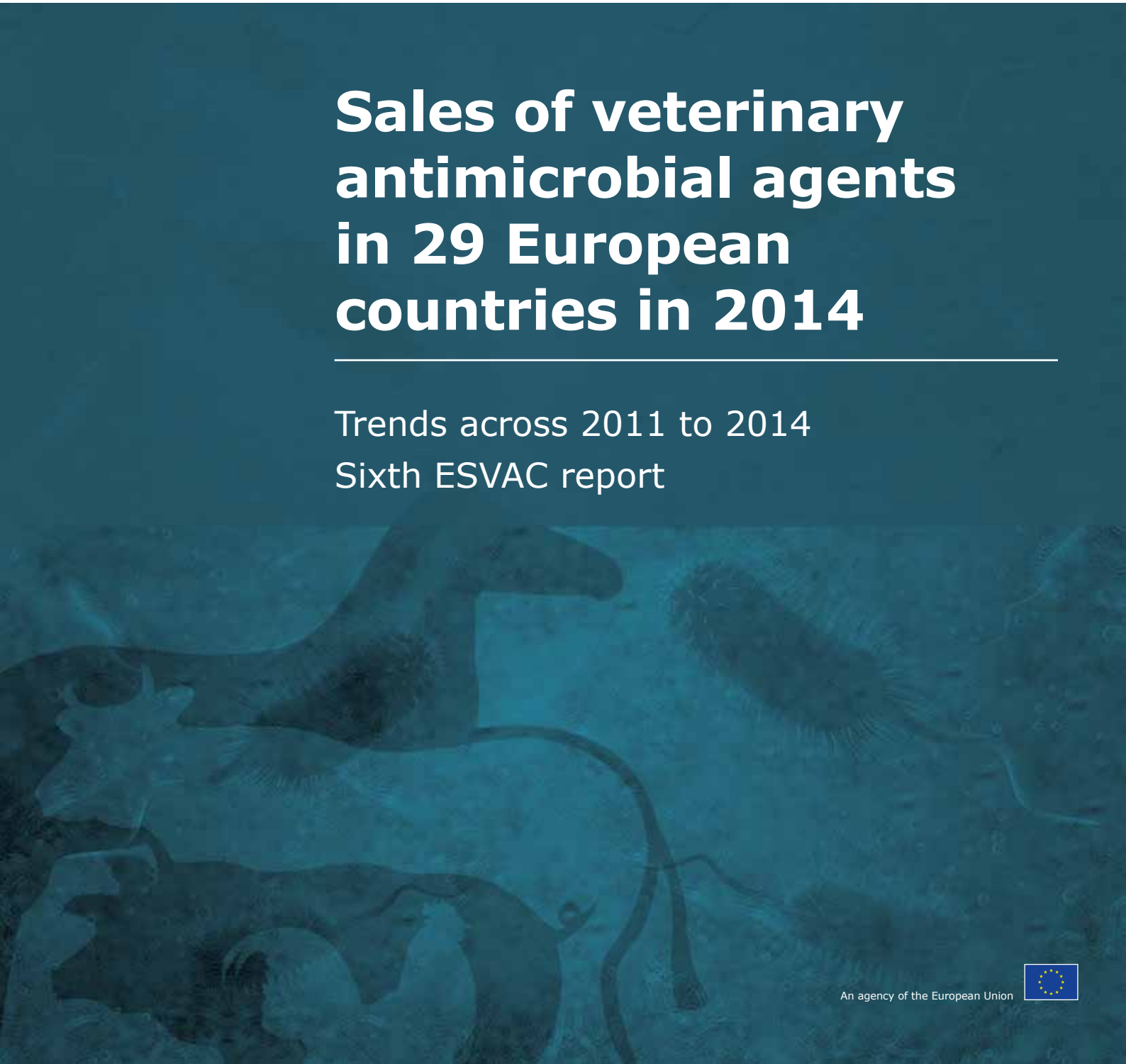
EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Sales of veterinary antimicrobial agents in 29 European countries in 2014

Trends across 2011 to 2014
Sixth 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 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 European Union (EU) and the European Economic Area (EEA) countries with the best-possible scientific advice on any questions relating to the evaluation of the quality, safety and efficacy of medicinal products for human or veterinary use referred to it in accordance with the provisions of EU legislation relating to medicinal products.

The founding legislation of the Agency is Regulation (EC) No 726/2004.

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.

Sales of veterinary antimicrobial agents in 29 European countries in 2014. Trends from 2011 to 2014

Sixth ESVAC report

14 October 2016
EMA/61769/2016
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[1] in relation to the use of antimicrobials and the risk of antimicrobial resistance, with the intention of promoting the continued availability of effective antimicrobials for use in animals, while at the same time acting to minimise risks to animals or humans arising from their use.

The European Surveillance of Veterinary Antimicrobial Consumption (ESVAC) project was launched by the Agency in September 2009, following a request from the 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 sixth ESVAC report presents data on the sales of veterinary antimicrobial agents from 29 European countries in 2014, provided at package level according to a standardised protocol and template[1]. In addition, it includes a chapter describing changes in consumption of veterinary antimicrobials for the years 2011–2014 (Chapter 2.8). Chapter 2.4.1. also includes supplementary information on polymyxins.

Chapter 2.8.2. focuses on the changes across time in each country. Explanations for the possible reasons for the changes across time in the various ESVAC participating countries have been provided by the ESVAC national contact points from each country. This chapter emphasises in particular on changes for certain classes of antimicrobials according to the categorisation recommended by the EMA Antimicrobial Advice ad hoc Expert Group (AMEG). The AMEG takes into account the WHO categorisation of antimicrobials, the hazard of zoonotic relevance in Europe, use of those antimicrobials in veterinary medicine and the risk of resistance transfer to humans. The classification can be found on the EMA webpage[2].

Category 2 of the AMEG categorisation includes those veterinary antimicrobials where the risk for public health is estimated to be higher than other classes of antimicrobials; fluoroquinolones and 3rd- and 4th-generation cephalosporins are included in this category. Macrolides are not included in category 2 of the AMEG categorisation[3]. Further considerations by AMEG on the categorisation of aminoglycosides and extended spectrum penicillins are ongoing. Aminoglycosides and certain penicillins have been included provisionally under category 2, but risk profiling has yet to be done by the EMA/CVMP. It is suggested that colistin should be added to the AMEG list in a higher-risk category (category 2) (link).

This report places special emphasis on food-producing animals.

It is generally agreed that it usually takes at least three to four years to establish a valid baseline for the data on sales of veterinary antimicrobial agents. Consequently, the data from countries that have collected such data for the first 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.

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

[2] Available from the European Medicines Agency website (www.ema.europa.eu): http://www.ema.europa.eu/docs/en_GB/document_library/Other/2014/07/WC500170253.pdf (page 29-31)

[3] Although macrolides are not included in category 2, the CVMP has made recommendations indicating that, amongst others, the responsible use of antimicrobials (*macrolides*) should be strongly promoted, and that although acknowledging that macrolides are first-line treatment against a number of animal diseases, there is a need to avoid unnecessary use.

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Summary

Key findings

A total of 29 European countries — 28 European Union (EU)/European Economic Area (EEA) countries and Switzerland — submitted data on sales or prescriptions (two countries) of antimicrobial veterinary medicinal products (VMPs) to the European Medicines Agency for 2014. In the ESVAC participating countries, use of antimicrobials as growth promoters is not allowed and ionophore coccidiostat feed additives are not included in the data.

A population correction unit (PCU) is applied as a proxy for the size of the food-producing animal population (including horses). The main indicator used in the current report to express the sales is milligrams active ingredient sold per population correction unit — mg/PCU.

A large difference in the sales, expressed as mg/PCU, was observed between the most- and least-selling countries (range 3.1–418.8 mg/PCU) for 2014.

Of the overall sales of antimicrobials in the 29 countries in 2014, the largest amounts, expressed as a proportion of mg/PCU, were accounted for by tetracyclines (33.4 %), penicillins (25.5 %) and sulfonamides (11.0 %). From the antimicrobial classes listed in the third World Health Organization (WHO) list of critically important antimicrobials (CIAs) with the highest priority in human medicine, the sales for food-producing animals of 3rd- and 4th-generation cephalosporins, fluoroquinolones[4] and macrolides accounted for 0.2 %, 1.9 % and 7.5 %, respectively, of the total sales in the 29 countries participating in ESVAC in 2014. Overall, the sales of polymyxins (mg/PCU) accounted for 6.6 % of the total sales, with colistin representing more than 99 % of the sales of polymyxins.

