EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Sales of veterinary antimicrobial agents in 26 EU/EEA countries in 2012

Fourth ESVAC report

An agency of the European Union

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

Legal role

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

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

Principal activities

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

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

Guiding principles

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

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Veterinary Medicines Division

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About the European Medicines Agency

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

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

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

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

About the report

This fourth ESVAC report presents data on the sales of veterinary antimicrobial agents from 26 EU/EEA countries, provided at package level according to a standardised protocol and template[1]. This report contains a new chapter describing changes on consumption of veterinary antimicrobials for the years 2010 - 2012 (pages 63-97). Explanations for the possible reasons for the changes have been provided by the ESVAC national contact points from each country. Data from Switzerland are included in Annex 9, as, due to confidentiality issues, data from Switzerland could not be delivered in accordance with the ESVAC data-collection form. This report has special emphasis on food-producing animals.

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

It should be emphasised that the data presented in this report should not be used alone as a basis for setting management priorities, but should always be considered together with data from other sources.

[1] Available from the European Medicines Agency website (www.ema.europa.eu) via Home > Veterinary regulatory > Antimicrobial resistance > European Surveillance of Veterinary Antimicrobial Consumption.

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Summary

A total of 26 European Union (EU)/European Economic Area (EEA) countries submitted to the European Medicines Agency their 2012 data on sales, at package level, of antimicrobial veterinary medicinal products (VMPs), according to a standardised protocol and using a common template. The 26 countries included in the ESVAC 2012 data cover approximately 95% of the food-producing animal population in the EU/EEA area.

Sixteen of the countries obtained the data from wholesalers, six from marketing-authorisation holders, two from both wholesalers and marketing-authorisation holders, and two from pharmacies. In some countries, feed mills provided the data on sales of premixes used in medicated feed.

In 23 of the 26 countries, a legal basis existed for the national competent authority to request data on sales or prescription of veterinary antimicrobial agents from the distributors of such products, while in three countries (France, the Netherlands and Spain), data were provided to the national competent authority voluntarily.

All countries provided sales data or prescription data (Denmark and Sweden) except for two countries that provided purchase data: Hungary for 2010 and Slovakia for 2011 and 2012. For Hungary, the 2010 data represent imports by wholesalers, while the 2011 and 2012 data represent sales from wholesalers to end-users; for Slovakia, data represent imports by wholesalers. Since wholesalers may not sell all the veterinary antimicrobial products the same year as they are imported, sales data for Hungary for 2010 are likely to be overestimated compared to the 2011 data. Similarly, the data for Slovakia are not likely to be fully comparable with those of the other countries.

In order to normalise the sales data for the animal population that can be subjected to treatment with antimicrobial agents, a population correction unit (PCU) was introduced as a proxy for the size of the animal population. Since statistics on numbers of dogs and cats were not available from all countries, these species were not included in the PCU, and therefore tablets, which are almost solely used in companion animals, were excluded from the further analysis of the sales data and the PCU data. Injectable veterinary antimicrobial agents are used in both food-producing and companion animals. Due to the relatively small proportion used in companion animals, in terms of weight of active ingredient, sales of injectable preparations are included in the statistics for food-producing animals.

The national sales data for antimicrobial agents (nominator) cover all food-producing species, including horses, thus the animal population 'at risk' of being treated with antimicrobial agents (denominator) includes all food-producing species. However, the use of antimicrobial agents in the various animal species varies considerably; for example, the use of antimicrobial agents in extensive production systems, e.g. sheep and goats is generally relatively low. Therefore, the interpretation of the data should take into account the distribution of the PCU value between the species in the various countries. It should also be emphasised that the PCU only represents a technical unit of measurement and not a real value for the animal population that could potentially be treated with antimicrobial agents.

The main indicator used in the current report to express the sales is mg active ingredient sold per population correction unit – mg/PCU.

Aggregated by the 26 countries, the sales (mg/PCU) of premixes accounted for 35.5% of the overall sales, while 33.7% were oral powders and 22.3% were oral solutions. The amount accounted by these three pharmaceutical forms varied considerably between the countries. The proportion of antimicrobial VMPs sold as injectable preparations was 7.5%, while 0.7% were intramammaries and 0.3% were oral pastes, bolus and intrauterine preparations.

The distribution of sales of the various antimicrobial classes and subclasses by pharmaceutical form varied considerably between the 26 countries. Overall for the 26 countries, 45.7% of tetracyclines were sold as premixes, 32.9% as oral powders, 18.7% as oral solutions and 2.3% as injectable preparations. For penicillins, premixes accounted for 17.2%, oral powders for 51.3%, oral solutions for 17.8% and injections for 11.9% of the total sales in the 26 countries. For sulfonamides, premixes accounted for 35.6%, oral powders for 35.2%, oral solutions for 23.7% and injections for 4.8%.

Of the sales (in mg/PCU) of 3rd- and 4th-generation cephalosporin preparations, none of the pharmaceutical forms was applicable for group treatment; 85.4% were injectable preparations and 14.6% were intramammary preparations. The proportion of fluoroquinolones sold as oral solution was 80.5% and injections accounted for 19.5% of the sales aggregated by the 26 countries. Premixes accounted for 36.9% of the total sales of macrolides in the 26 countries, oral powders for 25.9%, oral solutions for 30.4% and injectable preparations for 6.6%.

A large difference in the sales, expressed as mg/PCU, was observed between the most- and least-selling countries (range 3.8–396.5 mg/PCU) for 2012. This is in part likely to be due to differences in the composition of the animal population in the various countries (e.g. more pigs than cattle, or a high proportion of veal calves within the cattle population). There may also be considerable variation in terms of daily dose used for the various antimicrobial agents, length of treatment period, or formulations used; this may also in part explain some of the differences between the countries. However, these factors can only partly explain the differences in the sales observed between the 26 countries; other factors also need to be considered. Also, differences in the selection of data source may have an impact, but this is considered to be low.

Of the overall sales in the 26 countries in 2012, the largest proportions, expressed as mg/PCU, were accounted for by tetracyclines (37%), penicillins (22%) and sulfonamides (10%). For the antimicrobial classes belonging to the World Health Organization (WHO) list of critically important antimicrobials (CIAs) with highest priority in human medicine, namely 3rd- and 4th-generation cephalosporins, fluoroquinolones and macrolides, the sales for food-producing animals, including horses, accounted for 0.2%, 1.7% and 8%, respectively, of the total sales in the 26 countries in 2012.

The prescribing patterns of the various antimicrobial classes, expressed as mg/PCU, varied substantially between the countries. In 2012, notable variations between the countries in the proportion of 3rd- and 4th-generation cephalosporins, fluoroquinolones and macrolides sold were observed, with sales ranging from 0.01% to 1.2%, 0.02% to 11% and 0.04% to 17%, respectively.

The variations in prescribing patterns may be due to, for example, differences between countries in the veterinarians' prescribing behaviour, the relative proportion of the various animal species, animal-production systems (e.g. veal as opposed to beef cattle on pasture), the availability of veterinary antimicrobial products on the market, prices, or the general situation with regard to infectious diseases. These factors only partly explain the differences in the sales patterns between the countries.

Of the total numbers of product presentations of antimicrobial VMPs applicable for food-producing animals (including horses) sold in 2012 — i.e. product name, pharmaceutical form, strength and pack size (tablets not included) — 81.6% contained only one active ingredient, 16.5% contained two active ingredients, 1.7% contained three active ingredients and 0.2% contained four active ingredients (these were intramammaries).

For all 26 countries, the proportion of the sales in 2012 (tonnes) of antimicrobial VMPs applicable for group treatment containing two or more active ingredients was relatively low. Of the total sales, 84.4%, 14.9% and 0.7% of these pharmaceutical forms contained one, two and three active ingredients, respectively. However, as it is possible to mix more than one premix/oral powder and oral solution into feed or drinking water, respectively, these data do not provide a reliable estimate of treatment through feed or drinking water with two or more active ingredients.

Important variations between the sales and sales patterns, expressed in tonnes, of veterinary antimicrobial agents used in companion animals (tablets) were observed. This is in particular the case for the sales of tablets with the combination of penicillins + beta-lactamase inhibitors (tonnes of clavulanic acid not included in the data), which varied between 10% and 100% (8 countries) of the total sales of penicillin tablets. Where sales of penicillins + clavulanic acid tablets accounted for 100% of sales of penicillin tablets, it reflects that such combinations are the only penicillin tablets marketed in the country for companion animals. It has to be noted that, in companion animals, human medicinal products containing antimicrobial agents and injectable veterinary medicinal products containing antimicrobial agents may also be used, and thus the data on sales of tablets should be interpreted with great care.

Between 2010 and 2012, a total of 18 of the 20 countries that provided sales data to ESVAC for these years reported a decrease in sales (range 0.4%–49%) expressed as mg/PCU. Overall in those 20 countries, a 14.9% decline in the sales, in mg/PCU, was observed. As the PCU was stable (change -0.6%), the decrease was accounted for by decrease in sales in tonnes active ingredient (15.4%). For 3 of the 4 countries that delivered data for both 2011 and 2012 (but not earlier), a minor decline (range 2-3%) in sales was observed, while for one of the countries an increase of 7% was reported.

Tentative explanations provided by the countries (see Section 2.8.2) for the decline in sales are, among others, implementation of responsible-use campaigns, changes in animal demographics, restrictions of use, increased awareness of the threat of antimicrobial resistance, and/or the setting of targets. Additional detailed information on national programmes and campaigns on the responsible use of antimicrobial agents is needed before conclusions can be drawn on the efficacy of these campaigns in reducing the sales of antimicrobial agents. At the European level, this would provide data for interventions aimed at best practices for the use of antimicrobial agents in animals.

Introduction

Terms of reference from the European Commission

In 2008, the European Council, through the Council conclusions on antimicrobial resistance, called upon the Member States to strengthen surveillance systems and improve data quality on antimicrobial resistance and on consumption of antimicrobial agents within both human and veterinary sectors. In response to the Council conclusions, the European Commission requested the European Medicines Agency to take the lead in the collection of data on sales of veterinary antimicrobial agents in the Member States. In order to guarantee an integrated approach, the Agency was requested to consult the European Centre for Disease Prevention and Control (ECDC), the European Food Safety Authority (EFSA) and the European Community Reference Laboratory for Antimicrobial Resistance (EURL-AMR).

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

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

With regard to the data collection:

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

About ESVAC

Currently, the ESVAC project collects sales data on veterinary antimicrobial agents at package level from the EU Member States and EEA countries. The collection of consumption data by species and the establishment of technical units of measurement are in preparation, with the assistance of two ad hoc working groups. A draft reflection paper[1] was published for consultation on 18 December 2012.

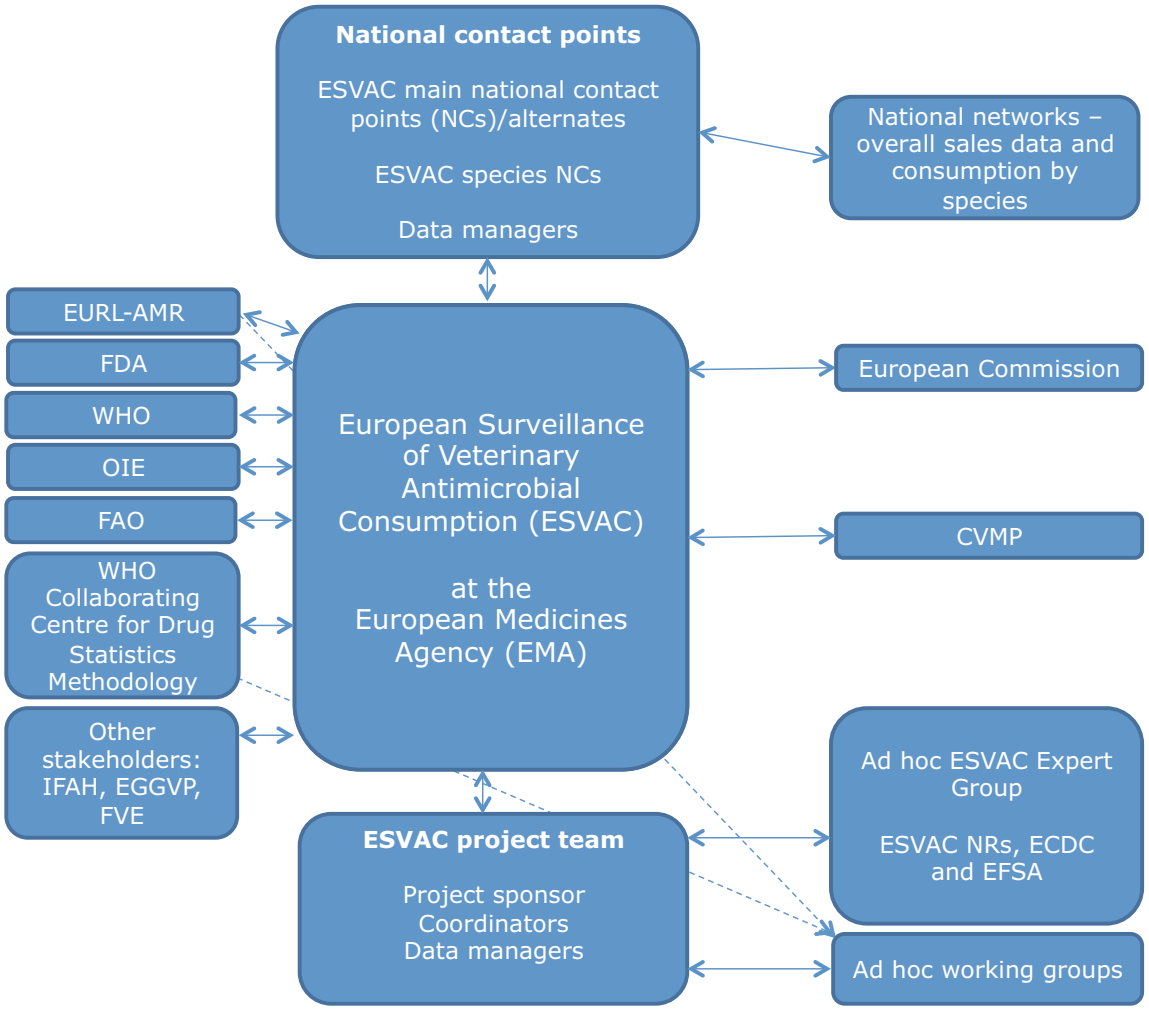
The organisation of the ESVAC project is illustrated in Figure 1.

The core of the ESVAC project is the ESVAC network of national representatives and alternates, nominated by the national competent authorities in the participating EU and EEA countries. The country and affiliation of the ESVAC national representatives/alternates can be found in Annex 7 of this report. The tasks of the ESVAC national representatives are to provide data on sales at package level to the ESVAC team at the European Medicines Agency following annual data calls, to revise the data in terms of quality and validity following requests from the ESVAC team, to validate the data applied to calculate the population correction unit, and to provide comments on the annual ESVAC report.

The ESVAC project is supported by an ad hoc expert group (ESVAC EG) that comprises representatives from the ESVAC network. There are also observers from the European Commission, ECDC and EFSA. The task of the ESVAC EG is to provide technical advice on surveillance of overall sales data of antimicrobial agents, including collection and analysis of data and preparation of the annual report. A list of the ESVAC EG members and observers can be found in Annex 8 of this report.

[1] EMA/286416/2012-Rev.1.

Figure 1. Organisation of the ESVAC project



An ESVAC-EMA Advisory Group has been set up to follow the current and new activities of the ESVAC project.

New activities of the ESVAC project include establishment of technical units of measurement, and collection of data per animal species. Further information on these projects can be found on the ESVAC web page[2].

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

1. Technical notes

1.1. Veterinary antimicrobial agents included in the data sets

To harmonise the veterinary antimicrobial agents to be included in the data sets, the Anatomical Therapeutic Chemical classification system for veterinary medicinal products (ATCvet[3]) was applied (Table 1). This includes all pharmaceutical forms and medicated feed except dermatological preparations (ATCvet group QD) and preparations for sensory organs (ATCvet group QS) (Table 1). The contribution from these groups of antimicrobial agents, in tonnes of active ingredient, to the total amount is minimal, and therefore the effect of the deviation is negligible.

To harmonise with the presentation of data on sales of antimicrobial agents in human medicine, the data are presented according to the ATCvet hierarchical system and ATCvet names, usually WHO international non-proprietary names (INN names), where available. If INN names are not assigned, the ATCvet system applies either USAN (United States Adopted Names) or BAN (British Approved Names).

Table 1. Categories and ATCvet codes[3] of antimicrobial veterinary medicinal products included in the data

Categories of veterinary antimicrobial agents	ATCvet codes
Antimicrobial agents for intestinal use	QA07AA; QA07AB
Antimicrobial agents for intrauterine use	QG01AA; QG01AE; QG01BA; QG01BE; QG51AA; QG51AG
Antimicrobial agents for systemic use	QJ01
Antimicrobial agents for intramammary use	QJ51
Antimicrobial agents used as antiparasitic agents	QP51AG

1.2. Variables reported for each antimicrobial veterinary medicinal product

Detailed information on the variables to be reported for each antimicrobial veterinary medicinal product (VMP) is given in Annex 2 of this report, as well as in the ESVAC protocol and ESVAC data-collection form published on the Agency's website[4]. In order to standardise the information, it has been agreed to apply one of the following categories of pharmaceutical form in ESVAC reporting: bolus, injection, intramammary, intramammary for dry cow treatment, intrauterine preparation, oral solution for individual treatment, oral solution for herd treatment, oral paste, oral powder for individual treatment, oral powder for herd treatment, premix or tablet (including capsules). This allows for a partial repartition of data into use in companion animals (tablets) and food-producing animals, including horses.

In order to present harmonised data, all oral solutions and oral powders have been aggregated to express oral solutions and oral powders for group treatment respectively.

In the current report, the term 'group treatment' is used for medication via feed or water.

For the 2010 and 2011 data, it was identified that many of the 'oral powders for solution' were reported as oral powder (i.e. given in feed instead of in water). In order to be able to quantify administration of antimicrobial VMPs through the drinking water, the Member States in question were asked to update the form to oral solution for the 2012 data. Because of this, many of the graphs and tables presenting data according to form have changed, for some countries substantially, compared to the data presented in the ESVAC 2010 and 2011 reports (EMA/ESVAC 2012, EMA/ESVAC 2013)[4].

1.3. Population correction unit

The amounts of veterinary antimicrobial agents sold in the different countries are, among others, linked to the animal demographics in each country. In this report, the annual sales figures in each country were divided by the estimated weight at treatment of livestock and of slaughtered animals in the corresponding year, taking into account the import and export of animals for fattening or slaughter in another Member State. The population correction unit (PCU) is used as the term for the estimated weight. The PCU is purely a technical unit of measurement, used only to estimate sales

[3] ATCvet codes: http://www.whocc.no/atcvet

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

corrected by the animal population in individual countries and across countries. In this report, 1 PCU = 1 kg of different categories of livestock and slaughtered animals. The data sources used and the methodology for the calculation of PCU are comprehensively described in Appendix 2 of the Agency's report 'Trends in the sales of veterinary antimicrobial agents in nine European countries: 2005-2009' (EMA/238630/2011)[5]. Animal categories included in the calculation of the PCU and the weights used are described in Annex 3.

1.4. Calculation of PCU

Essentially, the PCU for each animal category was calculated by multiplying numbers of livestock animals (dairy cows, sheep, sows and horses) and slaughtered animals (cattle, pigs, lambs, poultry and turkeys) by the theoretical weight at the time most likely for treatment. For animals exported or imported for fattening or slaughter (cattle, pigs and poultry), the PCU was calculated by multiplying the number of animals with a standardised weight.

For farmed fish, Eurostat data are given only as live-weight slaughtered, as information on weight at treatment was not identified; for fish, the PCU is taken as biomass live-weight slaughtered in each country. The PCU of the animals exported for fattening or slaughter in another Member State was added to the PCU of livestock and slaughter animals in the country of origin, because young animals are typically treated more frequently than other age classes; the PCU for animals imported for fattening or slaughter in another Member State was subtracted from the total PCU of livestock and slaughter animals, since it is included in the data on slaughter animals (Eurostat data).

PCU calculation by species, age class and production type

1. Number of animals slaughtered × estimated weight at treatment.
2. Number of livestock × estimated weight at treatment.
3. Number of animals transported (net export) to another country × estimated weight at treatment.

1.5. Animal species and categories included; selection of data sources

Eurostat, the Statistical Office of the European Union, covers data on numbers and biomass of food-producing animals slaughtered, as well as data on livestock food-producing animals. Therefore, Eurostat was selected as the source[6] for data on this animal category. In cases where data were not available in Eurostat (e.g. for rabbits), national statistics were applied. For horses (food-producing species according to EU legislation), national statistics provided by the ESVAC national representatives were used. As data on dogs and cats are not available in all participating countries, these species were not included in the PCU, in order to have comparable data. Therefore, antimicrobial VMPs approved for use in companion animals only, i.e. tablets, were excluded from the data sets prior to the normalisation of the sales by the PCU.

Animals exported for fattening or slaughter in another Member State are likely to have been treated with antimicrobial agents in the country of origin, and therefore it is important to correct for this for the major species (cattle, pigs, poultry and sheep). The Eurostat data on numbers of animals exported or imported for fattening or slaughter are not valid, as these are reported only when above a certain limit, which implies that the Eurostat data represent an underestimate of these for most species and countries. Such data were therefore obtained from TRACES (DG SANCO, European Commission), as these are based on health certificates, which are obligatory for all animals passing any border.

In cases where the deviation between the Eurostat data and/or TRACES data and national statistics was more than 5%, several countries applied national statistics.

1.6. Corrections of 2010 and 2011 data

There have been minor revisions of the 2011 sales data for four countries: France identified an error in reported number of packages sold for one product; Bulgaria identified an error in the calculation of ingredient content for one product and had applied an incorrect conversion factor for four products; data for Latvia for 2011 were updated as minor errors were identified in the calculation of sales; for Slovenia, minor errors in the ESVAC data analysis output for 2010 and 2011 were identified and corrected. Furthermore, the PCU has been updated for rabbits for Spain for 2010

[5] Available from the European Medicines Agency website (www.ema.europa.eu) via Home > Veterinary regulatory > Antimicrobial resistance > European Surveillance of Veterinary Antimicrobial Consumption.

[6] http://epp.eurostat.ec.europa.eu/portal/page/portal/statistics/themes

and 2011.

In the previous ESVAC reports, dihydrostreptomycin and streptomycin were included as 'others' instead of as aminoglycosides. This has been corrected for the current report; thus the apparent changes in the proportion accounted for by aminoglycosides and 'others' in 2012 compared to 2010 and 2011 are not real but due to reclassification.

1.7. Quality check and validation of the data

The data sets provided were checked for errors in terms of standardisation (logical errors) by the ESVAC project team, using an in-house program developed using the Java programming language as a standalone application with an Oracle database back-end, designed to manage data submitted in the ESVAC template format. Furthermore, data were checked manually in order to identify outliers either by checking against published data for previous years (25 countries). For Luxembourg, which delivered data to ESVAC for the first time for 2012, the ESVAC project team checked the data for outliers by identification of sales figures of classes/subclasses, pharmaceutical forms or individual products that appeared to be exceptional.

1.8. Reporting of the data

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

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

The data are presented according to the ATCvet hierarchical system, and for combination preparations, each active ingredient is allocated to the relevant ATCvet code for single substances (e.g. spectinomycin is included in 'Other antibacterials'). The maps on spatial consumption of the various veterinary antimicrobial agents were created using Quantum Geographic Information System (QGIS) version 1.8.0[7].

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

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

[7] Available from: http://www.qgis.org

Table 2. Summary of information on years collecting data, legal basis for collecting data at national level, national data providers, sources for ESVAC data and characteristics of data by country for 2012

Country	Years collecting data	Legal basis	National data provider to ESVAC	Sources for ESVAC data (approx. no)	Prescription data, sales data or purchase data[1]	Sales between wholesalers and/or MAHs[2] excluded (Yes/No)	Products used on special licence included (Yes/No)
Austria	3 years	Mandatory to report	Austrian Agency for Health and Food Safety	MAHs2 (n=12); wholesalers (n=6)	Sales to veterinarians	Yes	No
Belgium	>5 years	Mandatory to report	Federal Agency for Medicines and Health Products	Wholesalers (n=25); feed mills (n=57)	Sales to veterinarians and pharmacies. Sales by feed mills to farmers	Yes	No
Bulgaria	2 years	Mandatory to report	Bulgarian Food Safety Agency	Wholesalers (n=24)	Sales to veterinarians, farmers and pharmacies	Yes	No
Cyprus	2 years	Mandatory to report	Ministry of Agriculture, Natural Resources and Environment - Veterinary Services	Wholesalers (n=21)	Sales to pharmacies and veterinary clinics	Yes	Yes
Czech Republic	>5 years	Mandatory to report	Institute for State Control of Veterinary Biologicals and Medicines	Wholesalers (n=85); feed mills (n=58)	Sales to veterinarians, pharmacies and farmers. Sales by feed mills to farmers	Yes	Yes (only one product with significant consumption in 2012)
Denmark	>5 years	Mandatory to report	Danish Veterinary and Food Administration	VetStat (n=1) obtaining data from pharmacies (n=108); veterinarians (n=350); feed mills (n=3)	Prescription data from pharmacies, veterinarians distributors and feed mills	Yes	Yes
Estonia	>5 years	Mandatory to report	State Agency of Medicines	Wholesalers (n=7)	Sales to veterinarians and pharmacies	Yes	Yes
Finland	>5 years	Mandatory to report	Finnish Medicines Agency	Wholesalers (n=3); feed mills (n=1); importers of medicated feed (n=1)	Sales to pharmacies and veterinarians	Yes	Yes
France	>5 years	Not mandatory	National Agency for Veterinary Medicinal Products (Anses-ANMV)	MAHs (n=29)	Sales to veterinarians, farmers, wholesalers and feed mills	Not applicable	No

Country	Years collecting data	Legal basis	National data provider to ESVAC	Sources for ESVAC data (approx. no)	Prescription data, sales data or purchase data[1]	Sales between wholesalers and/or MAHs[2] excluded (Yes/No)	Products used on special licence included (Yes/No)
Germany	2 years	Mandatory to report	Federal Office of Consumer Protection and Food Safety	MAHs (n=39); wholesalers (n=16); PSURs[3] data for premix	Sales to veterinarians	Yes	No
Hungary	>5 years	Mandatory to report	National Food Chain Safety Office Directorate of Veterinary Medicinal Products	Wholesalers (n=69); wholesalers other countries (n=2)	Sales to veterinarians and feed mills	Yes	No
Iceland	3 years	Mandatory to report	Icelandic Medicines Agency	Wholesalers (n=2)	Sales by wholesalers to veterinarians and pharmacies	Yes	Yes
Ireland	4 years	Mandatory to report	Irish Medicines Board	MAHs (n=61)	Sales to pharmacies or veterinarians	Yes	No
Italy	3 years	Mandatory to report	Italian Ministry of Health	MAHs (n=50)	Sales to wholesalers, pharmacies, feed mills, and farms authorised to produce medicated feed for self-consumption	No	No
Latvia	3 years	Mandatory to report	Food and Veterinary Service	Wholesalers (n=24)	Sales to pharmacies, veterinarians and farmers	Yes	No
Lithuania	3 years	Mandatory to report	State Food and Veterinary Service	Wholesalers (n=31)	Sales to pharmacies, veterinarians and farmers	Yes	No
Luxembourg	1 year	Mandatory to report	Ministry of Health	Wholesalers (n=3)	Sales to pharmacies, veterinarians	Yes	Yes
Netherlands	>5 years	Not mandatory	Federation of the Dutch Veterinary Pharmaceu¬tical Industry (FIDIN)	MAHs (n=18)	Sales to veterinarians	Yes	No
Norway	>5 years	Mandatory to report	Norwegian Veterinary Institute	Wholesalers (n=5)	Sales to pharmacies, veterinarians and feed mills	Yes	Yes
Poland	2 years	Mandatory to report	Ministry of Agriculture and Rural Development	Wholesalers (n=127)	Sales to veterinarians	Yes	No

Country	Years collecting data	Legal basis	National data provider to ESVAC	Sources for ESVAC data (approx. no)	Prescription data, sales data or purchase data[1]	Sales between wholesalers and/or MAHs[2] excluded (Yes/No)	Products used on special licence included (Yes/No)
Portugal	2 years	Mandatory to report	General Directorate for Food and Veterinary Affairs	Wholesalers (n=64)	Sales to retailers, veterinarians, farmers, producer organisations, veterinary clinics and feed mills	Yes	No
Slovakia	2 years	Mandatory to report	Institute for State Control of Veterinary Biologicals and Medicaments	Wholesalers (n=59)	Purchase data	Not applicable	No
Slovenia	3 years	Mandatory to report	Administration of the Republic of Slovenia for Food Safety, Veterinary Sector and Plant Protection (AFSVSPP)	Wholesalers (n=11+1[4])	Sales to pharmacies and veterinarians	Yes	Yes
Spain	4 years	Not mandatory	Spanish Agency for Medicines and Health Products	MAHs (n=38)	Sales to wholesalers and retailers, i.e. veterinary organisations and pharmacies	Yes	No
Sweden	>5 years	Mandatory to report	National Veterinary Institute and Swedish Board of Agriculture	Apotekens Service AB (n=1) obtaining data from pharmacies	Dispensed prescriptions	Yes	Yes
United Kingdom	>5 years	Mandatory to report	Veterinary Medicines Directorate	MAHs (n=66)	Sales to veterinarians and veterinary pharmacies	Yes	No

[1] Purchase/import data from e.g. pharmaceutical industry and/or from wholesalers in other countries. [2] MAHs = marketing-authorisation holders. [3] PSURs = periodic safety update reports. [4] Indirect data acquisition from a storage facility operator for a single wholesaler, which had discontinued operation in Slovenia.

2. Results

2.1. Population correction unit

The value of the population correction unit (PCU), i.e. the estimated weight at treatment of livestock and of slaughter animals, for the various species and countries is shown in Table 3. The 26 countries included in the ESVAC 2012 data cover approximately 95% of the food-producing animal population measured as PCU in the EU/EEA countries.

The distribution of the various food-producing species by country, expressed by PCU, is shown in Table 3 and in Figures 2 and 3.

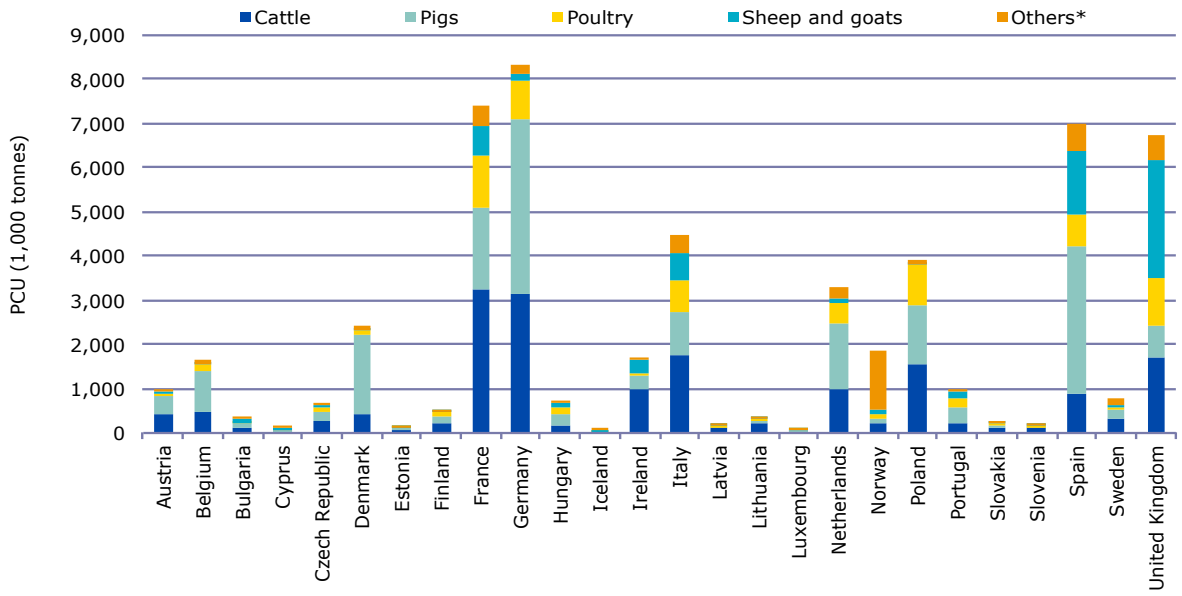
Overall, pigs, cattle, poultry and sheep/goats accounted for 34%, 32%, 13% and 12%, respectively, of the PCU in the 26 countries.

Table 3. Estimated PCU (in 1,000 tonnes) of the population of food-producing species[1] (including horses), by country, for 2012

Country	Cattle	Pigs	Poultry	Sheep/ goats	Fish	Rabbits	Horses	Total
Austria	435	384	81	35			30	966
Belgium	461	916	167	16	0.6	4	94	1,658
Bulgaria	134	62	45	99		0.01	48	388
Cyprus	16	51	13	32		0.2	2	113
Czech Republic	284	198	112	17	21	10	32	673
Denmark	410	1,808	105	2	34		66	2,424
Estonia	61	43	17	6	0.4		4	131
Finland	222	171	65	11	12.7		30	511
France	3,465	1,855	1,146	665	234	52	200	7,618
Germany	3,129	3,957	903	144	20		185	8,338
Hungary	144	277	180	96		0.01	31	727
Iceland	19	6	5	47	7		31	116
Ireland	1,007	267	83	304	36		28	1,725
Italy	1,746	991	715	611	195	33	210	4,500
Latvia	109	33	15	0.3			5	162
Lithuania	206	75	45	6			7	339
Luxembourg	37	11	0.03	0.03			2	50
Netherlands	991	1,475	496	99	46	3	169	3,279
Norway	221	127	66	101	1,321		14	1,851
Poland	1,542	1,345	901	18			102	3,908
Portugal	237	343	199	177	9	8	22	996
Slovakia	99	49	51	33			2	235
Slovenia	100	26	35	12	1	0.04	10	183
Spain	881	3,321	728	1,459	274	75	258	6,996
Sweden2	304	202	81	51			145	783
United Kingdom	1,709	733	1,040	2,700	172		395	6,749
Total 26 countries	**17,970**	**18,724**	**7,295**	**6,742**	**2,384**	**184**	**2,121**	**55,421**

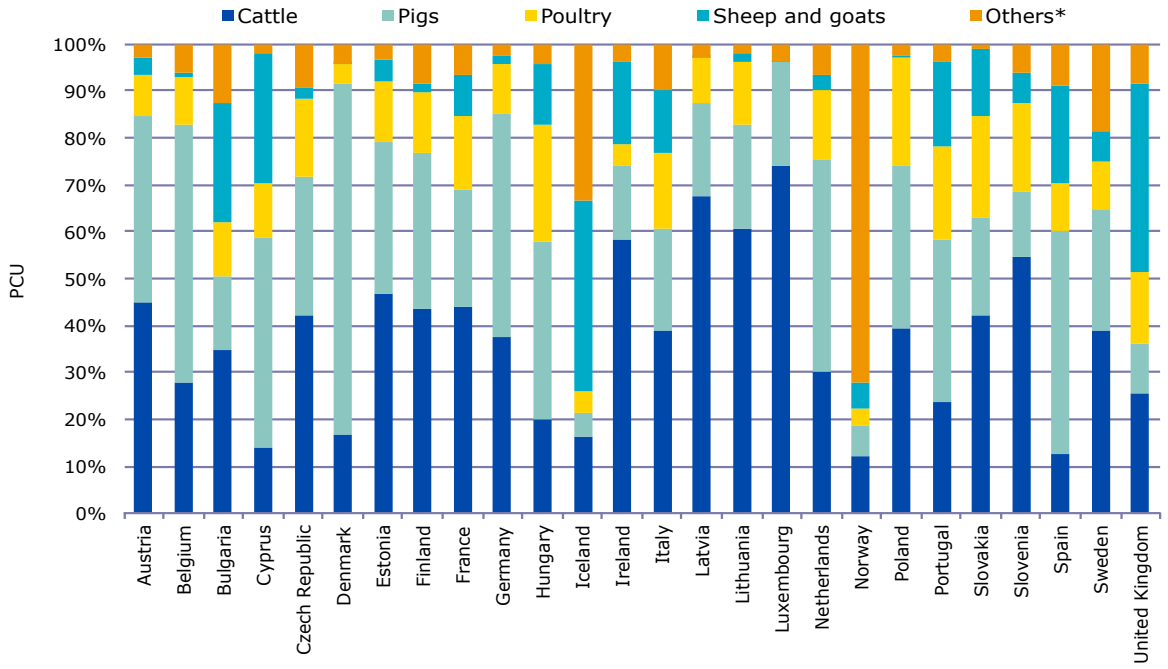
[1] For animal categories included, see Annex 3. [2] Farmed fish not included.

Figure 2. PCU (in 1,000 tonnes) of the various food-producing animal species, including horses, by country, for 2012[1]



[1] Farmed fish not included for Sweden. * Horses and, for some countries, fish and or rabbits.

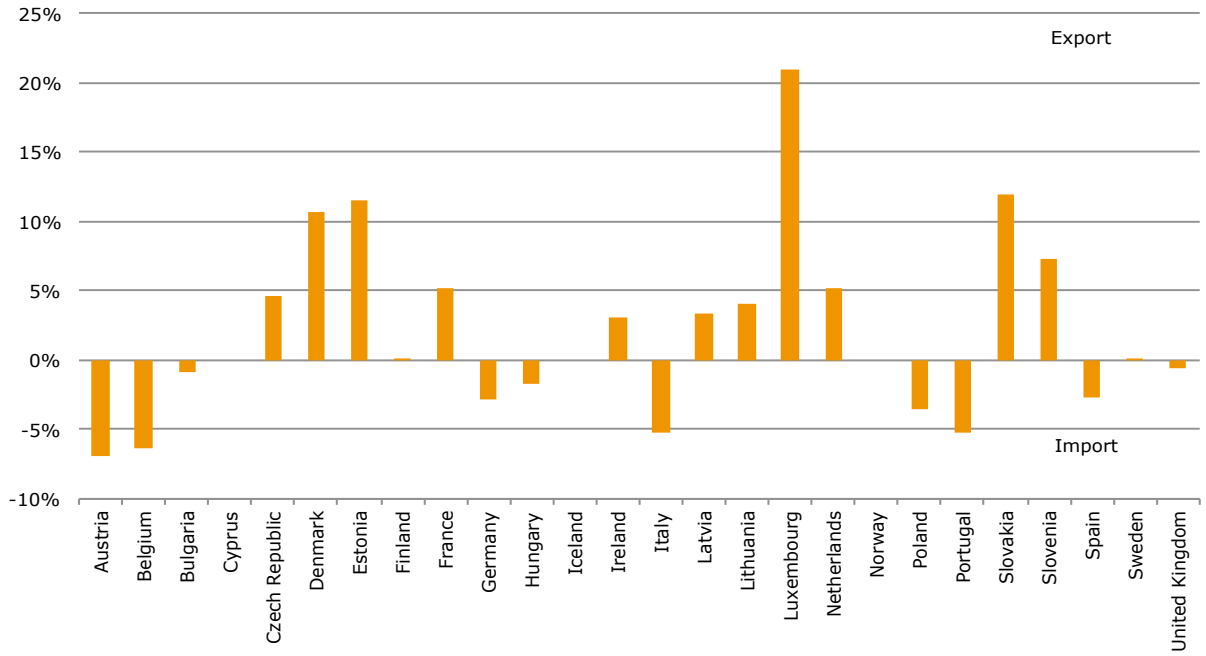
Figure 3. Distribution of PCU (1,000 tonnes) by food-producing animal species, including horses, by country, for 2012[1]



[1] Farmed fish not included for Sweden. * Horses and, for some countries, fish and/or rabbits.

The percentage of the total PCU accounted for by the net export or import of animals for slaughter and/or fattening is shown in Figure 4. Of the 26 countries, 6 countries had a net export of animals for slaughter and/or fattening to other Member States that accounted for ≥ 5% of the PCU.

Figure 4. Net export and net import[1], as a percentage of the total PCU, of animals for fattening or slaughter in another Member State, for 2012



[1] Data represent the net balance between export and import, i.e. a negative percentage means a net import.

