed fish. Medicinal products are dispensed to veterinarians, fish health biologists and animal owners from pharmacies or feed mills (as medicated feed); the latter is only relevant for farmed fish. Pharmacies and feed mills buy their medicinal products from authorised wholesalers.

Data on sales of VMPs at package level are collected from authorised wholesalers and feed mills by the Norwegian Public Health Institute (NPHI) from which the Norwegian Veterinary Institute (NVI) collects data for reporting sales of antimicrobials to the Agency.

System for collection of data on use of antimicrobial medicinal products in animals

The veterinary prescription registry (VetReg) was established for farmed fish in 2011 and for terrestrial animals in 2012. The VetReg database is owned by the Norwegian Food Safety Authority. Reporting to VetReg has, since the beginning, been mandatory by legislation and applies to veterinarians, fish health biologists, pharmacies and feed mills. Feed mills and pharmacies must report data for all medicines dispensed for terrestrial animals and farmed fish, including to veterinarians for use in their practices. Veterinarians are required to report all use of medicines for food-producing animal species (including horses), while it is voluntary to report the use of medicines for companion and fur animals.

Antimicrobial resistance policies and initiatives

In the National Strategy against Antibiotic Resistance (2015-2020), published in 2015, targets for reducing the use of antibiotics were set for terrestrial food-producing animals, companion animals and farmed fish. The aim was to reduce the use of antibiotics in terrestrial food-producing animals by 10% by 2020, and in companion animals by 30% by 2020, both with 2013 as the reference year. For farmed fish the target was that by 2020, the average consumption should be on the same level or lower than the average for the period 2004 to 2014. As a follow up of the national strategy, the Norwegian livestock industry's published and implemented a joint action plan on antimicrobial resistance in 2017. The targets set in this strategy were fully achieved.

The Norwegian Medicines Authority published comprehensive therapeutic guidelines on the use of antibiotics in terrestrial animals already in the late 1990's and these have thereafter been revised regularly.

In 2024, a National One Health Strategy Against Antimicrobial Resistance was published, covering the years 2024-2033. In this strategy, no target for reduction of use of antibacterials in the terrestrial animal or fish farming sector was set; however, it is pointed out that use data from VetReg should be used to evaluate if further reduction is possible.

Poland

National distribution system for VMPs

Most VMPs, including antimicrobial VMPs, are prescription-only medicines and are distributed by wholesalers to veterinarians. Antimicrobial VMPs are only available to animal owners from veterinarians. Veterinarians and medicated feed producers can buy medicated premixes from wholesalers.

National system for collection of data on use of antimicrobial medicinal products in animals

In the first year (2023), data on the use of antibiotics in animals are collected in the form of surveys conducted on farms by veterinary inspectors (interviewers). The surveys are mandatory. Data are collected electronically. Data on the use of antimicrobial VMPs were collected in the form of number of packages used. The data collection system was consistent for all animal species.

National antimicrobial resistance policies and initiatives

By Order No. 46 of the Minister of Agriculture and Rural Development of November 16, 2022, a team was established for combating resistance to antimicrobial agents used in veterinary medicine. Its tasks include preparing positions, opinions, policies, strategies and proposals for solutions regarding resistance to the agents in question. The team is preparing an outline of the national action plan to reduce the risk to animal health and public health related to the use of antimicrobials in veterinary medicine. The plan will include strategic goals that result directly from the applicable EU law, and their implementation is expected to lead to a reduction in the use of antimicrobials in animals, thus preventing the development of antibiotic resistance in both humans and animals. Since 2019, agricultural advisory centres have been conducting regular trainings for farmers on the risk of developing antimicrobial resistance. In 2023, a series of training courses for veterinarians was provided on reducing the use of antibiotics in poultry, cattle and pig farming. Since March 2024, as part of the "Animal Welfare" ecoscheme included in the Strategic Plan for the Common Agricultural Policy for 2023-2027, farmers have been trained in breeding and breeding methods used in animal production, aimed at reducing the use of antibiotics.