The prescribing patterns of the various antimicrobial classes, expressed as mg/PCU, varied substantially between the countries. In 2014, notable variations were observed between countries in the proportion of 3rd- and 4th-generation cephalosporins, fluoroquinolones and macrolides sold (mg/PCU), with sales ranging from 0.01 % to 1.5 %, 0.01 % to 11.9 % and 0 % to 16.9 %, respectively; the corresponding figures for polymyxins were 0 % to 8.7 % (Table 6).

Aggregated across the 29 countries, the sales (mg/PCU) of pharmaceutical forms for group treatment accounted for 91.6 % of the total sales; premixes accounted for 42.1 %, oral powders for 31.7 % and oral solutions for 17.8 %. The proportion accounted for by pharmaceutical forms for group treatment varied substantially between countries, ranging from 6 % to 96 %. Of sales of pharmaceutical forms for treatment of individual animals (12 %), 7.6 % were injectable preparations, 0.5 % were intramammary preparations and 0.3 % were oral pastes, boluses and intrauterine preparations.

For all 29 countries, the proportion of the sales in 2014 of veterinary antimicrobials applicable for group treatment (oral powder, oral solution and premix) containing two or more active ingredients was relatively low of the total sales. In addition, 80.8 %, 16.9 % and 2.2 % of these pharmaceutical forms contained one, two and three active ingredients, respectively.

In total, 25 countries have provided data for all the years between 2011 to 2014. A fall in sales (in mg/PCU) of more than 5 % was observed in 10 of these countries, whilst there was an increase of more than 5 % in five countries during the reference period (Table 8). The PCU was stable across the years, with only a 0.9 % reduction in the total PCU of the 25 countries, and there was also an overall reduction of 2.9 % in the volume of tonnes sold.

For 25 countries reporting sales data to ESVAC for the years 2011–2014, an overall fall in sales (mg/PCU) of 2.4 % was observed. The sales were 162 mg/PCU, 153 mg/PCU, 147 mg/PCU and 158 mg/PCU in 2011, 2012, 2013 and 2014, respectively (Figure 56).

Spain changed its system for collecting sales data in 2014, and there were indications that some of the highest selling VMPs for 2014 had not been reported by MAHs between 2011–2013, despite being marketed during this period. Therefore, the suggestion is that the sales data for Spain for 2011 to 2013 represent substantial underestimates. The consumption of antimicrobials in Spain is one of the highest among the European countries participating in ESVAC; sales aggregated by the 25 countries, e.g. 2011 and 2014, are thus not directly comparable.

[4] According to the WHO classification, fluoroquinolones are part of the highest priority CIA; however, it is stated on the WHO web page (http://www.who.int/foodsafety/cia/en/) that the wider group of quinolones are addressed.

By excluding Spain, an overall fall in sales (mg/PCU) of 12 % from 2011 to 2014 (from 138 mg/PCU in 2011 to 121 mg/PCU in 2014) was observed in the remaining 24 countries (Austria, Belgium, Bulgaria, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Hungary, Iceland, Italy, Ireland, Latvia, Lithuania, the Netherlands, Norway, Poland, Portugal, Slovakia, Slovenia, Sweden and the United Kingdom).

It should be noted that during these years other countries have also changed their national data collection systems, e.g. Slovenia in 2013, or have identified under-reporting for some of the years, e.g. Bulgaria 2014. This reiterates that changes observed over this period should be interpreted with caution.

Concluding remarks

Variations between the 29 countries on reported sales (mg/PCU) and on sales patterns for 2014 are likely to be due in part to differences in the composition of the animal population and in the production systems in various countries. There are considerable variations in terms of daily dose used for the various antimicrobial agents and pharmaceutical forms, period of treatment and prices. These factors may also partly explain some of the differences in sales (mg/PCU) and sales patterns between the countries. In addition, differences in the selection of data sources may have an impact, although this is considered to be low. However, these factors can only partly explain the differences in the sales observed between the 29 countries, so other factors must also be considered.

The sales data for antimicrobial agents (numerator) 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, interpretation of the data should take into account the distribution of the PCU value between the species in the various countries.

It should 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.

Tentative explanations provided by the countries (see Chapter 2.8.2) for the decline in sales across 2011 to 2014 include, among others, the implementation of responsible-use campaigns, changes in animal demographics, changes in systems for collecting data, restrictions of use, bench-marking, increased awareness of the threat of antimicrobial resistance, and/or the setting of targets.

Over the years, some countries have changed their national data collection systems (e.g. Slovenia in 2013 and Spain in 2014) and/or have identified under-reporting for some of the years (e.g. Bulgaria 2014, Spain 2014). This serves to emphasise that changes observed over years should be interpreted with caution.

The substantial decline in the sales of antimicrobials for food-producing species observed for some countries indicate that there is also a potential for a decrease in other countries. The European Commission has recently produced guidelines for the prudent use of antimicrobials in veterinary medicine[5]. The purpose of these guidelines is to provide practical guidance for Member States on the development and implementation of strategies to promote the prudent use of antimicrobials, especially antibiotics, in veterinary medicine.

[5] http://ec.europa.eu/health/antimicrobial_resistance/docs/2015_prudent_use_guidelines_en.pdf

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 the 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 EU 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 is collecting data on sales of antimicrobial veterinary medicinal products (VMP) at package level from the EU Member States (MSs), EEA countries and Switzerland. Furthermore, in 2016, ESVAC established defined daily doses animals (DDDvet) and defined course doses animals (DCDvet) (EMA/224954/2016[6]). Currently, ESVAC is preparing for the collection of data by animal species. The aim of this work stream is to further support countries in preparing for the requirements of the revised legislation on veterinary medicinal products (and the 'Animal Health Law') as it relates to the collection and supply of data on antimicrobial consumption. ESVAC is producing guidance/protocols for the collection of harmonised and standardised data from MSs on the use of antimicrobials. The ESVAC Vision and Strategy 2016-2020 has been published on the Agency's webpage[7].

Organisation of the ESVAC project is illustrated in Figure 1.

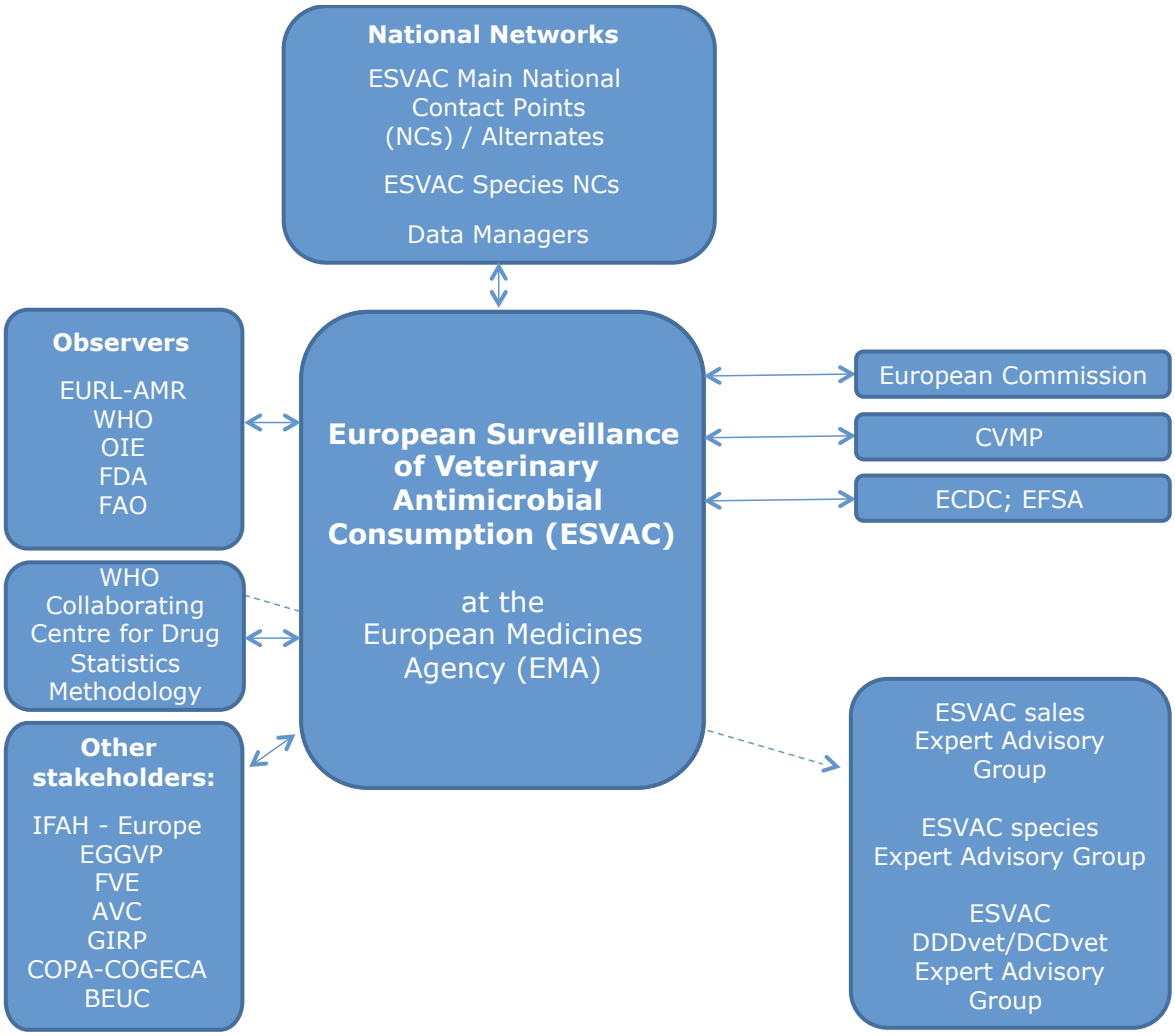
The core of the ESVAC sales project is the ESVAC network of main national contact points (NCs) and alternates, nominated by the national competent authorities in the participating EU and EEA countries. The country and affiliation of the ESVAC main NCs/alternates can be found in Annex 7 of this report.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