2.2. Overall sales of veterinary antimicrobial agents

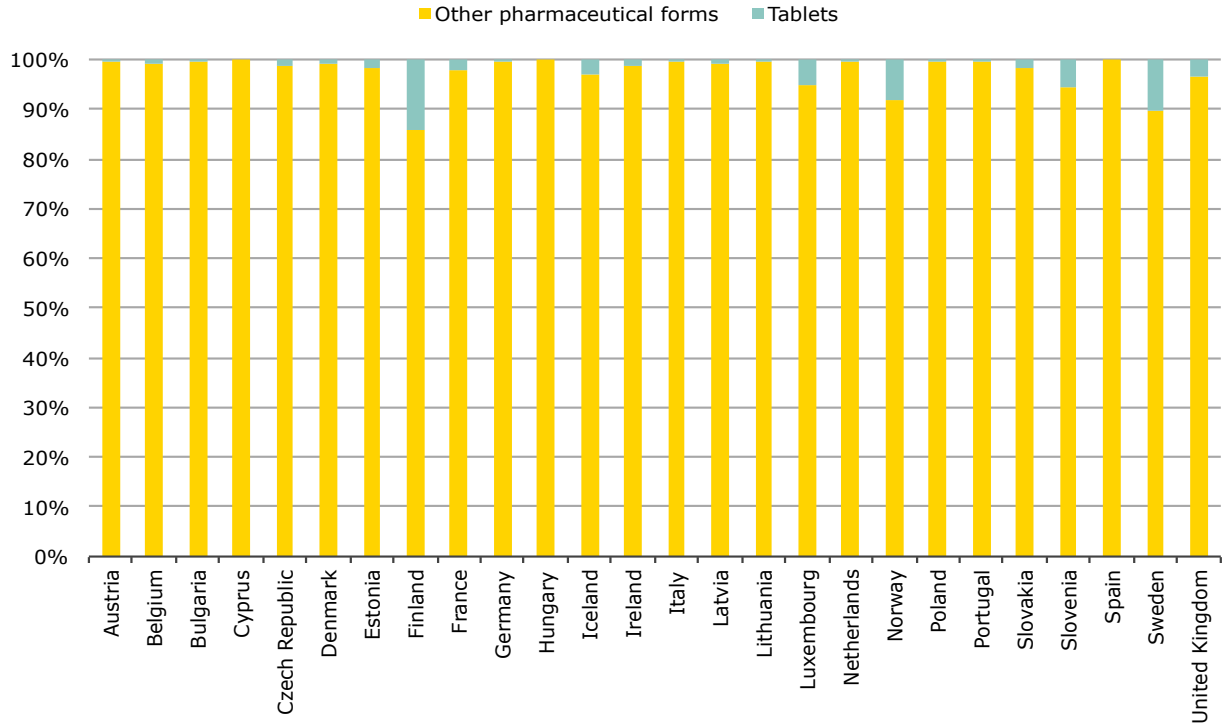
The overall national sales data provided covered sales for use almost solely in companion animals (mainly tablets) and food-producing animals, including horses (all other pharmaceutical forms). Injectable veterinary antimicrobial agents are also used in companion animals, but due to minor use, in terms of weight of active ingredient, such sales are included in the statistics for food-producing animals. Except for Finland, Norway and Sweden, where tablets accounted for 14.1%, 8.2% and 10.2%, respectively, sales of tablets, and therefore use in companion animals, accounted for a minor proportion of the total sales of veterinary antimicrobial agents in 2012 (Table 4; Figure 5). Overall in the 26 countries, the sales, in tonnes, of tablets represented 0.8% of the total sales.

Table 4. Distribution of overall sales, in tonnes of active ingredient, split into tablets (used in companion animals) and all other pharmaceutical forms (used mainly in food-producing animals, including horses), by country, for 2012

	Tablets		All other pharmaceutical forms		Total
Country	**Tonnes**	**% of overall sales**	**Tonnes**	**% of overall sales**	**Tonnes**
Austria	0.3	0.5	53.0	99.5	53.3
Belgium	1.7	0.6	267.2	99.4	268.9
Bulgaria	0.1	0.2	38.4	99.8	38.5
Cyprus	0.04	0.1	45.0	99.9	45.0
Czech Republic	0.6	1.2	53.7	98.8	54.4
Denmark	1.0	0.9	107.0	99.1	107.9
Estonia	0.1	1.6	7.3	98.4	7.5
Finland	2.0	14.1	12.2	85.9	14.2
France	16.9	2.2	761.5	97.8	778.4
Germany	7.4	0.4	1,707	99.6	1,714

Hungary	0.2	0.1	178.5	99.9	178.7
Iceland	0.02	2.8	0.7	97.2	0.7
Ireland	1.2	1.2	100.0	98.8	101.2
Italy	9.0	0.6	1,534	99.4	1,543
Latvia	0.05	0.7	6.7	99.3	6.7
Lithuania	0.03	0.2	13.4	99.8	13.4
Luxembourg	0.1	5.1	2.2	94.9	2.3
Netherlands	0.9	0.3	245.7	99.7	246.6
Norway	0.6	8.2	7.1	91.8	7.8
Poland	1.9	0.4	516.4	99.6	518.3
Portugal	0.3	0.2	156.5	99.8	156.8
Slovakia	0.2	1.5	10.2	98.5	10.3
Slovenia	0.4	5.7	6.8	94.3	7.2
Spain	1.7	0.1	1,693	99.9	1,694.7
Sweden	1.2	10.2	10.6	89.8	11.8
United Kingdom	16.4	3.5	447.4	96.5	463.8
Total 26 countries	**64.4**		**7,982**		**8,046.4**

Figure 5. Distribution of sales, in tonnes of active ingredient, split into tablets (used almost solely in companion animals) and all other pharmaceutical forms (used mainly in food-producing animals, including horses), by country, for 2012



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

The sales of veterinary antimicrobial agents for food-producing animals, stratified into pharmaceutical forms, by country are shown in Figure 6. Tablets are not included in the material as these are almost solely used in companion animals.

Figure 6. Distribution of sales of veterinary antimicrobial agents for food-producing animals (including horses), in mg per population correction unit (mg/PCU), by pharmaceutical form, by country, for 2012

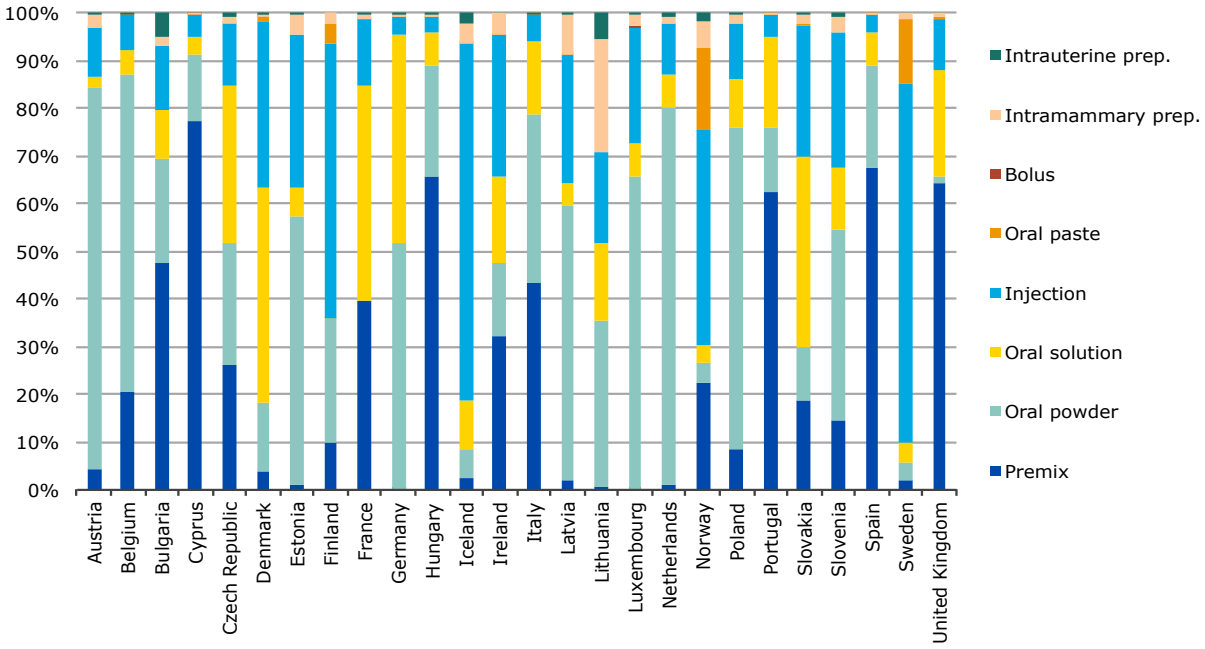


Figure 7. Oral solutions, oral powders and premixes as percentages of total sales, in mg per population correction unit (mg/PCU), of veterinary antimicrobial agents for food-producing animals (including horses), by country, for 2012

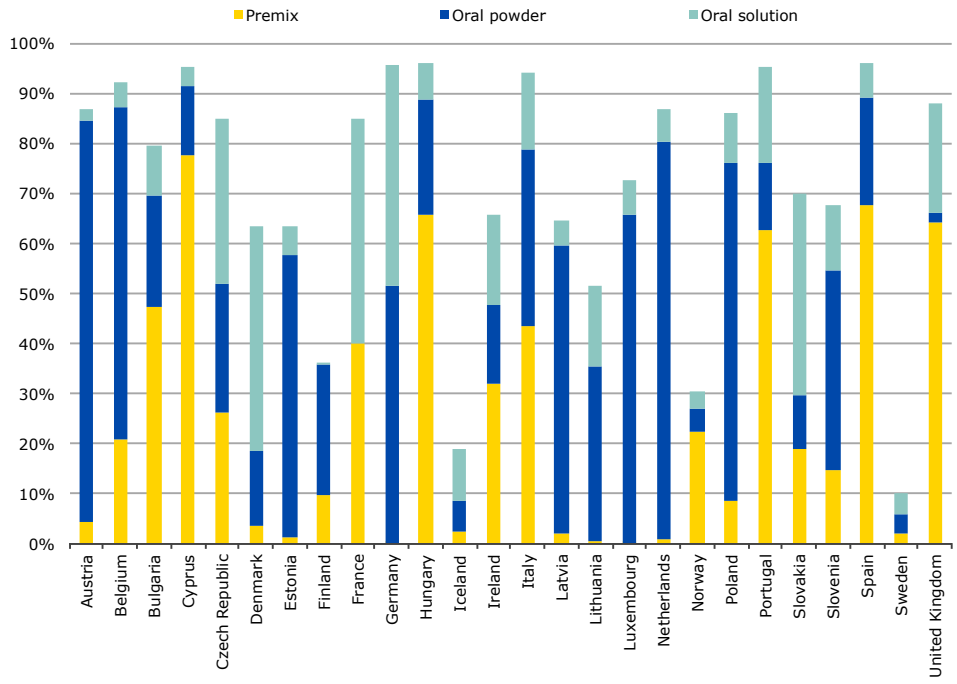
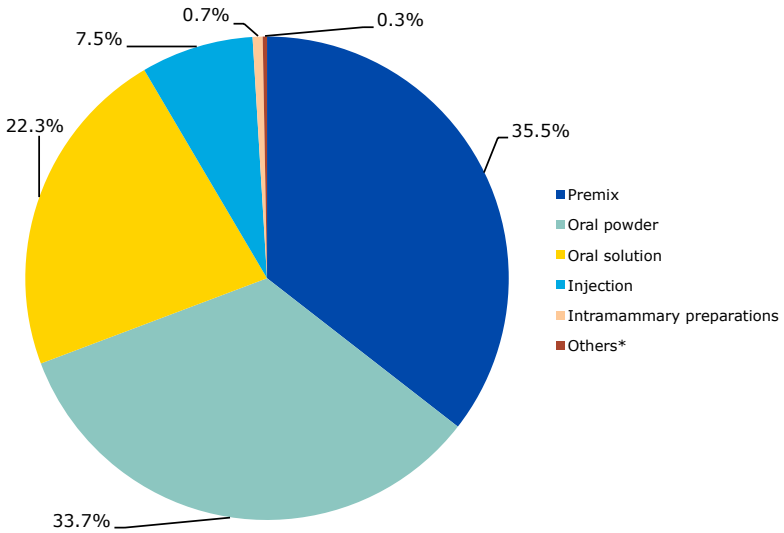


Figure 8. Distribution of sales, in mg/PCU, of the various pharmaceutical forms of veterinary antimicrobial agents for food-producing animals (including horses) aggregated by the 26 EU/EEA countries for 2012



* Oral paste, bolus and intrauterine preparations.

The proportions accounted for by premixes and oral powders vary considerably between the countries, which could be attributed to whether the country uses medicated feeding stuff prepared by a feed mill by use of premixes or whether group treatment is performed by application of oral powder as top-dressing on the feed at a farm. It could also be influenced by the distribution of the animal species, as mass medication is mostly used in poultry and pigs, and less in e.g. calves and sheep or goats; therefore, countries like Norway and Iceland with significantly smaller populations of pigs and poultry are exceptions. Also, the products available and national policies for feed medication can have an influence.

Although a small proportion of the oral powders and oral solutions are applicable for treatment of one individual animal or a very limited number of animals, the sales figures for these pharmaceutical forms are reasonable estimates of group treatment, including groups in one pen/house.

Aggregated by the 26 countries, the sales (mg/PCU) of premixes accounted for 35.5% of the overall sales, while 33.7% were oral powders, 22.3% were oral solutions, 7.5% were injectable preparations, 0.7% were intramammaries and 0.3% were oral pastes, bolus and intrauterine preparations.

2.4. Population-corrected sales for food-producing animals, including horses, by antimicrobial class

The sales of veterinary antimicrobial agents, expressed as mg sold per population correction unit (PCU), varied from 3.8 mg/PCU to 396.5 mg/PCU between the 26 countries. Also, the sales patterns of the antimicrobial classes varied substantially between the countries (Table 6; Figure 9).

Table 5. Sales, in tonnes of active ingredient, of veterinary antimicrobial agents marketed mainly for food-producing animals[1] (including horses), population correction unit (PCU) and sales in mg/PCU, by country, for 2012

Country	Sales (tonnes) for food-producing animals	PCU (1,000 tonnes)	mg/PCU
Austria	53.0	966	54.9
Belgium	267.2	1,658	161.1
Bulgaria	38.4	388	98.9
Cyprus	45.0	113	396.5
Czech Republic	53.7	673	79.8
Denmark	107.0	2,424	44.1
Estonia	7.3	131	56.0
Finland	12.2	511	23.8
France	761.5	7,419	102.6
Germany	1,707.5	8,338	204.8
Hungary	178.5	727	245.5
Iceland	0.7	116	5.9
Ireland	100.0	1,725	58.0
Italy	1,534.3	4,500	341.0
Latvia	6.7	162	41.1
Lithuania	13.4	339	39.4
Luxembourg	2.2	50	43.6
Netherlands	245.7	3,279	74.9
Norway	7.1	1,851	3.8
Poland	516.4	3,908	132.2
Portugal	156.5	996	157.1
Slovakia	10.2	235	43.2
Slovenia	6.8	183	37.0
Spain	1,693.0	6,996	242.0
Sweden	10.6	783	13.5
United Kingdom	447.4	6,749	66.3

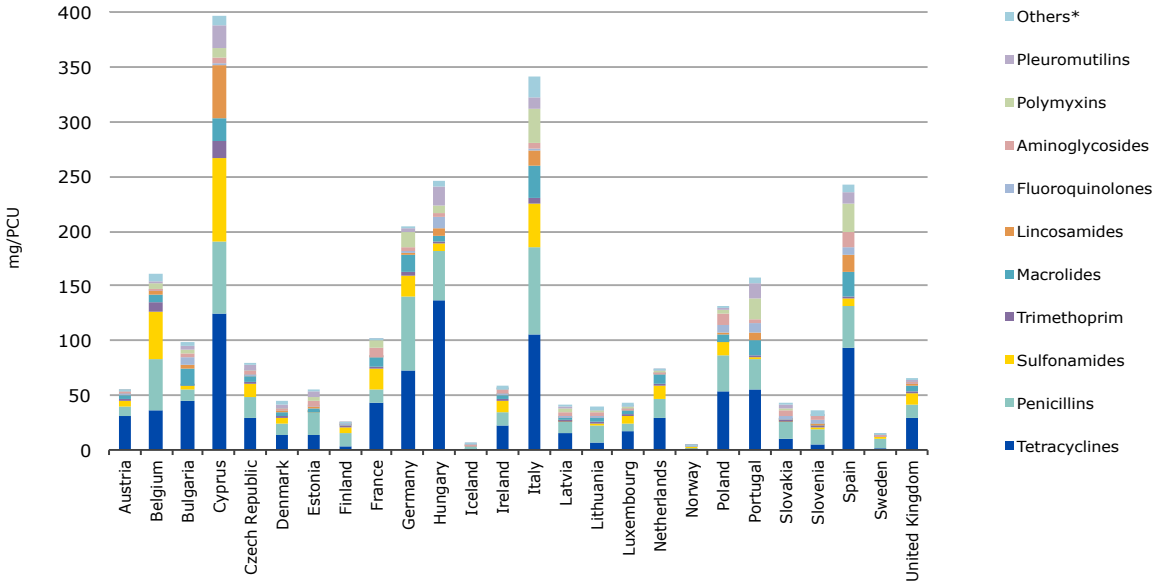
[1] Tablets excluded as almost solely used in companion animals; injectable antimicrobial VMPs can also be used in companion animals; a few other products may solely be used in companion animals, but as the proportional use is minor, these are included in the sales for food-producing animals.

Table 6. Percentages of sales for food-producing animals (including horses), in mg per population correction unit (mg/PCU), of the various veterinary antimicrobial classes, by country, in 2012

Country	Tetracyclines	Amphenicols	Penicillins	1-2 gen. cephalosporins	3-4 gen. cephalosporins	Sulfonamides	Trimethoprim	Macrolides	Lincosamides	Fluoroquinolones	Other quinolones	Aminoglycosides	Polymyxins	Pleuromutilins	Others*	Total mg/PCU
Austria	56.4	0.5	14.9	0.1	0.6	10.9	1.5	8.3	0.6	0.9		2.5	1.2	0.7	0.8	54.9
Belgium	22.5	0.5	28.7	0.04	0.3	26.8	5.4	4.6	2.0	0.5	1.0	0.6	3.6	0.9	2.5	161.1
Bulgaria	45.1	1.2	11.1	0.1	0.03	2.6	0.2	17.0	3.0	6.2	0.3	4.0	3.8	2.7	2.6	98.9
Cyprus	31.5	0.1	16.5	0.01	0.1	19.3	3.8	5.3	12.5	0.2	0.7	1.4	2.0	5.6	0.9	396.5
Czech Republic	37.2	0.7	22.9	0.3	0.4	16.0	1.4	7.1	0.5	2.3	0.1	3.2	1.1	5.9	0.8	79.8
Denmark	30.4	0.8	25.6	0.1	0.1	10.4	2.0	11.6	2.3	0.02	1.9	3.4	0.6	8.7	2.2	44.1
Estonia	24.1	0.3	35.9	1.0	1.0	1.5	0.3	6.2	2.0	1.7		w.9	7.8	7.6	2.7	56.0
Finland	14.5	0.5	52.6	0.3	0.1	20.6	4.1	4.7	1.0	0.7		0.3		0.5		23.8
France	42.4	0.6	10.6	0.2	0.3	18.6	2.8	7.6	0.6	0.6	0.7	7.2	6.6	0.7	0.5	100.0
Germany	35.1	0.3	33.1	0.03	0.2	9.5	1.5	7.8	1.0	0.6		1.8	7.2	1.3	0.6	204.8
Hungary	55.8	1.1	18.3	0.1	0.1	2.8	0.6	2.4	2.5	4.5	0.1	1.1	3.2	7.1	0.3	245.5
Iceland	5.5		49.7		0.1	6.4	0.9			0.1	2.5	34.4		0.5		5.9
Ireland	37.2	2.0	21.7	0.6	0.2	19.7	1.5	6.7	0.4	1.0		8.4	0.2	0.01	0.5	58.0
Italy	31.2	1.1	23.3	0.1	0.1	11.3	1.5	9.1	3.9	0.7	2.0	1.4	8.8	3.4	2.1	341.0
Latvia	37.7	0.1	23.3	0.5	1.0	3.4	0.7	4.0	0.3	4.2	0.02	11.0	6.2	6.7	1.0	41.1
Lithuania	17.7	1.1	37.0	2.4	0.1	7.1	1.7	11.1	1.1	1.4	0.6	11.0	3.3	1.4	2.9	39.4
Luxembourg	37.3	2.2	18.3	0.8	1.6	16.5	3.2	5.8	1.8	1.5	0.05	1.6	4.0	1.0	4.5	43.6
Netherlands	39.3	1.2	22.3	0.1	0.02	16.7	3.2	10.4	0.4	0.3	0.9	2.4	1.3	0.9	0.6	74.9
Norway	2.3	3.0	39.6		0.01	21.6	4.1	0.0		0.2	19.6	8.1		1.3	0.1	3.8
Poland	40.9	1.4	25.1	0.2	0.1	8.6	0.6	4.4	1.0	6.2	0.1	6.9	3.0	0.8	0.6	132.2
Portugal	35.5	0.6	17.1	0.1	0.2	1.8	0.5	9.0	4.3	5.9	0.1	2.2	11.8	8.9	2.0	157.1
Slovakia	25.2	1.3	33.3	0.8	1.2	3.2	0.6	1.5	0.6	7.5		10.5	4.9	8.5	0.8	43.2
Slovenia	12.4	2.8	39.8	0.4	0.4	5.1	2.0	3.1	2.5	11.0	0.04	7.5	0.2	1.3	11.4	37.0
Spain	38.8	0.7	15.5	0.02	0.1	3.3	0.6	8.8	6.8	2.9	0.3	5.8	10.5	4.8	1.3	242.0
Sweden	7.9	0.0	61.7		0.1	15.6	3.1	4.3	0.0	0.7		3.3	0.7	0.9	1.6	13.5
United Kingdom	44.2	0.7	18.3	0.2	0.3	14.5	2.9	9.1	1.1	0.5		3.0	0.1	3.2	1.9	66.3

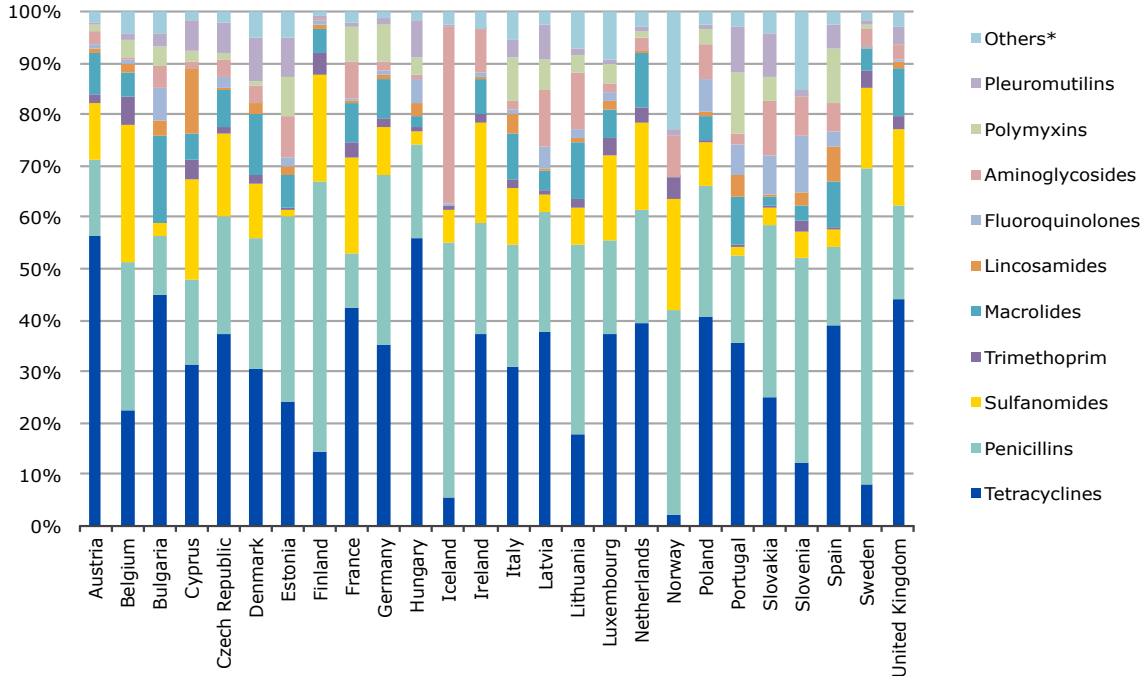
* Bacitracin, paromycin and spectinomycin (classified as 'Other antimicrobials' in the ATCvet system).

Figure 9. Sales for food-producing species, including horses, in mg/PCU, of the various veterinary antimicrobial classes, for 26 countries in 2012[1]



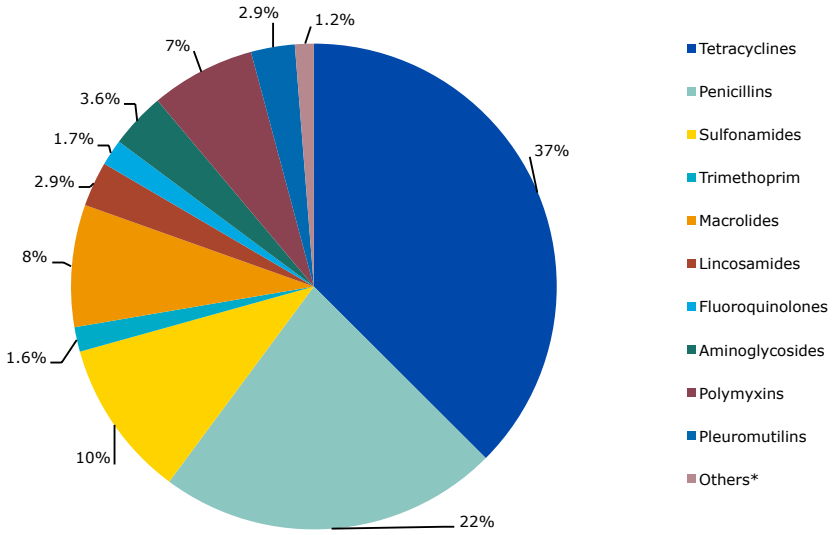
* Amphenicols, cephalosporins, other quinolones and other antibacterials (classified as such in the ATCvet system). [1] Differences between countries can partly be explained by differences in animal demographics, in the selection of antimicrobial agents, in dosage regimes and in type of data sources,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

Figure 10. Proportion of the total sales of the different veterinary antimicrobial classes, in mg/PCU, by country, for 2012



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

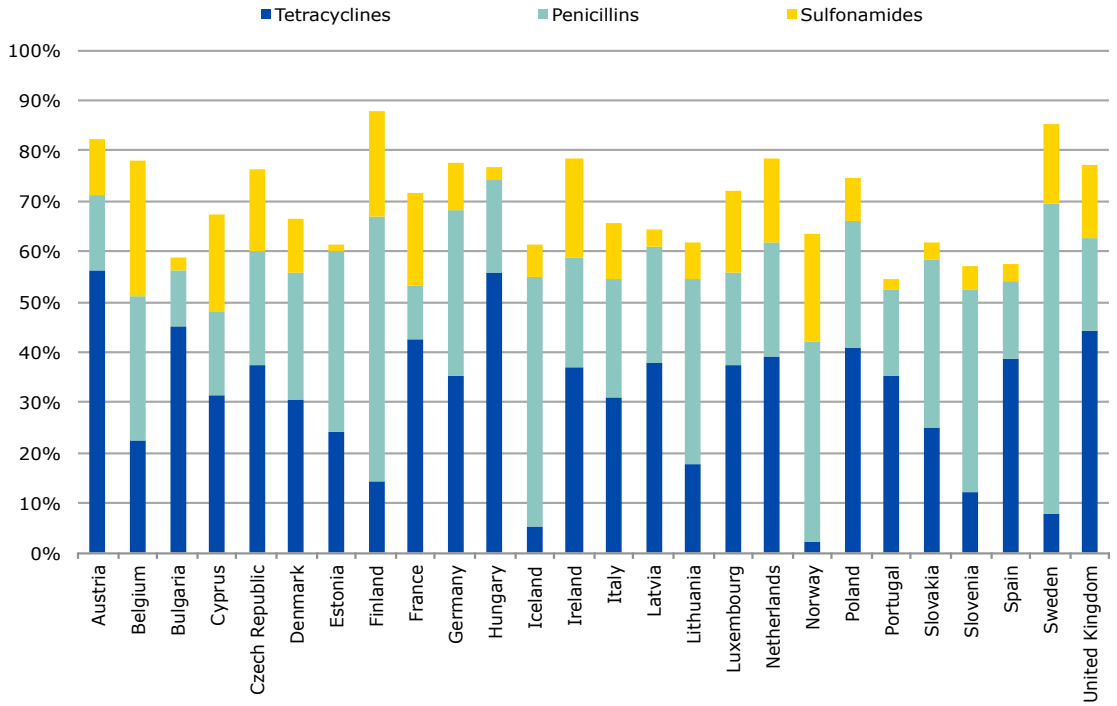
Figure 11. Sales of antimicrobial agents by antimicrobial class as percentage of the total sales for food-producing species (including horses), in mg/PCU, aggregated by 26 countries, for 2012



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

For all 26 countries, the sales of tetracyclines, penicillins and sulfonamides, in mg/PCU, accounted for 70% of the total sales in 2012 (Figure 11). Of the overall sales in the 26 countries, 0.1% were accounted for by 1st- and 2nd-generation cephalosporins, 0.2% were for 3rd- and 4th-generation cephalosporins, 0.8% were for amphenicols and 0.6% for other quinolones.

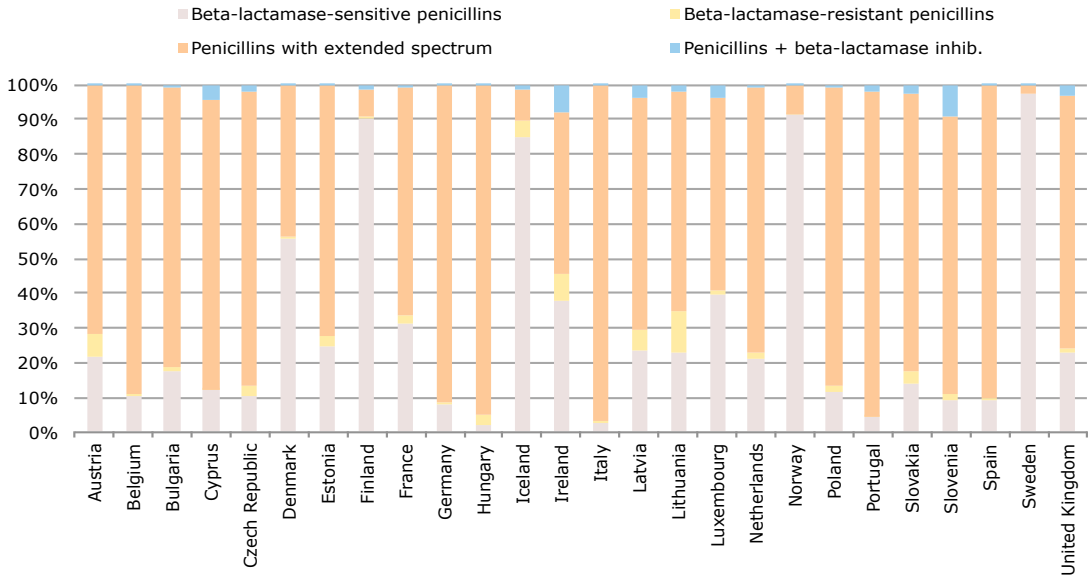
Figure 12. Sales of tetracyclines, penicillins and sulfonamides as a percentage of the total sales for food-producing species (including horses), in mg/PCU, by country, for 2012



The percentage of sales of penicillins attributed to the various subclasses differed substantially between the 26 countries (Figure 13); in the Nordic countries, the proportion of beta-lactamase-sensitive penicillins accounted for the

majority of penicillins sold, while for other countries, it was penicillins with extended spectrum that accounted for the major proportion of the sales of penicillins.

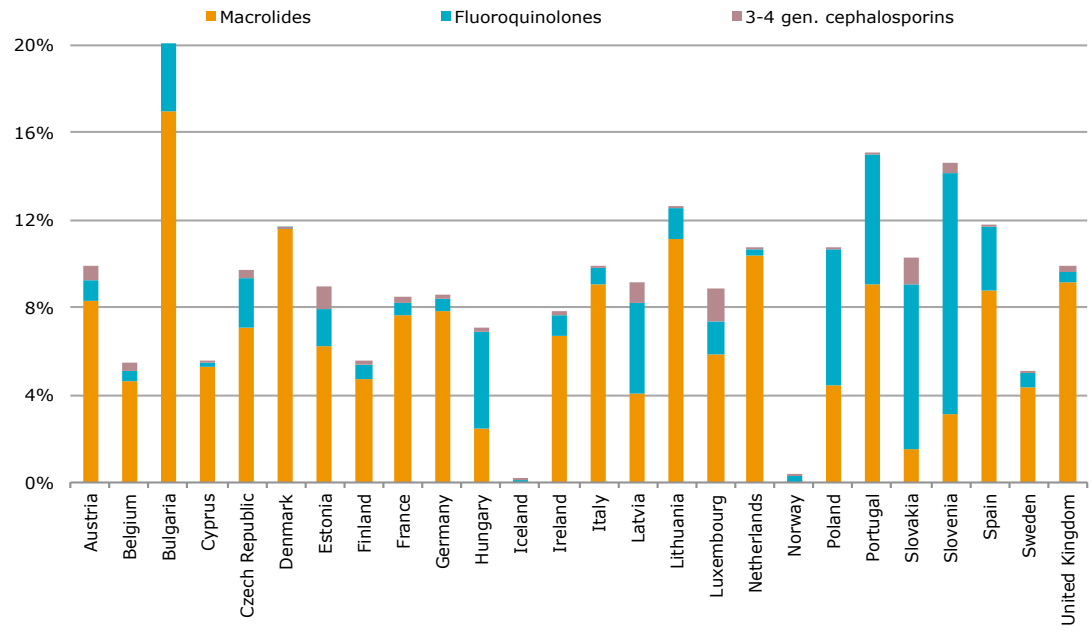
Figure 13. Distribution of the sales in mg/PCU of penicillins by subclass for food-producing species, including horses, by country, for 2012



The proportion sold of the critically important antimicrobials (CIAs) with the highest priority in human medicine according to the WHO — 3rd- and 4th-generation cephalosporins, fluoroquinolones and macrolides — in the different countries in 2012 varied substantially between the 26 countries, ranging from 0.01% to 1.2%, 0.02% to 11%, and 0.04% to 17%, respectively (Figure 14). The sales, in mg/PCU, of these classes/subclasses are shown in Figures 60–62.

Overall in the 26 countries, the sales (mg/PCU) of these CIAs accounted for 0.2%, 1.7% and 8%, respectively, of the total sales of antimicrobial VMPs in 2012.

Figure 14. Proportion of the total sales of macrolides, fluoroquinolones and 3rd- and 4th-generation cephalosporins for food-producing species, including horses, in mg/PCU, for 26 countries in 2012

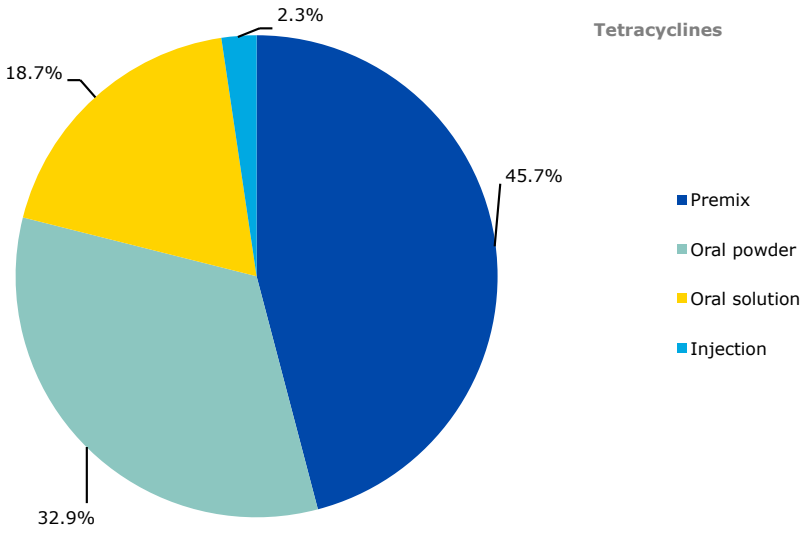


2.4.1. Distribution of sales for the most-selling antimicrobial classes and the most important CIAs by pharmaceutical form aggregated by the 26 EU/EEA countries

2.4.1.1. Tetracyclines

The overall sales of tetracyclines for the 26 countries, stratified into pharmaceutical forms, are shown in Figure 15. In addition, 0.4% were sold as intramammary preparations, intrauterine preparations and bolus.

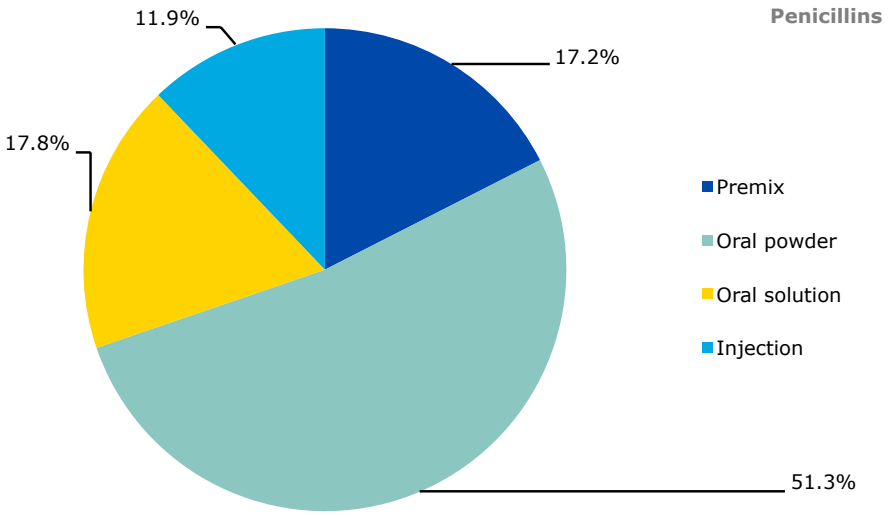
Figure 15. Distribution of sales of tetracyclines for food-producing animals (including horses), in mg/PCU, by the major pharmaceutical forms sold, aggregated by the 26 EU/EEA countries for 2012



2.4.1.2. Penicillins

The overall sales of penicillins for the 26 countries, stratified into pharmaceutical forms, are shown in Figure 16. In addition, 1.6% were accounted for by intramammary preparations, and 0.2% by bolus and intrauterine preparations.

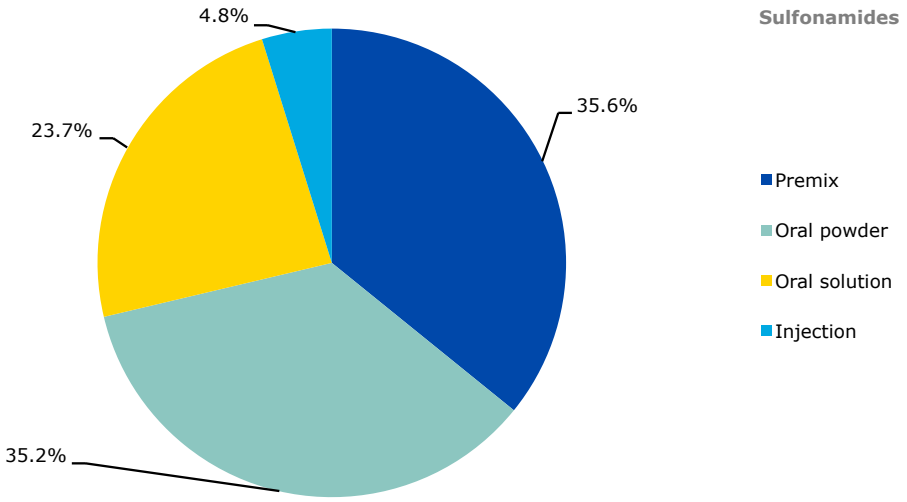
Figure 16. Distribution of sales of penicillins for food-producing animals (including horses), in mg/PCU, by the major pharmaceutical forms sold, aggregated by the 26 EU/EEA countries for 2012



2.4.1.3. Sulfonamides

The overall sales of sulfonamides in the 26 countries, stratified into pharmaceutical forms, are shown in Figure 17. Other pharmaceutical forms, i.e. intramammary preparations, intrauterine preparations and oral pastes, accounted for 0.8%.