Portugal

National distribution system for VMPs

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 VMPs used to treat animals in their care. Premixes are distributed through wholesalers or wholesaler-distributors directly to feed mills. Feed mills only distribute to farmers. Medicated feeds containing antimicrobial premixes must also be prescribed by a veterinarian and can only be manufactured by authorised feed mills.

National system for collection of data on use of antimicrobial medicinal products in animals

Data collected from electronic prescription database platform (PEMV). PEMV is a platform designed for veterinarians, with the purpose of issuing veterinary prescriptions including medicated feed.

National antimicrobial resistance policies and initiatives

Several initiatives are being implemented to promote the prudent use of antimicrobials in animals. Some of the main actions include:

- One Health Project **HubRAM** with 15 partners for the creation of a datahub that aggregates all national information on Big Data in the context of integrated management of surveillance data and monitoring the use of antimicrobials in animals. It seeks to develop platforms that enable data inter-operability on antimicrobial resistance, sharing relevant information with other sectors, including health and the environment. This project includes a strong communication plan that involves workshops and trainings to different target audiences.
- **PEMV (Electronic Veterinary Prescription Platform) implementation in 2022**: This platform was implemented to comply with Regulation (EU) 2019/6, which establishes measures regarding the use of veterinary medicines. PEMV allows veterinarians to issue electronic prescriptions, ensuring better control and monitoring of VMPs.
- The implementation of the **National Action Plan for the Reduction** to promote the prudent use of antimicrobials, eradicating the use of antibiotics to replace poor management practices, and promoting good practices. This national plan under the One Health approach involving the human, veterinary and environment sectors, with an operational plan and measurable objectives based on previous results, was established for 2019–2023 and the sectorial report is available for consultation here.
- Initiatives have been taken, namely voluntary programmes for the reduction of the use of antimicrobials in dairy cattle, rabbits, poultry and the use of colistin in pigs.

Since 2010, the national annual reports monitoring the antimicrobial consumption of VMPs approved for use in food-producing and companion animals are publicly available on the Directorate-General for Food and Veterinary website.

Romania

National distribution system for VMPs

The wholesale distribution of VMPs is carried out only to veterinary pharmacies, units where veterinary medical assistance activities are carried out, veterinary pharmaceutical points, other wholesale distributors of VMPs, the county and municipal food safety departments, national reference veterinary institutes, pharmaceutical research units, VMP manufacturing units, zoos, animal nature reserves, dolphinariums, ministries, town halls/local councils that own animal shelters, associations/ legally established organisations for the protection of animals that own animal shelters, commercial animal holdings and medicated feed producing units. The purchase of VMPs from wholesale distributors is carried out only on the basis of an order note. Animal-owning facilities receiving VMPs, except for ministries or specialised state service structures for safety and public order, must be registered/sanitarily authorised as animal-owning units, according to the legislation in force. The retail sale of VMPs based on medical prescription is carried out only through authorised veterinary pharmacies. Animal owners or keepers may possess and administer those VMPs that are legally

acquired, either by purchase on the basis of a prescription, or by purchase without a prescription, as appropriate, under the supervision of a veterinarian.

National system for collection of data on use of antimicrobial medicinal products in animals

The veterinarians in the territory sent the data to the County Veterinary Sanitary Directorates, which centralised the information at county level (42 counties). These data were then sent to the Institute for Control of Biological Products and Veterinary Medicines, where they were centralised at country level, in order to send them to the EMA.

National antimicrobial resistance policies and initiatives

Data on AMR surveillance in zoonotic bacteria and indicators from animals and food are collected annually by ANSVSA. Usually, the AMR data recorded in veterinary medicine are below the European average according to the outcome indicators of the full susceptibility of bacteria in food-producing animal populations.