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

[7] Available on the EMA website (www.ema.europa.eu) via: Home > Veterinary regulatory > Antimicrobial resistance > European Surveillance of Veterinary Antimicrobial Consumption (http://www.ema.europa.eu/docs/en_GB/document_library/Regulatory_and_procedural_guideline/2016/04/WC500204522.pdf)

The ESVAC project is supported by an Expert Advisory Group which comprises representatives of the ESVAC main NCs or alternate network. There are also observers from the European Commission, European Centre for Disease Prevention and Control (ECDC) and the European Food Safety Authority (EFSA). The task of the ESVAC EG sales 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.

Figure 1. Organisation of the ESVAC project



New activities in the ESVAC project include the web-based delivery of sales data (starting with 2014 data), and publication by Business Intelligence of the core graphs and tables taken from the ESVAC reports available on the Agency's website.

1. Technical notes

1.1. Veterinary antimicrobial medicinal products included in the data sets

In order to harmonise which veterinary antimicrobial medicinal products should be included in the data sets, the Anatomical Therapeutic Chemical classification system for veterinary medicinal products (ATCvet[8]) was applied (Table 1). This includes all pharmaceutical forms[9] except dermatological preparations (ATCvet group QD) and preparations for sensory organs (ATCvet group QS). The contribution from these groups of antimicrobial agents, in tonnes of active ingredient, to the total amount is minimal and the effect of the deviation is negligible. It should be noted that antimicrobial growth promoters are not allowed in the ESVAC participating countries. Ionophore coccidiostat feed additives are not included in the data material.

To harmonise the data on sales of veterinary medicinal products with the data on sales of antimicrobial agents in human medicine, they are presented according to the classes/subclasses defined by the ATCvet hierarchical system, using WHO international non-proprietary names (INN), where available. If INNs have not been assigned, the ATCvet system applies either USAN (United States Adopted Names) or BAN (British Approved Names).

Table 1. Categories and ATCvet codes[8] 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 for antiparasitic use[1]	QP51AG

[1] Solely sulfonamides

1.2. Variables reported for each antimicrobial veterinary medicinal product

Detailed information on the variables to be reported for each antimicrobial veterinary medicinal product 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[10]. In order to standardise the information, the following categories of pharmaceutical forms have been applied for reporting the sales data to ESVAC: boluses, injections, intramammary preparations for lactating cows, intramammary preparations for dry cow treatment, intrauterine preparations, oral solutions (powders for use in drinking water), oral pastes, oral powders (powder to be administered with the feed), premixes (premix for medicated feeding stuff) and tablets (including capsules). It should be noted that when, for example, there are instructions such as "powder for solution" or "powder for administration in drinking water" in the name/label and/or SPC of the product, this should be reported as oral solution. Premixes are veterinary medicinal products, usually in form of powders or granules, which are intended to be mixed into animal feed by feed mills.

1.3. Sales

The ESVAC participating countries provided the number of packages sold for each product presentation – i.e. name, pharmaceutical form, strength and pack size. The sales (in weight of active substance) for each product presentation were calculated by multiplying the number of packages sold by the amount of the active ingredient (strength) in each package; in the case of combination preparations, the amount sold is calculated for all ingredients.

[8] www.whocc.no/atcvet/
[9] Includes premixes used to produce medicated feed.
[10] Available on the EMA website (www.ema.europa.eu) via: Home > Regulatory > Veterinary medicines > Antimicrobial resistance > European Surveillance of Veterinary Antimicrobial Consumption.

1.4. Population correction unit (PCU)

The amounts of veterinary antimicrobial agents sold in the different countries are linked, among others, 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 the term used for the estimated weight. The PCU is purely a surrogate for the animal population at risk, to normalise the sales by animal population in individual countries: 1 PCU equals 1 kg. The data sources used and the methodology for the calculation of PCU are described comprehensively 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)[11]. Animal categories included in the calculation of the PCU and the weights used to calculate the PCU are described in Annex 3.

1.4.1. Calculation of PCU

The PCU for each animal category is calculated by multiplying numbers of livestock animals (dairy cows, sheep, sows and horses) and slaughtered animals (cattle, goat, pigs, sheep, poultry, rabbits and turkeys) by the theoretical weight at the most likely time for treatment. Note that due to the limited availability of living goat data in Eurostat, this category was not included when the PCU methodology was established for the first ESVAC report[12]. For countries with a relatively high number of goats compared to other food-producing animals, this results in an underestimate of the PCU and an overestimate of the mg/PCU compared to countries with a low number of goats. For animals exported or imported for fattening or slaughter (cattle, goat, pigs, sheep and poultry), the PCU was calculated by multiplying the tnumber of animals by a standardised weight.

For farmed fish, Eurostat data are given only as live-weight slaughtered not numbers slaughtered, and 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) and to avoid double counting (counting by both the exporting and importing country).

The PCU is calculated for each species, weight class and/or production type, as follows:

PCU domestic

- Number of animals slaughtered × estimated weight at treatment.
- Number of livestock × estimated weight at treatment.

PCU export

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

PCU import

- Number of animals imported from another country for fattening or slaughter × estimated weight at treatment.

Total PCU is calculated as follows: PCU = total $PCU_{Domestic}$ + total PCU_{Export} – total PCU_{Import}

The total PCU by country is calculated according to the above data.

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

[12] Trends in the sale of veterinary antimicrobial agents in nine European countries (http://www.ema.europa.eu/docs/en_GB/document_library/Report/2011/09/WC500112309.pdf).

1.4.2. 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[13] for data on this animal category. Where data were not available in Eurostat (e.g. for rabbits and fish), national statistics were applied. In addition, national statistics on animal categories were applied for Iceland, Norway and Switzerland. For horses (food-producing species according to EU legislation), national statistics provided by the ESVAC NCs 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. Tablets are typically approved only for companion animals and therefore, 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 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 only reported 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 (TRAde Control and Expert System run by the European Commission's DG SANTE), as these are based on health certificates, which are obligatory for all animals crossing any border.

In cases where the deviation between the Eurostat data and/or TRACES data and national statistics was more than 5%, several countries provided national statistics for the calculation of PCU.