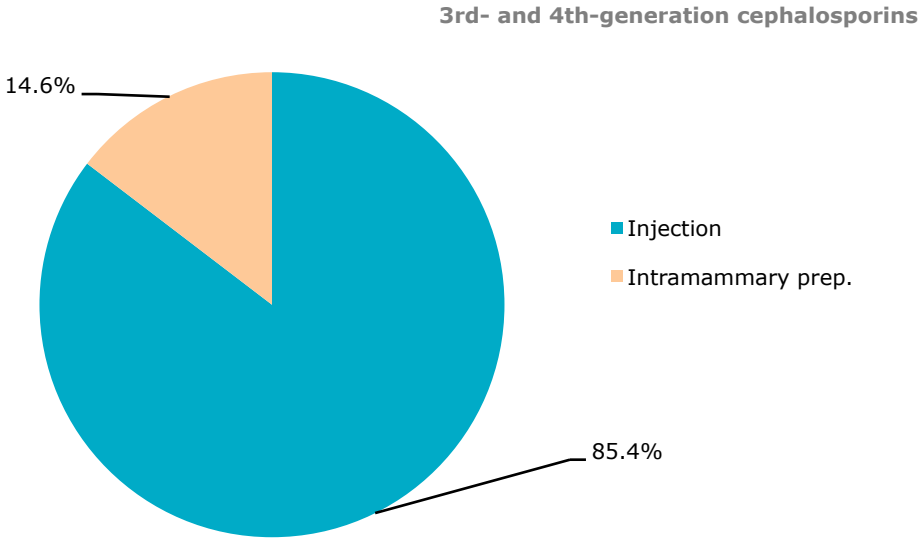
Figure 17. Distribution of sales of sulfonamides for food-producing animals (including horses), in mg/PCU, by the major pharmaceutical forms sold, aggregated by the 26 EU/EEA countries for 2012



2.4.1.4. 3rd- and 4th-generation cephalosporins

The pharmaceutical forms of 3rd- and 4th-generation cephalosporins sold are injections and intramammaries (Figure 18).

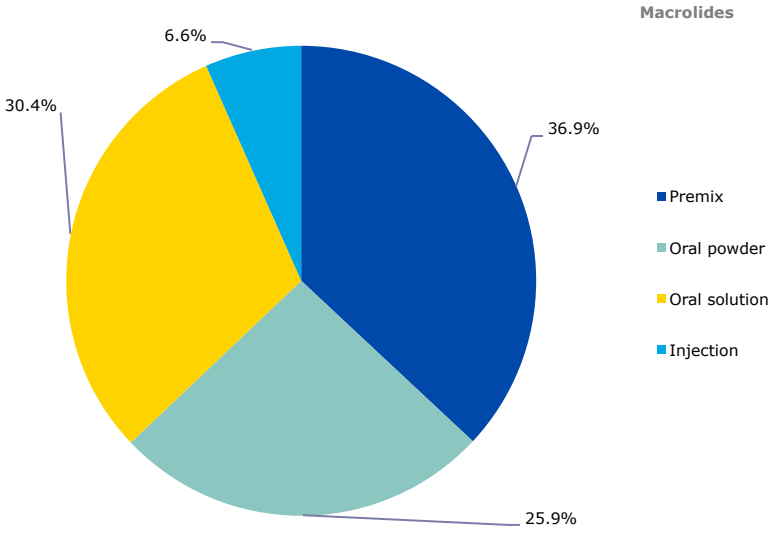
Figure 18. Distribution of sales of 3rd- and 4th-generation cephalosporins for food-producing animals (including horses), in mg/PCU, by pharmaceutical form sold, aggregated by the 26 EU/EEA countries for 2012



2.4.1.5. Macrolides

The overall sales of macrolides for the 26 countries, stratified into pharmaceutical forms, are shown in Figure 19. In addition, 0.2% of the macrolides were sold as intramammary and intrauterine preparations.

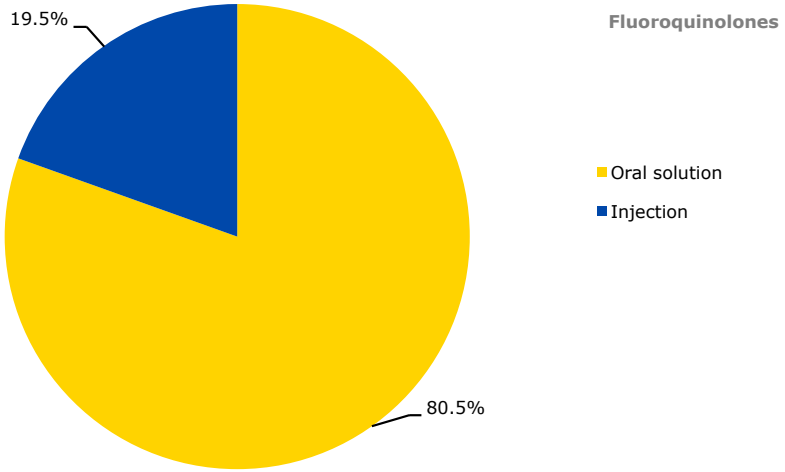
Figure 19. Distribution of sales of macrolides for food-producing animals (including horses), in mg/PCU, by pharmaceutical form sold, aggregated by the 26 EU/EEA countries for 2012



2.4.1.6. Fluoroquinolones

The overall sales of fluoroquinolones for the 26 countries, stratified into pharmaceutical forms, are shown in Figure 20. In addition, 0.1% was sold as bolus, oral powders and oral paste.

Figure 20. Distribution of sales of fluoroquinolones for food-producing animals (including horses), in mg/PCU, by the major pharmaceutical forms sold, aggregated by the 26 EU/EEA countries for 2012



2.5. Distribution of sales for food-producing animals, including horses, by antimicrobial class and pharmaceutical form

The distribution of sales, in mg/PCU, of the various antimicrobial classes by pharmaceutical form varied considerably for the various classes of antimicrobial agents, both aggregated by 26 EU/EEA countries and between countries.

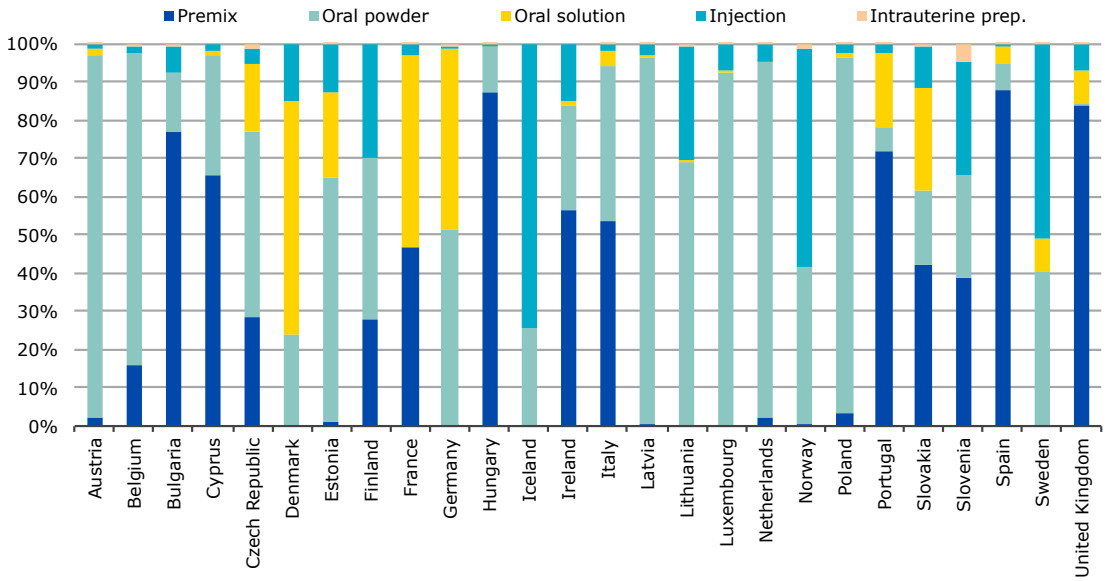
2.5.1. Distribution of sales of antimicrobial classes and forms by country

See the following pages for the distribution per country.

2.5.1.1. Tetracyclines

Figure 21. Spatial distribution of sales of tetracyclines for food-producing animals, in mg/PCU, for 26 countries, for 2012

Figure 22. Distribution of sales by pharmaceutical forms of tetracyclines, in mg/PCU, by country, for 2012[1]



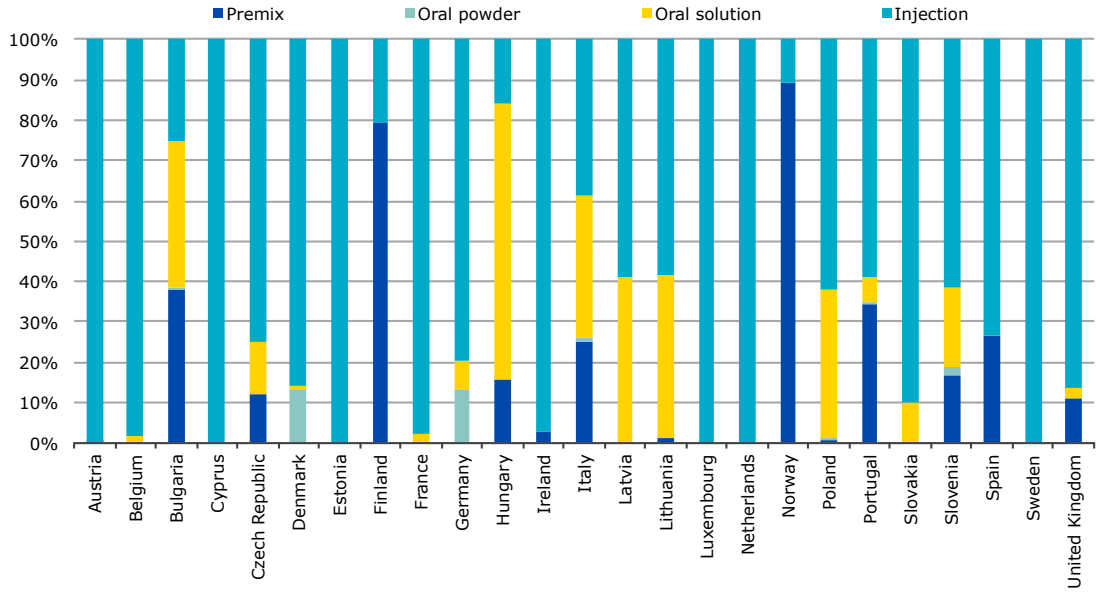
[1] In addition, negligible amounts were sold as bolus, intramammary preparations and/or oral paste in some countries.

2.5.1.2. Amphenicols

Figure 23. Spatial distribution of sales of amphenicols, in mg/PCU, for 26 EU/EEA countries, for 2012[1]

[1] No sales in Iceland.

Figure 24. Distribution of sales by pharmaceutical form of amphenicols, in mg/PCU, by country, for 2012[1,2,3]

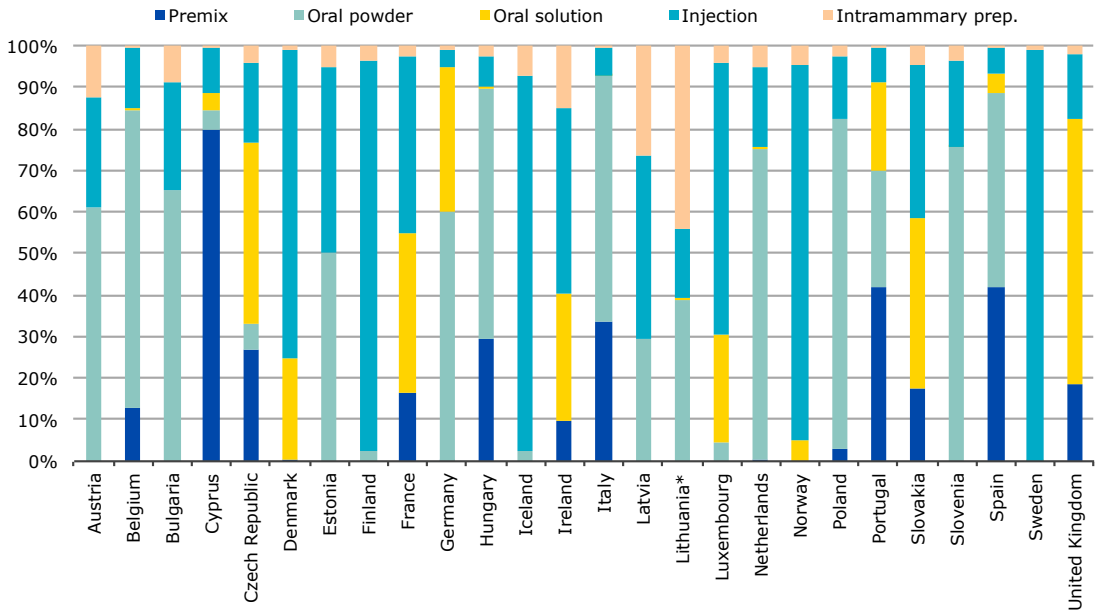


[1] No sales in Iceland. [2] In addition, negligible amounts were sold as intramammary preparations and/or oral pastes in two countries. [3] Sales ≤ 1 kg in Latvia and Sweden.

2.5.1.3. Penicillins

Figure 25. Spatial distribution of sales of penicillins for food-producing animals, in mg/PCU, in 26 EU/EEA countries, for 2012

Figure 26. Distribution of sales by pharmaceutical form for penicillins, in mg/PCU, by country, for 2012[1]



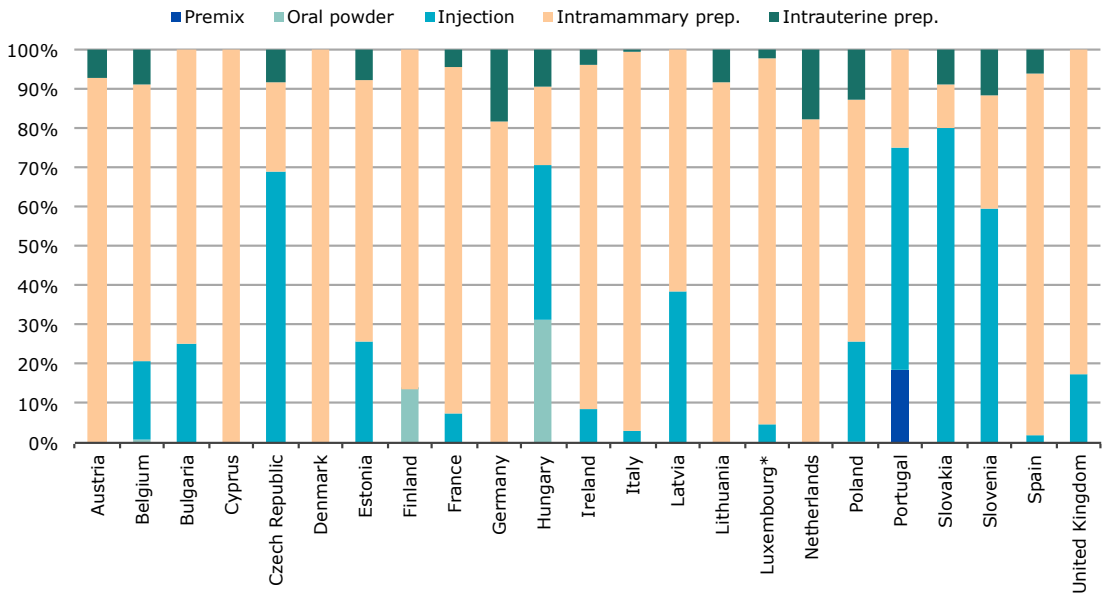
[1] In addition, negligible amounts were sold as bolus, intrauterine preparations and/or oral pastes in some countries. * In Lithuania, 7% were sold as intrauterine preparations.

2.5.1.4. 1st- and 2nd-generation cephalosporins

Figure 27. Spatial distribution of sales of 1st- and 2nd-generation cephalosporins, in mg/PCU, in 26 EU/EEA countries, for 2012[1]

[1] No sales in Iceland, Norway or Sweden.

Figure 28. Distribution of sales by pharmaceutical form for 1st- and 2nd-generation cephalosporins, in mg/PCU, by country, for 2012[1,2,3]



[1] No sales in Iceland, Norway or Sweden. [2] Sales ≤ 1 kg in Cyprus. [3] In addition, negligible amounts were sold as oral solution in some countries.

* In Luxembourg, 66% were sold as oral solution.

2.5.1.5. 3rd- and 4th-generation cephalosporins

Figure 29. Spatial distribution of sales of 3rd- and 4th-generation cephalosporins, in mg/PCU, in 26 EU/EEA countries, for 2012

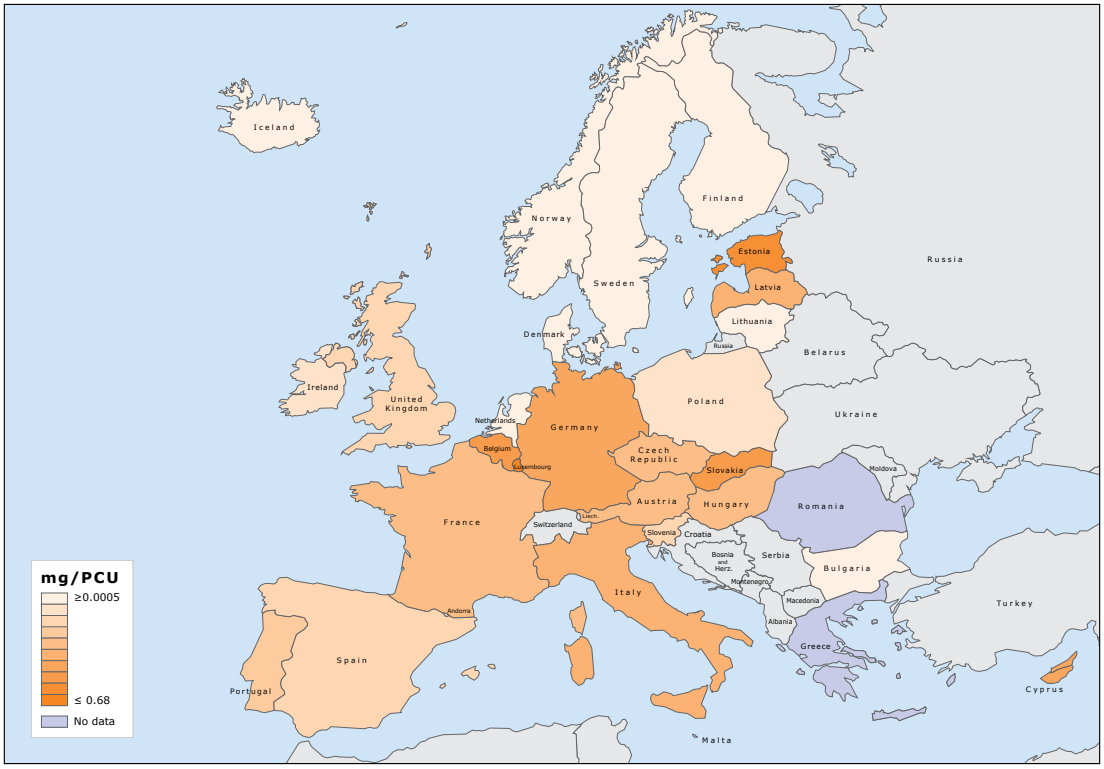
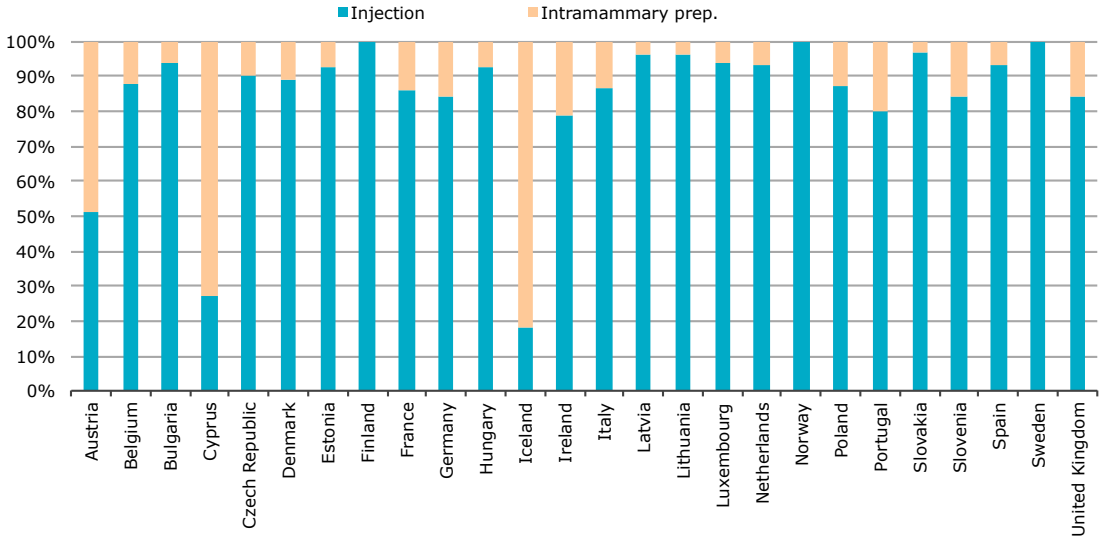


Figure 30. Distribution of sales by pharmaceutical form for 3rd- and 4th-generation cephalosporins, in mg/PCU, by country, for 2012[1]

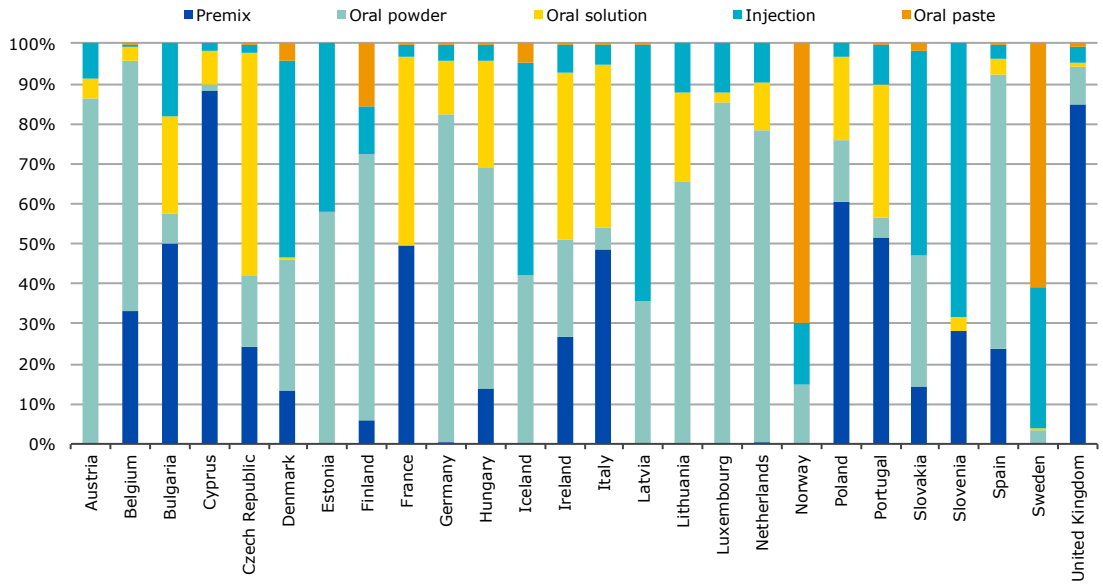


[1] Sales < 1 kg in Iceland.

2.5.1.6. Sulfonamides

Figure 31. Spatial distribution of sales of sulfonamides, in mg/PCU, in 26 EU/EEA countries, for 2012

Figure 32. Distribution of sales by pharmaceutical form for sulfonamides, in mg/PCU, by country, for 2012[1]

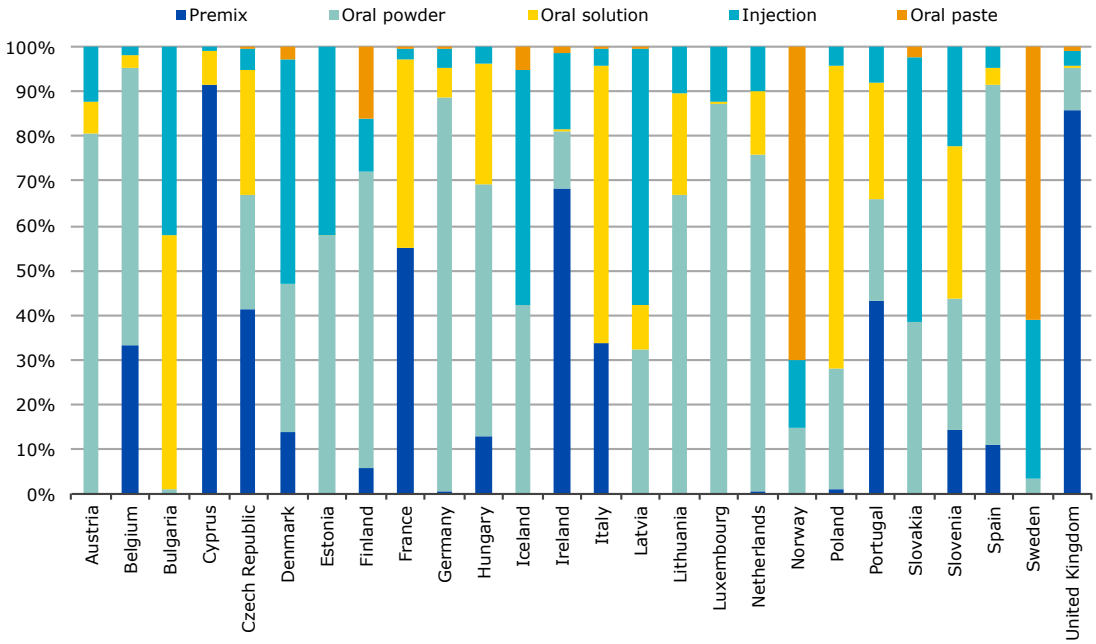


[1] In addition, negligible amounts were sold as bolus, intramammary and/or intrauterine preparations in some countries.

2.5.1.7. Trimethoprim

Figure 33. Spatial distribution of sales of trimethoprim, in mg/PCU, in 26 EU/EEA countries, for 2012

Figure 34. Distribution of sales by pharmaceutical form for trimethoprim, in mg/PCU, by country, for 2012[1]



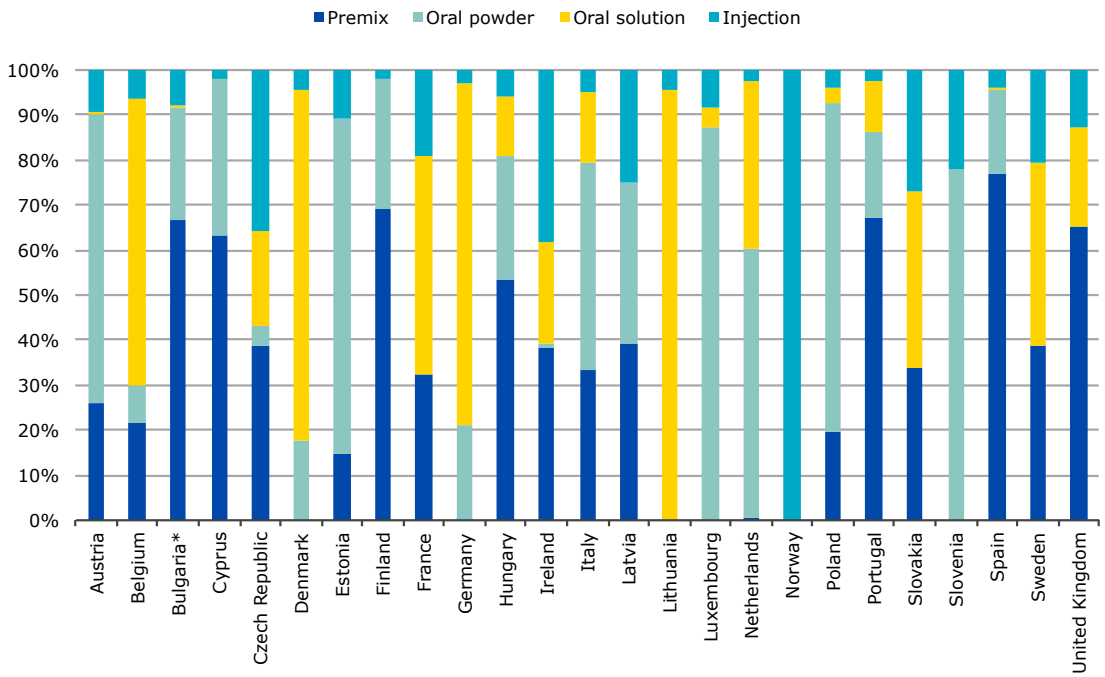
[1] In addition, negligible amounts were sold as intramammary preparations in some countries.

2.5.1.8. Macrolides

Figure 35. Spatial distribution of sales of macrolides, in mg/PCU, in 26 EU/EEA countries, for 2012[1]

[1] No sales in Iceland.

Figure 36. Distribution of sales by pharmaceutical form for macrolides, in mg/PCU, by country, for 2012[1,2,3]



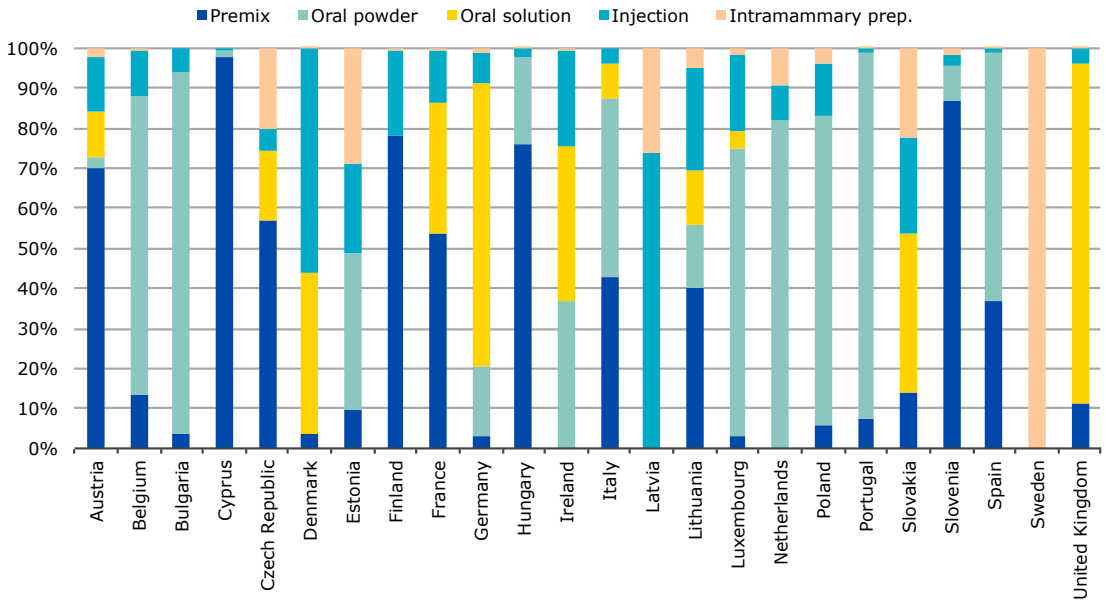
[1] No sales in Iceland. [2] In addition, negligible amounts were sold as intramammary preparations in some countries. [3] Sales ≤ 1 kg in Norway. * In Bulgaria, 14% were sold as intrauterine preparations.

2.5.1.9. Lincosamides

Figure 37. Spatial distribution of sales of lincosamides, in mg/PCU, in 26 EU/EEA countries, for 2012[1]

[1] No sales in Iceland and Norway.

Figure 38. Distribution of sales by pharmaceutical form for lincosamides, in mg/PCU, by country, for 2012[1,2]



[1] No sales in Iceland or Norway. [2] Sales ≤ 1 kg in Sweden.

2.5.1.10. Fluoroquinolones

Figure 39. Spatial distribution of sales of fluoroquinolones, in mg/PCU, in 26 EU/EEA countries, for 2012

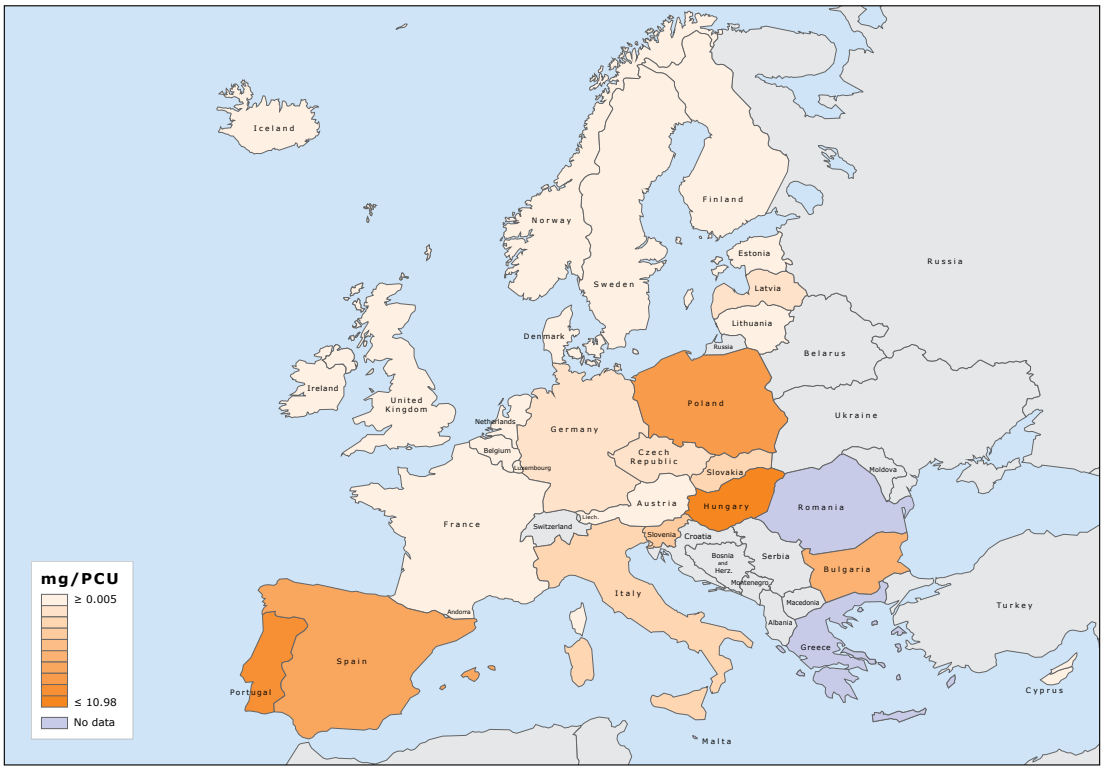
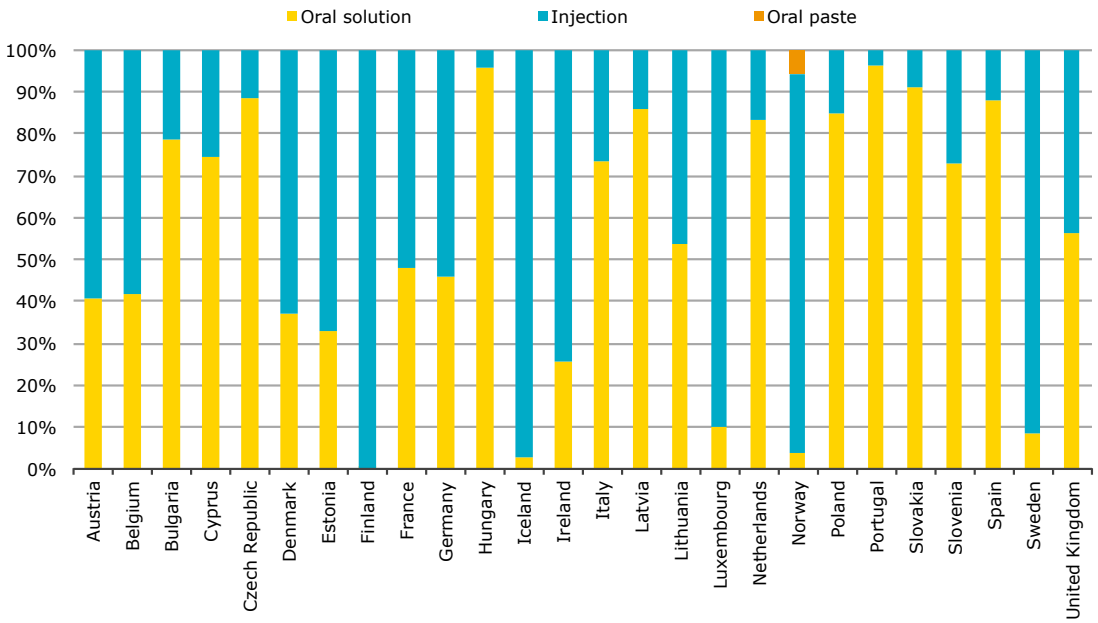


Figure 40. Distribution of sales by pharmaceutical form for fluoroquinolones, in mg/PCU, by country, for 2012[1,2]



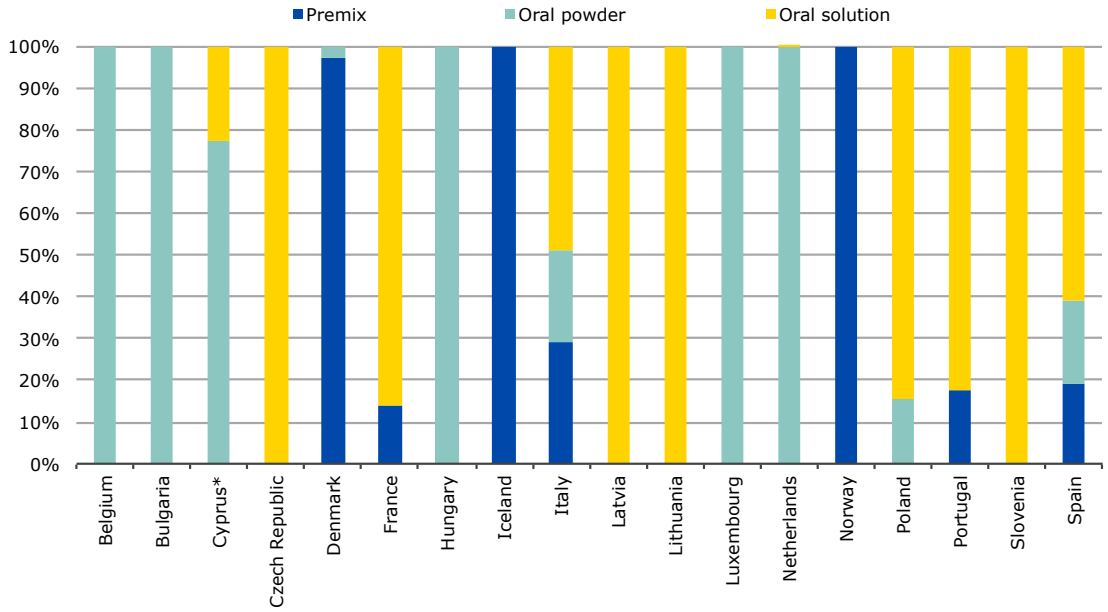
[1] In addition, negligible amounts were sold as bolus, oral powder and premix in some countries. [2] Sales < 1 kg in Iceland.

2.5.1.11. Other quinolones

Figure 41. Spatial distribution of sales of other quinolones, in mg/PCU, in 26 EU/EEA countries, for 2012[1]

[1] No sales in Austria, Estonia, Finland, Germany, Ireland, Slovakia, Sweden or the United Kingdom.