In October 2023, the National Strategy 2023-2030 for preventing and limiting healthcare-associated infections and combating the phenomenon of antimicrobial resistance in Romania was approved by Government Decision. The vision of the strategy is to create sustainable premises for improving the health status of the Romanian population in the medium and long term, by preventing and limiting the occurrence of healthcare-associated infections (HAI), reducing the risk associated with AMR and encouraging the judicious use of antibiotics both in human medicine as well as in veterinary medicine.

Slovakia

National distribution system for VMPs

In Slovakia, all VMPs containing antimicrobial agents are prescription-only medicines, including medicated feeding stuffs manufactured from medicated premixes containing antimicrobial agents. There are five categories of receivers of antimicrobial VMPs from wholesalers: wholesalers (when selling to each other), pharmacies, veterinarians, military forces and The State Veterinary and Food Administration (SVFA). 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. The collection of import data is based on a national law on pharmaceuticals: Act. No 362/2011.

National system for collection of data on use of antimicrobial medicinal products in animals

The attending veterinarian is obliged, in accordance with applicable legislation, to record every treatment of animals intended for food production in the treatment logbooks. Subsequently, twice a year, they are obliged to enter the consumption of VMPs according to animal species and category of animal species in the electronic system to the web application on consumption of VMPs according to the animal species provided by the SVFA. Subsequently, the consumption of VMPs by animal species and category is summarised by the central competent authority - SVFA SR. SR is in the final phase of testing the electronic treatment logbooks through a new electronic comprehensive veterinary and food system.

National antimicrobial resistance policies and initiatives

The main initiative of the Slovak Republic is the preparation of the national action plan which, in addition to the principles of prudent use of antimicrobial substances, also includes regular education of

students of veterinary medicine in the field of AMR (provided by the University of Veterinary Medicine and Pharmacy in Košice), private veterinarians (provided by the Chamber of Veterinarians) and state veterinarians (provided by the State Veterinary and Food Administration and Institute for the Education of Veterinary Doctors). The State Veterinary and Food administration, as a competent authority, annually prepares a national training plan for veterinary inspectors and official veterinarians. The educational institute is the Institute for the Education of Veterinary Doctors in Košice ("IVVL"). IVVL Košice is an educational and congress facility of the Ministry of Agriculture and Rural Development of the Slovak Republic primarily focused on the development of human resources.

Slovenia

National distribution system for VMPs

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

National system for collection of data on use of antimicrobial medicinal products in animals

Veterinary organisations must report the use of antimicrobial medicines to The Administration of the Republic of Slovenia for food safety, veterinary sector and plant protection. The legal basis for reporting by veterinary organisations is given in the national Regulation on the Implementation of the Delegated Regulation (EU) regarding requirements for the collection of data on the scope and use of antimicrobial drugs in animals (Official Gazette of the Republic of Slovenia, No. 77/2023).

There are no differences in the use data collection systems between the different species (cattle, pigs, chickens, turkeys).

The use data can be reported as package or as unit. Reports in unit are converted and calculated as packages.

National antimicrobial resistance policies and initiatives

On national level the requirements of the state strategy are met. The Government has adopted the National One Health Strategy for the Management of Microbial Resistance (2019-2024) with an action plan for 2019-2021.

The purpose of the strategy is to ensure cross-sectoral and interinstitutional action to stop or reduce resistance to antimicrobials in the fields of healthcare, veterinary medicine, agriculture and the environment.

Spain

National distribution system for VMPs

In Spain, all VMPs containing antimicrobials are prescription-only medicines. 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).

National system for collection of data on use of antimicrobial medicinal products in animals

ESVAC is the data collection system on volume of sales and use of antimicrobial medicinal products at animal species level. It is a web-based application used by MAHs, pharmacies and retailers to report data on antimicrobials sales and use on a yearly basis. The panel of medicinal products available for reporting are mapped with UPD identifiers. There are two APIs in testing phase that aim to integrate with retailers' systems to eliminate manual reporting. There is an automated process in place that fills in the ASU templates, it validates and adjusts the different editable fields and populates the number of packages sold or used based on the ESVAC data collected for the current year.