1.5. Corrections of historical data

1.5.1. Sales data

The testing of the web-based delivery of sales data through Business Intelligence served as a validation of the data delivered and analysed under the previous system (for 2011 to 2013) (see section 1.6 Quality check of the data), and minor errors in the calculations were identified for some countries. Furthermore, some countries revised the number of packages sold for some products. This resulted in corrections of the sales data for Estonia, Finland, Germany, Iceland and Lithuania for one or more of the years from 2011 to 2013. Therefore, the magnitude of mg/PCU shows minor deviations for these countries compared to previous ESVAC reports for one or more of the years from 2011 to 2013.

In addition, the prodrug conversion factor for benzathine benzylpenicillin has been revised and the historical data recalculated accordingly. Due to very low sales of products containing this ingredient, differences between data reported in previous ESVAC reports and the current edition are negligible.

1.5.2. PCU data

Minor changes have been introduced to the PCU figures compared to the ESVAC 2013 report. For Denmark, the turkey data were revised for 2013, and for Slovakia, living sow, rabbit and turkey data were revised for 2013.

1.6. Quality check and validation of the data

The ESVAC participating countries uploaded sales data directly using a web-based submission tool designed for this purpose. Automated warning and error messages are displayed instantaneously when any of the figures uploaded do not meet standardisation requirements. To support endorsement of the data validation, reports are created using the Business Intelligence application. Furthermore, data were also checked by the ESVAC team in order to identify outliers, mainly by checking against published data for previous years.

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

1.7. Analysis and reporting of the data

It is optional to report to ESVAC for which species the VMPs are being marketed although, based on the assumption that tablets are almost solely used for companion animals (boluses in food-producing animals) tablets are excluded from the dataset used to report sales for food-producing animals. In this report, sales data for tablets is reported as used for companion animals, and that all other pharmaceutical forms as sold for use in food-producing animals, including horses. In the current report, the term 'group treatment' is used for medication via feed or water; intramammary preparations for lactating cows and for dry cow treatment are reported aggregated.

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

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

In this report, the term food-producing species includes horses. The data are presented according to the ATCvet hierarchical system, and for combination preparations, each active ingredient is allocated a relevant ATCvet class/subclass for the single substances in question (e.g. spectinomycin is included in 'Other antibacterials'). Maps on the spatial consumption of the various veterinary antimicrobial agents were created using Adobe Illustrator CC 2015.

It should be noted that data presented in this report are calculated using the exact sales figures for each product (to five decimals), but in the tables and graphs the numbers are aggregated and rounded, therefore the totals in the tables, for example, may differ slightly from the data presented in the detailed figures.

All data presented in this report reflect the datasets available at 15 June 2016; any updates made to the data at a later stage are not included in the data analyses.

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

Information on years of collecting data, the legal basis for the data collection at national level, national data sources, systems for the 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.

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 2014

Country	Years collecting data	Legal basis	National data provider to ESVAC	Sources for ESVAC data (approx. no)	Sales data, prescription data or purchase data[1]	Sales between wholesalers and/or MAHs[2] excluded (Yes/No)	Products sold on special licence included (Yes/No)
Austria	5 years	Mandatory to report	Austrian Agency for Health and Food Safety	MAHs (n=9); Wholesalers (n=8)	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	Yes
Bulgaria	4 years	Mandatory to report	Bulgarian Food Safety Agency	Wholesalers (n=31)	Sales to veterinarians, farmers and pharmacies	Yes	No
Croatia	1 year	Mandatory to report	Ministry of Agriculture, Veterinary Directorate	Wholesalers (n=22)	Sales to pharmacies and veterinarians	Yes	No
Cyprus	4 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=98); Feed mills (n=52)	Sales to veterinarians, pharmacies and farmers. Sales by feed mills to farmers	Yes	Yes
Denmark	>5 years	Mandatory to report	Danish Veterinary and Food Administration	VetStat (n=1) obtaining data from Pharmacies (n=350); Veterinarians (n=150); Feed mills (n=3)	Prescription data from pharmacies, veterinarians distributors and feed mills	Yes	Yes (0.1%)
Estonia	>5 years	Mandatory to report	State Agency of Medicines	Wholesalers (n=10)	Sales to veterinarians and pharmacies	Yes	Yes (1.3% of tonnes sold)
Finland	>5 years	Mandatory to report	Finnish Medicines Agency	Wholesalers (n=4); Feed mills (n=1); Importers of medicated feed (n=1)	Sales to pharmacies and veterinarians	Yes	Yes

Country	Years collecting data	Legal basis	National data provider to ESVAC	Sources for ESVAC data (approx. no)	Sales data, prescription data or purchase data[1]	Sales between wholesalers and/or MAHs[2] excluded (Yes/No)	Products sold on special licence included (Yes/No)
France	>5 years	Not mandatory[3]	National Agency for Veterinary Medicinal Products (Anses-ANMV)	MAHs (n=42)	Sales to veterinarians, pharmacies, whole–salers and feed mills	Not applicable	Yes
Germany	4 years	Mandatory to report	Federal Office of Consumer Protection and Food Safety	MAHs (n=36); Wholesalers (n=20); PSURs[4] data for premix	Sales to veterinarians	Yes	No
Hungary	>5 years	Not mandatory	National Food Chain Safety Office Directorate of Veterinary Medicinal Products	Wholesalers (n=70)	Sales to veterinarians, feed mills, farmers and retailers	Yes	No
Iceland	5 years	Mandatory to report	Icelandic Medicines Agency	Wholesalers (n=2)	Sales by wholesalers to veterinarians and pharmacies	Yes	Yes
Ireland	5 years	Mandatory to report	Health Products Regulatory Authority	MAHs (n=68)	Sales to pharmacies or veterinarians, far-mers and wholesalers within the country	Yes	No
Italy	5 years	Mandatory to report	Italian Ministry of Health	MAHs (n=49)	Sales to wholesa-lers, pharmacies, feed mills, and farms authorised to produce medicated feed for self-consumption	No	No
Latvia	5 years	Mandatory to report	Food and Veterinary Service	Wholesalers (n=24)	Sales to pharmacies, veterinarians, ve-terinary clinics and farmers	Yes	No
Lithuania	5 years	Mandatory to report	State Food and Veterinary Service	Wholesalers (n=38)	Sales to pharmacies, veterinarians and farmers	No	No

Country	Years collecting data	Legal basis	National data provider to ESVAC	Sources for ESVAC data (approx. no)	Sales data, prescription data or purchase data[1]	Sales between wholesalers and/or MAHs[2] excluded (Yes/No)	Products sold on special licence included (Yes/No)
Luxembourg	3 years	Mandatory to report	Ministry of Health	Wholesalers (n=4)	Sales to pharmacies, veterinarians	Yes	Yes (60 %)
Netherlands	>5 years	Not mandatory	Federation of the Dutch Veterinary Pharma–ceutical Industry (FIDIN)	MAHs (n=22)	Sales to veterinarians, pharmacies and feed mills	Yes	No
Norway	>5 years	Mandatory to report	Norwegian Veterinary Institute	Wholesalers (n=5) Feed mills (n=1)	Sales to pharmacies, veterinarians (and feed mills deliver VMPs only to fish farmers)	Yes	Yes
Poland	4 years	Mandatory to report	Ministry of Agriculture and Rural Development	Wholesalers (n=128)	Sales to veterinarians	No	No
Portugal	5 years	Mandatory to report	General Directorate for Food and Veterinary Affairs	Wholesalers (n=72)	Sales to retailers, ve-terinarians, farmers, producer organi-sations, veterinary clinics and feed mills	Yes	No
Romania	1 year	Mandatory to report	Institute for Control of Biological Products and Veterinary Medicines	Wholesalers (n=37), MAHs (n=11)[5]	Sales to pharmacies, veterinarians and farmers	Yes	No
Slovakia	4 years	Mandatory to report	Institute for State Control of Veterinary Biologicals and Medicaments	Wholesalers (n=46)	Sales to veterinarians, pharmacies, medi-cated feed mills and farmers	Yes	No
Slovenia	5 years	Mandatory to report	Administration of the Republic of Slovenia for Food Safety, Veterinary Sector and Plant Pro-tection (AFSVSPP)	Wholesalers (n=11)	Sales to pharmacies, feed mills and veteri-narians	Yes	Yes (9 %)
Spain	5 years	Not mandatory	Spanish Agency for Medicines and Health Products	MAHs (n=57)	Sales to wholesalers and retailers, i.e. ve-terinary organisations and pharmacies	No	No