Figure 42. Distribution of sales by pharmaceutical form for other quinolones, in mg/PCU, by country, for 2012[1,2,3]



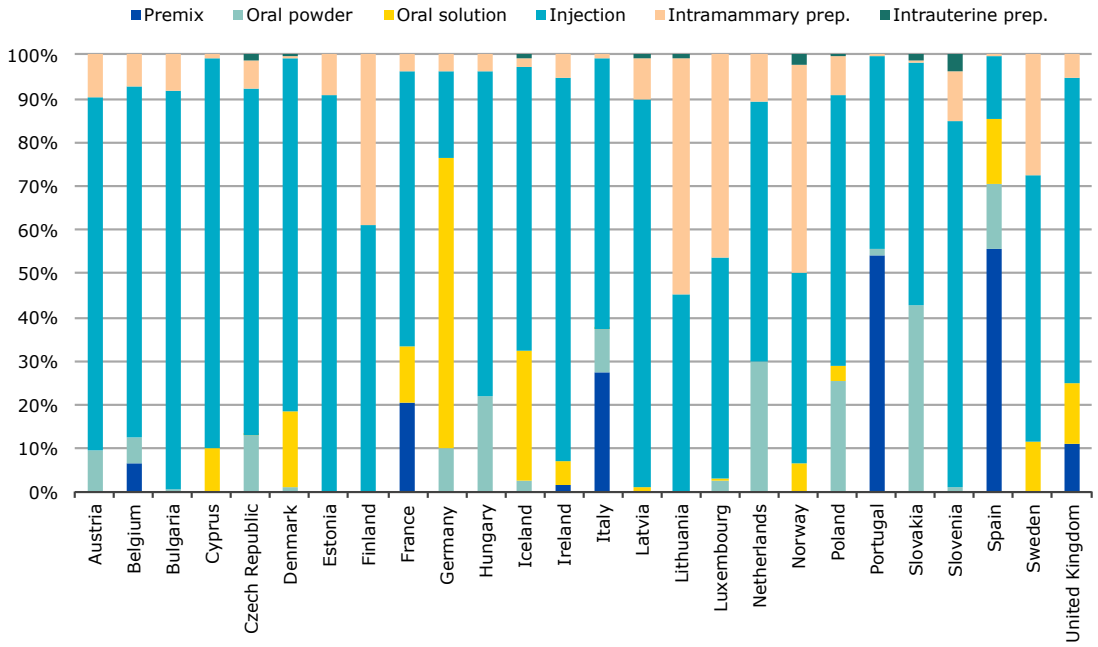
[1] No sales in Austria, Estonia, Finland, Germany, Ireland, Slovakia, Sweden or the United Kingdom. [2] In addition, negligible amounts were sold as injection (*9%), intramammaries and/or oral paste in some countries. [3] Sales ≤ 1 kg in Latvia, Luxembourg and Slovenia.

2.5.1.12. Aminoglycosides

Figure 43. Spatial distribution of sales of aminoglycosides, in mg/PCU, in 26 EU/EEA countries, for 2012[1]

[1] Higher sales compared to the data presented in the ESVAC 2010 and 2011 reports due to correction of classification – i.e. streptomycin and dihydrostreptomycin were classified as 'others' in previous reports.

Figure 44. Distribution of sales by pharmaceutical form for aminoglycosides, in mg/PCU, by country, for 2012[1]



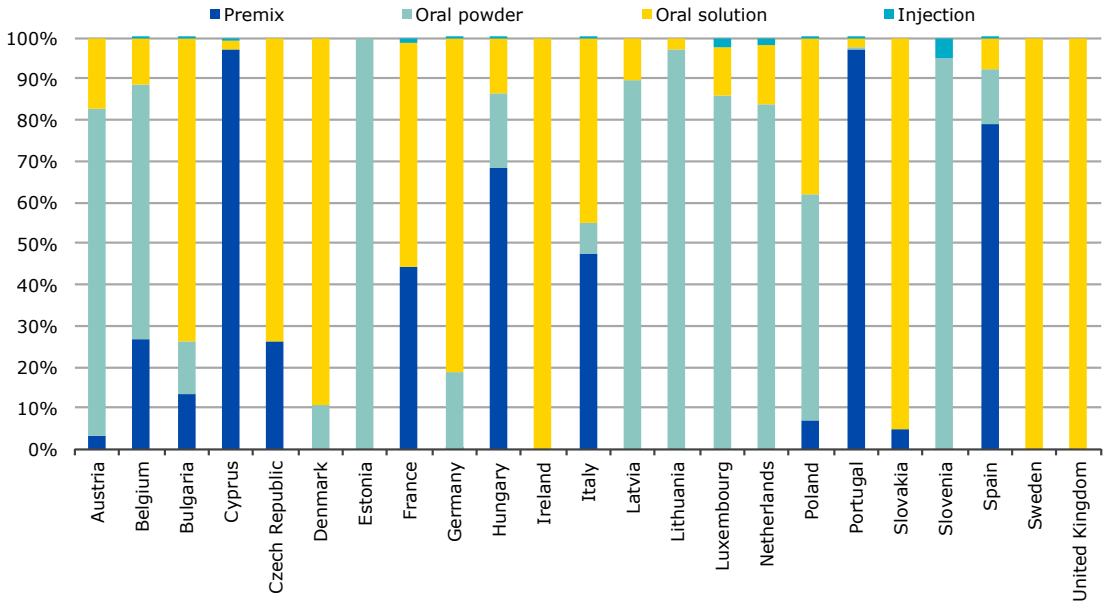
[1] Changes compared to the data presented in the ESVAC 2010 and 2011 reports due to correction of classification – i.e. streptomycin and dihydrostreptomycin were classified as 'others' in previous reports.

2.5.1.13. Polymyxins

Figure 45. Spatial distribution of sales of polymyxins, in mg/PCU, in 26 EU/EEA countries, for 2012[1]

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

Figure 46. Distribution of sales by pharmaceutical form for polymyxins, in mg/PCU, by country, for 2012[1,2]

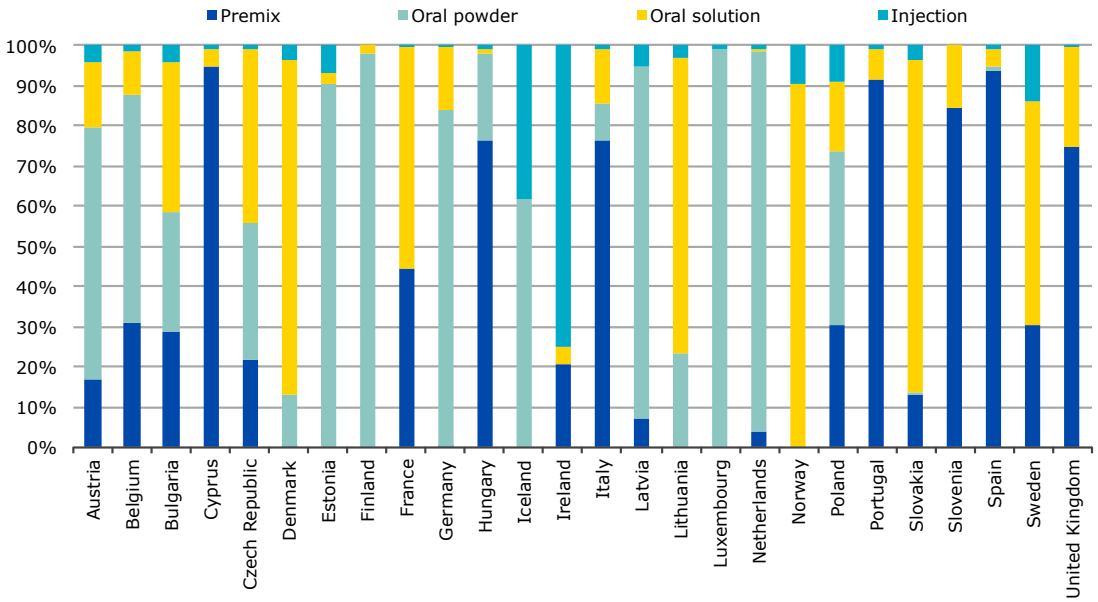


[1] No sales in Iceland, Finland or Norway. [2] In addition, negligible amounts were sold as bolus, oral paste, intramammary and/or intrauterine preparations in some countries.

2.5.1.14. Pleuromutilins

Figure 47. Spatial distribution of sales of pleuromutilins, in mg/PCU, in 26 EU/EEA countries, for 2012

Figure 48. Distribution of sales by pharmaceutical form for pleuromutilins, in mg/PCU, by country, for 2012[1]



[1] Sales < 1 kg in Iceland.

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

Of the 10,074 product presentations for which sales were reported — i.e. product name, form, strength and pack size (tablets excluded) — 81.6% contained only one active ingredient, 16.5% contained two active ingredients and 1.7% contained three active ingredients (Table 7). In addition, 0.2% (n=18) of the product presentations contained four active ingredients. Sales of products with three active ingredients were almost solely accounted for by products for individual treatment (intramammary and intrauterine preparations), and sales of products containing four ingredients were only accounted for by intramammary preparations.

Table 7. Number of product presentations (product name, form, strength and pack size) containing 1, 2 and 3 antimicrobial agents[1] sold, by country, for 2012 (tablets excluded from the data)

Country	1 ingredient	2 ingredients	3 ingredients	Total number[1]
Austria	211	51	9	271
Belgium	338	49	1	388
Bulgaria	159	45	2	206
Cyprus	122	39	3	164
Czech Republic	180	23	0	203
Denmark	247	64	6	317
Estonia	133	33	8	174
Finland	64	20	2	86
France	396	131	3	530
Germany	574	98	8	680
Hungary	322	60	7	389
Iceland	33	9	2	44
Ireland	488	65	9	563
Italy	998	203	20	1,223
Latvia	237	69	20	334
Lithuania	137	38	6	181
Luxembourg	198	59	3	260
Netherlands	236	66	5	307
Norway	66	19	2	87
Poland	436	83	8	528
Portugal	529	107	22	658
Slovakia	808	108	11	930
Slovenia	130	40	4	176
Spain	655	101	6	762
Sweden	97	26	1	124
United Kingdom	422	58	8	489
Total 26 countries	**8,216**	**1,664**	**176**	**10,056**

[1] In addition, 18 intramammary preparations contained 4 active ingredients, accounting for 0.2% of the product presentations in the 26 countries.

Table 8. Number of product presentations (product name, form, strength and pack size) of premixes, oral powders and oral solutions sold containing 1, 2 and 3 antimicrobial agents, by country, for 2012

Country	1 ingredient	2 ingredients	3 ingredients	Total number of product presentations for premixes, oral powder and oral solution
Austria	88	24	6	118
Belgium	129	20	0	149
Bulgaria	88	14	0	102
Cyprus	57	20	0	77
Czech Republic	315	50	2	367
Denmark	105	15	1	121
Estonia	33	6	0	39
Finland	33	4	0	37
France	320	97	0	417
Germany	276	46	0	322
Hungary	188	28	0	216
Iceland	11	2	0	13
Ireland	184	18	0	202
Italy	607	116	8	731
Latvia	81	13	0	94
Lithuania	52	7	0	59
Luxembourg	67	25	0	92
Netherlands	96	27	0	123
Norway	25	2	0	27
Poland	242	42	0	284
Portugal	220	50	11	281
Slovakia	424	62	5	491
Slovenia	39	17	1	57
Spain	388	23	0	411
Sweden	28	2	0	30
United Kingdom	178	24	0	202
Total 26 countries	**4,274**	**754**	**34**	**5,062**

For all 26 countries, 84.4% of the product presentations of pharmaceutical forms of antimicrobial VMPs applicable for group treatment — premixes, oral powders and oral solutions — were for products with one active ingredient (Table 8).

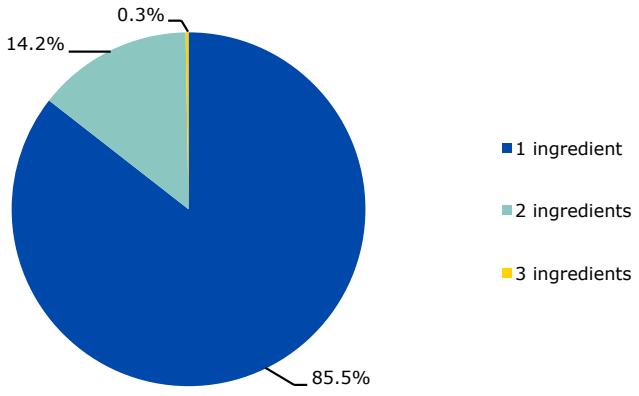
Table 9. Sales, in tonnes of active ingredient, of antimicrobial agents sold as premixes, oral powders and oral solutions containing 1, 2 and 3 active ingredients, by country, for 2012

Country	1 ingredient		2 ingredients		3 ingredients		Tonnes[1]
	Tonnes	%	Tonnes	%	Tonnes	%	
Austria	38	82%	6.1	13%	2.3	5%	46.0
Belgium	156	63%	90	37%			246.0
Bulgaria	28	93%	2.1	7%			30.6
Cyprus	31	72%	12	28%			42.8
Czech Republic	16	88%	2.3	12%			18.7
Denmark	59	86%	9.2	14%	0.0002	<0.01%	67.7
Estonia	4.4	95%	0.2	5%			4.7
Finland	1.3	59%	0.9	41%			2.1
France	385	79%	104	21%			489.0
Germany	1,471	90%	162	10%			1,633.0
Hungary	156	91%	15	9%			171.2
Iceland	0.1	87%	0.02	13%			0.1
Ireland	55	84%	10	16%			65.8
Italy	1,058	73%	371	26%	16	1%	1,445.1
Latvia	4.0	93%	0.3	7%			4.3
Lithuania	5.8	85%	1.0	15%			6.9
Luxembourg	1.1	69%	0.5	31%			1.6
Netherlands	170	80%	44	20%			213.6
Norway	1.9	88%	0.3	12%			2.2
Poland	412	93%	33	7%			444.9
Portugal	139	93%	10	7%	0.2	0.2%	149.0
Slovakia	6.3	89%	0.8	11%			7.1
Slovenia	2.9	64%	1.5	32%	0.2	4%	4.6
Spain	1,445	98%	26	2%			1,471.6
Sweden	1.0	94%	0.1	6%			1.1
United Kingdom	307.7	78%	86	22%			394.0
Total 26 countries	**5,956.6**	**85.5%**	**988.4**	**14.2%**	**18.5**	**0.3%**	**6,963.5**

[1] Premixes, oral powders and oral solutions.

Of the total sales of premixes, oral powders and oral solutions in the 26 countries, in tonnes of active ingredient, 85.5%, 14.2% and 0.3% were accounted for by products containing one, two and three active ingredients, respectively (Figure 49).

Figure 49. Percentage of sales, in tonnes of active ingredient, of premixes, oral powders and oral solutions containing 1, 2, and 3 antimicrobial agents in 2012

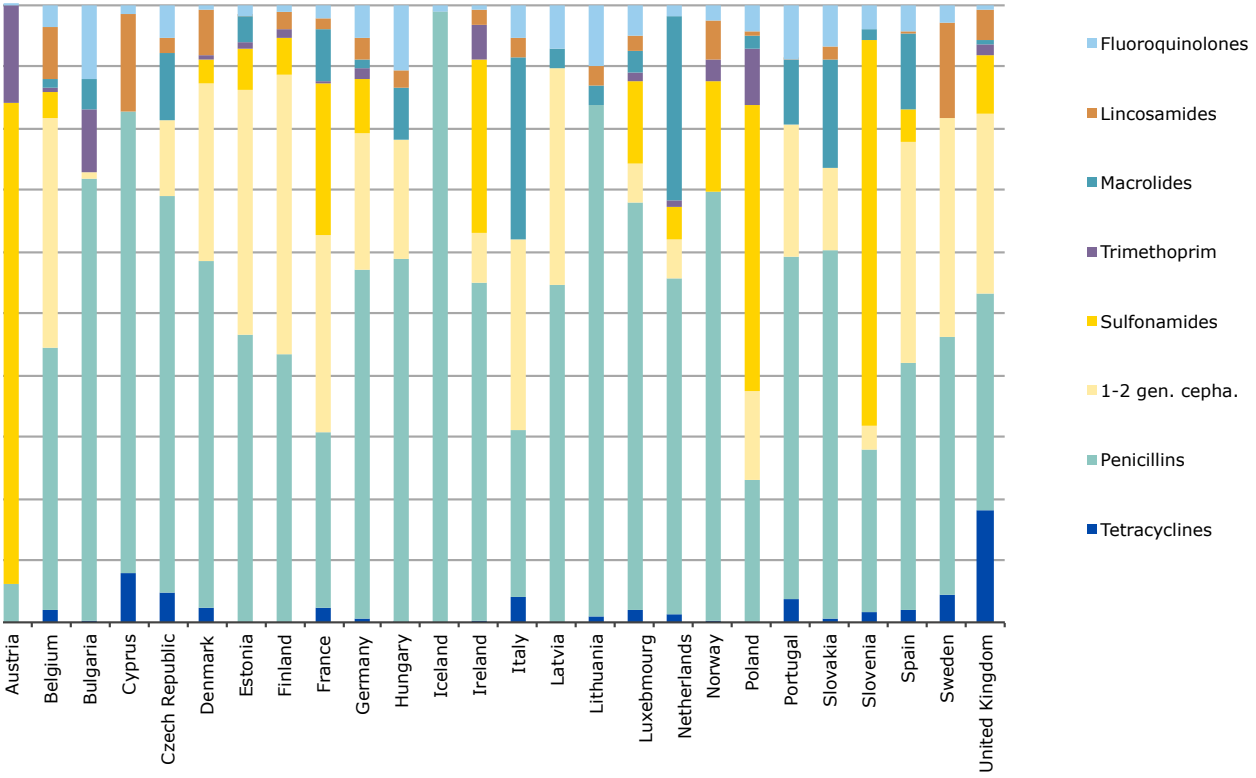


2.7. Sales of tablets by veterinary antimicrobial class for companion animals

Figure 50 shows the distribution of sales of tablets, in tonnes of active ingredient, by antimicrobial class and country for 2012. For the majority of countries, penicillins (mainly in combinations with beta-lactamase inhibitor, see Figure 51) were the most-sold veterinary antimicrobial agent in tablet form; the sales patterns varied substantially between the countries.

Since the tablets included in the data sets are almost solely used for companion animals, the sales figures presented are thought to be a good estimate for sales of tablets of veterinary antimicrobial agents for companion animals. Antimicrobial products marketed for human use are also used in companion animals, in application of Article 10 of Directive 2004/28/EC of the European Parliament and of the Council. Such sales are included in the sales data for human antimicrobial agents (ESAC-net data) if they are based, for instance, on the sales of pharmacies, and not on the reimbursement of physicians' prescriptions as provided by insurance companies. In the current report, all injectable veterinary antimicrobial products are included in the sales for food-producing animals, but some of these products are used in companion animals as well. Consequently, the data presented in Figure 50 do not give a complete picture of the sales patterns of antimicrobial agents in companion animals for 2012.

Figure 50. Distribution of sales of tablets, in tonnes of active ingredient, by antimicrobial class (reported according to the ATCvet hierarchical system), by country, for 2012[1]

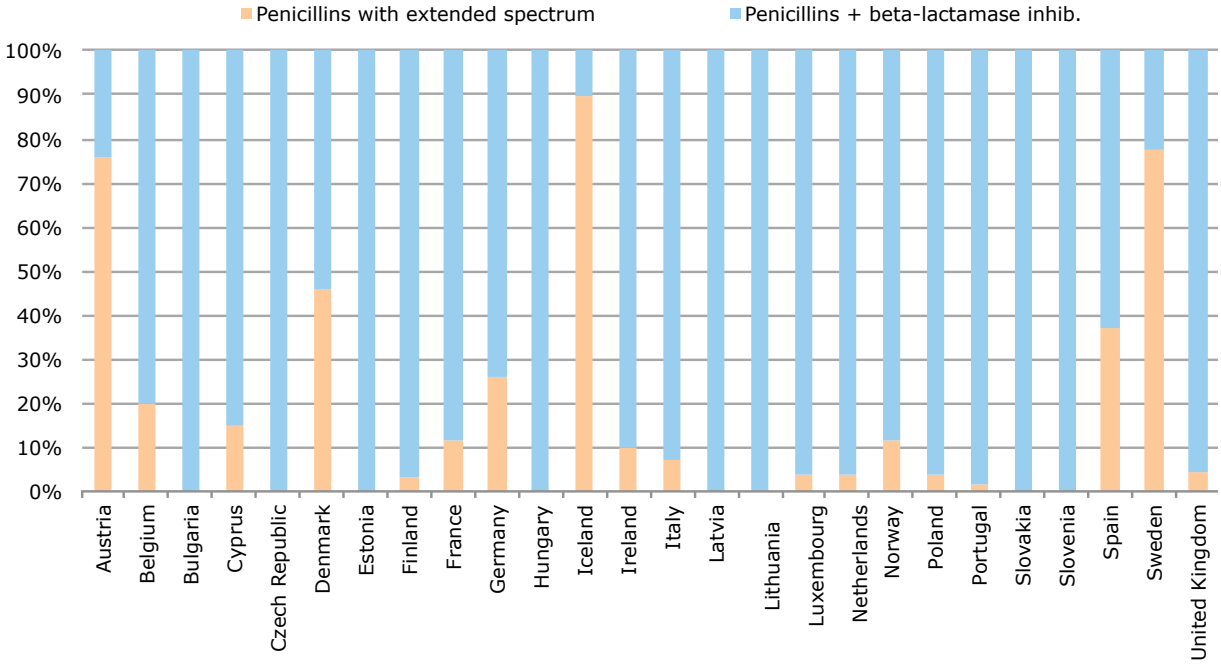


[1] Minor amounts of aminoglycosides, amphenicols, other quinolones, imidazole derivatives and other antibacterials (classified as such in the ATCvet system) were sold, which are not included in this figure.

Aggregated by 26 countries, penicillins (35%), 1st- and 2nd-generation cephalosporins (27%), sulfonamides (13%) and macrolides (7%) were the most-sold antimicrobial classes of tablets.

The distribution of penicillins by subclasses varied significantly between the 26 countries for the veterinary penicillins available as tablets (Figure 51). The sales of tablets with the combination of penicillins + beta-lactamase inhibitors (tonnes of clavulanic-acid inhibitors not included in the data) accounted for between 10% and 100% of the total sales of penicillin tablets.

Figure 51. Distribution of sales of tablets containing penicillins by subclass (in weight of active ingredient), by country, for 2012



2.8. Changes across time (2010–2012)

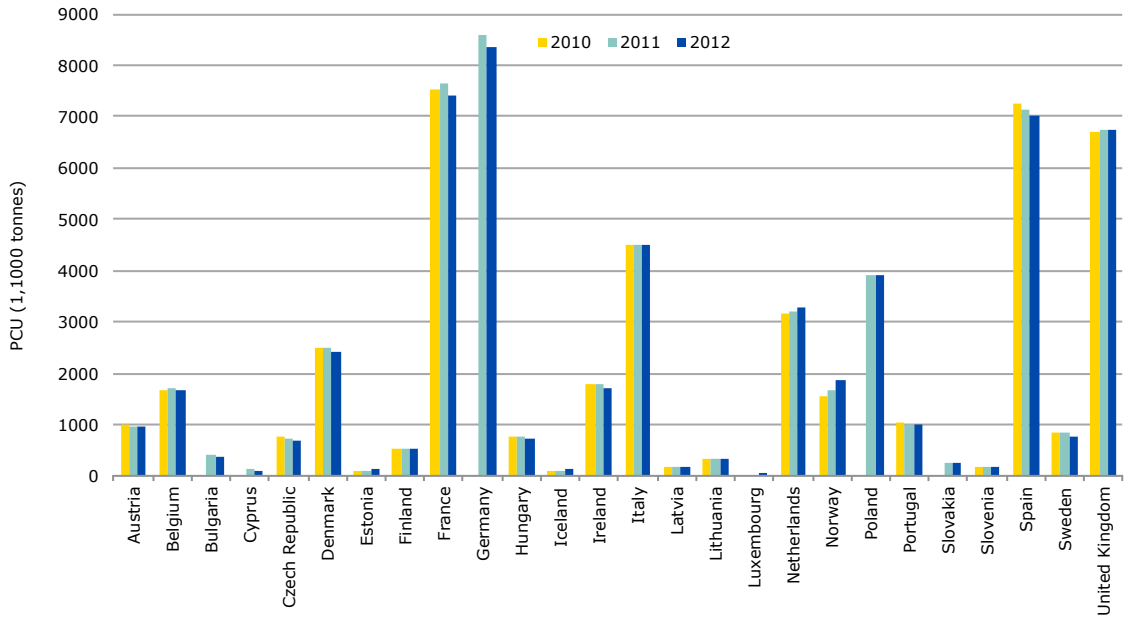
2.8.1. All countries

2.8.1.1. Changes by PCU

The PCU (estimated weight at treatment of livestock and of slaughtered animals) showed a minor decrease for 14 of the 20 countries that have reported sales for 2010, 2011 and 2012 (Fig. 52).

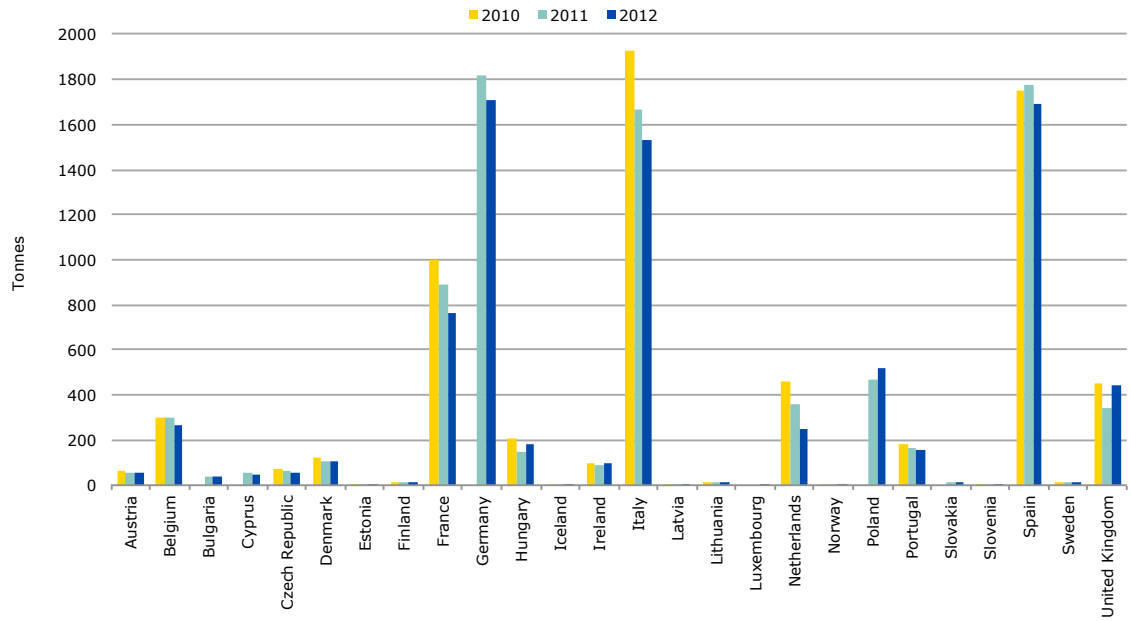
For Estonia, a notable increase (14%) in the PCU is seen for 2012, and this is mainly accounted for by a substantial increase in the export of pigs for slaughter reported by TRACES, but also by an increase in the numbers of slaughtered poultry (national statistics). For Norway, a substantial increase (20%) in the PCU is observed, and this is almost solely due to increased production of farmed fish. For Sweden, the PCU decreased by 6%; data on sales of antimicrobial agents for fish were not available for 2012, and therefore fish are not included in the PCU for Sweden, but this only explains 1% of the change.

Figure 52. Population correction unit (PCU) for food-producing animals, including horses, in 1,000 tonnes, by country, during 2010 to 2012



2.8.1.2. Changes in tonnes of active ingredients

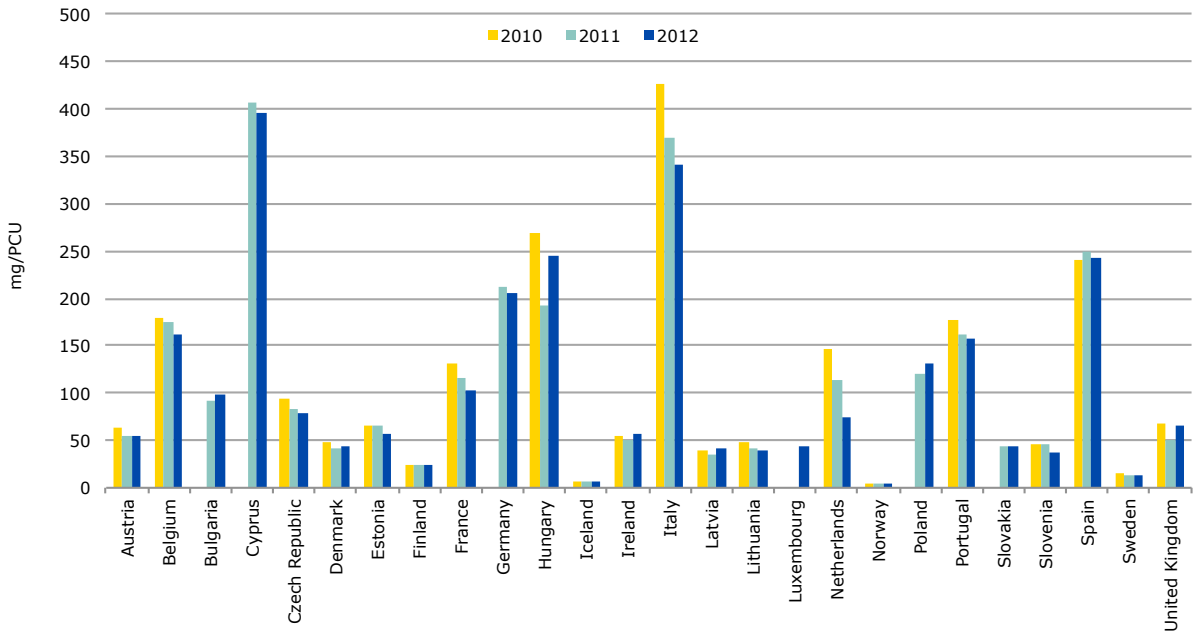
Figure 53. Sales, in tonnes of active ingredient, of veterinary antimicrobials for food-producing animals, including horses, during 2010 to 2012, for 26 EU/EEA countries[1,2,3]



[1] Data for Latvia for 2011 updated as minor errors were identified in the calculation of sales. [2] Data for 2010 and 2011 have been updated for Slovenia as minor errors were identified in the ESVAC data analysis output. [3] Substantial underreporting was identified for Spain for 2010, indicating that the sales have actually decreased from 2010 to 2011.

2.8.1.3. Changes in mg/PCU

Figure 54. Total sales of veterinary antimicrobial agents for food-producing species, including horses, in mg/PCU, during 2010 to 2012, for 26 EU/EEA countries[1,2,3]



[1] Data for 2011 for Latvia updated as minor errors were identified in the calculation of sales. [2] Data for 2010 and 2011 have been updated for Slovenia as minor errors were identified in the ESVAC data analysis output. [3] Substantial underreporting was identified for Spain for 2010, indicating that the sales have actually decreased from 2010 to 2012.

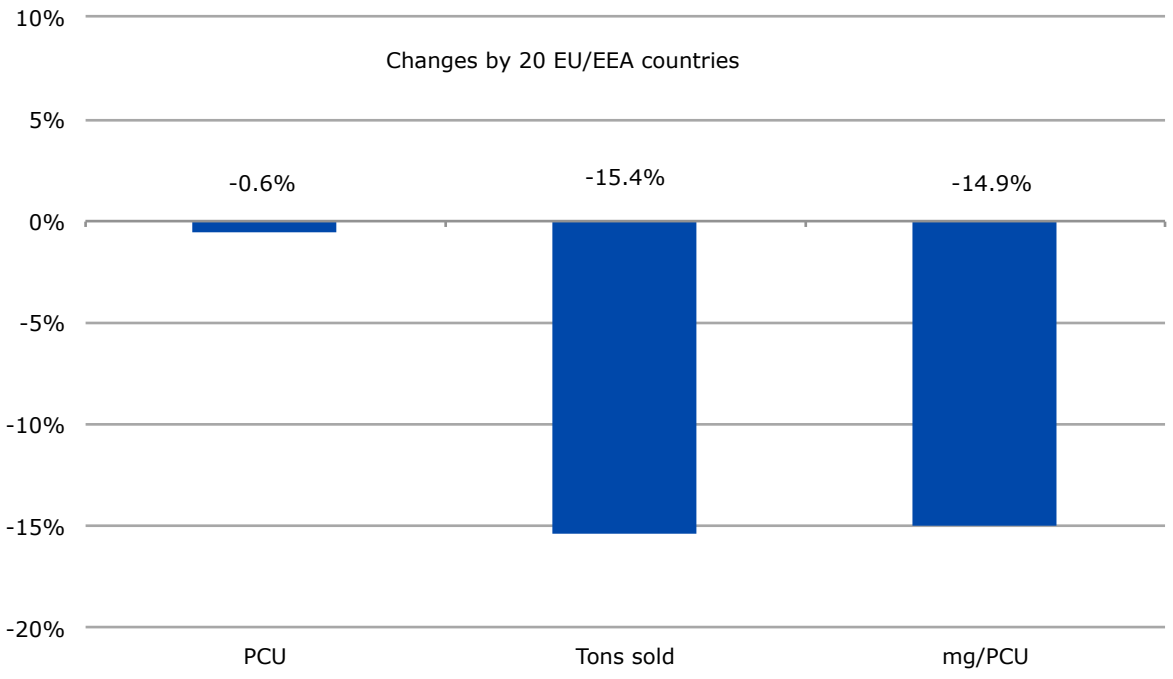
Table 10. Sales of veterinary antimicrobial agents for food-producing species, including horses, in mg/PCU, during 2010 to 2012, for 26 EU/EEA countries

Country	2010	2011	2012	% change 2010-2012
Austria	63	54	55	-13%
Belgium	180	175	161	-11%
Bulgaria		93	99	7%
Cyprus		408	397	-3%
Czech Republic	94	83	80	-15%
Denmark	47	43	44	-7%
Estonia	66	66	56	-15%
Finland	25	24	24	-4%
France	132	117	103	-22%
Germany		211	205	-3%
Hungary	268	192	246	-8%
Iceland	7.2	6.3	5.9	-19%
Ireland	54	49	58	7%
Italy	427	370	341	-20%

Latvia[1]	40	35	41	3%
Lithuania	48	42	39	-18%
Luxembourg			44	
Netherlands	146	114	75	-49%
Norway	4.1	3.7	3.8	-7%
Poland		120	132	10%
Portugal	178	161	157	-12%
Slovakia		44	43	-2%
Slovenia[2]	47	46	37	-21%
Spain[3]	241	250	242	0.2%
Sweden	15	14	13	-11%
United Kingdom	68	51	66	-2%

[1] Data for 2011 updated as minor errors were identified in the calculation of sales. [2] Data for 2010 and 2011 have been updated as minor errors were identified in the ESVAC data analysis output. [3] Note that sales are underreported for 2010 (see page 35 in the ESVAC 2011 report).

Figure 55. Percentage changes in sales of veterinary antimicrobial agents for food-producing species, including horses, in mg/PCU, from 2010 to 2012, aggregated by 20 EU/EEA countries[1]



[1] Austria, Belgium, the Czech Republic, Denmark, Estonia, Finland, France, Hungary, Iceland, Italy, Ireland, Latvia, Lithuania, the Netherlands, Norway, Portugal, Slovenia, Spain, Sweden and the United Kingdom.

2.8.1.4. Changes in sales by antimicrobial class in mg/PCU

Sales of tetracyclines are shown in Figure 56. Due to the high volume of sales of tetracyclines and the fact that doxycyclines require a lower dose to treat animals than other tetracyclines, doxycycline sales are also presented separately (Figure 57). If there is a shift in the proportion of sales of doxycyclines of the sales of other tetracyclines, this may be a potential explanation for increase or decrease of tetracyclines (Figure 56).