National antimicrobial resistance policies and initiatives

The Spanish National Action Plan against AMR (PRAN) started in 2014, coordinated by the Spanish Agency for Medicines and Medical Devices (AEMPS). Ever since, the PRAN is resolutely committed to tackling the growing threat of AMR through a multifaceted strategy. The PRAN advocates for a One Health approach, addressing the problem of antibiotic resistance through six strategic lines of action: surveillance, control, prevention, research, training and communication.

- Surveillance: PRAN monitors antimicrobial use and resistance across human, animal, and environmental health with enhanced systems, identifying trends for targeted interventions.
- Stewardship Programs: these programs promote rational antimicrobial use, reducing unnecessary prescriptions and supporting alternative treatments.
- Infection Prevention (IP): Initiatives improve hygiene, vaccination, and biosecurity from a One Health perspective, reducing antibiotic use, hence, reducing the appearance of resistant pathogens.
- Research: PRAN supports academia, European, and global partners for innovative solutions against AMR.
- Training: Training programs targeting healthcare providers, veterinarians, and farmers at all stages of their professional life on antimicrobial use.
- Communication and awareness: Communication aimed at the public and specific population groups with public campaigns raising awareness about the AMR risks. To raise awareness of the problem of antibiotic resistance and contribute to the prudent use of antibiotics.

Spain's national policy framework to combat antimicrobial resistance and ensure the responsible use of antimicrobials in animals is robust and multifaceted. Key elements include:

- Legislation and Guidelines: Strict laws govern veterinary antimicrobial use, guiding veterinarians and farmers to use antibiotics sparingly and effectively.
- Monitoring and Surveillance: Continuous monitoring tracks antimicrobial use and resistance in animals, informing policy decisions and evaluating interventions.
- Good Agricultural Practices (GAP): Promoting best practices in animal husbandry reduces antibiotic reliance, emphasizing nutrition, housing, and vaccination for improved animal health.

- Reduction Programs: Incentives encourage farmers to minimise antibiotic use by category, reducing AMR risks.
- Veterinary Stewardship: Educational programs educate on stewardship principles, emphasising accurate diagnosis and appropriate antibiotic use.
- Public-Private Partnerships: Collaborations promote antibiotic alternatives like probiotics and biosecurity measures.

Spain's comprehensive PRAN strategy, aligned with One Health principles, positions it as a proactive leader in combating AMR, fostering cross-sector collaboration and ongoing adaptation to address evolving challenges.

Sweden

National distribution system for VMPs

In Sweden, antimicrobial VMPs may only be sold on prescription or on requisition by a veterinarian. VMPs and HMPs for use in animals can only be dispensed by pharmacies, which are supplied by drug wholesalers or MAHs. Feed mills in Sweden may only mix antimicrobial VMPs in feed if they are controlled and authorised by the Swedish Board of Agriculture (SBA) and they may only buy VMPs from pharmacies. 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 SBA has controlled and authorised the establishment for this purpose. In such cases, the premix is purchased on prescription and dispensed by a pharmacy. Medicated feed for fish is traded from Norway and Denmark, and VMPs mixed in the feed are acquired in the country of origin.

National system for collection of data on use of antimicrobial medicinal products in animals

The base model for Sweden's system for collection of use data is that veterinarians submit the actual amount of product used, in the unit for package size given in the product database of the Swedish eHealth Agency. The amount is then calculated to number of packages before reporting to EMA.

Veterinarians submit the information to SBA in one of two ways:

1. Via a system for record keeping that continuously transfers data to an SBA database.
2. Via SBA's e-service for reporting antimicrobial medicinal products.