Country	Years collecting data	Legal basis	National data provider to ESVAC	Sources for ESVAC data (approx. no)	Sales data, prescription data or purchase data[1]	Sales between wholesalers and/or MAHs[2] excluded (Yes/No)	Products sold on special licence included (Yes/No)
Sweden	>5 years	Mandatory to report	National Veterinary Institute and Swedish Board of Agriculture	The Swedish eHealth Agency[6] (n=1) obtaining data from pharmacies	Dispensed prescriptions	Yes	Yes (around 5% of total of tonnes of active substance)
Switzerland	>5 years	Mandatory to report	Federal Office of Food Safety and Veterinary Affairs	MAHs (n=20)	Sales to veterinarians, pharmacies, medi-cated feed mills	No	No
United Kingdom	>5 years	Mandatory to report	Veterinary Medicines Directorate	MAHs (n=70)	Sales to wholesalers, veterinarians, farmers and veterinary pharmacies	Yes	No

[1] Purchase/import data from e.g. pharmaceutical industry and/or from wholesalers in other countries. [2] MAHs = marketing authorisation holders. [3] Since 2015, it has been mandatory for MAHs to report sales in France. [4] PSURs = periodic safety update reports. [5] Since 2015, it has been mandatory only for MAHs to report sales in Romania. [6] The activities of the Apotekens Service were transferred to the Swedish eHealth Agency on 1 January 2014.

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 EU countries included in the ESVAC 2014 data cover > 95% of the food-producing animal population measured as PCU in the EU.

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

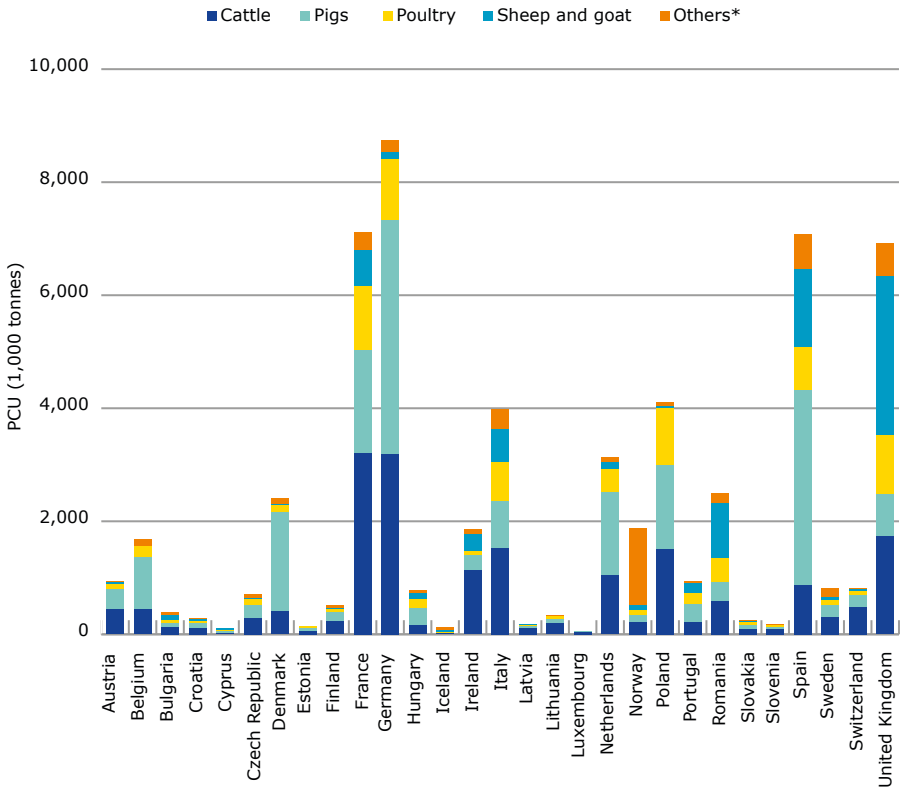
Overall, pigs, cattle, poultry and sheep/goats accounted for 33%, 32%, 14% and 13%, respectively, of the PCU in the 29 countries.

Table 3. Estimated PCU (in 1,000 tonnes) of the population of food-producing species[1,2], including horses, by country, for 2014

Country	Cattle	Pigs	Poultry	Sheep/ goats	Fish	Rabbits	Horses	Total
Austria	438	370	77	33	0	0	29	948
Belgium	441	931	183	11	0	4	108	1,678
Bulgaria	134	66	43	101	0	0	49	393
Croatia	115	79	35	45	0	0	0	273
Cyprus	16	45	15	29	0	0	2	107
Czech Republic	290	215	118	18	21	8	33	703
Denmark	405	1,766	118	13	43	0	70	2,415
Estonia	65	49	20	7	1	0	4	144
Finland	225	162	68	11	13	0	30	509
France	3,209	1,817	1,134	641	42	52	224	7,120
Germany	3,192	4,135	1,071	139	26	0	185	8,749
Hungary	155	303	171	100	19	7	24	779
Iceland	18	6	5	48	8	0	31	116
Ireland	1,131	266	76	300	34	0	60	1,866
Italy	1,524	828	702	569	175	32	148	3,977
Latvia	109	35	19	7	0	0	4	173
Lithuania	194	74	50	9	0	0	7	335
Luxembourg	39	11	0	0	0	0	2	52
Netherlands	1,043	1,469	415	111	47	0	51	3,135
Norway	216	126	76	101	1,332	0	14	1,866
Poland	1,515	1,485	1,007	20	0	0	83	4,109
Portugal	215	318	199	173	10	8	18	942
Romania	584	344	408	975	5	0	185	2,502
Slovakia	99	60	52	32	3	0	3	248
Slovenia	94	20	37	8	2	0	10	171
Spain	868	3,456	752	1,387	306	73	235	7,077
Sweden	308	203	93	49	11	0	145	811
Switzerland	484	209	64	36	0	1	23	816
United Kingdom	1,731	745	1,042	2,825	177	0	395	6,915
Total 29 countries	**18,855**	**19,593**	**8,050**	**7,801**	**2,274**	**186**	**2,173**	**58,931**

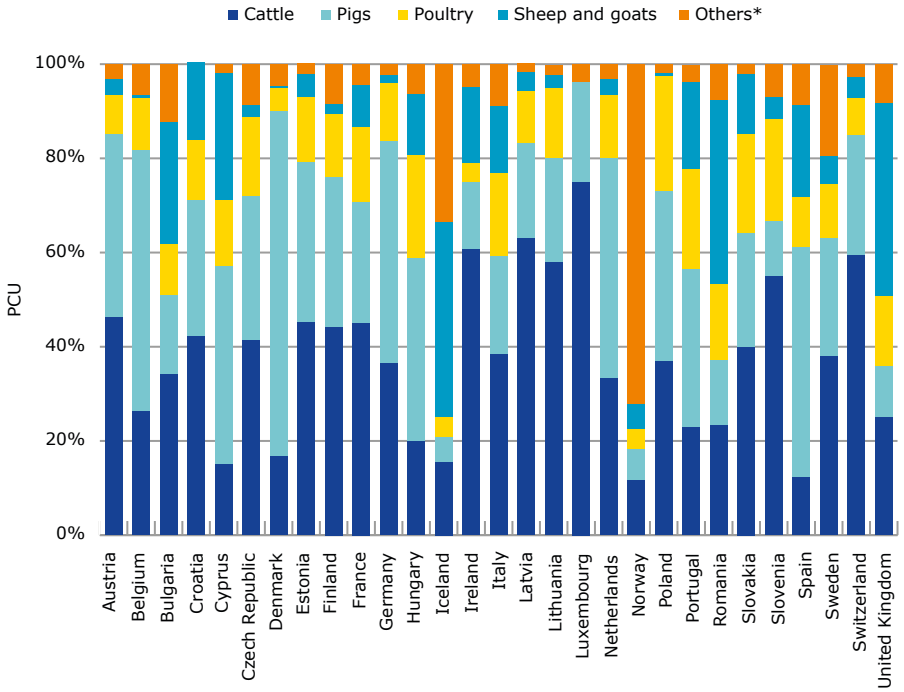
[1] See Annex 3 for animal categories included; [2] When PCU is given as zero it indicates zero or insignificant production.

Figure 2. The denominator (PCU) and its distribution by the food-producing animal species, including horses, (PCU = 1 kg), by country, in 2014



* Includes horses and, for some countries, fish and/or rabbits.