Figure 56. Sales of tetracyclines for food-producing species, including horses, in mg/PCU, by 26 EU/EEA countries, during 2010 to 2012

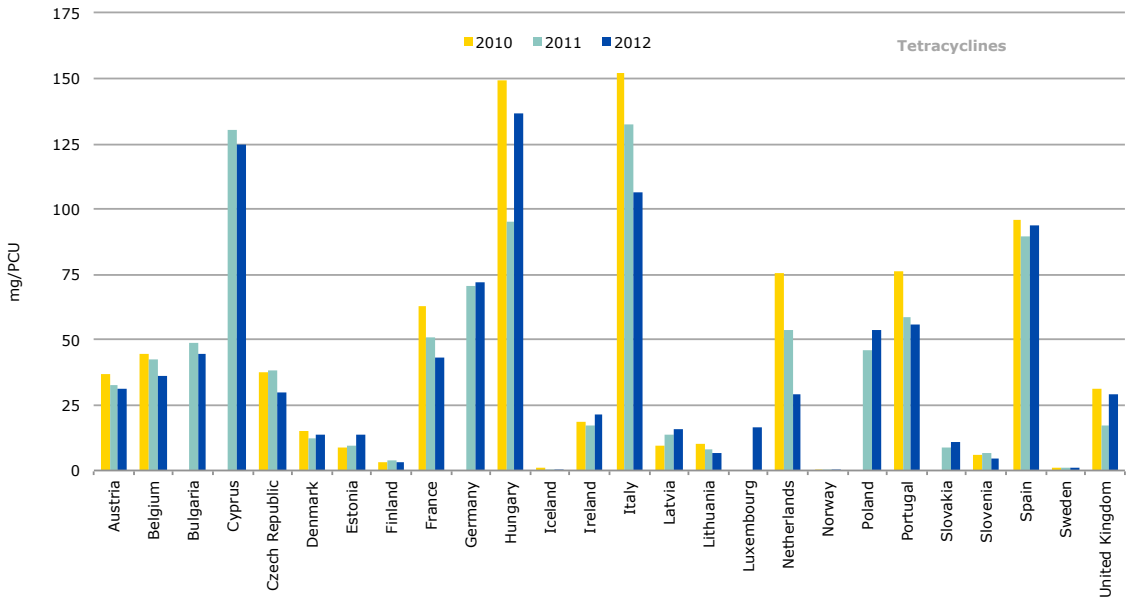


Figure 57. Sales of doxycycline for food-producing species, including horses, in mg/PCU, by 26 EU/EEA countries, during 2010 to 2012

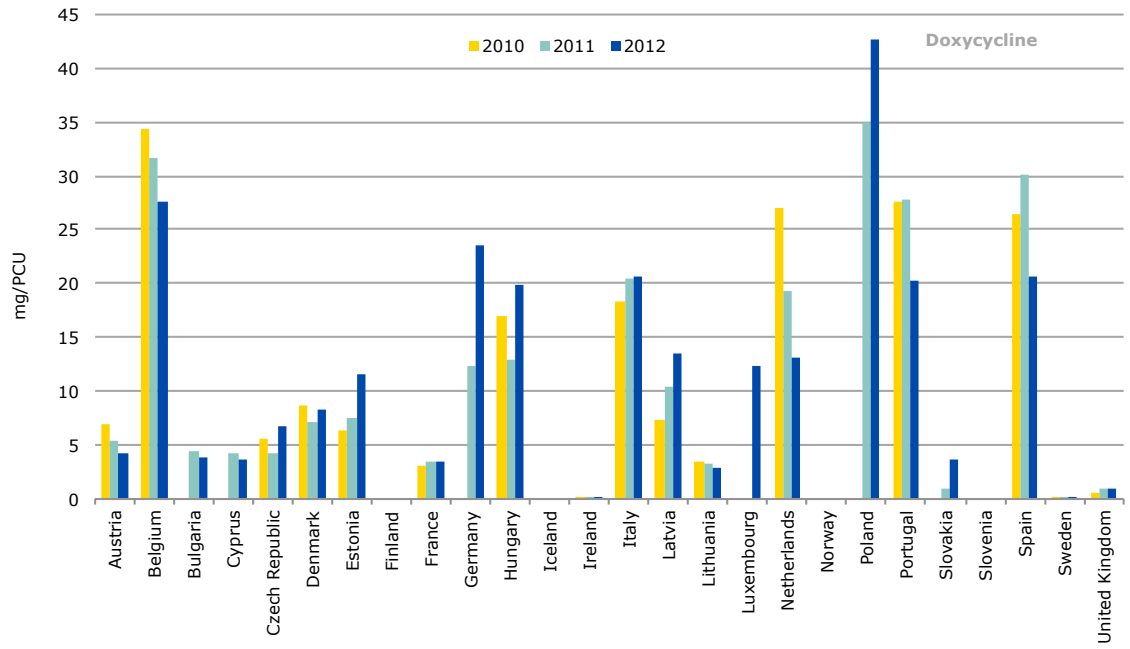


Figure 58. Sales of penicillins for food-producing species, including horses, in mg/PCU, by 26 EU/EEA countries, during 2010 to 2012

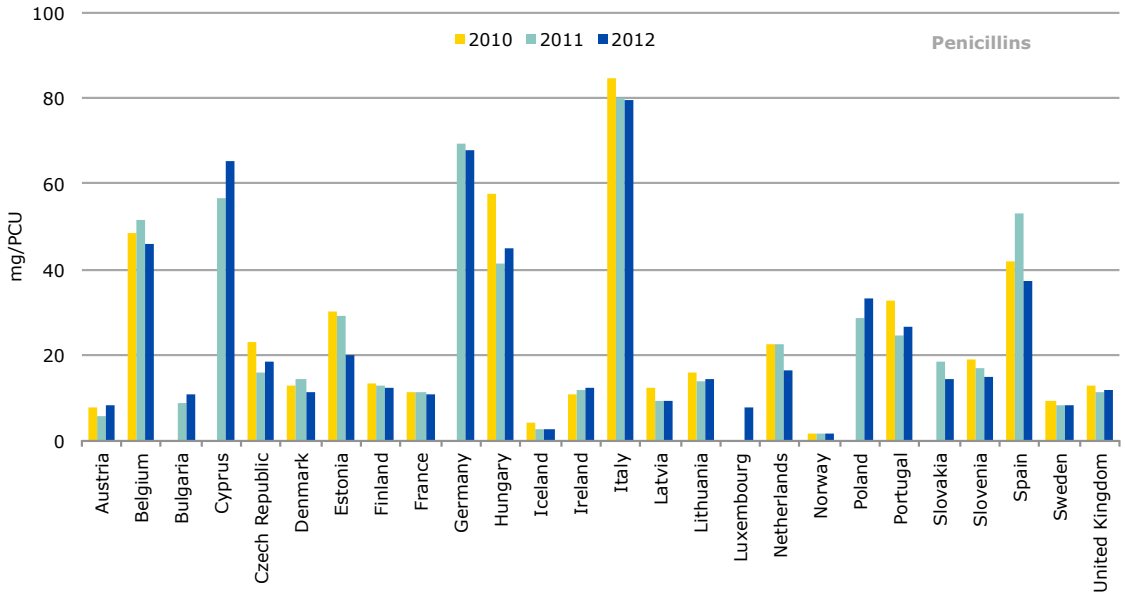


Figure 59. Sales of sulfonamides for food-producing species, including horses, in mg/PCU, by 26 EU/EEA countries, during 2010 to 2012

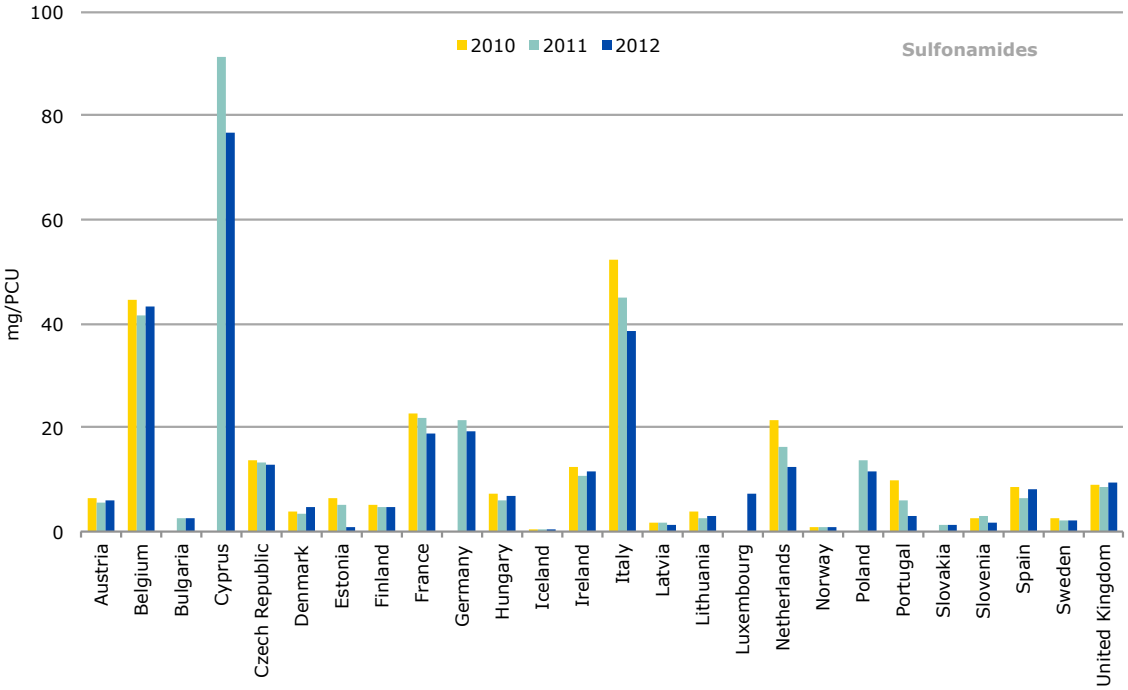


Figure 60. Sales of 3rd- and 4th-generation cephalosporins for food-producing species, including horses, in mg/PCU, by 26 EU/EEA countries, during 2010 to 2012

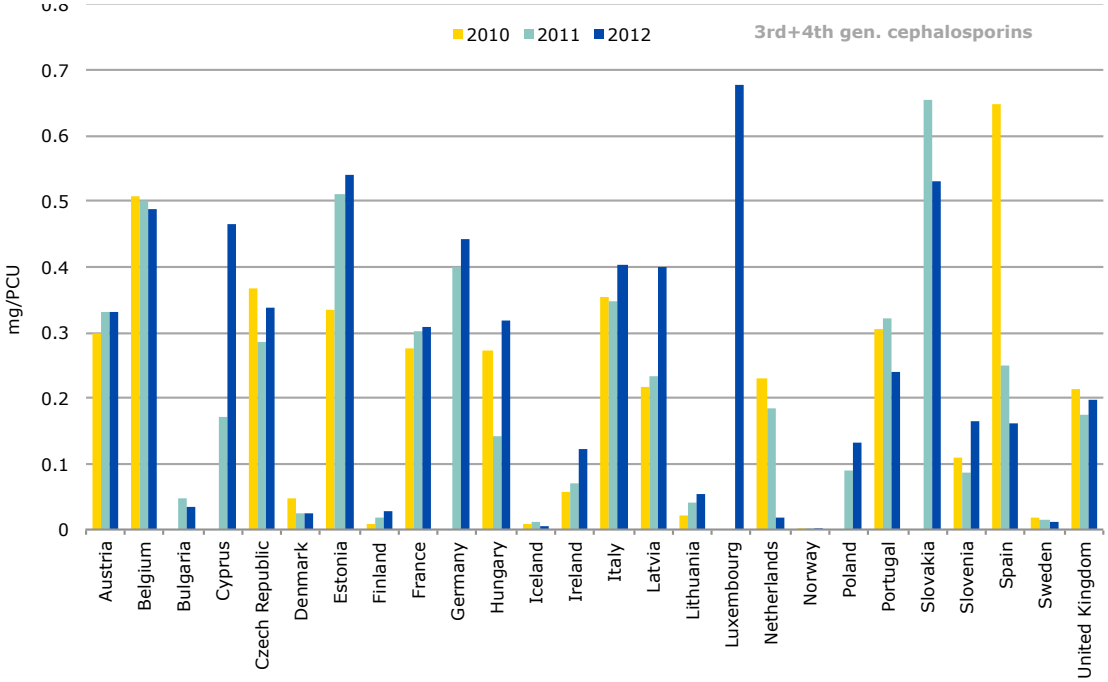


Figure 61. Sales of macrolides for food-producing species, including horses, in mg/PCU, by 26 EU/EEA countries, during 2010 to 2012

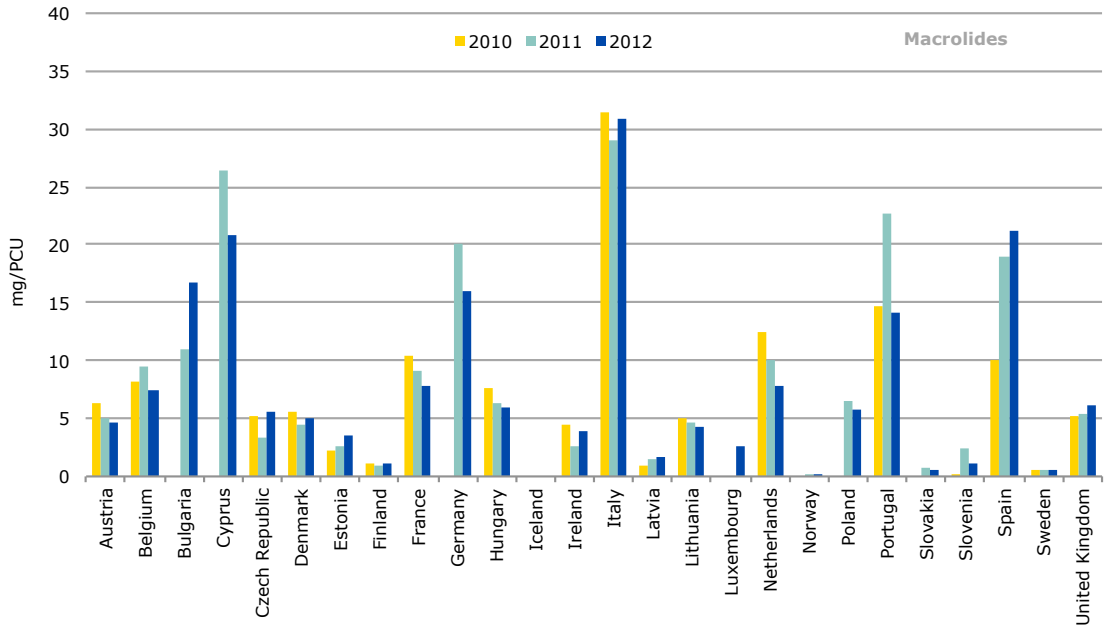
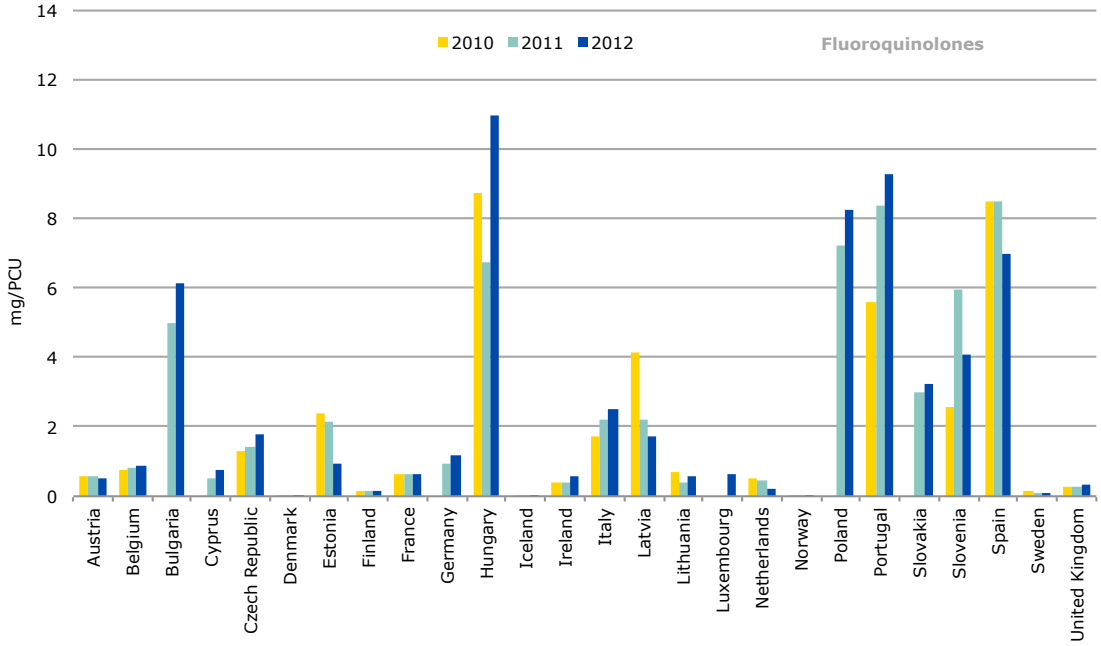


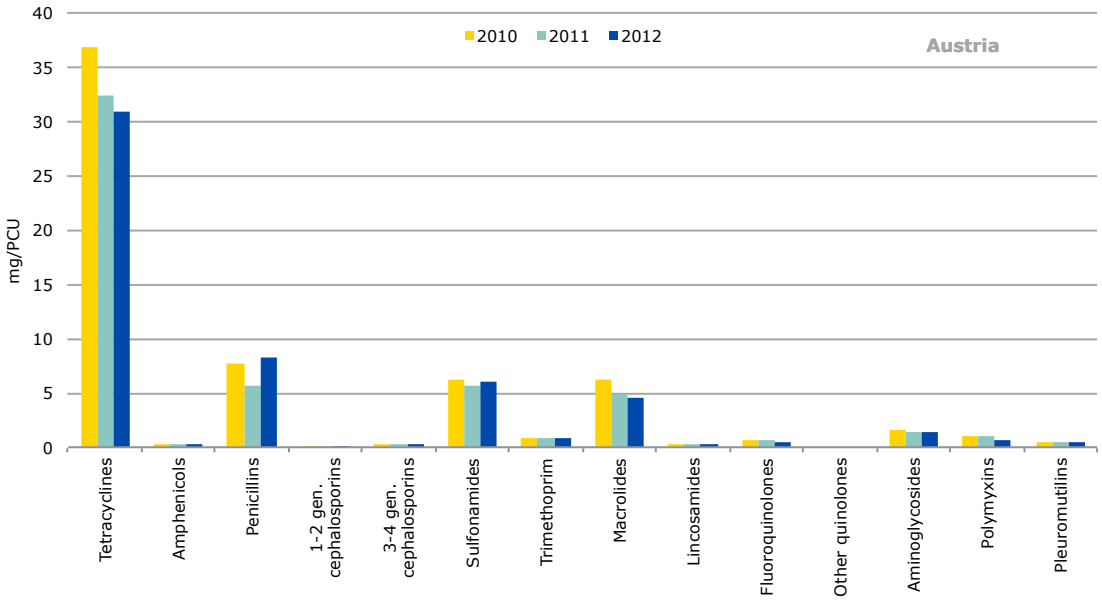
Figure 62. Sales of fluoroquinolones for food-producing species, including horses, in mg/PCU, by 26 EU/EEA countries, during 2010 to 2012



2.8.2. Changes by country

Austria

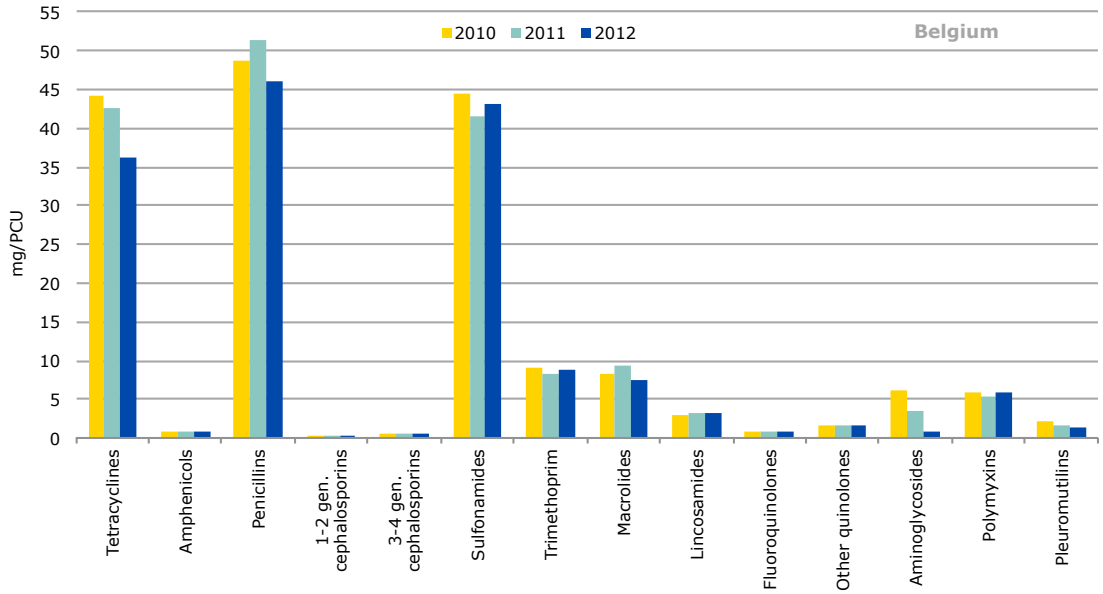
Figure 63. Sales (mg/PCU) by antimicrobial class for food-producing species, including horses, in Austria for the years 2010 to 2012



A decline in the sales (in mg/PCU) of 13% from 2010 to 2011 was observed, whereas the decline from 2011 to 2012 was only 0.41%. The major part of the reduction was for tetracyclines and macrolides for systemic use (oral application). For penicillins, the sales in 2012 achieved nearly the same level as in 2010. The sales patterns from 2011 to 2012 were relatively stable. Most of the reduction from 2010 to 2011 can be explained by a decrease in the sales of five products from two companies.

Belgium

Figure 64. Sales (mg/PCU) by antimicrobial class for food-producing species, including horses, in Belgium for the years 2010 to 2012

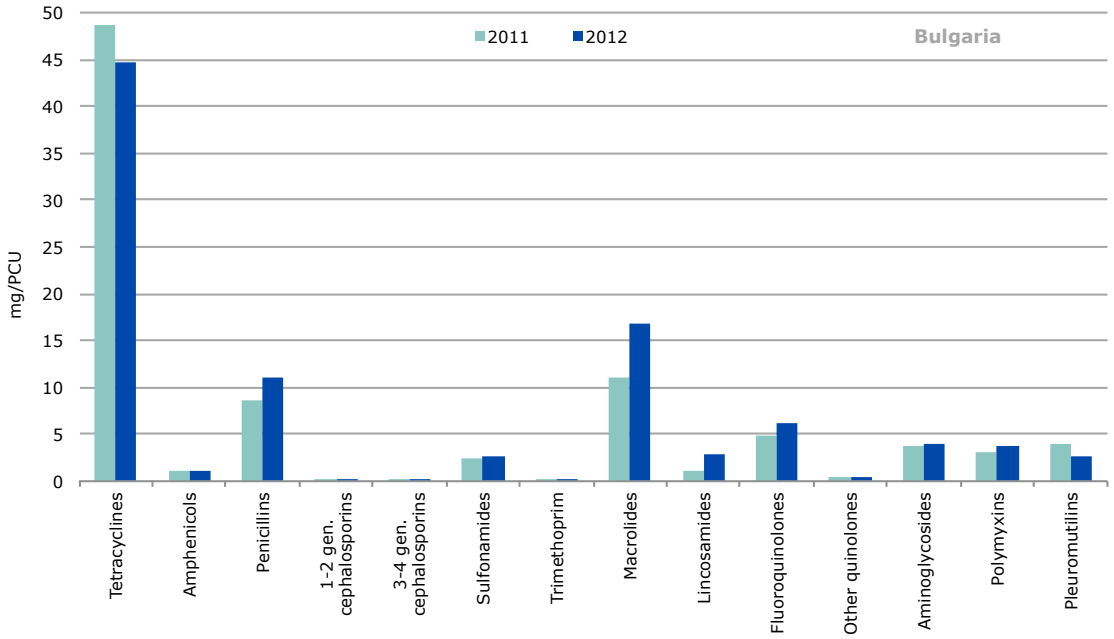


A total decrease in sales of veterinary antimicrobial agents, in mg/PCU, of 11% was observed in Belgium from 2010 to 2012. As there was no major change in biomass content over these years, the decrease reflects mostly a decrease in amounts of ingredients sold. Regarding the consumption of CIAs with highest priority for human medicine, there is a decrease in the use of macrolides particularly for the last reported year. Sales of cephalosporins and fluoroquinolones were stable to slightly increasing over these years.

From January 2012 onwards, prudent-use campaigns (starting with emphasis on food-producing species but also in companion animals and horses) took place in Belgium by the Center of Expertise on Antimicrobial Consumption and Resistance in Animals (AMCRA: http://www.amcra.be/en). AMCRA is the major source of recommendations to support action plans to promote responsible use, minimising the emergence of resistance. AMCRA is composed of different stakeholders (farmers, feed manufacturers, pharmaceutical industry, veterinarians, veterinary faculties) whereby recommendations are validated by the competent authorities. General guidelines on prudent use of antimicrobial agents were elaborated by AMCRA or farmers and veterinarians. Specific formularies on the use of antimicrobials were developed and distributed to veterinarians and students; antimicrobial agents are categorised as 1st to 3rd choice according to species and disease or pathogen, based on pharmacological characteristics and appropriateness of use of the respective classes. Within each class, a colour code (yellow, orange, red) indicates the importance of this antibiotic in relation to human health (CIAs) and in second place animal health. The prudent-use campaign initiated by AMCRA and repeated political and media attention on the risk related to resistance emergence is thought to have contributed to the decrease in sales of veterinary antimicrobials from 2011 to 2012. In 2013, a further decrease in sales of antibiotics of 6.3% is observed from 2012 to 2013 (http://www.amcra.be/en/belvet-sac-report-2013).

Bulgaria

Figure 65. Sales (mg/PCU) by antimicrobial class for food-producing species, including horses, in Bulgaria for the years 2011 to 2012

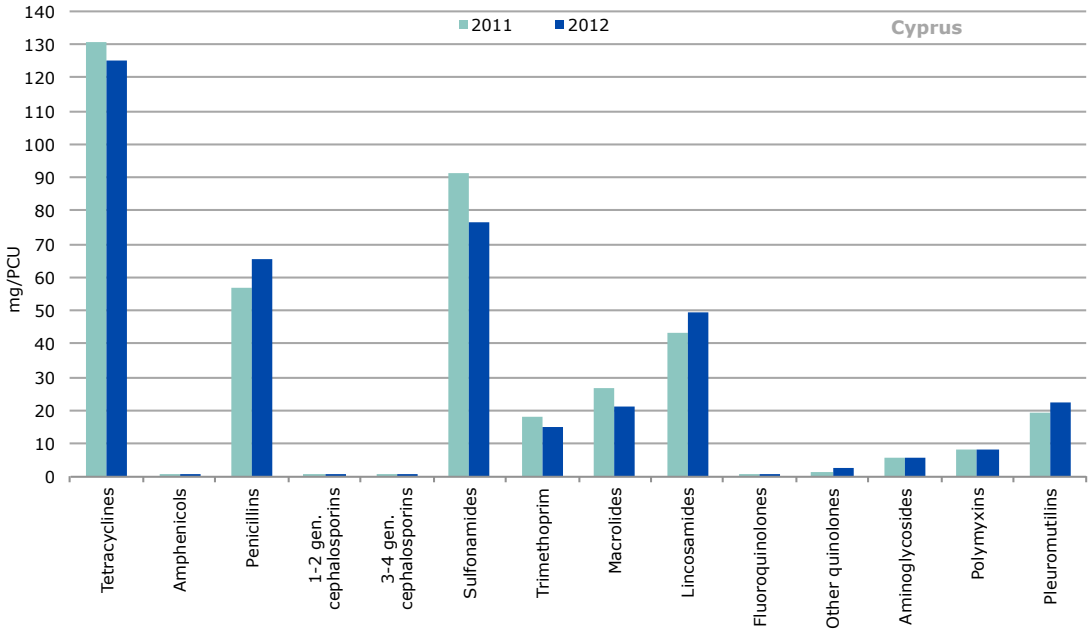


For Bulgaria, an increase (7%) in the sales of veterinary antimicrobial agents, in mg/PCU, is seen from 2011 to 2012, and this is mainly related to the increase in sales of macrolides, penicillins and fluoroquinolones, while for cephalosporins there were no changes.

There are currently no data available that can explain the observed increase in the sales or the changes in the sales patterns of veterinary antimicrobial agents.

Cyprus

Figure 66. Sales (mg/PCU) by antimicrobial class for food-producing species, including horses, in Cyprus for the years 2011 to 2012



Data for Cyprus for 2012 indicate a slight decrease (-3%) in total sales of antimicrobial agents when compared to 2011. It should be noted that the 2012 data used on special licence were also included in the dataset, in contrast to the 2011 data, thus the sales for 2011 may be slightly underestimated.

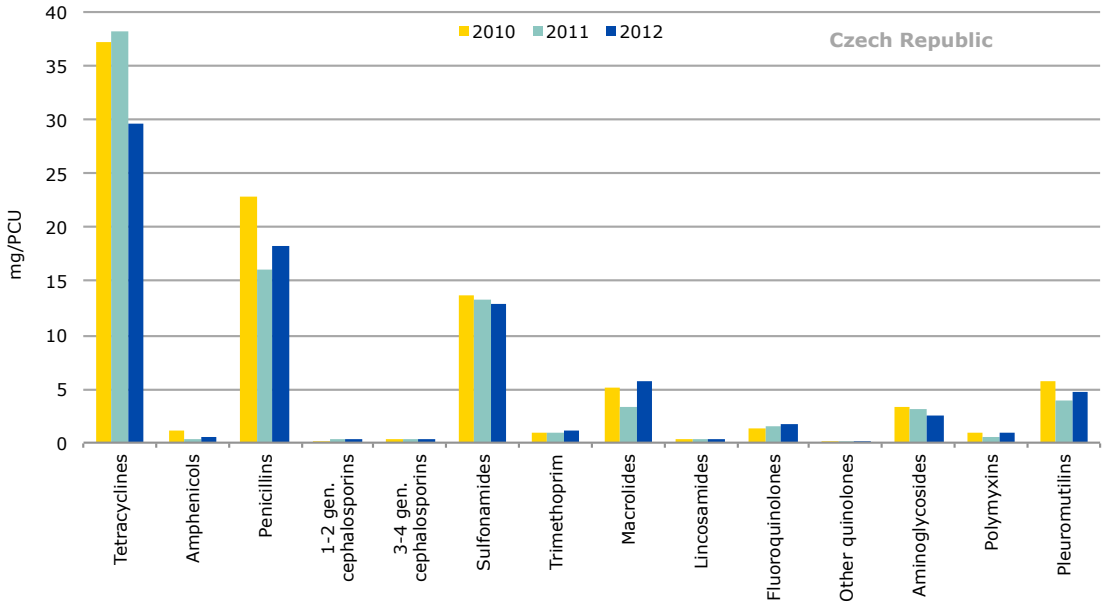
The observed decrease should be interpreted with caution, as it has been the result of the first two years of collecting data following the ESVAC common template, bearing in mind that the overall sales, in tonnage, can fluctuate from year to year. Some seasonal factors in disease occurrence or minor changes in the population and distribution of the various food-producing species of animals in Cyprus could lead to this result.

In Figure 66, it can be seen that tetracyclines, penicillins and sulfonamides/trimethoprim still accounted for the largest proportion of antibiotic sales. Of note is 2012's reduction in sulfonamides/trimethoprim and tetracyclines sales. The key driver in the apparent very light decrease in the total tonnage sold for 2012 may be primarily attributed to the increased sales of penicillins and lincosamides.

In order to decrease the sales of antimicrobial agents in Cyprus even further, the VMPs Section of the Veterinary Services is: (a) in line with EU risk-management decisions, gradually updating the labelling of the newer antimicrobial classes to include the so called 'responsible use' warnings; (b) trying to improve professional education, training and public engagement; (c) working with animal owners to promote the responsible use of antimicrobial agents in farmed animals, and with veterinarians in the continuation of raising the awareness of antimicrobial resistance so that they have the right information to make responsible decisions when prescribing antimicrobial agents.

Czech Republic

Figure 67. Sales (mg/PCU) by antimicrobial class for food-producing species, including horses, in the Czech Republic for the years 2010 to 2012



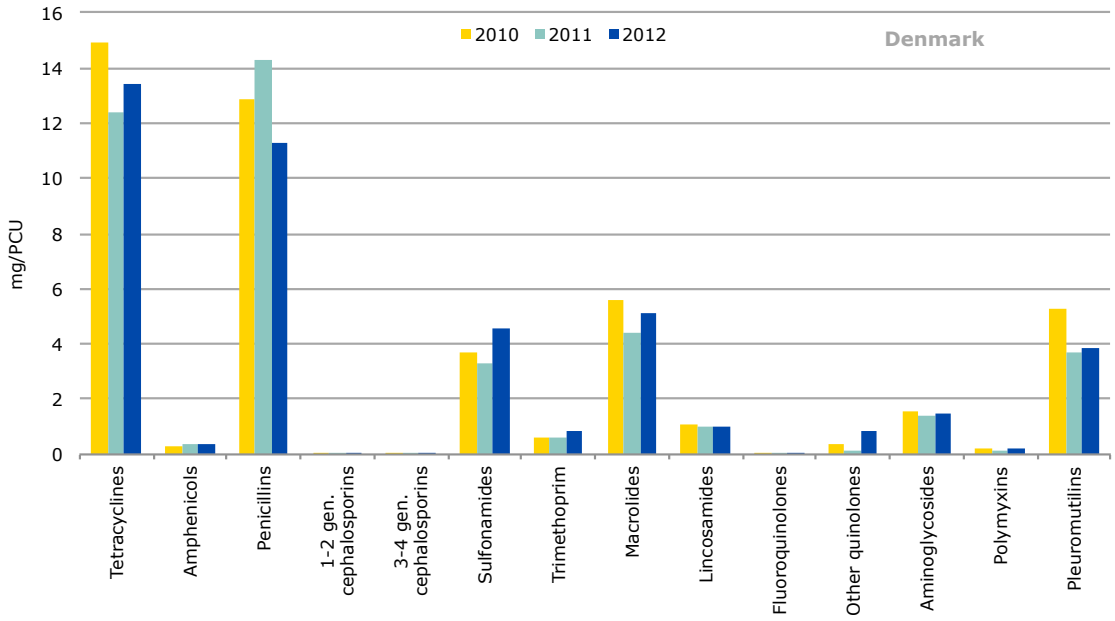
The total sales, in mg/PCU, decreased by 15% from 2010 to 2012 (from 94 mg/PCU to 80 mg/PCU), and in tonnes decreased by 24.4% from 2010 to 2012 (from 71 tonnes to 54 tonnes). The highest decreases were identified in the three groups with highest consumption: tetracyclines, penicillins and sulphonamides. The highest drop is accounted for by the class of tetracyclines, but these results should be interpreted with caution, due to an increase of doxycycline (lower dose compared to older tetracyclines) within this group. Also, a decrease in the pig population, where tetracyclines are the most frequently used for herd/group medication, may account for the decreased sales of tetracyclines.

There is fluctuation in the sales of 3rd- and 4th-generation cephalosporins (of total tonnes: 44% in 2010, 38% in 2011 and 48% in 2012), with an increasing trend when compared to the 1st and 2nd generations. Fluoroquinolones increased by 9.3% (tonnes) comparing 2010 to 2012, mainly accounted for by enrofloxacin use in poultry. As these antimicrobials are under the prudent-use regimen specified by national law in the Czech Republic, implementation was of low scale in practice, resulting in targeted inspections of those end-users with the highest consumption of CIAs being carried out in 2013.

Further aspects connected with some trends in use of antimicrobials should be mentioned, for example a close relation to the stratification of the animal population, and a decrease in sales and consumption of premixes, reflecting closely the decrease in pig population and certain measures (e.g. repopulation, new farm technologies) in the pig-farming sector. Dynamics in poultry farming (population, farming intensity) reflect certain trends (e.g. use of enrofloxacin). In some pharmaceutical forms, trends in sales can be clearly linked to measures such as intramammary VMPs used in mastitis in cattle and a stepwise decrease of consumption influenced for example by the introduction of 'in house' ready-to-use tests, better zoohygienical measures and better feed balance.

Denmark

Figure 68. Sales (mg/PCU) by antimicrobial class for food-producing species, including horses, in Denmark for the years 2010 to 2012



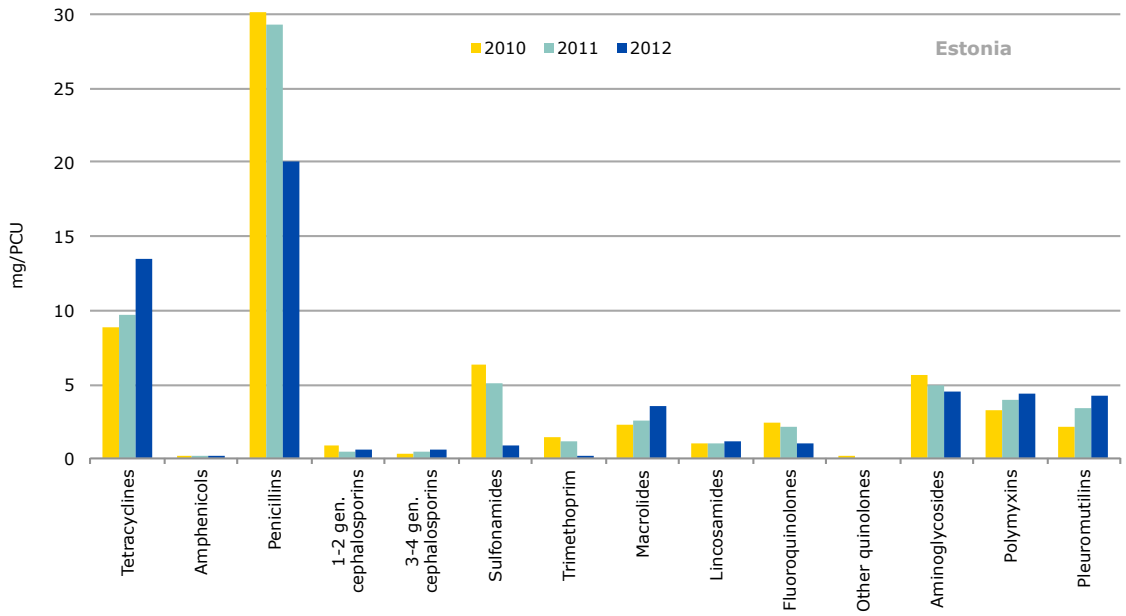
The overall consumption of veterinary antimicrobial agents decreased 7% from 2010 to 2012, mainly due to new regulations directed towards the 5–10% of pig producers that used most of the antimicrobial agents. After a decrease of 9% between 2010 and 2011, the consumption increased slightly during 2012 (Table 10).

The consumption of cephalosporins, especially 3rd and 4th generations, is relatively low (in 2012 a total of 201 kg, of which only 26% were 3rd and 4th generations). From 2010 to 2012, the total consumption of 3rd and 4th generations decreased more than 50%, mainly due to a voluntary agreement. The total use of fluoroquinolones for food-producing animals was only 11 kg in 2012, but increased from 1 kg in 2010. The reason for this rather low figure is a strict regulation on use in production animals.

The consumption of macrolides counts for approximately 10% of the total sales. From 2010 to 2012, the consumption of macrolides in food-producing animals decreased by 11%. Approximately 90% (mostly tylosin) of the macrolides are used for pigs. There are no obvious explanations for the reduction in consumption of macrolides.

Estonia

Figure 69. Sales (mg/PCU) by antimicrobial class for food-producing species, including horses, in Estonia for the years 2010 to 2012



The total sales of veterinary antimicrobial agents, in tonnes, in Estonia remained relatively stable during the years 2010 to 2012. However, the population correction unit (PCU) for food-producing animals rose in 2012, and therefore total sales in mg/PCU have decreased in 2012. Over all three years, penicillins represent the highest proportion of the sales, followed by tetracyclines, sulfonamides and aminoglycosides.

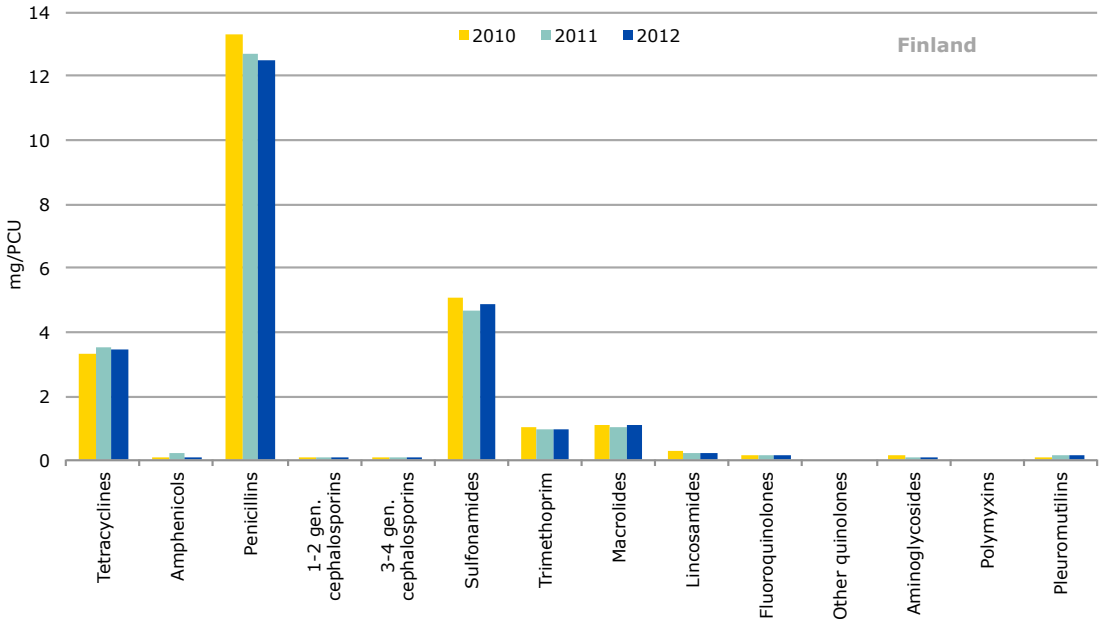
The sales of tetracyclines increased by 52% - from 8.8 mg/PCU in 2010 to 13.4 mg/PCU in 2012. This significant increase may be due to the decline in sales of other antimicrobial agents. The sales of penicillins with extended spectrum decreased by 33% (from 29.9 mg/PCU in 2010 to 20.1 mg/PCU in 2012). The sales of sulfonamides combined with trimethoprim decreased by 87% (from 7.6 mg/PCU in 2010 to 1.0 mg/PCU in 2010), which may be related to the increase in sales of tetracyclines, which are all authorised products, while sulphonamides and trimethoprim combination products for oral use are not, and therefore a special permission for use is required.

During 2010 to 2012, overall sales of the critically important antimicrobials (CIAs) with highest priority for human medicine have been stable (4.9 mg/PCU). The sales of 3rd- and 4th-generation cephalosporins have increased from 0.3 mg/PCU to 0.6 mg/PCU, fluoroquinolones have decreased from 2.4 mg/PCU to 0.95 mg/PCU, and macrolides have increased considerably from 2.2 mg/PCU to 3.5 mg/PCU.

Since Estonia is a small country, every change in treatment strategy of one or two major farms may significantly influence the sales figures.

Finland

Figure 70. Sales (mg/PCU) by antimicrobial class for food-producing species, including horses, in Finland for the years 2010 to 2012



From 2010 to 2011, a 4% decline in sales of veterinary antimicrobial agents (in mg/PCU) was observed in Finland. In 2012, sales remained at the same level as in 2011. The proportion accounted for by the various antimicrobial classes remained quite stable, despite a 6% decrease in the sales of penicillins from 2010 to 2012.