Veterinarians may submit either the amount of medicinal product used for each treatment or group of treatments, or the total amount used each month. When submitting, the amount of medicinal product used is divided between the following three categories:

1. Amount used by the veterinarian in connection with a visit or left with the animal keeper to use for a specific treatment until a prescription can be collected from a pharmacy.
2. Amount prescribed for a specific treatment.
3. Amount used at a farm within conditional use of medicinal products, in Swedish: villkorad läkemedelsanvändning (ViLA).

Conditional use of medicinal products (ViLA) means that a veterinarian, under certain conditions and as part of preventive animal health care, can prescribe some medicinal products so that an animal keeper can, according to a signed agreement, treat certain predetermined symptoms without contacting the

veterinarian before each treatment. ViLA is only applicable for farms with cattle, pigs, sheep or goats and there are several legal prerequisites that must be followed. The veterinarian collects information from the farmer about the amounts of VMPs used.

In 2023, the base model was used for cattle, chickens, and turkeys. For pigs an alternative use data collection model was applied, where the number of packages of antimicrobial VMPs prescribed for pigs and dispensed from pharmacies was reported.

National antimicrobial resistance policies and initiatives

In 1986, Sweden stopped using antibiotics as growth promoters. The comparatively favourable situation in Sweden with regards to use of antibiotics and antibiotic resistance are the results of decades of inter-sectorial collaboration. The need for antimicrobials is reduced through, for example, biosecurity, disease-control programmes and optimised management and husbandry. Biosecurity programmes run by animal health organisations contribute to the prevention of spread of animal diseases and zoonotic pathogens. The motto of the work is “Healthy animals do not need antibiotics”

In 2020, the Swedish government updated the strategy on antimicrobial resistance. An inter-sectoral coordinating mechanism was initiated in 2012. In 2023, the group included representatives from 26 authorities and organisations working with the public health, animal, food and environmental sectors. Joint action plans based on the government's objectives are regularly updated and adopted by the group.

Current regulations on the use of antibiotics are in line with the guidance on prudent use: antibiotics should only be used when needed, and the risk of resistance should be considered when prescribing.

In addition to the EU-regulations, national regulations state that mupirocin or rifabutin may not be used for animals. Furthermore, third generation cephalosporins, quinolones and colistin may only be prescribed when other antibiotics are not applicable. There are also legal requirements for Infection prevention and control (IPC) in animal health care.

When antimicrobials are needed, guidance for veterinarians on their prudent use is available. Authorities, academia, professional advisors, veterinarians and farmers all collaborate with the aim of ensuring a continuous improvement of animal health and the prudent use of antimicrobials. More information on Sweden's work against antimicrobial resistance, including the One Health perspective can be found on the websites of the Board of Agriculture, the Swedish Veterinary Agency and the Public Health Agency of Sweden.

Annex 8. Abbreviations and definitions

AMEG categorisation - EMA's antimicrobial categorisation system developed by the Antimicrobial Advice ad hoc Expert Group categorisation and published in 2019. It categorises antimicrobials based on their importance in veterinary medicine, the probability of AMR transfer from animals to humans, and the WHO Critically Important Antimicrobial List for Human Medicine (6th revision).

AMEG category A (avoid) – The category includes those antimicrobials that are not authorised as veterinary medicines in the EU and, consequently, should not be used in food-producing animals but may be given to companion animals under exceptional circumstances[89].

AMEG category B (restrict) - Antimicrobials in this category are critically important in human medicine and use in animals should be restricted to mitigate the risk to public health. These should be considered only when there are no antibiotics in categories C or D that could be clinically effective. Use should be based on antimicrobial susceptibility testing.

AMEG category C (caution) - Antimicrobials that should be considered in the treatment of animals only when there are no antibiotics in category D that could be clinically effective. Alternatives in human medicine exist for antibiotics in this category.

AMEG category D (prudence) - Antimicrobials that are first line treatments in animals, whenever possible. These should always be used prudently, only when medically needed.