Figure 3. Distribution of PCU in weight by food-producing animal species, including horses, by country, in 2014



* Includes horses and, for some countries, fish and/or rabbits.

Of the 29 countries, in 2014, 12 had a net export of animals for slaughter and/or fattening to other Member States that accounted for ≥ 5% of the total PCU, whilst 9 countries had a net import accounting for ≥ 5% of the total PCU.

Table 4. PCU domestic, net export and net import (1,000 tonnes) of animals for fattening or slaughter, respectively, in another MS and PCU (net balance) in 2014 used to analyse and report data

Country	PCU - domestic	PCU - export	Proportion, export	PCU - import	Proportion, import	PCU
Austria	1,033	15	2%	-99	-10%	948
Belgium	1,779	118	7%	-219	-13%	1,678
Bulgaria	397	0.1	0.03%	-4	-1%	393
Croatia	298	3	1%	-28	-10%	273
Cyprus	106	0	0.4%	0	0%	107
Czech Republic	634	80	11%	-11	-2%	703
Denmark	2,088	327	14%	-0.03	-0.001%	2,415
Estonia	126	18	13%	-0.01	-0.01%	144
Finland	509	0	0%	0	0%	509
France	6,879	283	4%	-42	-1%	7,120
Germany	8,666	455	5%	-372	-4%	8,749
Hungary	776	50	6%	-47	-6%	779
Iceland	116	0	0%	0	0%	116
Ireland	1,812	68	4%	-13	-1%	1,866
Italy	4,176	7	0%	-206	-5%	3,977
Latvia	164	16	10%	-8	-4%	173
Lithuania	329	19	6%	-13	-4%	335
Luxembourg	42	15	29%	-5	-9%	52
Netherlands	3,099	409	13%	-373	-12%	3,135
Norway	1,866	0	0%	0	0%	1,866
Poland	4,231	14	0.3%	-136	-3%	4,109
Portugal	1,008	31	3%	-97	-10%	942
Romania	2,470	50	2%	-19	-1%	2,502
Slovakia	201	63	25%	-15	-6%	248
Slovenia	161	17	10%	-7	-4%	171
Spain	7,069	135	2%	-127	-2%	7,077
Sweden	807	3	0.4%	0	0%	811
Switzerland	818	0.01	0.001%	-1	-0.2%	816
United Kingdom	6,955	10	0.1%	-50	-1%	6,915

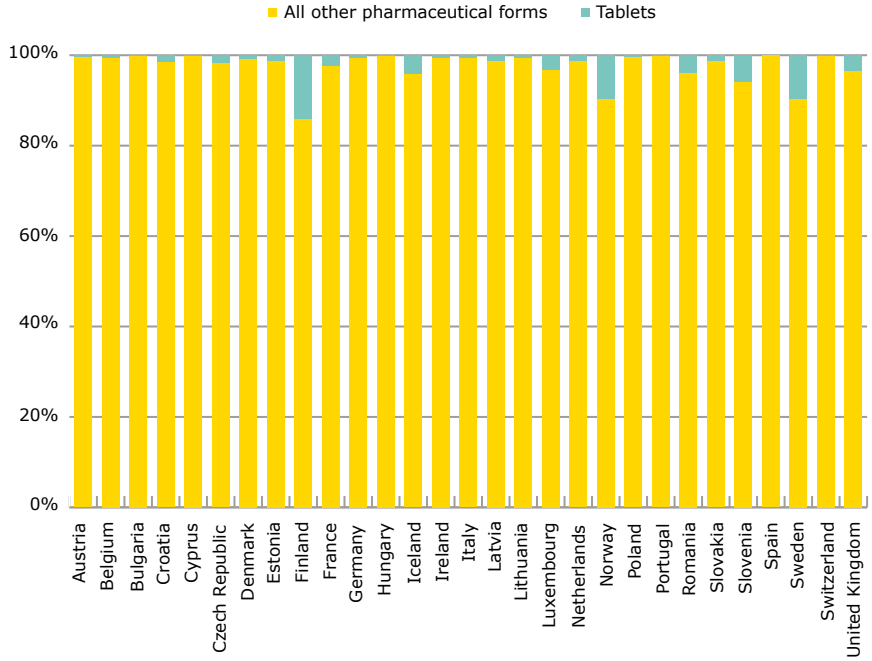
2.2. Overall sales of veterinary antimicrobial agents

The overall national sales data cover sales of antimicrobial VMPs for use in food-producing animals, including horses (all pharmaceutical forms except tablets) and sales of tablets that are used almost solely in companion animals. 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. Sales of tablets, and therefore use in companion animals, accounted for a minor proportion of the total sales of veterinary antimicrobial agents in 2014, except in Finland, Norway, Slovenia and Sweden, where they represented 14.1%, 9.7%, 5.9% and 9.7% of the total sales, respectively (Table 5, Figure 4). Overall, the sales of tablets in the 29 countries represented 0.8% of the total sales in tonnes.

Table 5. 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), by country, in 2014

Country	Tablets		All other pharmaceutical forms		Total tonnes
	Tonnes	% of overall sales	Tonnes	% of overall sales	
Austria	0.3	0.5%	53.4	99.5%	53.7
Belgium	1.8	0.7%	265.7	99.3%	267.5
Bulgaria	0.1	0.2%	32.6	99.8%	32.7
Croatia	0.7	1.6%	40.2	98.4%	40.9
Cyprus	0.1	0.1%	41.7	99.9%	41.8
Czech Republic	1.0	1.8%	55.9	98.2%	56.9
Denmark	0.9	0.9%	106.8	99.1%	107.7
Estonia	0.1	1.3%	9.8	98.7%	9.9
Finland	1.9	14.1%	11.4	85.9%	13.2
France	18.1	2.3%	761.5	97.7%	779.6
Germany	7.9	0.6%	1,305.8	99.4%	1,313.7
Hungary	0.2	0.1%	150.4	99.9%	150.6
Iceland	0.03	4.3%	0.6	95.7%	0.6
Ireland	0.6	0.6%	89.6	99.4%	90.2
Italy	10.0	0.7%	1,431.6	99.3%	1,441.6
Latvia	0.1	1.3%	6.3	98.7%	6.4
Lithuania	0.1	0.6%	11.9	99.4%	12.0
Luxembourg	0.1	3.3%	2.1	96.7%	2.2
Netherlands	3.1	1.4%	214.5	98.6%	217.5
Norway	0.6	9.7%	5.8	90.3%	6.4
Poland	2.8	0.5%	578.5	99.5%	581.3
Portugal	0.5	0.3%	190.0	99.7%	190.5
Romania	4.1	4.0%	98.1	96.0%	102.2
Slovakia	0.2	1.4%	16.3	98.6%	16.6
Slovenia	0.4	5.9%	5.7	94.1%	6.1
Spain	1.6	0.1%	2,963.9	99.9%	2,965.5
Sweden	1.0	9.7%	9.3	90.3%	10.3
Switzerland	0.1	0.2%	46.4	99.8%	46.5
United Kingdom	15.6	3.5%	429.6	96.5%	445.3
Total 29 countries	**73.8**	**0.8%**	**8,935.7**	**99.2%**	**9,009.5**

Figure 4. 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), by country, for 2014



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

The sales of veterinary antimicrobial agents for food-producing animals, including horses (hereafter designated as food-producing animals), stratified into pharmaceutical forms, by country, are shown in Figure 5. Tablets are not included in the data as these are used almost solely in companion animals.