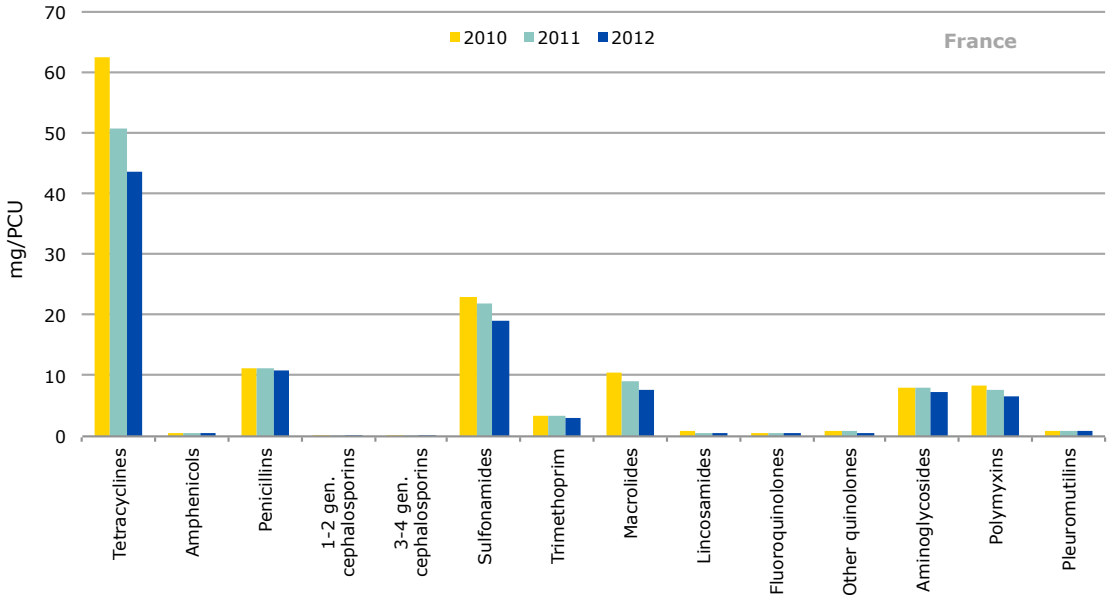
Total population of production animals (measured as PCU) has remained stable. A significant decrease in the number of sows (-12%) was observed from 2010 to 2012. However, the decline in the number of slaughtered pigs was only 5% during the same period. The number of broilers has increased by 31% since 2010.

Sales of CIAs with highest priority for human medicine are low. Almost all macrolides are used as group treatment (premix and oral solution), whereas fluoroquinolones and 3rd-generation cephalosporins are only available as injectable products for food-producing animals.

No new large-scale national campaigns to guide the use of antimicrobials in animals have been implemented during the observation period. However, the prudent-use guidelines that have been available since 1996 (updated in 2003 and 2009: http://www.evira.fi/portal/fi/tietoa+evirasta/julkaisut/?a=view&productId=135) still apply. Third-generation cephalosporins have been available for food-producing animals since 2010, and in the national legislation, their use is restricted to the indications approved in the SPC (i.e. cascade use is not allowed). Specific guidance on possible outbreaks is given for example by the Association for Animal Disease Prevention (e.g. mycoplasma bovis, first isolated in Finland in 2011).

France

Figure 71. Sales (mg/PCU) by antimicrobial class for food-producing species, including horses, in France for the years 2010 to 2012



Total sales of antimicrobial agents, in mg/PCU, have decreased by 22% in France in 2012 compared to 2010.

Overall sales, in mg/PCU, of fluoroquinolones and 3rd- and 4th-generation cephalosporins were stable during the period 2010 to 2012.

In France, data are available per animal species, and the evolution of the consumption varies between the different species. For example, following a voluntary restriction by the pig industry in 2010 on the use of 3rd- and 4th-generation cephalosporins in pigs, a decrease of 62.1% of the consumption of cephalosporins was observed in 2012 compared to 2010.

Using exposure indicators (ALEA, an indicator based on Animal Course Dose used), the exposure has on average decreased by 6.1% for all animal species.

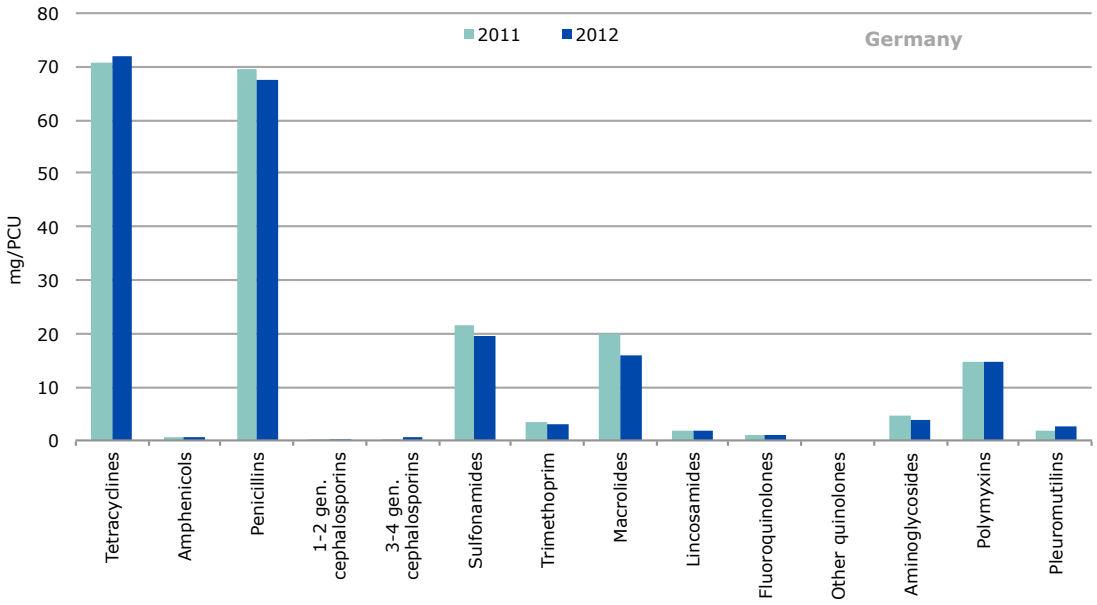
The decrease was 19.9% for rabbits, 10.1% for pigs, 8.4% for dogs, 5.6% for poultry and 0.6% for cattle.

The animal sectors where voluntary actions have been initiated show a higher decrease in consumption of antimicrobial agents.

The overall decrease of the sales of antimicrobial agents can be linked to the French national action plan, initiated in 2011, to reduce the risks of antimicrobial resistance in veterinary medicine. This plan includes a target for decreasing the usage of all antimicrobial agents by 25% in five years.

Germany

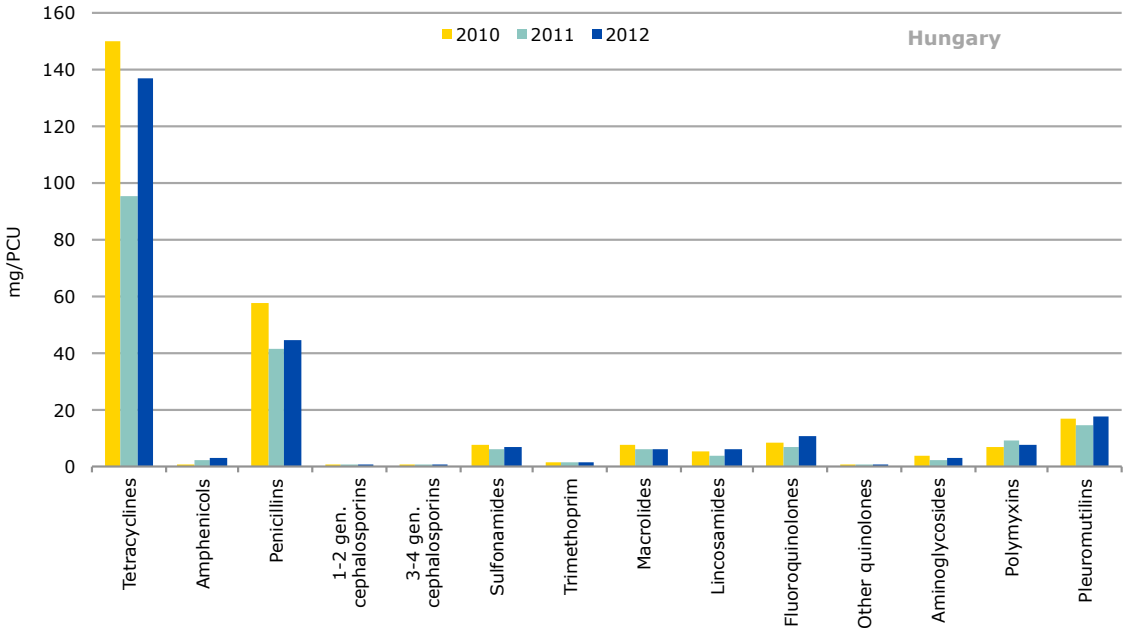
Figure 72. Sales (mg/PCU) by antimicrobial class for food-producing species, including horses, in Germany for the years 2011 to 2012



From 2011 to 2012, a 3% decrease in the overall sales of veterinary antimicrobial agents (in mg/PCU) was observed in Germany. The greatest decrease was observed for penicillins, macrolides and sulfonamides, while for other classes, such as pleuromutilins, cephalosporins, fluoroquinolones and tetracyclines, a small increase was observed. Since the comparable sales data are only available for two years in Germany, no trend can be drawn out of these data.

Hungary

Figure 73. Sales (mg/PCU) by antimicrobial class for food-producing species, including horses, in Hungary for the years 2010 to 2012

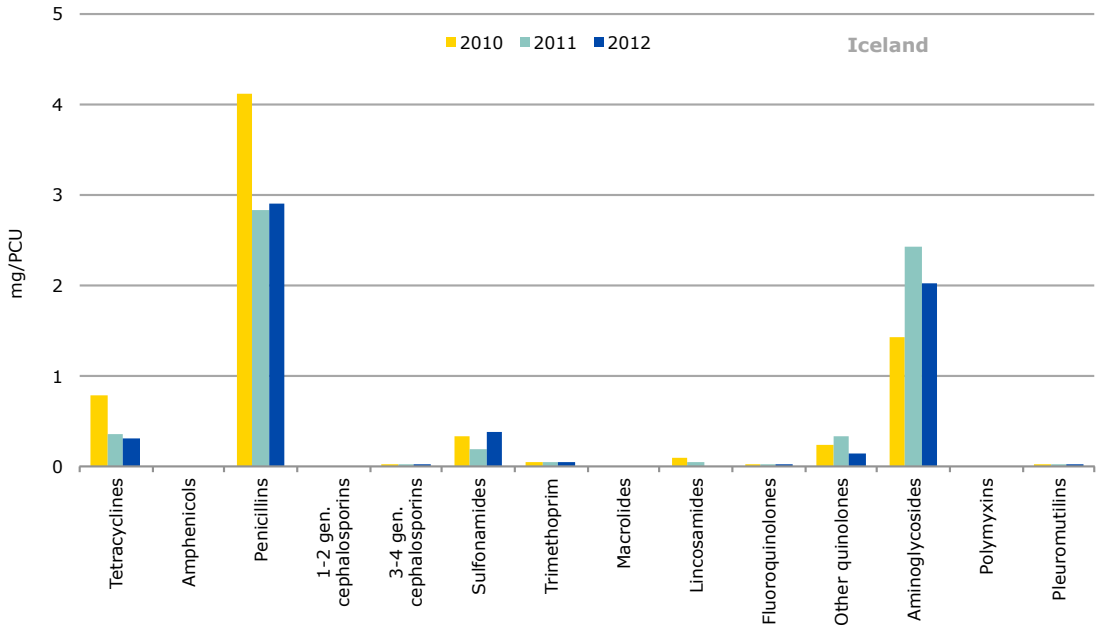


Sales data for 2010 were based on import/purchase data obtained from wholesalers, while 2011 and 2012 data represent sales from wholesalers to end-users. Since wholesalers may not sell all the veterinary antimicrobial products the same year as they are imported, sales data for Hungary for 2010 are likely to be overestimated compared to the 2011 and 2012 data. The observed decrease (Table 10) in the sales of 8%, in mg/PCU, from 2011 to 2012 should therefore be interpreted with great care, since an increase in the sales, in mg/PCU, was observed from 2011 to 2012 (from 192 mg/PCU to 246 mg/PCU); this is mainly accounted for by an increase in the sales of tetracyclines.

There were no changes regarding methodology in 2011 to 2012. The animal production showed a minor decrease between 2010 and 2012 (computed PCU decreased by 7.3%).

Iceland

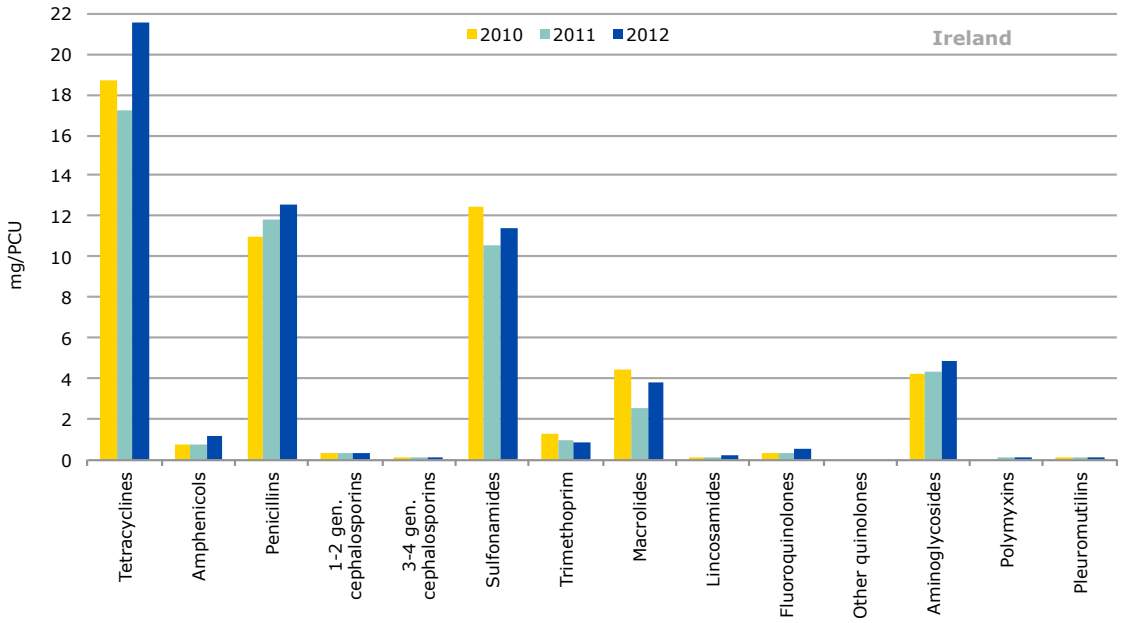
Figure 74. Sales (mg/PCU) by antimicrobial class for food-producing species, including horses, in Iceland for the years 2010 to 2012



A decrease in sales, in mg/PCU, of 19% is observed from 2010 to 2012 (Table 10). The decrease from was caused by a reduction in the sales of many of the products. However, no definite conclusion as to what caused these changes can be reached for the time being.

Ireland

Figure 75. Sales (mg/PCU) by antimicrobial class for food-producing species, including horses, in Ireland for the years 2010 to 2012



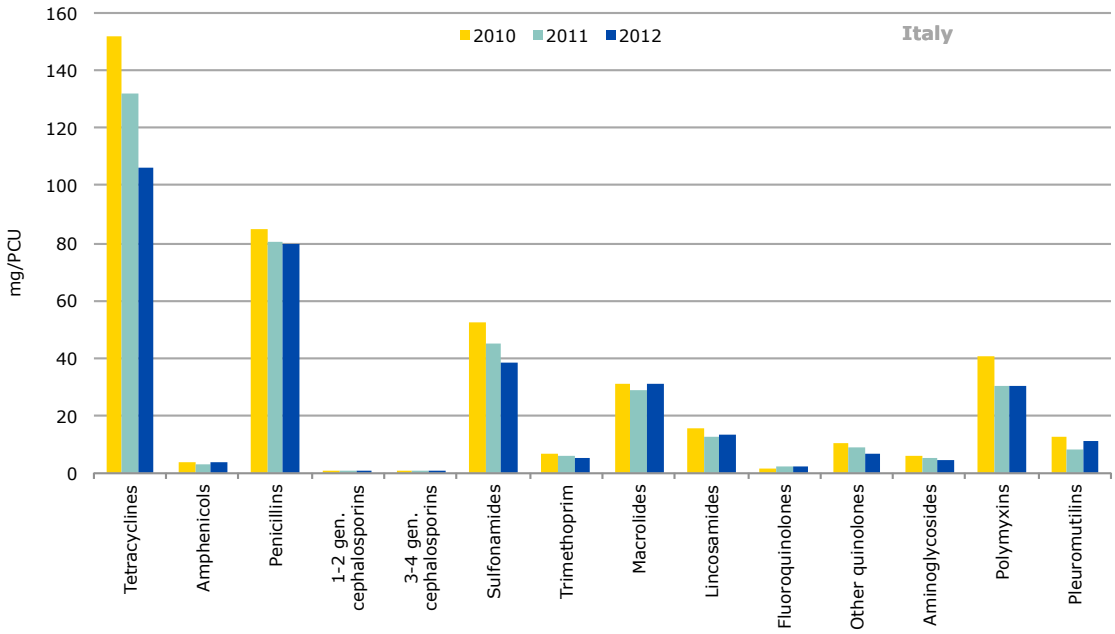
During the years 2010 to 2012, fluctuations in the sales (mg/PCU) of veterinary antimicrobials in Ireland are observed (Table 10): the sales were 54 mg/PCU, 49 mg/PCU and 58 mg/PCU in 2010, 2011 and 2012, respectively. Overall sales of veterinary antimicrobial agents increased by 7% (mg/PCU) in 2012 compared with 2010. The sales of tetracyclines accounted for the largest part of the observed increase.

A modest increase in sales of the CIAs with highest priority for human medicine — fluoroquinolones — was observed during 2010 to 2011, while for macrolides the sales fluctuated during this period; however, the proportion accounted for by this class decreased. A modest increase in the sale of 3rd- and 4th-generation cephalosporins (Figure 60) is seen.

The apparent increase in sales of veterinary antimicrobial agents from 2010 to 2012 and the observed fluctuations should be interpreted with caution. The increase from 2011 to 2012 could be due to seasonal factors and the impact on certain diseases, or to a change in the numbers of animals kept or to competition in the marketplace.

Italy

Figure 76. Sales (mg/PCU) by antimicrobial class for food-producing species, including horses, in Italy for the years 2010 to 2012



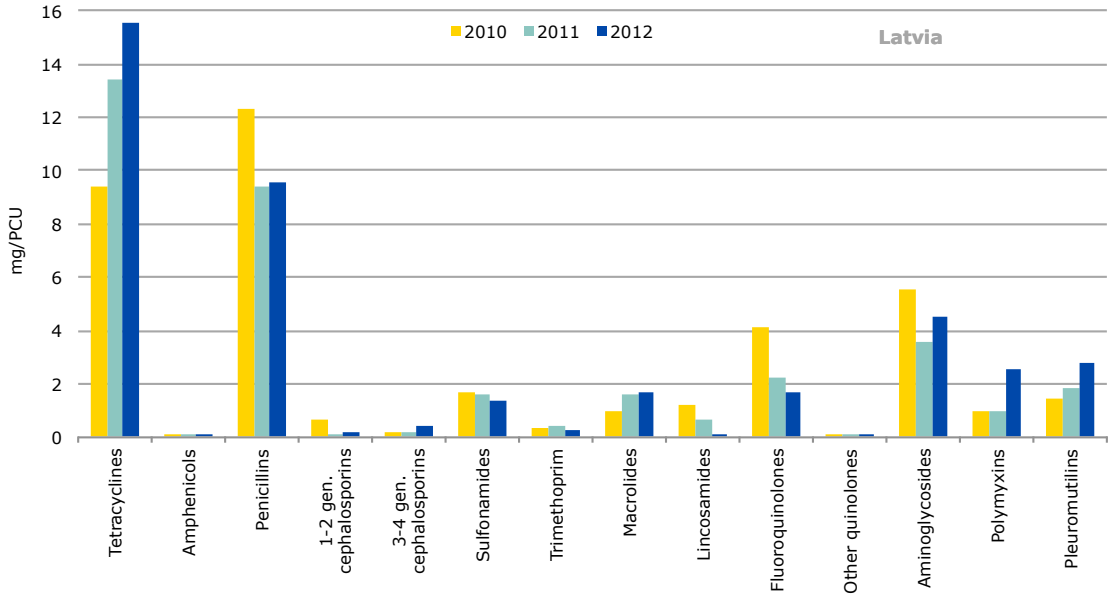
In Italy, a 20% overall sales reduction, expressed as mg/PCU, occurred in the period 2010 to 2012. This decrease seems to be correlated mainly with a progressive decline in sales of tetracyclines and sulfonamides. On the other hand, a slight increase in sales of 3rd- and 4th-generation cephalosporins has been reported in 2012 (Fig. 60). For macrolides (Fig. 61), the sales fluctuated during this period, but were slightly lower in 2012 compared to 2010, while a modest increase in the sales of fluoroquinolones in the three-year period has been observed (Fig. 62). The reduced sales are likely to have been caused by the following factors:

- In 2009, the Ministry of Health launched awareness campaigns[8] against prophylactic use of antimicrobial agents in breeding farms. Furthermore, an online training course on veterinary medicines surveillance and pharmacovigilance was published[9].
- In 2010, an information system was implemented in order to estimate the number of prescriptions of veterinary antimicrobials issued throughout each Italian region. These data allow the local competent authorities to identify the most problematic sectors where antimicrobial resistance has to be tackled in the following year. Furthermore, training courses were held in collaboration with the National Reference Laboratory for Antimicrobial Resistance in Rome in 2010 and 2011. During the same year, in accordance with CE Regulation 852/2004, the Ministry of Health validated and published species-specific Good Husbandry Practices (GHP) Manuals in which basic principles for medicines management in farms are addressed.
- In February 2012, a 'Manual for prudent use of antimicrobials in poultry, pig and rabbit production', addressed to farmers and veterinarians, was developed by the Italian authorities[10]. Also, a Ministerial 'Guideline for official controls on distribution and use of veterinary medicines' for local Official Veterinary Services was published in January 2012.

[8] http://www.salute.gov.it/portale/temi/p2_5.jsp?lingua=italiano&area=veterinari&menu=antibiotici (in Italian).
[9] http://www.trentagiorni.it/numeroDettaglio.php?numeriId=3 (in Italian).
[10] http://www.salute.gov.it/farmaciVeterinari/newsFarmaciVeterinari.jsp?id=1917&menu=inevidenza&lingua=italiano (in Italian).

Latvia

Figure 77. Sales (mg/PCU) by antimicrobial class for food-producing species, including horses, in Latvia for the years 2010 to 2012



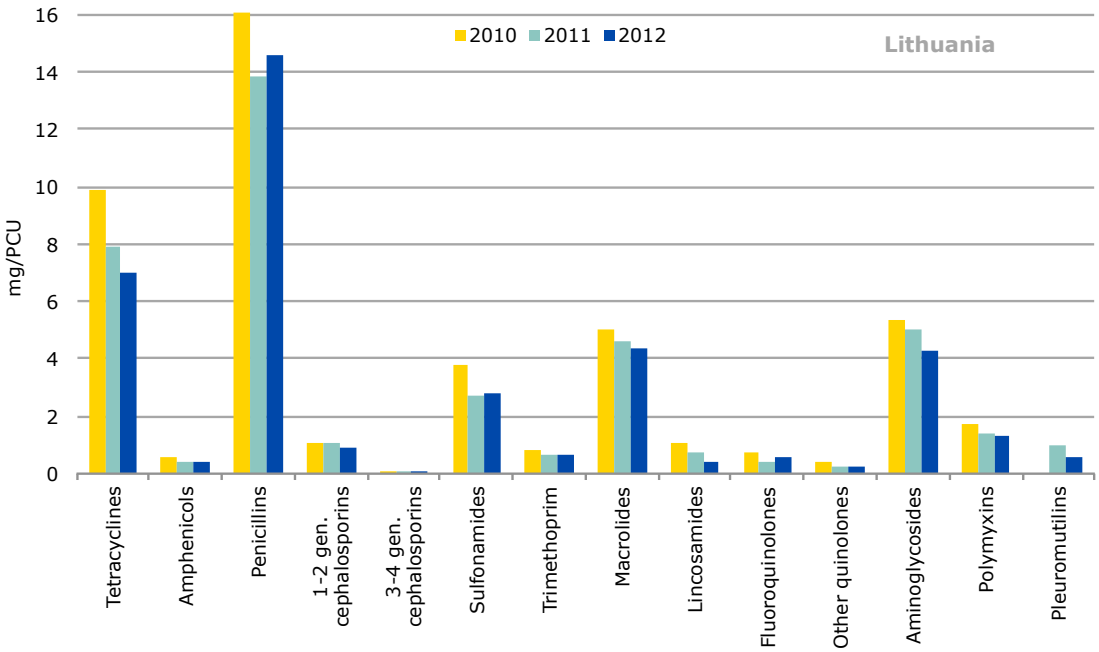
Between 2010 and 2012, a 3% increase in the sales, in mg/PCU, was observed; however, fluctuations were seen (Table 10).

The increase from 2011 to 2012 is accounted for by increased sales of tetracyclines, 3rd- and 4th-generation cephalosporins, macrolides, polymyxins and pleuromutilins. At the moment, there are no precise data available to explain the change in sales patterns.

In order to improve the situation regarding the consumption of veterinary antimicrobial agents in Latvia, a number of activities to inform farmers and animal owners, as well as giving additional information to veterinarians about the prudent use of antimicrobial agents in animals, have taken place during the years 2013 and 2014. For example, in 2013, employees of the Food and Veterinary Service and Veterinary Medicine Faculty participated as speakers at the 'Responsible Use of Veterinary Medicines' conference organised by the Latvian Association of Veterinarians, and at the 'One World, One Health' conference organised jointly by the Association of Doctors and the Association of Veterinarians. In 2013, the Food and Veterinary Service published an informative brochure called 'Responsible use of Veterinary Medicines'. At the moment, a list of first- and second-choice antimicrobial agents is under development. During 2013 and 2014, several training courses were organised for inspectors performing inspections of the distribution and use of veterinary medicines and for veterinary practitioners.

Lithuania

Figure 78. Sales (mg/PCU) by antimicrobial class for food-producing species, including horses, in Lithuania for the years 2010 to 2012



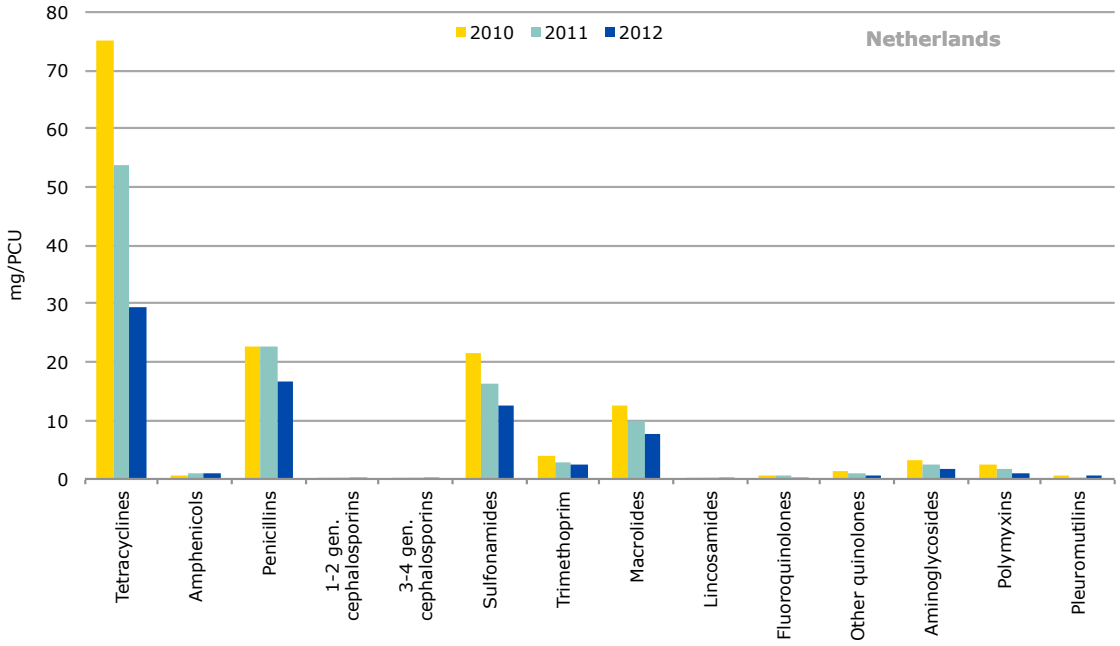
An apparent 18% decrease in sales (in mg/PCU) from 2010 to 2012 was seen in Lithuania, and this is accounted for by all antimicrobial classes. The sales patterns remained relatively stable.

The decrease is mainly accounted for by a reduction in the reported sales of tetracyclines, penicillins and sulfonamides.

However, the data reported for 2010 included sales between wholesalers. The 2010 data are therefore likely to represent an overestimate, and thus the real decline in the reported sales from 2010 to 2011 and from 2011 to 2012 is likely to be lower than 18%.

Netherlands

Figure 79. Sales (mg/PCU) by antimicrobial class for food-producing species, including horses, in the Netherlands for the years 2010 to 2012



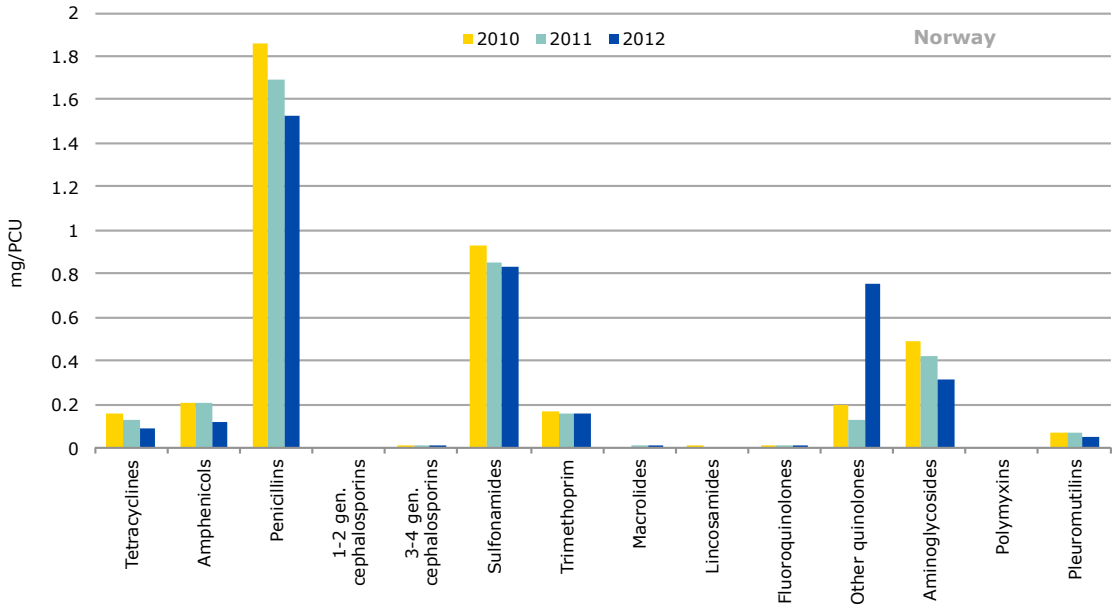
In the Netherlands, a decrease of 49% in the sales (in mg/PCU) of veterinary antimicrobial agents is observed from 2010 to 2012. From 2011 to 2012, sales reduced by 34%. This is the result of efforts of the major production sectors and veterinarians, who in 2010 agreed with the government to set reduction targets for the use of antimicrobial agents in animal production: -20% for 2011 and -50% for 2013, with reference to 2009. In 2012, the government set a new reduction target: -70% for 2015, with reference to 2009.

The sales of 3rd- and 4th-generation cephalosporins decreased by 94% and the sales of fluoroquinolones decreased by 45% from 2011 to 2012. This result was achieved by efforts of the private quality-production systems. The private quality systems in the pig sector banned the use of 3rd- and 4th-generation cephalosporins; the private quality system in the dairy sector banned the use of 3rd- and 4th-generation cephalosporins for drying off cows.

In 2012, a legal base was created for mandatory sensibility testing before using third-choice antibiotics. This legal base came into force at the beginning of 2013.

Norway

Figure 80. Sales (mg/PCU) by antimicrobial class for food-producing species, including horses, in Norway for the years 2010 to 2012



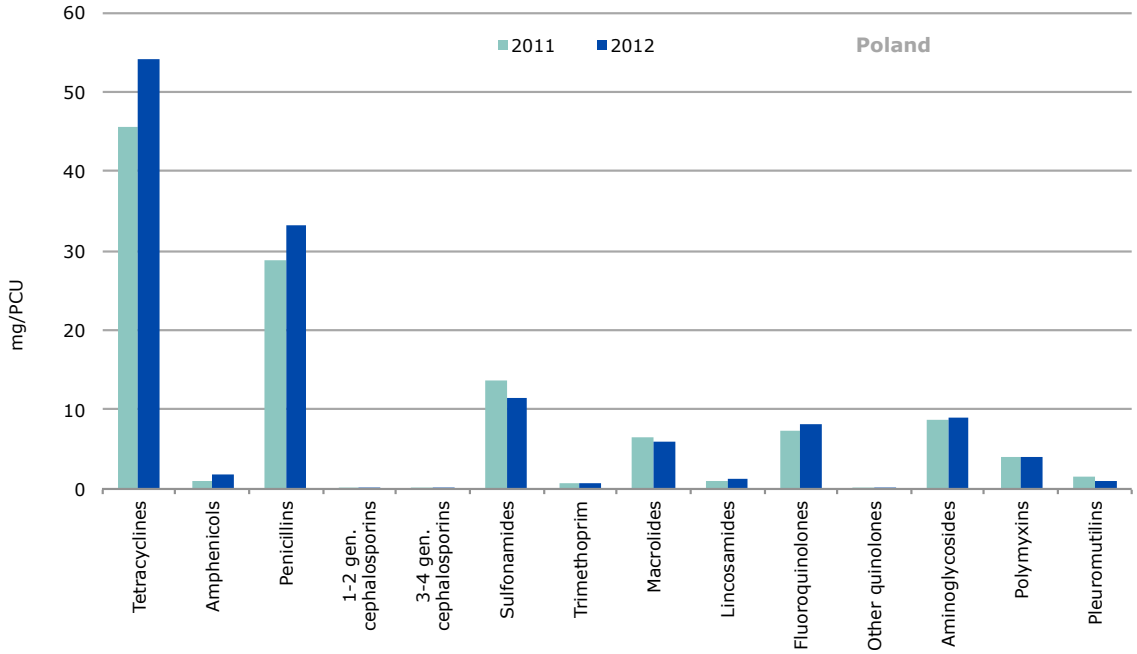
From 2010 to 2012, a decrease in the total sales of antimicrobial agents for food-producing animals of 7%, in mg/PCU, is observed. This is mainly accounted for by decreased sales of penicillins, aminoglycosides and sulfonamides for terrestrial animals. A substantial increase of sales of other quinolones is observed; this is due to increased use in farmed fish. The sales of third-generation cephalosporins, fluoroquinolones and macrolides are low, and changed by -30%, -40% and 52%, respectively, expressed as mg/PCU.

Norway has not recently set any targets for reduction of consumption of veterinary antimicrobial agents. But in 1996, the Norwegian Husbandry Organisations (NHO) set a target for reducing the consumption of antimicrobial agents in terrestrial food-producing animals by 25% in five years, with 1995 as the reference year. In parallel, the NHO initiated a responsible-use campaign, among other initiatives, by implementing therapeutic guidelines published by the NHO in connection with the campaign. More comprehensive therapeutic guidelines were published by the Norwegian Medicines Authority (NMA) in the late 1990s, and have recently been revised.

From 1995 to 1999, a 40% reduction was obtained. Since then, the sales of antimicrobial agents for use in terrestrial food-producing animals have been relatively stable, showing only minor fluctuations (http://www.vetinst.no/eng/Publications/NORM-NORM-VET-Report).

Poland

Figure 81. Sales (mg/PCU) by antimicrobial class for food-producing species, including horses, in Poland for the years 2011 to 2012

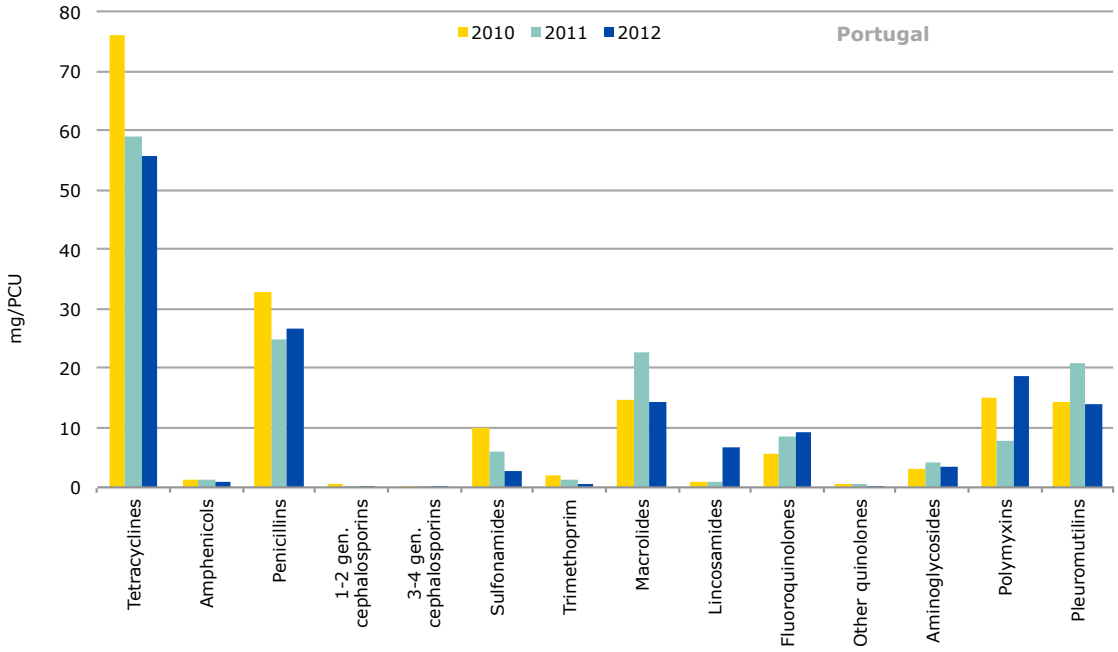


For Poland, an increase (10%) in sales of veterinary antimicrobial agents, in mg/PCU, is seen from 2011 to 2012, and this is mainly related to the increase in sales of tetracyclines and penicillins in particular, but also of amphenicols, fluoroquinolones and aminoglycosides, while for other classes a small decrease was observed.

There are currently no data available that can explain the observed increase in sales or the changes in the sales patterns of veterinary antimicrobial agents.

Portugal

Figure 82. Sales (mg/PCU) by antimicrobial class for food-producing species, including horses, in Portugal for the years 2010 to 2012



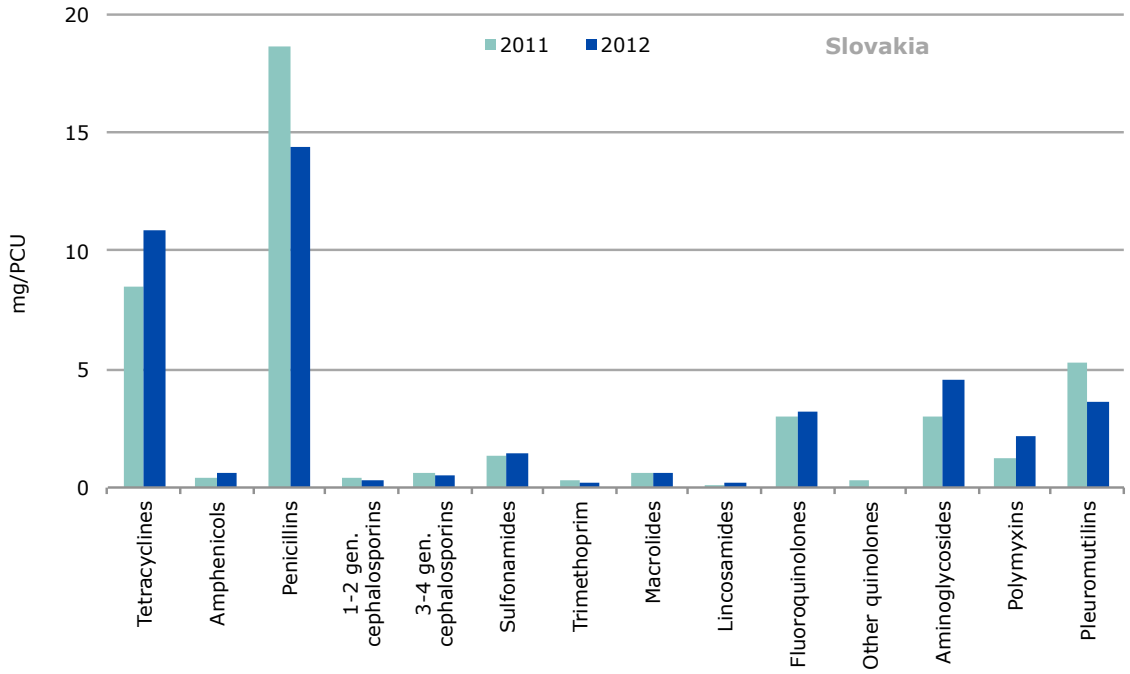
From 2010 to 2012, total sales of veterinary antimicrobial agents for food-producing species, including horses, in mg/PCU, decreased by 12% in Portugal, with greater expression within the most-consumed class of antimicrobial agents, reflecting an increased awareness of the global antimicrobial resistance issue, but also an increased implementation of responsible use, reinforced by targeted biosafety measures and re-orientated prophylactic management measures.