AMR - Antimicrobial resistance. It means the ability of micro-organisms to survive or to grow in the presence of a concentration of an antimicrobial agent which is usually sufficient to inhibit or kill micro-organisms of the same species, as per Article 4(11) of Regulation (EU) 2019/6.

Antibiotic - any substance with a direct action on bacteria that is used for treatment or prevention of infections or infectious diseases (Article 4(14) of Regulation (EU) 2019/6).

Antimicrobial - any substance with a direct action on micro-organisms used for treatment or prevention of infections or infectious diseases, including antibiotics, antivirals, antifungals and antiprotozoals (Article 4(12) of Regulation (EU) 2019/6).

ASU Platform – antimicrobial sales and use web interface developed by the Agency to allow MSs to report, validate, verify and amend their data on volume of sales of VMPs, use of antimicrobial medicinal products in animals and animal population data by electronic means and in a timely manner.

ATC - Anatomical Therapeutic Chemical classification system.

ATCvet - Anatomical Therapeutic Chemical classification system for veterinary medicinal products.

CVMP - Committee for Veterinary Medicinal Products.

Denominator (animal biomass) - For the purpose of this document, proxy for the animal population likely to be treated with antimicrobials within a reporting year, expressed as animal biomass (kg) per year and calculated based on a combination of the number of animals slaughtered during the data collection period and of the number of live animals present in a Member State at a given point during the data collection period, multiplied by standardised animal weights.

EC - European Commission.

ECDC - European Centre for Disease Prevention and Control.

[89] Many substances from this category are included in the list of substances reserved for treatment of certain infections in humans, as per Commission Implementing Regulation (EU) 2022/1255.

EEA - European Economic Area.

EFSA - European Food Safety Authority.

EMA - European Medicines Agency.

ESVAC - European Surveillance of Veterinary Antimicrobial Consumption.

EU – European Union.

HMP – Human medicinal product.

Indicators - In the context of this document, a measure of (animal) exposure to antimicrobials; it consists of a numerator derived from sales or use data and a denominator which represents the biomass of animals or the number of animals likely to be treated with antimicrobials in the year for which the data on sales or use are reported.

Mandatory scope – In the context of this report, the mandatory scope refers to the antimicrobial medicinal product's ATCvet (for VMPs) or ATC (for HMPs) codes for which countries must collect and report sales and use data to the Agency, as per Article 1 and Article 3 of Commission Delegated Regulation (EU) 2021/578, respectively. The antimicrobial substances in the medicinal products that fall under the mandatory scope as outlined in the Annex of the delegated act, points 1 and 3, are antibacterials, antiprotozoals with antibacterial effect, intramammary antimycobacterials, and antiinfective agents, all of which have antibiotic activity.

Numerator - In the context of this report, the quantity of antimicrobials sold or used in animals expressed in units of weight of active substance and used for calculation of indicators.

PCU - Population Correction Unit, established as a denominator for the sales data in the ESVAC project 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 and 1 PCU unit is equivalent to 1 kg of animal biomass.

SMS – Substance Management Services (EMA).

SPOR – Substance, Product, Organisation and Reference (SPOR) data management service (EMA).

UPD – Union Product Database.

VMP – Veterinary medicinal product.

Voluntary scope - In the context of this report, the mandatory scope refers to the antimicrobial medicinal product's ATCvet (for VMPs) or ATC (for HMPs) codes for which countries may collect and report sales and use data to the Agency, as per Article 2 and Article 4 of Commission Delegated Regulation (EU) 2021/578, respectively. The antimicrobial substances in the medicinal products that fall under the voluntary scope as outlined in the Annex of the delegated act, points 2 and 4, include antivirals, antifungals, topical antibacterials, antiprotozoals and antiinfectives.

Withdrawal period - The time that must elapse between the last administration of a veterinary medicine and the slaughter or production of food from that animal, to ensure that the food does not contain levels of the medicine that exceed the maximum residue limit.

WHO - World Health Organization.

WOAH - World Organisation for Animal Health.

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