Figure 5. Distribution of sales of veterinary antimicrobial agents for food-producing animals, in mg per population correction unit (mg/PCU), by pharmaceutical form in 29 European countries for 2014

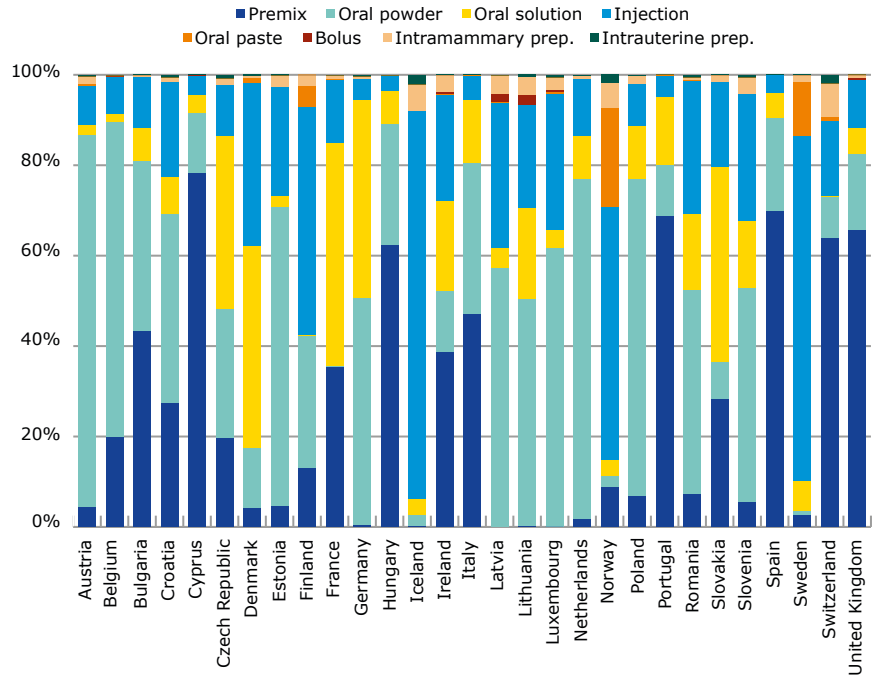


Figure 6. Oral solutions, oral powders and premixes as percentages of total sales, in mg per population correction unit (mg/PCU), of veterinary antimicrobial agents for food-producing animals, in 29 European countries for 2014

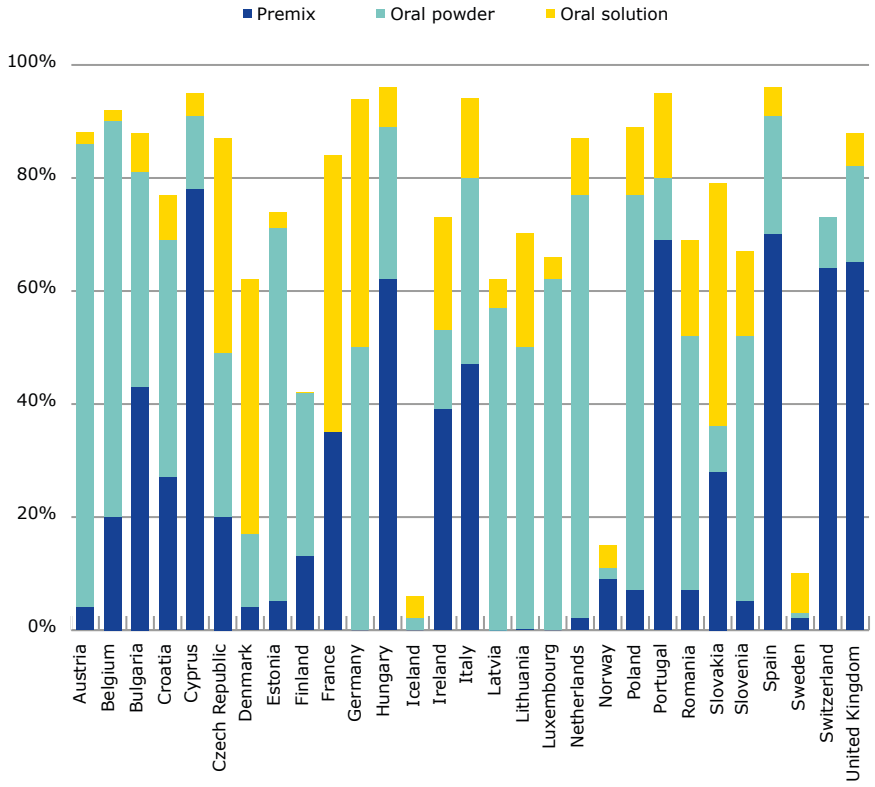
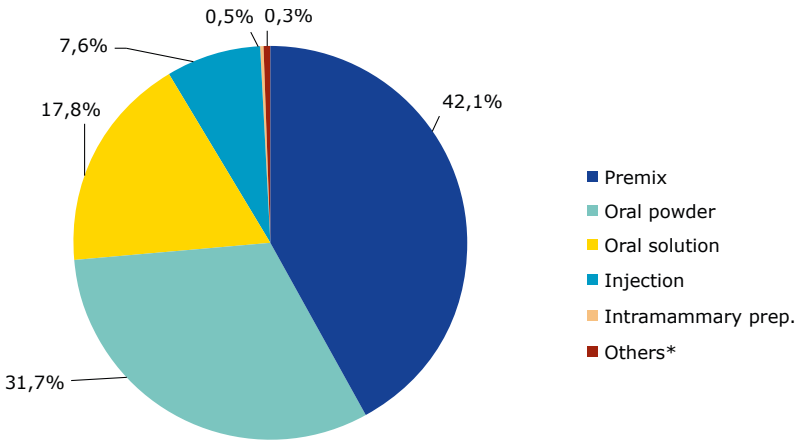


Figure 7. Distribution of sales, in mg/PCU, of the various pharmaceutical forms of veterinary antimicrobial agents for food-producing animals, aggregated by the 29 European countries for 2014



* Oral pastes, boluses and intrauterine preparations.

The proportions accounted for by premixes and oral powders vary considerably between the countries, which could be attributed to whether or not the farmers in the country administer medicated feed stuff prepared by a feed mill by using premixes or whether group treatment is performed by the application of oral powder as a top dressing on the feed at the farm. It could also be influenced by the distribution of the animal species, as group medication is used mainly in poultry and pigs, and less, for example, in sheep or goats. Also, the products available and national policies for feed medication can have an influence on the patterns of forms sold.

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 29 countries, the sales (mg/PCU) of premixes accounted for 42.1 % of the overall sales, while 31.7 % were oral powders, 17.8 % were oral solutions, 7.6 % were injectable preparations, 0.5 % were intramammary preparations, and 0.3% were oral pastes, boluses and intrauterine preparations (others).

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), ranged from 3.1 mg/PCU to 418.8 mg/PCU across the 29 countries. The sales patterns of the antimicrobial classes also varied substantially between the countries (Table 7, Figure 8).

Table 6. Sales, in tonnes of active ingredient, of veterinary antimicrobial agents marketed mainly for food-producing animals[1], population correction unit (PCU) and sales in mg/PCU, by country, for 2014

Country	Sales (tonnes) for food-producing animals	PCU (1,000 tonnes)	mg/PCU
Austria	53.4	948.3	56.3
Belgium	265.7	1,678.0	158.3
Bulgaria	32.6	393.5	82.9
Croatia	40.2	273.4	147.2
Cyprus	41.7	106.6	391.5
Czech Republic	55.9	702.6	79.5
Denmark	106.8	2,415.3	44.2
Estonia	9.8	144.4	68.0
Finland	11.4	509.4	22.3
France	761.5	7,119.8	107.0
Germany	1,305.8	8,748.6	149.3
Hungary	150.4	779.1	193.1
Iceland	0.6	115.8	5.2
Ireland	89.6	1,866.4	48.0
Italy	1,431.6	3,977.4	359.9
Latvia	6.3	173.0	36.7
Lithuania	11.9	335.0	35.5
Luxembourg	2.1	52.0	40.9
Netherlands	214.5	3,135.2	68.4
Norway	5.8	1,866.1	3.1
Poland	578.5	4,108.8	140.8
Portugal	190.0	942.2	201.6
Romania	98.1	2,501.8	39.2
Slovakia	16.3	248.1	65.9
Slovenia	5.7	171.2	33.4
Spain	2,963.9	7,077.1	418.8
Sweden	9.3	810.8	11.5
Switzerland	46.4	816.3	56.9
United Kingdom	429.6	6,914.7	62.1