In relation to the CIAs with highest priority in human medicine, during 2012, after serious outbreaks of some diseases of high economic impact, sales of macrolides decreased as a result of better housing and animal welfare, by favouring autogenous vaccination, applying more rigorous control of drinking-water quality and using newly marketed vaccines, as well as new techniques of vaccination, more use of pre- and probiotics, that allowed, in conjunction, a significant reduction in the use of antimicrobial agents in animal production, in a particularly hard climatic and economic environment. On the other hand, the decrease in the sales of macrolides might have been related to increased sales of polymyxins; this increase has coincided with colistin becoming a last resort antimicrobial for use in humans and, therefore, subject to further attention when used in animals.

Still based on the sales data only, monitoring of overall antibiotic consumption in Portugal, on the advisable prudent use in animals, is being followed under the scope of a National Plan of Action for the Reduction of the Use of Antibiotics in Animals, that has been published (http://www.dgv.min-agricultura.pt) and implemented from 1 January 2014 onwards for a five-year period.

Slovakia

Figure 83. Sales[1] (mg/PCU) by antimicrobial class for food-producing species, including horses, in Slovakia for the years 2011 to 2012



[1] For Slovakia, the data represent amounts of veterinary antimicrobial agents imported by wholesalers.

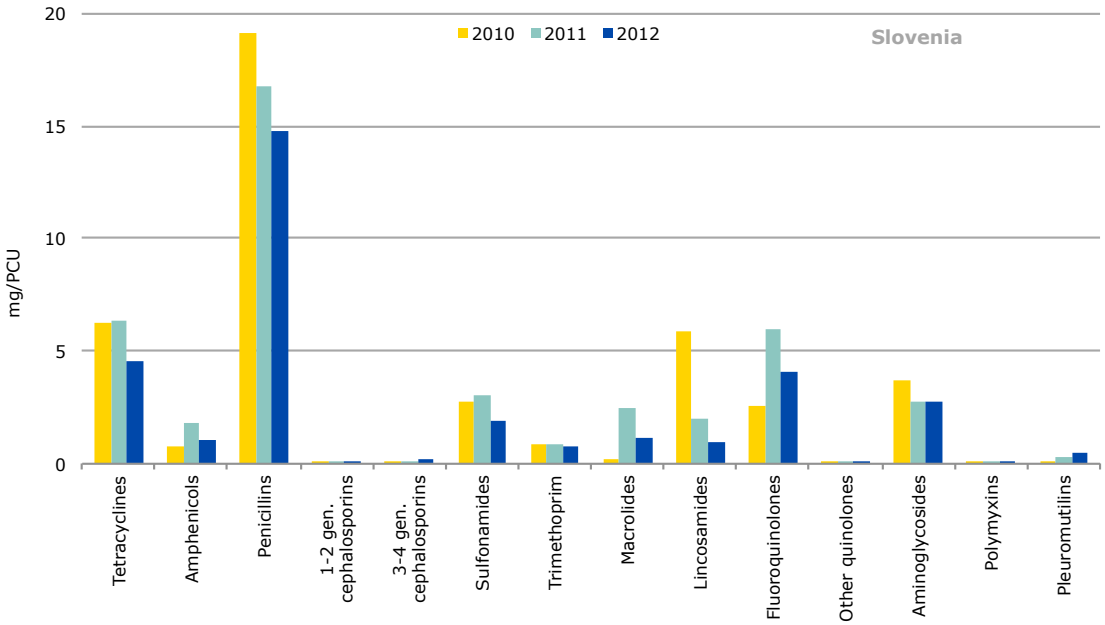
The total sales, expressed as mg/PCU, of veterinary antimicrobial agents in Slovakia were relatively stable during 2011 and 2012; a minor decrease of 2% is observed.

A change in the sales patterns is observed in particular for the most-selling classes, i.e. tetracyclines (increased from 8.4 to 10.9 mg/PCU) and penicillins (decreased from 18.6 to 14.4 mg/PCU). For aminoglycosides, the sales increased from 3 to 4.6 mg/PCU, for polymyxins the sales increased from 1.2 to 2.1 mg/PCU, while for pleuromutilins a decrease from 5.3 to 3.7 mg/PCU is reported.

Currently, there are no data available to explain the changes in the sales patterns. However, as the data for Slovakia presented in the current report are actually based on imported amounts and not sales to end-users, the changes could be due to changes in the stocking of veterinary antimicrobial agents by the wholesalers.

Slovenia

Figure 84. Sales (mg/PCU) by antimicrobial class for food-producing species, including horses, in Slovenia for the years 2010 to 2012



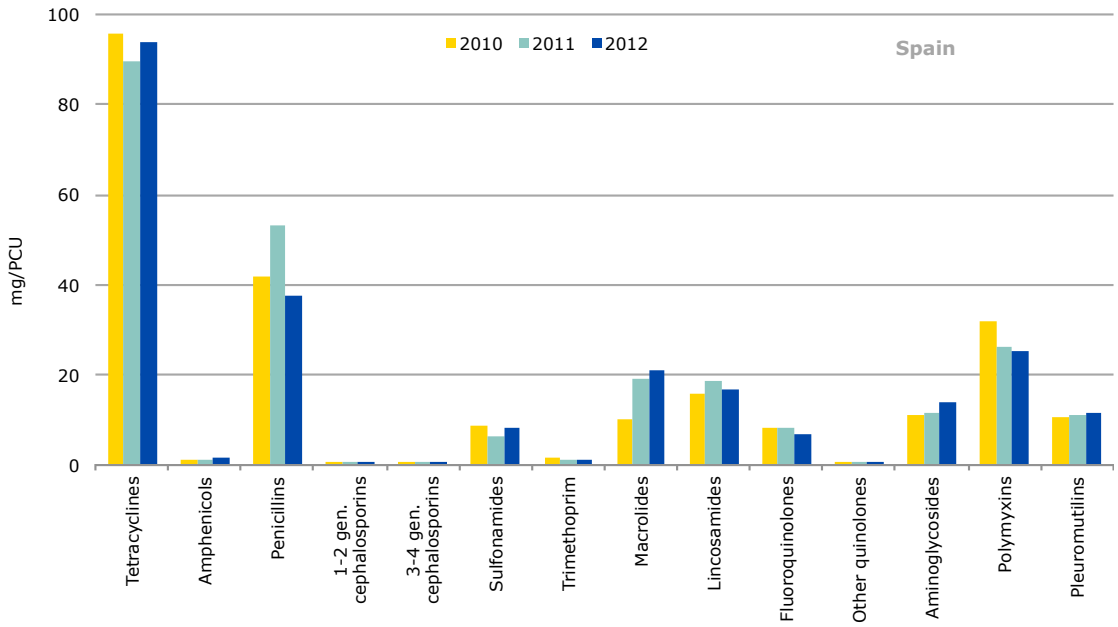
In Slovenia, following the awareness campaigns on more prudent use of antimicrobials conducted every year since 2008 for the veterinary sector and animal keepers, and based on data submitted by the wholesalers of VMPs, a decrease in the sales of veterinary antimicrobial agents (in mg/PCU), from 47 mg/PCU in 2010 to 37 mg/PCU 2012, has been noticed, which means a 21% decrease in the sales of antimicrobials.

Certain deviations have been noticed for aminoglycosides, fluoroquinolones and certain other groups of antimicrobial classes, in conjunction with relevant animal-health treatments.

In the case of a single wholesaler, we were able to obtain data for 2012 only indirectly, on account of the cessation of the wholesaler's activity.

Spain

Figure 85. Sales (mg/PCU) by antimicrobial class for food-producing species, including horses, in Spain for the years 2010 to 2012



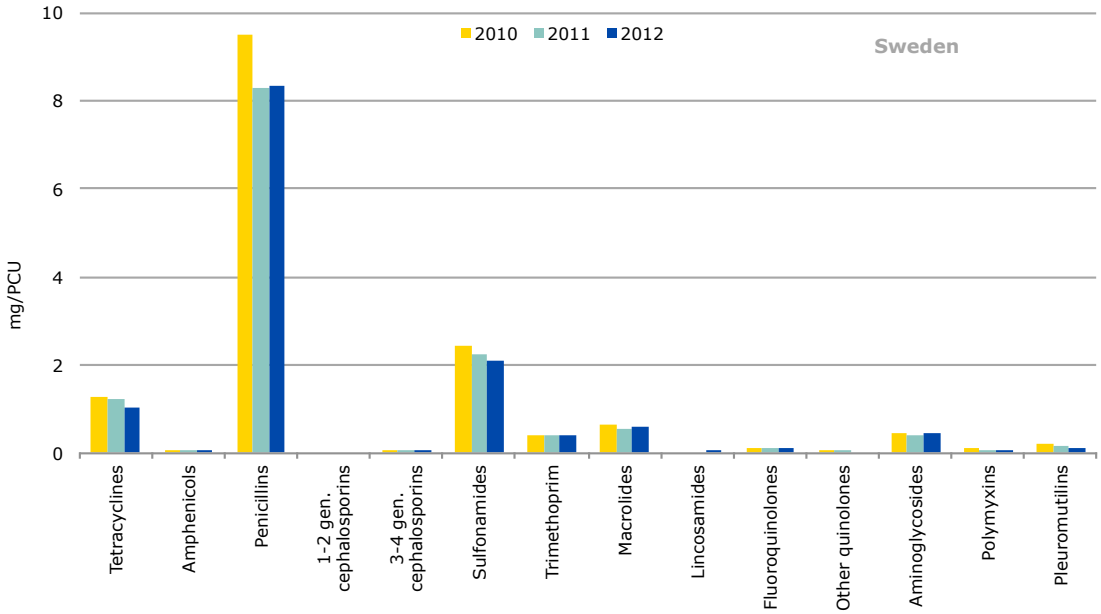
In Spain, the observed total sales, reported as mg/PCU, of veterinary antimicrobial agents fluctuated during 2010 to 2012, but were on the same level in 2010 and 2012 (Table 10). However, one marketing-authorisation holder failed to report the sales data in 2010; for this company, the reported sales were 21% of the total sales in 2011. Provided that the sales for this company were at the same level in 2010, the sales of veterinary antimicrobial agents have actually declined considerably (see ESVAC 2011 report).

The sales of tetracyclines fluctuated during the period 2010 to 2012, but an apparent increase was observed from 2011 to 2012. For penicillins, fluctuations in sales are also observed, but in contrast to tetracyclines, the sales of this class declined. Since the sales in 2011 and 2012 for the company that failed to report sales in 2010 were mainly tetracyclines and penicillins, but also fluoroquinolones, this should also be taken into account when interpreting the changes in the sales patterns.

An increase in sales was observed for macrolides. Conversely, a relatively large decrease in the sales of 3rd- and 4th-generation cephalosporins (Fig. 60) and a modest decline in the sales of fluoroquinolones (Fig. 62) between 2010 and 2012 are shown. Sales of other antimicrobial agents remained almost constant. Various factors, among which the economic conjecture in the country is an important one, could explain the changes. Tetracyclines and macrolides are most commonly used in pig production, which is the largest proportion of food-animal production in Spain. Reductions in the sales of 3rd- and 4th-generation cephalosporins and fluoroquinolones may be due to the information and training related to responsible and prudent use of veterinary medicinal products. Nevertheless, not enough accurate data are available to confirm the impact of these measures.

Sweden

Figure 86. Sales (mg/PCU) by antimicrobial class for food-producing species, including horses, in Sweden for the years 2010 to 2012



From 2010 to 2012, the total sales of antimicrobials for food-producing animals decreased from 15.2 mg/PCU to 13.5 mg/PCU. Decreases were noted for most classes. Sales of third-generation cephalosporins, fluoroquinolones and macrolides decreased by 46%, 28% and 9%, expressed as mg/PCU.

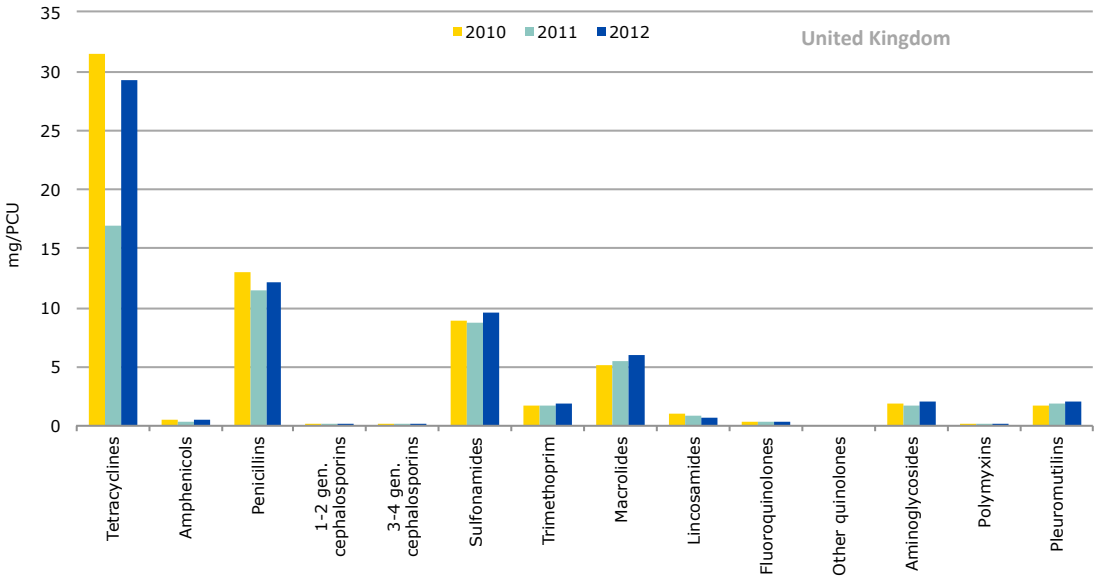
The Swedish pharmacy market was re-regulated in July 2009. Following this, some problems with lack of completeness in the sales data have been identified. From 2011, products sold under special licence are not fully captured by the system, but from 2012, this has been corrected by adding information on sales of such products collected from pharmaceutical companies. Furthermore, concerns have been raised about a lack of completeness in the statistics on sales of products with a marketing authorisation. No information on the magnitude of this problem in 2012 is available, but for 2013, it was estimated to be 5–10% of the overall sales (see SWEDRES-SVARM 2013 for more information; http://www.sva.se). This will be further investigated by the competent authority.

Antimicrobials used in aquaculture were included in the data for 2010 and 2011, but not for 2012. However, the effect of this on the overall changes is marginal.

A decreasing trend in the sales of products for group medication has been noted since the early 1990s, and for all products since 2007. For 2009, the sales were 16.4 mg/PCU (calculated by ESVAC standards): a difference of 17% compared to 2012. As this is larger than the estimated lack of completeness, there is a true decrease, but its magnitude is uncertain. The long-term changes are the result of a working model built on continuous collaboration between academia, governmental organisations, advisers in preventive medicine, veterinarians and farmers. The core element of the strategy is to reduce the need for antimicrobials through, for example, biosecurity, disease-control programmes, and optimised management and husbandry. When antimicrobials are needed, guidance on their prudent use is available.

United Kingdom

Figure 87. Sales (mg/PCU) by antimicrobial class for food-producing species, including horses, in the United Kingdom for the years 2010 to 2012



From 2010 to 2012, a 3% decrease in the sales of veterinary antimicrobial agents (in mg/ PCU) was observed in the United Kingdom; however, from 2011 to 2012, an increase is observed (Table 10). The predominant increase was observed in tetracycline sales. One explanation for this could be altered product-purchasing behaviour in anticipation of a change of marketing-authorisation holder(s) for certain tetracycline-containing products between 2010 and 2011, leading to an increase in sales prior to the change and a corresponding subsequent reduction in sales in early 2011. Data collected for sales of tetracycline products in 2012 are in line with figures from previous years, before the change in marketing-authorisation holder(s). This increase in sales is therefore not considered necessarily to be reflective of a change in actual use of this antimicrobial class.

3. Discussion

3.1. Materials and methods

It is important to note that the results presented in this report may differ slightly from those presented in national reports, because, for example, of differences in inclusion criteria for veterinary antimicrobial agents and in the reporting of data in the national surveillance systems, e.g. reporting of the data as base instead of salt (see references to national reports in Annex 6).

As all antimicrobial growth promoters were phased out in the European Union by 1 January 2006, the data sets provided to ESVAC represent sales exclusively of antimicrobial agents sold as veterinary medicinal products.

Dermatological preparations (ATCvet group QD) and preparations for sensory organs (ATCvet group QS) were not included in the data sets. Since these pharmaceutical forms represent only, for example in Denmark, 0.13% (E. Jacobsen, unpublished data), in the Czech Republic 0.2% (Lucie Pokludová, unpublished data), in France 0.35% (G. Moulin, unpublished data), in Norway 0.002% (http://www.vetinst.no/eng/Publications/Norm-Norm-Vet-Report) and in the UK 0.49% (Hannah Reeves, unpublished data) of the total tonnes sold, the contribution from these groups of antimicrobial agents, in tonnes of active ingredients, to the total amounts is thought to be minimal, and therefore the effect of the deviation is negligible.

Injectable antimicrobial agents are used both in food-producing and in companion animals. With the exception of some long-acting products, injection of antimicrobial agents is generally limited to hospitalised animals or perioperative (one injection) treatments. In Denmark and France, respectively, approximately 0.1% and 1.2% of the injectable antimicrobial VMPs were used for dogs and cats (E. Jacobsen and G. Moulin, unpublished data). Therefore, the assumption that all injectable antimicrobials are used in food-producing species has minimal impact on the accuracy of the data for injectable preparations.

Nine countries (Table 2) included veterinary antimicrobial agents obtained on special licence (use on exemption from marketing authorisation, i.e. obtained from another Member State) in the data sets. For five of these countries — Denmark, Norway, Finland, Estonia and Sweden — the proportion of sales of antimicrobial veterinary medicinal products (VMPs) on special licence is reported by the ESVAC national contact points/alternates to be approximately 0.01%, 1%, 3%, 9% and 10% of the total sales, respectively[11]. These are all countries with a comparatively low number of antimicrobial VMPs on the market (Table 7). As the proportion of antimicrobial products used on special licence (obtained from another Member State) is likely to be negligible in countries with a relatively high number of antimicrobial VMPs on the market, the impact caused by deviations in the included data sets is considered relatively low, and does not influence significantly the general results.

Depending on the source of the data, countries had requested data on sales to end-users, or had asked the national data providers to exclude sales between data sources, e.g. between wholesalers, and consequently, double reporting is assumed to have been avoided.

All countries provided sales data or prescription data (Denmark and Sweden), except for two countries that provided purchase data (Hungary in 2010 and Slovakia in 2011). For Hungary, the 2010 data represented imports by wholesalers (purchase data), while the 2011 data represented sales from wholesalers to end-users. For Slovakia, the 2011 data represented imports by wholesalers. Since wholesalers may not sell all the veterinary antimicrobial products the same year as they were imported, sales data for Hungary for 2010 are likely to represent an overestimate compared to the 2011 data. Similarly, the 2011 data for Slovakia are not likely to be fully comparable with those for other countries.

Regarding the material and methods, it should be noted that in all the participating countries, antimicrobial agents have a 'prescription only' status; according to Directive 2001/82/EC of the European Parliament, all veterinary medicinal products, including veterinary antimicrobial agents, have to be sold through distributors authorised by the competent authority in each country. This allowed the 26 countries to identify all distributors of antimicrobial VMPs in their country, and consequently 100% data source coverage could be obtained. However, some data providers may fail to deliver the data, as happened in Spain for 2010, when one provider did not provide such data, or data providers

[11] EMA/ESVAC. 2011. European Medicines Agency, European Surveillance of Veterinary Antimicrobial Consumption (ESVAC). Trends in the sales of veterinary antimicrobial agents in nine European countries. Reporting period: 2005-2009. http://www.ema.europa.eu/docs/en_GB/document_library/Report/2011/09/WC500112309.pdf

may deliver incomplete data. For those countries (20) that delivered data to the ESVAC for more than one year, the raw data were checked manually in order to identify outliers as described in Section 1.7: Quality check and validation of the data. It is therefore reasonable to assume that the data presented in this report provide a good picture of the total sales of antimicrobial agents in the 26 countries.

Data presented in the current report on sales of veterinary antimicrobial agents for companion animals are solely based on the sales of tablets. For countries with a relatively low number of dogs and cats, the market for antimicrobial VMPs as tablets is typically low, and thus the proportion of human antimicrobial agents that are used according to the cascade could account for a higher proportion than in countries with a high number of dogs and cats. Furthermore, injectable antimicrobial VMPs are used in both food-producing animals, including horses, and companion animals. Therefore, the data on sales of veterinary antimicrobial agents for companion animals presented in this report are likely to be underestimates, while the data on sales for food-producing animals are slight overestimates. The national sales data (nominator) cover all food-producing species, including horses, which are considered as food-producing species according to EU legislation; thus, the animal population 'at risk' of being treated with antimicrobial agents (denominator) includes all food species. However, the use of antimicrobial agents in the various animal species varies considerably; for example, the use in sheep is relatively low, due to the generally extensive production system. Therefore, the interpretation of the data should take into account the distribution of the PCU value between the species in the various countries. It should also be emphasised that the PCU only represents a technical unit of measurement and not a real value for the animal population that could potentially be treated with antimicrobial agents.

The dosing of the various antimicrobial agents between and within classes, as well as between animal species, varies substantially. For example, the dose for a whole treatment with a fluoroquinolone may be 2–5 mg/kg (for terrestrial animals), while with a tetracycline this may be 140 mg/kg, i.e. up to 70 times higher. This implies that a given weight of active ingredient of fluoroquinolone sold can be used to treat 70 times as many animals as the same weight of active ingredient of tetracycline. Furthermore, within an antimicrobial class there may be different dosages for different substances; for example, the dosage of doxycycline is about one quarter of the dosage of oxytetracycline. Another consideration is that the treatment dosage may differ significantly according to species; for fish, the typical tetracycline dosage for the whole treatment is 800 mg/kg, or some six times higher than that for terrestrial animals. The data in this report cover all food-producing animals together, and therefore it was not possible to take into account differences in dosing when reporting the data. Since the sales patterns and the animal demographics vary substantially between countries, comparison of the sales data between the countries should be done with great care.

The ESVAC template differentiates between preparations applicable for individual and group treatment for oral solutions and powder forms. However, during the analysis of the data, it was identified that the categorisation of oral solutions and oral powders into individual or group treatment differed substantially between the countries. The data have therefore been aggregated to express oral solutions and oral powders. Because the proportions of sales of small packages of oral powders and oral solutions sufficient for treatment of only a single or a few animals are very low compared to those applicable for group treatment, the data presented in this report are thought to be a reasonable estimate of sales of antimicrobial agents for group treatment.

Product information requested in the ESVAC template includes marketing-authorisation number. However, not all countries provided these numbers, thus the numbers of different antimicrobial products reported by country are reported as product presentations (product name, form, strength and pack size), which overestimates the number of antimicrobial VMPs available to treat animals.

3.2. Results

A total of 18 of the 20 countries that reported sales to ESVAC in 2010, 2011 and 2012 reported a decrease in sales (range 0.4%–49%) expressed as mg/PCU.

Tentative explanations provided by some of the countries (see Section 2.8.2) for the decline in sales are, among others, implementation of responsible-use campaigns, changes in animal demographics, restrictions of use, increased awareness about the threat of antimicrobial resistance, and/or the setting of targets. Additional detailed information on national programmes and campaigns on the responsible use of antimicrobial agents is needed before conclusions can be drawn on the efficacy of these campaigns to reduce the sales of antimicrobial agents. At the European level, this would provide data for interventions aimed at best practices for the use of antimicrobial agents in animals.

A large difference in the sales, expressed as the indicator mg/PCU, is observed between the most- and least-selling

countries. This is likely to be partly due to differences in the composition of the animal population (e.g. more pigs than cattle, or a high proportion of veal calves within the cattle population) in the various countries. There is also considerable variation in terms of daily dosage and length of treatment between the various antimicrobial agents and formulations used, and other factors also need to be considered. Furthermore, differences in the selection of data source — i.e. prescriptions, sales data or purchase data may have an impact, but this is considered to be low.

The prescribing patterns of the various veterinary antimicrobial classes, expressed as mg/PCU, varied substantially between the countries in 2012. Notable variations between the different countries in the proportion accounted for by the CIAs with highest priority in human medicine — 3rd- and 4th-generation cephalosporins, fluoroquinolones and macrolides — were observed; proportions ranged from 0.01% to 1.2%, 0.02% to 11% and 0.04% to 17%, respectively. Since the major proportion of the sales of these classes/subclasses was accounted for by macrolides, the observed variations between the countries are likely, in part, to reflect differences between the countries in the relative proportion of the various animal species, and in particular, differences in pig production (use of macrolides).

Part of the variations in the sales patterns and in the magnitudes of sales may be due to differences between the countries in the relative proportion of the various animal species, the availability of veterinary antimicrobial products on the market, prices, animal-production systems (e.g. veal as opposed to beef cattle on pasture) and the general situation with regard to infectious diseases. These factors can, however, not fully explain the differences. Other factors, such as focus on disease prevention by management, or vaccines, or implementation of responsible-use campaigns in some countries have also impacted on the sales patterns. Also, important variations between the sales, expressed in tonnes, of veterinary antimicrobial agents used almost solely in food-producing animals and of those used in companion animals (tablets) were observed. However, it has to be noted that human medicinal products containing antimicrobial agents and injectable veterinary medicinal products containing antimicrobial agents may also be used in companion animals, and thus the data on sales of tablets should be interpreted with great care.

Another important finding was that the total sales, both in tonnes and in mg/PCU, of veterinary antimicrobial agents in the 26 EU/EEA countries were mainly accounted for by pharmaceutical forms applicable for mass treatment (premixes) or group treatment (oral powder and oral solution); however, this varies noticeably between the countries.

Of the total numbers of product presentations of antimicrobial VMPs applicable for food-producing animals (including horses) sold in 2012 — i.e. product name, pharmaceutical form, strength and pack size (tablets not included) — 81.6% contained only one active ingredient, 16.5% contained two active ingredients, 1.7% contained three active ingredients and 0.2% contained four active ingredients (these were intramammaries).

For all 26 countries, the proportion of sales in 2012 (tonnes) of antimicrobial VMPs applicable for group treatment containing two or more active ingredients was relatively low. Of the total sales, 84.4%, 14.9% and 0.7% of these pharmaceutical forms contained one, two and three active ingredients, respectively. However, as it is possible to mix more than one premix/oral powder and oral solution into feed or drinking water, respectively, these data do not provide a reliable estimate of treatment through feed or drinking water with two or more active ingredients.

4. Concluding remarks

In the current report, the sales of veterinary antimicrobial classes and some subclasses, as well as pharmaceutical forms, are documented for 26 of the 30 EU/EEA countries in 2012. This covers approximately 95% of the food-producing animal population in the EU/EEA area. Identification of the determining factors and reasons behind the variations and changes observed in the consumption of different classes or subclasses of antimicrobial agents remains difficult without data by species, and without taking into account differences in daily dose and length of treatment.

Annex 1. Tables

Table A1. Sales, in tonnes of active ingredient, of veterinary antimicrobial agents applicable mainly for food-producing animals, including horses, by antimicrobial class (presented according to the ATCvet hierarchical system) by country for 2012 (tablets not included)

Country	Tetracyclines	Amphenicols	Penicillins	1-2 gen. cephalosporins	3-4 gen. cephalosporins	Sulfonamides	Trimethoprim	Macrolides	Lincosamides	Fluoroquinolones	Other quinolones	Aminoglycosides	Polymyxins	Pleuromutilins	Others[1]	Total tonnes
Austria	29.9	0.3	7.9	0.1	0.3	5.7	0.8	4.4	0.3	0.5		1.3	0.7	0.4	0.4	53.0
Belgium	60.0	1.4	76.5	0.1	0.8	71.7	14.4	12.3	5.2	1.4	2.7	1.6	9.6	2.4	6.7	267.2
Bulgaria	17.3	0.5	4.3	0.02	0.01	1.0	0.1	6.5	1.2	2.4	0.1	1.6	1.5	1.0	1.0	38.4
Cyprus	14.2	0.1	7.4	0.004	0.1	8.7	1.7	2.4	5.6	0.1	0.3	0.6	0.9	2.5	0.4	45.0
Czech Republic	20.0	0.4	12.3	0.2	0.2	8.6	0.8	3.8	0.3	1.2	0.05	1.7	0.6	3.2	0.4	53.7
Denmark	32.5	0.8	27.4	0.1	0.1	11.1	2.2	12.4	2.5	0.02	2.1	3.6	0.6	9.3	2.4	107.0
Estonia	1.8	0.02	2.6	0.1	0.1	0.1	0.02	0.5	0.1	0.1		0.6	0.6	0.6	0.2	7.3
Finland	1.8	0.1	6.4	0.04	0.01	2.5	0.5	0.6	0.1	0.1		0.03		0.1		12.2
France	323.0	4.7	80.9	1.6	2.3	141.4	21.2	57.9	4.4	4.6	5.3	54.8	50.1	5.7	3.6	761.5
Germany	599.3	5.4	564.5	0.5	3.7	161.6	26.2	133.0	16.4	10.0		31.4	123.6	22.3	9.6	1,707.5
Hungary	99.5	2.0	32.6	0.2	0.2	4.9	1.1	4.3	4.5	8.0	0.2	1.9	5.7	12.8	0.6	178.5
Iceland	0.04		0.3		<0.001	0.04	0.01			<0.001	0.02	0.2		0.003		0.7
Ireland	37.2	2.0	21.7	0.6	0.2	19.7	1.5	6.7	0.4	1.0		8.4	0.2	0.01	0.5	100.0
Italy	478.2	16.9	358.1	1.1	1.8	174.0	22.8	139.0	59.6	11.4	30.2	22.0	135.3	51.5	32.3	1,534.3
Latvia	2.5	0.005	1.6	0.03	0.1	0.2	0.05	0.3	0.02	0.3	0.001	0.7	0.4	0.4	0.1	6.7
Lithuania	2.4	0.2	4.9	0.3	0.02	0.9	0.2	1.5	0.1	0.2	0.1	1.5	0.4	0.2	0.4	13.4
Luxembourg	0.8	0.05	0.4	0.02	0.03	0.4	0.1	0.1	0.04	0.03	0.001	0.04	0.1	0.02	0.1	2.2
Netherlands	96.6	3.0	54.7	0.2	0.1	41.0	7.8	25.5	0.9	0.8	2.3	6.0	3.2	2.2	1.5	245.7
Norway	0.2	0.2	2.8		0.001	1.5	0.3	0.003		0.02	1.4	0.6		0.1	0.004	7.1
Poland	211.1	7.1	129.4	0.9	0.5	44.6	3.2	22.8	5.3	32.2	0.5	35.6	15.6	4.3	3.3	516.4
Portugal	55.5	1.0	26.7	0.1	0.2	2.9	0.7	14.2	6.7	9.2	0.2	3.4	18.5	13.9	3.2	156.5
Slovakia	2.6	0.1	3.4	0.1	0.1	0.3	0.1	0.2	0.1	0.8		1.1	0.5	0.9	0.1	10.2
Slovenia	0.8	0.2	2.7	0.03	0.03	0.3	0.1	0.2	0.2	0.7	0.003	0.5	0.02	0.1	0.8	6.8
Spain	656.9	11.6	261.8	0.3	1.1	56.2	9.6	148.3	115.7	49.0	4.4	97.6	177.1	81.0	22.2	1,693.0
Sweden	0.8	<0.001	6.5		0.01	1.6	0.3	0.5	<0.001	0.1		0.3	0.1	0.1	0.2	10.6
United Kingdom2	197.6		81.8	0.7	1.3	65.0	12.8	40.9	5.0	2.3		13.6		14.2	12.2	447.4
Total 26 countries	**2,943**	**58**	**1,780**	**7**	**13**	**826**	**129**	**638**	**235**	**136**	**50**	**291**	**545**	**229**	**102**	**7,982**

[1] Bacitracin, paromycin and spectinomycin (classified as 'Other antibacterials' in the ATCvet system). [2] Polymyxins and amphenicols are aggregated with 'Others' for confidentiality reasons.

Table A2. Distribution of sales, in mg/PCU, of veterinary antimicrobial agents applicable mainly for food-producing animals, including horses[1], by administration route/form and country for 2012

Country	Premix	Oral powder	Oral solution	Injection	Oral paste	Bolus	Intramammary prep.	Intrauterine prep.	Total mg/PCU
Austria	2.5	43.9	1.3	5.5	0.00005		1.4	0.3	54.9
Belgium	33.4	107.3	7.7	11.9	0.03		0.5	0.2	161.1
Bulgaria	46.9	22.0	9.9	13.5			1.8	5.0	98.9
Cyprus	307.8	54.7	14.7	18.5	0.10	0.1	0.6	0.01	396.5
Czech Republic	21.1	20.4	26.5	10.3	0.04		1.1	0.4	79.8
Denmark	1.7	6.5	19.8	15.5	0.5	0.006	0.2	0.1	44.1
Estonia	0.7	31.5	3.4	17.9			2.3	0.2	56.0
Finland	2.4	6.2	0.003	13.8	0.9		0.5		23.8
France	41.0		46.3	14.1	0.1		1.0	0.2	102.6
Germany	0.4	105.2	90.2	7.1	0.10		1.1	0.6	204.8
Hungary	161.4	56.8	17.3	8.2	0.010		1.5	0.3	245.5
Iceland	0.1	0.4	0.6	4.4	0.02		0.2	0.1	5.9
Ireland	18.6	8.9	10.5	17.3	0.06		2.5	0.01	58.0
Italy	148.2	119.8	53.1	18.6	0.2	0.00002	0.7	0.2	341.0
Latvia	0.9	23.6	2.0	11.1	0.004		3.4	0.1	41.1
Lithuania	0.0	28.6	3.0	10.5	0.003	0.1	1.1	0.1	43.6
Luxembourg	0.2	13.7	6.4	7.6			9.3	2.1	39.4
Netherlands	0.7	59.3	5.1	8.3			1.1	0.4	74.9
Norway	0.9	0.2	0.1	1.7	0.7		0.2	0.1	3.8
Poland	11.5	88.8	13.5	15.5			2.5	0.2	132.2
Portugal	98.3	21.2	30.1	7.3	0.003		0.2	0.02	157.1
Slovakia	8.2	4.6	17.4	11.9	0.03		0.9	0.2	43.2
Slovenia	5.4	14.8	4.8	10.4			1.2	0.3	37.0
Spain	163.4	51.9	17.0	9.4	0.02		0.2	0.04	242.0
Sweden	0.3	0.5	0.6	10.2	1.8		0.2	0.002	13.5
United Kingdom	42.5	1.2	14.6	7.3	0.1		0.5	0.005	66.3

[1] Injectable antimicrobial VMPs included are also used in companion animals. Tablets not included.

Table A3. Percentage of sales, in mg/PCU, of premixes by veterinary antimicrobial class (according to ATCvet system) by country for 2012[1]

Country	Tetracyclines	Amphenicols	Penicillins	Sulfonamides	Trimethoprim	Macrolides	Lincosamides	Other quinolones	Aminoglycosides	Polymyxins	Pleuromutilins	Others[2]	Total mg/PCU premixes
Austria	29.3	0.04				48.3	9.4			0.9	2.6	9.4	2.5
Belgium	17.5		17.9	43.2	8.6	4.8	1.3		0.2	4.6	1.4	0.6	33.4
Bulgaria	72.9	1.0		2.7		20.5	0.2			1.1	1.6		46.9
Cyprus	26.6		17.0	22.0	4.4	4.3	15.7			2.6	6.9	0.5	307.8
Czech Republic	40.0	0.3	23.3	14.8	2.2	10.3	1.1			1.1	4.9	1.9	21.1
Denmark			2.3	36.2	7.3		2.3	49.5			0.5	2.0	1.7
Estonia	15.2					70.2	14.5						0.7
Finland	40.5	4.0		12.3	2.5	32.9	8.0						2.4
France	49.6		4.4	23.0	3.8	6.1	0.8	0.2	3.7	7.3	0.8	0.2	41.0
Germany	33.0		11.4	20.0	3.7	0.5	13.2			5.0	0.01	13.2	0.4
Hungary	74.1	0.3	8.2	0.6	0.1	2.0	2.9			3.3	8.3	0.2	161.4
Iceland								100.0					0.1
Ireland	65.2	0.2	6.6	16.4	3.3	7.9			0.4		0.007		18.6
Italy	38.3	0.6	18.0	12.7	1.2	6.9	3.8	1.3	0.9	9.7	5.9	0.8	148.2
Latvia	6.8					71.8					21.4		0.9
Lithuania		3.3					96.7						0.2
Luxembourg							50.0					50.0	0.05
Netherlands	77.6		5.9	6.3	1.3	5.3					3.6		0.7
Norway	0.0	12.0						87.9					0.9
Poland	16.0	0.1	8.0	59.8	0.1	10.0	0.7			2.4	3.0	<0.001	11.5
Portugal	40.6	0.3	11.5	1.5	0.3	9.7	0.5	0.03	1.9	18.4	13.0	2.2	98.3
Slovakia	55.9		30.9	2.5		2.7	0.4			1.3	5.8	0.4	8.2
Slovenia	31.9	3.2		9.8	2.0		15.1				7.3	30.7	5.4
Spain	50.3	0.3	9.6	1.2	0.1	10.0	3.7	0.1	4.8	12.3	6.6	1.1	163.4
Sweden						85.5					14.5		0.3
United Kingdom	57.7	0.1	5.3	19.2	3.8	9.2	0.2		0.5		3.7	0.2	42.5

[1] Negligible amounts of 1st- and 2nd-generation cephalosporins and fluoroquinolones sold not included in the table. [2] Bacitracin and spectinomycin (classified as 'Other antibacterials' in the ATCvet system).

Table A4. Percentages of sales, in mg/PCU, of oral powders by antimicrobial class (according to ATCvet system) by country for 2012[1,2]

Country	Tetracyclines	Penicillins	Sulfonamides	Trimethoprim	Macrolides	Lincosamides	Other quinolones	Aminoglycosides	Polymyxins	Pleuromutilins	Others[3]	Total mg/PCU oral powder
Austria	66.6	11.3	11.7	1.5	6.7	0.0		0.3	1.2	0.5	0.02	43.9
Belgium	27.4	30.8	25.2	5.1	0.6	2.2	1.5	0.1	3.3	0.8	3.0	107.3
Bulgaria	31.1	32.7	0.8	0.01	16.5	12.3	0.7	0.1	2.2	3.6		22.0
Cyprus	71.8	5.5	1.7		13.3	1.3	3.7				2.7	54.7
Czech Republic	71.2	5.7	11.1	1.4	1.2			1.6		7.8		20.4
Denmark	49.4		22.7	4.6	14.0		0.4	0.3	0.4	7.5		6.5
Estonia	27.6	32.0	1.5	0.3	8.3	1.4			13.8	12.3	2.8	31.5
Finland	23.8	5.3	52.8	10.6	5.3					2.1		6.2
Germany	34.8	38.6	15.1	2.6	3.2	0.3		0.4	2.6	2.1	0.05	105.2
Hungary	28.0	47.5	6.5	1.4	2.9	2.4	0.4	1.0	2.5	6.6	0.6	56.8
Iceland	22.9	19.9	31.7	6.4				14.3		4.8		0.4
Ireland	66.6		30.9	1.2	0.4	0.9						8.9
Italy	36.0	39.4	1.7		12.0	4.9	1.2	0.4	1.9	0.9	1.5	119.8
Latvia	63.2	11.9	2.0	0.4	2.5	<0.001			9.7	10.3	0.0001	23.6
Lithuania	34.9	38.3	13.0	3.1		0.5			9.2	1.0		13.7
Luxembourg	51.6	1.2	21.2	4.2	7.7	1.9	0.1	0.1	5.2	1.5	5.4	28.6
Netherlands	46.4	20.7	16.5	3.0	7.8	0.4	1.2	0.9	1.4	1.1	0.7	59.3
Norway	21.1		65.7	13.2								0.2
Poland	56.1	29.4	2.0	0.3	4.8	1.2	0.0	2.6	2.5	0.5	0.7	88.8
Portugal	17.2	35.2	0.7	0.8	12.6	29.2		0.2	0.2		3.8	21.2
Slovakia	45.8		9.9	2.0				42.0		0.4		4.6
Slovenia	8.0	75.1		1.5	6.0	0.5		0.2	0.6		8.0	14.8
Spain	13.1	33.6	10.6	2.1	7.6	19.8	0.2	4.0	6.4	0.3	2.2	51.9
Sweden	83.4		13.8	2.8								0.5
United Kingdom	7.4		77.2	15.4	0.001					0.001		1.2

[1] Negligible amount of amphenicols, 1st- and 2nd-generation cephalosporins and fluoroquinolones sold not included in the table. [2] France has no sales of oral powder. [3] Bacitracin, paromycin and spectinomycin (classified as 'Other antibacterials' in the ATCvet system).

Table A5. Percentage of sales, in mg/PCU, of oral solutions by antimicrobial class (according to ATCvet system) by country for 2012

Country	Tetracyclines	Amphenicols	Penicillins	Sulfonamides	Trimethoprim	Macrolides	Lincosamides	Fluoroquinolones	Other quinolones	Aminoglycosides	Polymyxins	Pleuromutilins	Others[1]	Total mg/PCU oral solution
Austria	34.9			22.0	4.4	0.6	2.9	15.9			8.8	4.7	5.8	1.3
Belgium	0.01	0.2	3.1	16.9	3.1	61.5		4.6			8.4	2.1	0.1	7.7
Bulgaria		4.3		6.4	1.4	0.7		49.1			28.0	9.9	0.2	9.9
Cyprus	11.1		18.5	43.6	7.5	0.2		3.9	4.0	3.8	1.3	6.1		14.7
Czech Republic	19.9	0.3	29.9	26.9	1.2	4.5	0.3	6.1	0.3	0.03	2.6	7.7	0.4	26.5
Denmark	41.4	0.01	13.6	0.1		20.1	2.1	0.01		1.3	1.1	16.1	4.1	19.8
Estonia	87.1			0.03	0.01			9.3				3.6		3.4
Finland								11.2				88.8		0.003
France	47.0	0.03	9.0	19.6	2.6	8.1	0.4	0.6	1.3	2.1	8.0	0.9	0.4	46.3
Germany	38.0	0.1	25.8	2.9	0.2	13.4	1.5	0.6		2.8	13.3	0.5	1.0	90.2
Hungary	3.0	10.8	0.6	10.6	2.3	4.6		60.6			6.0	1.2	0.4	17.3
Iceland								0.03		100.0				0.6
Ireland	2.5	0.003	36.5	45.0	0.04	8.1	0.8	1.4		2.6	1.1	0.002	1.9	10.5
Italy	7.8	2.5	0.1	29.8	5.9	8.9	2.1	3.5	6.2	0.01	25.3	3.0	4.8	53.1
Latvia	3.1	0.6			1.4			72.4	0.4	2.3	13.0		6.8	2.0
Lithuania	0.6	2.8	0.6	9.4	2.3	65.3	0.9	4.8	3.9		0.6	6.5	2.4	6.4
Luxembourg[2]	3.2	0.1	67.0	6.9	0.1	3.4	1.1	2.2		0.1	6.5		2.2	3.0
Netherlands	0.1		0.04	29.3	6.6	57.2		4.0	0.004		2.7	0.1		5.1
Norway			54.9					0.2		14.0		30.9		0.1
Poland	4.5	5.0		17.7	4.2	1.4		51.7	0.7	2.4	11.1	1.4		13.5
Portugal	36.4	0.2	18.9	3.2	0.6	5.5		29.7	0.4		1.5	3.5		30.1
Slovakia	16.7	0.3	33.6			1.5	0.6	17.0			11.6	17.5	1.2	17.4
Slovenia		4.2	0.2	1.4	5.3			62.2	0.3			1.5	24.9	4.8
Spain	22.3	0.02	10.5	1.8	0.3	0.9		36.2	2.2	12.0	10.9	2.8		17.0
Sweden	16.3		1.3	1.9		40.8		1.4		9.1	16.7	12.4		0.6
United Kingdom	17.7	0.1	52.9	0.5	0.04	9.1	4.3	1.3		1.9	0.6	3.6	7.9	13.7

[1] Spectinomycin (classified as 'Other antibacterials' in the ATCvet system). [2] Of total sales, 7% were sold as 1st- and 2nd-generation cephalosporins.

Table A6. Percentage of sales, in mg/PCU, of injection preparations by antimicrobial class (according to ATCvet system) by country for 2012[1]

Country	Tetracyclines	Amphenicols	Penicillins	1-2 gen. cephalosporins	3-4 gen. cephalosporins	Sulfonamides	Trimethoprim	Macrolides	Lincosamides	Fluoroquinolones	Aminoglycosides	Pleuromutilins	Others[2]	Total mg/PCU injection prep.
Austria	6.3	5.3	38.1		3.0	9.4	1.9	7.8	0.8	5.5	19.9	0.3	1.6	5.5
Belgium	5.8	7.1	55.0	0.1	3.6	3.5	1.3	4.1	3.0	4.2	6.4	0.2	5.6	11.9
Bulgaria	23.5	2.2	21.0	0.1	0.2	3.4	0.7	8.5	1.3	9.7	27.0	0.8	1.6	13.5
Cyprus	12.3	3.1	38.5		0.7	8.3	0.7	2.3	1.2	1.1	26.9	1.3	2.1	18.5
Czech Republic	11.1	4.1	34.4	1.7	2.9	2.7	0.5	19.6	0.2	2.0	19.8	0.5	0.4	10.3
Denmark	13.1	1.9	52.9		0.1	14.3	2.9	1.5	3.7	0.03	7.8	0.9	0.9	15.5
Estonia	9.5	0.9	49.7	0.8	2.8	1.9	0.4	2.1	1.4	3.6	22.5	1.6	2.7	17.9
Finland	7.4	0.2	85.1	0.003	0.2	4.3	0.9	0.2	0.4	1.2	0.3			13.8
France	8.3	4.3	32.7	0.1	1.9	3.7	0.5	10.7	0.6	2.3	33.2	0.02	1.2	14.1
Germany	4.4	7.3	39.3		5.2	10.9	1.9	7.0	2.0	9.1	10.7	0.2	1.9	7.1
Hungary	7.5	5.4	39.0	1.6	3.6	3.4	0.7	4.3	1.5	5.9	24.2	1.7	1.1	8.2
Iceland	5.4		60.1		0.02	2.0	0.4			0.1		0.1	35.2	4.6
Ireland	18.5	6.5	32.5	0.2	0.6	4.6	0.9	8.6	0.3	2.5	24.6	0.03	0.3	17.3
Italy	10.8	7.8	28.8	0.0	1.9	9.8	1.0	8.4	2.8	3.6	16.2	0.5	8.2	18.7
Latvia	3.5	0.2	38.1	0.7	3.5	7.5	1.5	3.8	0.8	2.1	36.1	1.4	1.0	11.1
Lithuania	27.1	3.5	29.5		0.7	4.4	0.9	2.6	1.5	3.4	25.6	0.2	0.8	7.6
Luxembourg	10.6	9.2	48.6	0.1	6.0	8.1	1.6	2.1	1.4	5.7	3.4	0.03	2.9	10.5
Netherlands	15.7	11.2	38.7		0.2	14.3	2.9	2.3	0.3	0.5	13.2	0.1	0.5	8.3
Norway	2.9	0.7	79.3		0.03	7.0	1.4	0.1		0.4	7.8	0.3		1.7
Poland	8.1	7.3	32.2	0.4	0.7	2.4	0.2	1.5	1.1	8.1	36.4	0.7	0.8	15.5
Portugal	17.3	7.8	31.1	0.6	2.6	4.1	0.8	4.5	0.8	4.3	20.9	2.2	2.8	7.3
Slovakia	10.0	4.3	44.5	2.3	4.3	6.0	1.2	1.5	0.5	2.3	21.1	1.1	1.0	11.9
Slovenia	12.5	6.1	29.5	0.8	1.3	12.3	1.6	2.4	0.2	10.6	22.3		0.2	11.2
Spain	10.5	13.0	25.2	0.01	1.6	3.3	0.7	8.9	1.8	9.1	21.8	1.2	2.5	9.7
Sweden	5.3	0.003	80.9		0.1	7.3	1.5	1.2		0.9	2.6	0.2		10.2
United Kingdom	28.1	5.2	25.3	0.2	2.3	5.2	0.9	10.9	0.4	2.0	19.4	0.1	0.1	7.3

[1] Negligible amount of other quinolones and polymyxins not included in the table. [2] Paromycin and spectinomycin (classified as 'Other antibacterials' in the ATCvet system).

Annex 2. Variables to be reported for each antimicrobial veterinary medicinal product; standardisation of the data

Table A7. Variables reported to ESVAC for each antimicrobial veterinary medicinal product for 2012

	Variable	Description of variable	Justification
	COUNTRY	**ISO code** (http://www.iso.org/iso/country_codes)	To identify place of collected sales data.
	YEAR		To identify time period for collected sales data.
PRODUCT INFORMATION	**MA**	**Marketing-authorisation number**	To allow a unique identification of the veterinary medicinal product (VMP) and enable link with other databases. To allow for market analysis if all the products are available.
	ID	**Medicinal product package code value** Digit code being a unique identifier for each package size, strength and formulation of the VMP. Because it is a key variable in many databases it has to be stable over time, i.e. so that VMPs no longer available on the market or that are no longer registered can still be identified to allow for analysis of historical data.	To allow for analysis of historical data. To allow for identification of duplicate reporting of sales.
	NAME	**Medicinal product name (in national language)** E.g. Harmony vet tablets 2 x 30; Harmony vet longacting injection 10 ml.	For validation purposes. To e.g. allow for analysis of use of e.g. longacting preparations and antimicrobial resistance.
	FORM	**Pharmaceutical form** Bolus (BOLUS), Injection (INJ), Intramammary (INTRAMAM), Intramammary dry cow treatment (INTRAMAM-DC), Oral solution individual treatment (ORAL SOLU-IND), Oral solution herd treatment (ORAL SOLU-HERD), Oral paste (ORAL PASTE), Oral powder individual treatment (ORAL POWD-IND), Oral powder herd treatment (ORAL POWD-HERD), Premix (PREMIX), Capsules and Tablets etc. (TABL), Intrauterine preparation (INTRAUT).	Important to avoid misinterpretation of pharmaceutical form if given in a language other than English. Allows for reporting of data as individual or flock treatment.
	PACKSIZE	**Content quantity in package: pack size (numerical only)** E.g. 100 for 100 tablets or 100 intramammaries; 10 for 10 ml injection; Package of 2 kg premix: 2; Box of 10 blisters of 30 tablets: 300; Box of 12 injectors: 12.	To allow for calculation of the amount of active ingredient in each package/ product.
	PACKSIZEU	**Content unit of measurement** E.g. ML, L, G, KG, PIECE (for e.g. tablets, capsules, bolus and intramammaries).	To allow for calculation of amount active ingredient in each package/ product.

	Variable	Description of variable	Justification
	ATCvet - 5th LEVEL	**ATCvet: Anatomical Therapeutic Chemical (Classification) Veterinary** WHO ATCvet code last version to be used.	Generally, a classification system is necessary to have common language when reporting use and analysing data with data on AMR, e.g. for 3rd- and 4th-generation cephalosporins. To have a common language for defining confidentiality of the data (can be converted into ATCvet 3rd level).
	SPECIES	**Animal species** All the animal species for which the VMP is approved, e.g. cattle (CA), poultry (POU).	Optional.
	NO SOLD	**Number of packages sold/year/country**	To calculate weight of active ingredient sold.
INGREDIENT	**INGR**	**Active ingredient name (ATCvet name)** In case of multi-ingredient VMP, the ATCvet names of all the ingredients have to be given.	Important to avoid misinterpretation of ingredient name if given in a language other than English. Use of ATCvet names facilitates the identification of active ingredients as well as standardised reporting.
	SALT	**Salt of active ingredient** E.g. colistin sulfate and colistin methanesulfonate.	Only in cases when the strength is given in IU, IU/ML or IU/UNIT and when different salts exist, to allow for conversion to weight of active ingredient.
	PRODRUG	**Prodrug name (ATCvet name)** E.g. procaine penicillin that is prodrug for benzylpenicillin.	Only in cases when a product contains a prodrug.
	STRENGTH	**Quantity of the active ingredient in each unit as declared in name/SPC: strength (numerical only)** E.g. 10 for 10 MG/TABLET, 10 IU/TABLET, 10 MG/ML, 10 IU/ML, 10 MG/PIECE or 10 IU/PIECE. In case of a multi-ingredient VMP, strength has to be given for each ingredient on a separate line.	To allow for calculation of amount active ingredient in each package/ product and to validate INGR CONTENT.
	STRENGTHU	**Unit of measurement for strength** E.g. IU, IU/G, IU/ML, IU/PIECE, G, G/KG, G/L, MG, MG/ML, MG/PIECE. In case of a multi-ingredient VMP, unit of measurement strength has to be given for each ingredient on a separate line.	To allow for calculation of the amount of active ingredient in each package/ product and to validate INGR CONTENT.
	CONV FACT IU	**Conversion factor IU** When strength is given as IU, IU/ML or IU/PIECE.	When strength is only given as IU, IU/ML or IU/PIECE. To allow for calculation of weight of the active ingredient in package.
	CONV FACT PRODR	**Conversion factor prodrug** Only when strength is given for the prodrug and not for the active ingredient (e.g. procaine penicillin that is prodrug for benzylpenicillin).	To allow for calculation of weight of the active ingredient in package.
	INGR CONTENT	**Content of active ingredient in package** In case of a multi-ingredient VMP, the content in the package has to be given separately for each ingredient on a separate line.	Optional. To allow for validation of the ESVAC calculations.

	Variable	Description of variable	Justification
	CONT UNIT (G)	**Unit of active ingredient in package** To be given in grams (g) for all substances. In case of a multi-ingredient VMP, the content unit has to be given separately for each ingredient on a separate line.	Optional. To allow for validation of the ESVAC calculations.
	TONS SOLD	**Tonnes sold of active ingredient**	

Note: For antimicrobial veterinary medicinal products containing more than one active ingredient, information on active ingredient name, strength and strength unit has to be given for these as well.

Table A8. Conversion factors used to convert from international units (IU) to weight (mg) of active ingredient based on WHO standards[1]

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

[1] WHO standards (http://crs.pheur.org/db/4DCGI/search?vSelectName=4&vContains=1&vtUserName=ISA&OK=Search).
[2] WHO Pharmacopoeia (http://apps.who.int/phint/en/p/docf/).
[3] WHO International Biological Reference Preparations (http://www.who.int/bloodproducts/catalogue/AntiJan10.pdf).
[4] Martindale (http://www.medicinescomplete.com/mc/martindale/current/141-b.htm?q=procain%20penicillin&t=search&ss=text&p=2#_hit).

Table A9. Conversion factors used to convert from prodrug content to content of active ingredient[1]

Prodrug	Conversion factor	Active ingredient
Benethamine benzylpenicillin	0.65	Benzyl penicillin
Benzathine benzylpenicillin	0.39	Benzyl penicillin
Benzathine phenoxymethylpenicillin	0.37	Phenoxymethylpenicillin
Cefapirin benzathine	0.41	Cefapirin
Cefalexin benzathine	0.36	Cefalexin
Cloxacillin benzathine	0.43	Cloxacillin
Oxacilline benzathine	0.69	Oxacilline
Penethamate hydriodide	0.63	Benzyl penicillin
Procaine benzylpenicillin	0.61	Benzyl penicillin

[1] Martindale (http://www.medicinescomplete.com/mc/martindale/current/141-b.htm?q=procain%20penicillin&t=_search&ss=text&p=2#_hit).

Annex 3. Population correction unit (PCU)

Table A10. Animal categories included in the calculation of the population correction unit (PCU) and data types to be reported

Animal category	Numbers/tonnes
Cattle (heads)	
Slaughtered cows	
Slaughtered heifers	
Slaughtered bullocks and bulls	
Slaughtered calves and young cattle	
Import slaughter	
Export slaughter	
Import fatteners	
Export fatteners	
Living dairy cows	
Pigs (heads)	
Slaughtered pigs	
Import slaughter	
Export slaughter	
Import fatteners	
Export fatteners	
Living sows	
Poultry (heads)	
Slaughtered broilers	
Slaughtered turkeys	
Import slaughter	
Export slaughter	
Caprinae (heads)	
Slaughtered sheep and goats	
Import sheep slaughter	
Export sheep slaughter	
Import sheep fatteners	
Export sheep fatteners	
Living sheep	
Import goats slaughter	
Export goats slaughter	
Import goats fatteners	
Export goats fatteners	
Equidae (heads)	
Living horses	
Rabbits (heads)	
Slaughtered rabbits	
Fish (tonnes)	
Biomass slaughter weight	

Table A11. Weights used to calculate the population correction unit

Animal category	Weight in kg
Slaughtered or livestock (Eurostat)	
Slaughtered cow	425
Slaughtered heifer	200
Slaughtered bullocks and bulls	425
Slaughtered calves and young cattle	140
Dairy cow	425
Slaughtered pig	65
Living sow	240
Broiler	1
Turkey	6.5
Slaughtered sheep and goat	20
Living sheep	75
Horse	400
Rabbit	1.4
Imported/exported for fattening or slaughter (TRACES data)	
Slaughtered bovine	425
Fattening bovine	140
Slaughtered pig	65
Fattening pig	25
Slaughtered poultry	1
Slaughtered sheep	20
Fattening sheep	20
Slaughtered goat	20
Fattening goat	20

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

The table below includes all the substances for which sales have been reported, divided by class or subclass.

Pharmacologically active substances that may be used in food-producing animals have to be listed in Table 1 of the Annex to Commission Regulation (EU) No 37/2010. The table details, among others, the food-producing animal species for which those substances are allowed to be used. Table 2 of that annex contains substances that are prohibited from being used in any food-producing species; some of these substances are included in Table A12 below, because they are used in companion animals for which no maximum residue limits (MRLs) are required.

Table A12. List of substances reported sold in ESVAC

Class/subclass	Substances		
Tetracyclines			
	Chlortetracycline	Doxycycline	Oxytetracycline
	Tetracycline		
Amphenicols			
	Chloramphenicol[1]	Florfenicol	Thiamphenicol
Penicillins			
Beta-lactamase-sensitive penicillins			
	Benzathine benzylpenicillin	Benzathine phenoxymethylpenicillin	Benzylpenicillin
	Penethamate hydriodide	Phenoxymethylpenicillin	Procaine benzylpenicillin
Beta-lactamase-resistant penicillins			
	Cloxacillin	Dicloxacillin	Nafcillin
	Oxacillin		
Penicillins with extended spectrum			
	Amoxicillin	Ampicillin	Metampicillin[2]
Cephalosporins[3]			
First-generation cephalosporins			
	Cefacetrile	Cefadroxil[2]	Cefalexin
	Cefalonium	Cefapirin	Cefazolin
Third-generation cephalosporins			
	Cefoperazone	Cefovecin[2]	Ceftiofur
Fourth-generation cephalosporins			
	Cefquinome		
Sulfonamides and trimethoprim			
Sulfonamides			
	Formosulfathiazole	Phthalylsulfathiazole	Sulfacetamide
	Sulfachlorpyridazine	Sulfaclozine	Sulfadiazine

Class/subclass	Substances		
	Sulfadimethoxine	Sulfadimidine	Sulfadoxine
	Sulfafurazole	Sulfaguanidine	Sulfamerazine
	Sulfamethizole	Sulfamethoxazole	Sulfamethoxypyridazine
	Sulfanilamide	Sulfapyridine	Sulfaquinoxaline
	Sulfathiazole	Sulfamonomethoxine	
Trimethoprim and derivatives			
	Trimethoprim		
Macrolides and lincosamides			
Macrolides			
	Erythromycin	Gamithromycin	Oleandomycin[2]
	Spiramycin	Tildipirosin	Tilmicosin
	Tulathromycin	Tylosin	Tylvalosin
Lincosamides			
	Clindamycin[2]	Lincomycin	Pirlimycin
Aminoglycosides			
	Amikacin[2]	Apramycin	Framycetin
	Gentamicin	Kanamycin	Neomycin
Quinolones			
Fluoroquinolones			
	Danofloxacin	Difloxacin	Enrofloxacin
	Ibafloxacin[2]	Marbofloxacin	Norfloxacin[2]
	Orbifloxacin[2]	Pradofloxacin[2]	
Other quinolones			
	Cinoxacin[2]	Flumequine	Oxolinic acid
Imidazole derivatives			
	Metronidazole[1]		
Pleuromutilins			
	Tiamulin	Valnemulin	
Polymyxins			
	Colistin	Polymyxin B[2]	
Streptomycins			
	Dihydrostreptomycin	Streptomycin	
Nitrofuran derivatives			
	Furazolidone[1]		
Others			
	Bacitracin	Furaltadone[1]	Nitroxoline[2]
	Novobiocin	Spectinomycin	Paromomycin
	Rifaximin	Natamycin	

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

Annex 5. Distribution of veterinary medicines; legal framework and data sources by country

Austria

Distribution of veterinary medicines

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

Legal basis for the monitoring of sales

The collection of sales data by pharmaceutical companies and wholesalers is based on the national law on animal drug control, CELEX-Nr.: 390L0167 (Tierarzneimittelkontrollgesetz).

Data sources

Sales data are collected from pharmaceutical companies producing or importing VMPs and from wholesalers that are assigned by the industry to distribute a product.

Belgium

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

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

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

Legal basis for the monitoring of sales

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

Data sources

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

The data collection for both concerned parties is organised via a secure web application with a login and password they receive by letter.

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

Bulgaria

Distribution of veterinary medicines

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

Legal basis for the monitoring of sales

The collection of sales data is based on the national law on veterinary activities, promulgated in the State Gazette (SG), Issue №7/25.01.2013. Wholesalers, pharmacies and farmers are obliged to keep records of all sales, and to deliver these records to the Bulgarian Food Safety Agency on a yearly basis.

Data sources

Sales data are collected from all wholesalers. The data contain the sales to veterinarians, farms and pharmacies.

Cyprus

Distribution of veterinary medicines

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

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

Legal basis for the monitoring of sales

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

Data sources

The data on sales of the included veterinary antimicrobial agents are obtained each year from the authorised wholesalers.

Czech Republic

Distribution of veterinary medicines

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

Legal basis for the monitoring of sales

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

Data sources

Sales data were collected from all wholesalers and feed mills licensed in the Czech Republic.

Brief description of data collection

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

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

Denmark

Distribution of veterinary medicines

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

Legal basis for the monitoring of sales

All sales of prescription medicines by pharmacies, dispensing companies and feed mills are mandated to be reported to the VetStat database, owned by the Ministry of Food, Agriculture and Fisheries. The pharmacy/dispensing-company sales records include sales of all prescription medicines to animal owners, as well as medicines purchased by veterinary practitioners for use in their practice.

Data sources

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

Estonia

Distribution of veterinary medicines

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

Legal basis for the monitoring of sales

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

Data source

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

Finland

Distribution of veterinary medicines

In Finland, all VMPs that contain antimicrobials are prescription-only medicines. They are available either from pharmacies on veterinarian's 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 to Finland, but always require a prescription by a veterinarian.

Legal basis for the monitoring of sales

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

Data source

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

France

Distribution of veterinary medicines

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

Legal basis for the monitoring of sales

There is no specific national legal framework for monitoring the sales of antimicrobial VMPs in France; the data are provided by the marketing-authorisation holders on a voluntary basis.

Data sources

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

Germany

Distribution of veterinary medicines

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

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

Legal basis for the monitoring of sales

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

Data sources

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

Hungary

Distribution of veterinary medicines

In Hungary, all VMPs that contain antimicrobials are prescription-only medicines. All VMPs have to be dispensed through authorised retailers, which are supplied by authorised wholesalers only. Wholesalers and retailers are authorised by the National Food Chain Safety Office.

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

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

Legal basis for the monitoring of sales

The collection of sales data is based on a national law (Decree of the Minister of Agriculture and Rural Development on VMPs).

Data sources

Data were collected from marketing-authorisation holders, wholesalers in Hungary, wholesalers from other Member States that deliver VMPs directly to final Hungarian wholesalers, and retailers that import directly from other Member States. These companies only submit data for those products that were put into circulation by themselves (there is no double reporting).

Iceland

Distribution of veterinary medicines

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

Legal basis for the monitoring of sales

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

Data sources

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

Ireland

Distribution of veterinary medicines

In Ireland, antimicrobial veterinary medicinal products may be supplied only on prescription. The products are supplied into the trade by wholesalers that are authorised by the Department of Agriculture, Food and the Marine. In accordance with the prescription of the prescribing veterinarian, the prescribed products can be dispensed either by the veterinarian or by a pharmacist. By way of exception to this principle, intramammary antimicrobial substances can also be dispensed by licensed agricultural merchants. Medicated feeds containing antimicrobials are prepared from authorised premixes, again under veterinary prescription. They are incorporated into the feed under a special

authorisation granted by the Department of Agriculture, Food and the Marine. The licences for incorporation are granted either to feed mills or to farms that possess appropriate facilities for inclusion. It should be noted that the sale, supply, or possession of any unauthorised veterinary medicine in Ireland is a criminal offence.

Legal basis for the monitoring of sales

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

Data sources

Each year, the Irish Medicines Board (IMB) collects data from veterinary pharmaceutical manufacturers that hold current Irish marketing authorisations. The marketing-authorisation holders are requested by the IMB to report only sales in Ireland. The IMB checks the information provided against data collected for previous years. Fluctuations in the data from year to year are followed up with the individual company to guard against data errors. Importation of medicated feed is permitted. However, in practice, given the logistics involved, this is not seen as a major route of supply into the country.

Italy

Distribution of veterinary medicines

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

Wholesale of veterinary medicines

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

Wholesale of veterinary medicinal products includes transactions between:

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

Direct sale of veterinary medicinal products

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

Retail veterinary medicinal products

The retail sale of veterinary medicinal products containing antibiotics can occur only at pharmacies and only under veterinary prescription, and can only be carried out in the presence of a pharmacist.

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

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

Legal basis for the monitoring of sales

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

Data sources

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

Latvia

Distribution of veterinary medicines

In Latvia, all VMPs containing antimicrobial agents are prescription-only medicines. This includes medicated feed manufactured from medicated premixes containing antimicrobial agents. VMPs are distributed through wholesalers to pharmacies, veterinarians and animal owners.

Legal basis for the monitoring of sales

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

Data sources

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

Lithuania

Distribution of veterinary medicines

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

Legal basis for the monitoring of sales

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

Data sources

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

Luxembourg

Distribution of veterinary medicines

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

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

Legal basis for the monitoring

Wholesalers, pharmacies, veterinarians and farmers are legally obliged to keep records of all sales. The data are provided under legal requirements to give any information they are asked for.

Data sources

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

Netherlands

Distribution of veterinary medicines

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

Legal basis for the monitoring of sales

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

Data sources

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

Norway

Distribution of veterinary medicines

In Norway, all VMPs are prescription-only medicines, and have to be dispensed through pharmacies, which are supplied by drug wholesalers only. Veterinarians are not allowed to dispense VMPs except in emergency situations in the field, in which case they have to be sold at cost price. Medicated feeds for livestock (terrestrial animals) are not produced in feed mills, due to the small size of livestock herds compared to those of most other European countries. However, group/flock treatment of livestock with antimicrobial agents is possible, again subject to veterinary prescription, through drinking water or as top-dressing on feed.

Legal basis for the monitoring of sales

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

Data sources

The data on sales of the included veterinary antimicrobial agents at package level are obtained from the Norwegian Institute of Public Health (NIPH), which collects its data from authorised wholesalers. The wholesalers are asked by the NIPH to only report sales to pharmacies and animal owners in Norway, to avoid double reporting by including sales among the wholesalers.

Poland

Distribution of veterinary medicines

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

Legal basis for the monitoring of sales

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

Data sources

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

Portugal

Distribution of veterinary medicines

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

Wholesaler-distributors obtain the VMPs from a wholesaler or from the marketing-authorisation holder/manufacturer. Antimicrobial VMPs are only available to animal owners/farmers by delivery on an official veterinary prescription. Veterinarians do not sell VMPs, as they may only charge for those they use. Premixes are distributed through wholesalers or wholesaler-distributors directly to feed mills. From feed mills, only farmers are receivers. Medicated feed is always on an official veterinary prescription.

Legal basis for the monitoring of sales

The collection of sales data is based on the national law n.º 148/2008, dated 29 July (Art. 120), amended and reprinted by national law n.º 314/2009, dated 28 October.

Data sources

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

Slovakia

Distribution of veterinary medicines

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

Legal basis for the monitoring of sales

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

Data sources

Import data were collected from all wholesalers licensed in the Slovak Republic.

Brief description of data collection

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

Slovenia

Distribution of veterinary medicines

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

Legal basis for the monitoring of sales

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

Data sources

Data on sales of veterinary antimicrobial agents at package level were obtained from the wholesalers, and from veterinary prescriptions for medicated feeds manufactured in other EU Member States and intended for use in the Republic of Slovenia.

For a single wholesaler, which had discontinued the sale of medicinal products in Slovenia, we were able to collect data only on the basis of data on quantities of medicinal products, which had been delivered to another company, where they were kept stored up to their distribution.

Spain

Distribution of veterinary medicines

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

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

Legal basis for the monitoring of sales

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

Data sources

The sales data were collected from marketing-authorisation holders at package level by the Spanish Agency for Veterinary Medicinal Products (AEMPS), in collaboration with the Spanish veterinary medicine industry association (Veterindustria) and the Spanish business association of additives and premixes for animal health and nutrition (Adiprem).

Sweden

Distribution of veterinary medicines

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

Legal basis for the monitoring of sales

All pharmacies in Sweden are required to provide sales statistics on a daily basis to an infrastructure company owned by the state, Apotekens Service AB, which maintains a database. All feed mills and farms authorised to mix medicated feed are requested to report their purchases and sales on a yearly basis to the Board of Agriculture.

Data sources

Data on sales at package level were obtained from Apotekens Service AB.

United Kingdom

Distribution of veterinary medicines

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

Legal basis for the monitoring of sales

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

Data sources

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

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Annex 7. Country and affiliation of the ESVAC national representatives/alternates

Table A13. List of ESVAC national representatives/alternates 2014

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Annex 8. ESVAC ad hoc Expert Group members and observers

Table A14. List of ESVAC ad hoc Expert Group members from EU Member States

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Table A15. List of ESVAC ad hoc Expert Group observers from the European Commission, ECDC and EFSA

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Annex 9. Data from Switzerland

As Switzerland is outside the framework of the European Union, it was not possible to obtain detailed data at package level, due to confidentiality issues. For this reason, it was not possible to include the Swiss data in the ESVAC database, and it was therefore not possible to integrate those data in the analysis of the ESVAC data. Furthermore, the Swiss data were not subjected to the quality check in terms of standardisation by the ESVAC data program.

Table A16. Information on years collecting data, legal basis for collecting data, national data providers of ESVAC data, data sources for ESVAC data and assumed data coverage

Country	Years collecting data	Legal basis	Data sources (approx. no)	Data coverage
Switzerland	>5 years	Mandatory to report	Marketing-authorisation holders (n=20)	Assumed to be 100%

Table A17. Estimated population correction unit (PCU) (in 1,000 tonnes) of the animal population, for 2012

Country	Cattle	Pigs	Poultry	Sheep/ goats	Fish	Rabbits	Horses	Total
Switzerland	485	211	58	37	0	1	23	815

Table A18. Sales, in tonnes of active ingredient, split into sales of veterinary antimicrobial agents marketed for food-producing animals (terrestrial animals), marketed for companion animals only (i.e. tablets) and total sales, for 2012

	Tablets		All other pharmaceutical forms		Total
	Tonnes	% of total	Tonnes	% of total	Tonnes
Switzerland	0.9	2	56.1	98	56.9

Table A19. Sales, in tonnes of active ingredient, of veterinary antimicrobial agents marketed for food-producing animals, including horses, population correction unit (PCU), and mg active ingredients of veterinary antimicrobial agents sold per PCU, for 2012

Country	Sales (tonnes) for food-producing animals	PCU (1,000 tonnes)	mg/PCU
Switzerland	56.1	815	68.8

Table A20. Sales, in tonnes of active ingredient, of veterinary antimicrobial agents for food-producing animals, including horses, split into administration route/form, for 2012

Country	Premix	Oral powder	Oral solution	Injection	Intramammary prep.	Intrauterine prep.	Oral paste	Bolus	Total
Switzerland	36.6[1]	4.5	–[1]	9.4	4.7	0.8	–[1]	0.1[2]	56.1

[1] Oral pastes and oral solutions aggregated with premixes for confidentiality reasons. [2] Includes all tablets/bolus authorised for food-producing animals only.

Table A21. Sales for food-producing animals, in tonnes of active ingredient, of the various veterinary antimicrobial classes, for 2012

Country	Tetracyclines	Amphenicols	Penicillins	1-2 gen. cepha.	3-4 gen. cepha.	Sulfonamides	Trimethoprim	Macrolides	Lincosamides	Fluoroquinolones	Other quinolones	Aminoglycosides	Polymyxins	Pleuromutilins	Others	Total
Switzerland	11.8	–[1]	12.8	0.1	0.2	21.6	1.4	3.3	–[2]	0.3	–[1]	3.2	1.1	–[1]	0.4	56.1

[1] Grouped with 'Others' for confidentiality reasons. [2] Grouped with macrolides for confidentiality reasons.

Table A22. Sales for food-producing animals, in mg per population correction unit (mg/PCU), of the various veterinary antimicrobial classes, for 2012

Country	Tetracyclines	Amphenicols	Penicillins	1-2 gen. cepha.	3-4 gen. cepha.	Sulfonamides	Trimethoprim	Macrolides	Lincosamides	Fluoroquinolones	Other quinolones	Aminoglycosides	Polymyxins	Pleuromutilins	Others	Total
Switzerland	14.5	–[1]	15.7	0.1	0.2	26.5	1.7	4.1	–[2]	0.4	–[1]	3.9	1.3	–[1]	0.5	68.8

[1] Grouped with 'Others' for confidentiality reasons. [2] Grouped with macrolides for confidentiality reasons.

Table A23. Number of product presentations of premixes, oral powders and oral solutions containing 1, 2 and 3 active ingredients, for 2012

Country	1	2	3	Total number
Switzerland	47	13	28	88

Table A24. Sales, in tonnes of active ingredient, of veterinary antimicrobial agents as premixes, oral powders and oral solutions containing 1, 2 and 3 active ingredients, for 2012

Country	1	2	3	Tonnes (premixes, oral powders and oral solutions)
Switzerland	8.9	7.4	24.4	40.7

Distribution of veterinary medicines

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

Legal basis for the monitoring of sales

The legal basis for data collection is Art. 36 of the Federal Ordinance on Veterinary Medicines, enacted in September 2004. It requests Swissmedic to "specifically establish a statistic about usage of veterinary antimicrobials for the purpose of monitoring resistances." The data are therefore requested, processed and analysed by the Swiss Agency for Therapeutic Products (Swissmedic). Sales of veterinary antimicrobials are published yearly in the ARCH-VET report , covering sales and resistances to veterinary antimicrobials.

Note that figures published in the ARCH-VET differ from figures in the present Annex since all ATCvet groups are included in the national report.

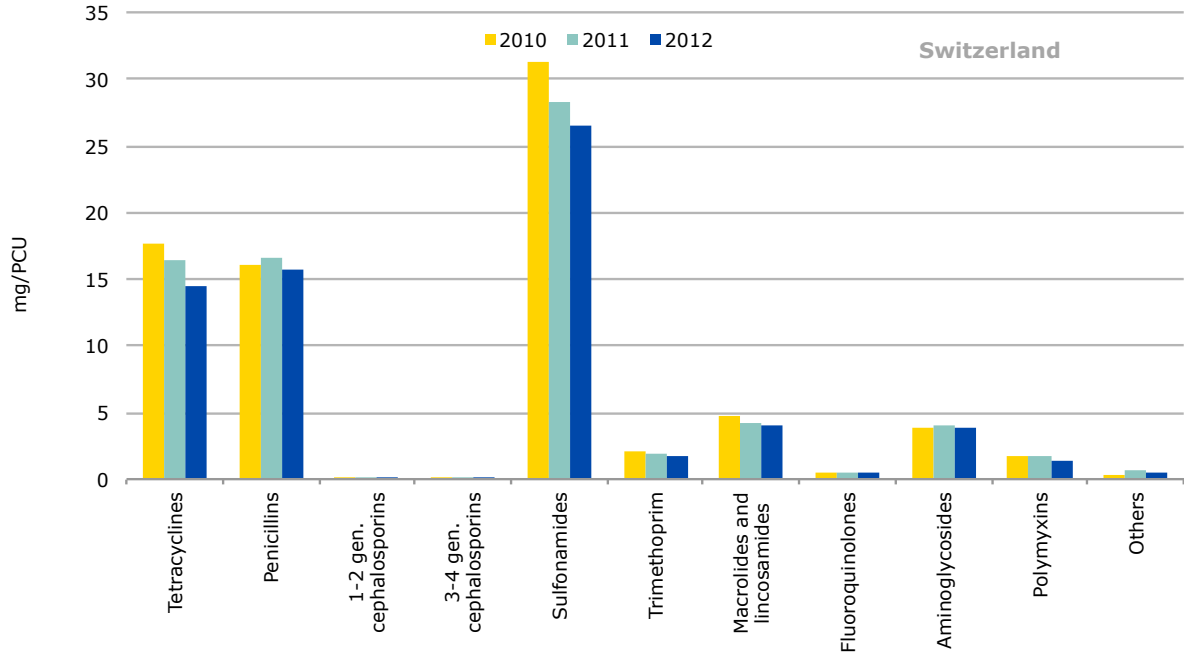
Data sources

Data are obtained at package level from the marketing-authorisation holders. Due to confidentiality reasons and Switzerland not being an EU Member State, data were analysed and processed at national level before transmission. Aggregation was done when necessary to keep sales figures confidential.

Data coverage

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

Figure 88. Sales (mg/PCU) by antimicrobial class for food-producing species, including horses, in Switzerland for the years 2010 to 2012



The general decrease of total sales of 12.8%, in mg/PCU, observed during the years 2010 to 2012 is mainly due to reduced sales of sulfonamides and tetracyclines. Sales (mg/PCU) of other classes remained either stable or decreased slightly (polymyxins) during this period.

Of the critically important antimicrobial classes with highest priority for human medicine, sales in mg/PCU of both macrolides and fluoroquinolones decreased, whereas they remained stable for 3rd- and 4th-generation cephalosporins.

In the time frame under investigation, the overall total PCU decrease was 0.4%, whereas total sales decreased by 13.1%. The small decrease in PCU might not be seen as a factor, but further investigations show a rather significant decrease in the pig population (-3% slaughtered pigs and -7.3% sows) and a small decrease in calf population (-0.3%). The total PCU is mainly compensated by increases in poultry (12.8%), rabbits (7.8%), goats (6.3%) and horses (5.1%), representing populations in which only moderate antimicrobial use takes place in Switzerland, and which might therefore partly explain the diverging trend between population biomass and sales.

Intensified continuing education on prudent use of antimicrobials for pig producers and their associated veterinarians, as well as the national program for eradication of bovine viral diarrhoea, which started in 2009 and was completed during 2012, may have contributed to the reduction.

Data provider

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