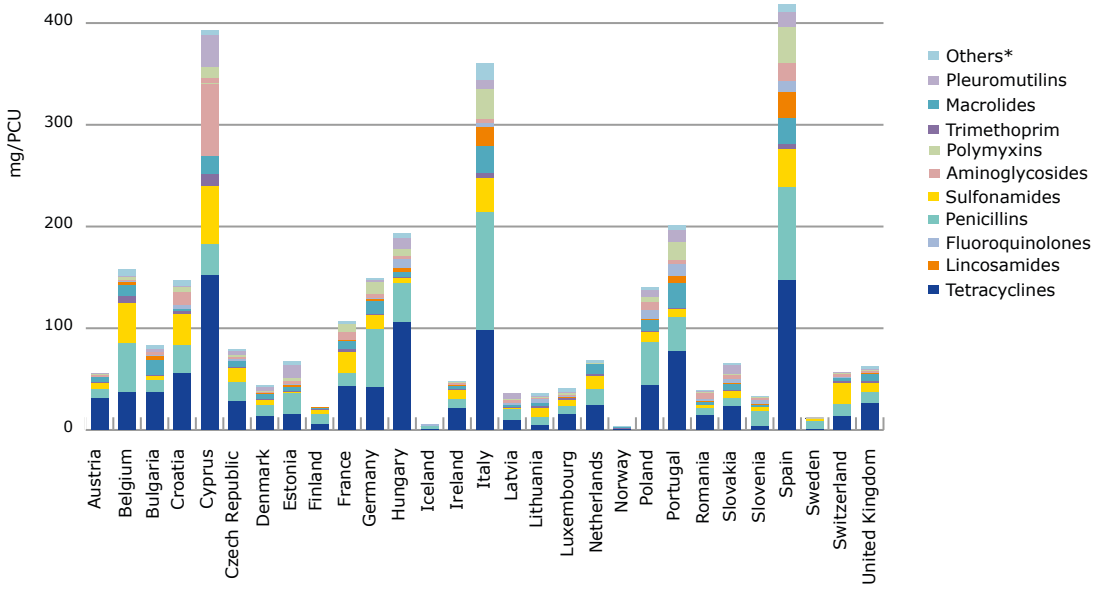
[1] Tablets excluded as used almost solely in companion animals; injectable antimicrobial VMPs can also be used in companion animals; a few other products may solely be used in companion animals, but as their proportional use is minor, these are included in the sales for food-producing animals.

Table 7. Percentages of sales for food-producing animals, in mg per population correction unit (mg/PCU), of the various veterinary antimicrobial classes in the 29 European countries in 2014[1]

Country	Tetracyclines	Amphenicols	Penicillins	1st- and 2nd-gen. cephalosporins	3rd- and 4th-gen. cephalosporins	Sulfonamides	Trimethoprim	Macrolides	Lincosamides	Fluoroquinolones	Other quinolones	Aminoglycosides	Polymyxins	Pleuromutilins	Others*	Total mg/PCU
Austria	55.6%	0.6%	15.0%	0.1%	0.3%	11.0%	1.5%	8.6%	0.2%	0.9%	0%	2.2%	2.9%	0.8%	0.3%	56.3
Belgium	23.2%	0.6%	30.8%	0.1%	0.3%	24.2%	4.9%	6.9%	1.8%	0.7%	0.6%	0.4%	2.1%	0.4%	3.0%	158.3
Bulgaria	44.9%	3.5%	13.6%	0.03%	0.1%	5.9%	0.8%	16.9%	4.9%	2.2%	0%	3.0%	0.6%	3.2%	0.6%	82.9
Croatia	38.1%	2.7%	18.1%	0.3%	0.1%	20.7%	2.4%	1.3%	0.2%	2.5%	0.5%	9.3%	2.7%	1.0%	0.3%	147.2
Cyprus	38.6%	0.3%	8.0%	0.002%	0.2%	14.6%	2.8%	4.5%	17.9%	0.2%	0.15%	1.2%	2.9%	7.9%	0.6%	391.5
Czech Republic	35.7%	0.6%	23.5%	0.4%	0.5%	16.3%	2.4%	6.9%	0.4%	2.2%	0.03%	2.9%	1.3%	6.0%	0.8%	79.5
Denmark	29.2%	1.0%	26.0%	0.1%	0.04%	11.2%	2.0%	11.1%	2.1%	0.01%	1.6%	3.2%	0.9%	9.5%	2.0%	44.2
Estonia	22.0%	0.5%	31.3%	0.3%	0.8%	1.7%	0.3%	5.9%	3.1%	2.0%	0%	4.4%	4.1%	18.6%	4.9%	68.0
Finland	22.7%	0.7%	44.7%	0.2%	0.1%	20.3%	4.1%	4.6%	1.2%	0.8%	0%	0.3%	0%	0.4%	0%	22.3
France	40.3%	0.8%	12.1%	0.2%	0.3%	18.8%	3.0%	7.5%	0.6%	0.6%	0.7%	7.1%	6.6%	0.8%	0.5%	107.0
Germany	27.8%	0.4%	38.4%	0.04%	0.3%	9.3%	1.2%	8.3%	1.1%	0.9%	0%	2.0%	8.2%	1.2%	0.8%	149.3
Hungary	54.8%	0.8%	19.8%	0.1%	0.1%	2.6%	0.6%	2.2%	2.2%	4.7%	0.1%	1.4%	3.7%	5.5%	1.3%	193.1
Iceland	6.3%	0%	59.5%	0%	0.1%	5.9%	0.8%	0%	0%	0.1%	0%	27.3%	0%	0%	0%	5.2
Ireland	43.4%	1.7%	18.7%	0.4%	0.3%	19.4%	1.6%	7.0%	0.4%	0.8%	0%	5.7%	0.1%	0.03%	0.6%	48.0
Italy	27.1%	1.3%	32.3%	0.1%	0.1%	9.5%	1.2%	7.6%	5.1%	0.9%	1.1%	1.2%	8.2%	2.5%	1.9%	359.9
Latvia	26.7%	0.1%	27.3%	0.5%	1.0%	5.1%	0.7%	6.3%	0.4%	4.3%	0.02%	10.7%	2.1%	14.1%	0.7%	36.7
Lithuania	12.0%	1.1%	23.8%	0.3%	0.5%	24.4%	5.5%	7.4%	1.5%	8.9%	2.4%	5.5%	0.3%	5.0%	1.5%	35.5
Luxembourg	38.4%	3.6%	17.7%	0.4%	1.5%	15.8%	3.0%	2.4%	1.7%	1.7%	0.1%	2.4%	6.0%	0.4%	5.0%	40.9
Netherlands	35.2%	2.0%	23.0%	0.1%	0.01%	18.9%	3.5%	13.1%	0.2%	0.2%	1.6%	0.9%	0.7%	0.5%	0.3%	68.4
Norway	2.2%	7.2%	49.5%	0%	0.01%	25.0%	4.7%	0.1%	0%	0.2%	1.9%	8.1%	0%	1.1%	0%	3.1
Poland	31.4%	1.6%	29.4%	0.2%	0.1%	7.3%	0.7%	7.9%	0.5%	6.4%	0.05%	5.6%	3.6%	4.6%	0.7%	140.8
Portugal	38.2%	0.9%	17.0%	0.2%	0.2%	3.4%	0.7%	12.2%	3.4%	5.6%	0.1%	2.1%	8.7%	6.0%	1.3%	201.6
Romania	36.3%	1.0%	18.2%	0.1%	0.1%	7.4%	1.3%	6.6%	2.6%	5.2%	0.6%	12.8%	2.9%	3.7%	1.0%	39.2
Slovakia	34.4%	0.5%	13.2%	0.9%	0.7%	10.0%	1.4%	9.8%	1.0%	6.4%	0.04%	5.0%	2.3%	12.7%	1.8%	65.9
Slovenia	9.9%	2.2%	46.0%	0.3%	0.4%	10.2%	1.8%	5.6%	1.9%	11.9%	0.01%	7.3%	0.2%	0.4%	1.8%	33.4
Spain	35.2%	0.9%	21.7%	0.01%	0.1%	9.0%	1.3%	6.1%	6.1%	2.4%	0.2%	4.3%	8.6%	3.3%	0.9%	418.8
Sweden	8.3%	0.5%	61.2%	0.001%	0.02%	18.2%	3.4%	3.5%	0.005%	0.3%	0.002%	2.6%	0.9%	1.2%	0%	11.5
Switzerland	23.0%	0.4%	21.4%	0.1%	0.4%	36.6%	2.4%	6.0%	0.1%	0.8%	0.003%	6.6%	1.7%	0.4%	0.1%	56.9
United Kingdom	42.0%	0.7%	18.7%	0.2%	0.3%	13.5%	2.7%	11.2%	1.6%	0.6%	0%	3.1%	0.2%	2.9%	2.6%	62.1

* Bacitracin, paromomycin and spectinomycin (classified as 'Other antibacterials' in the ATCvet system). [1] 0% refers to no sales

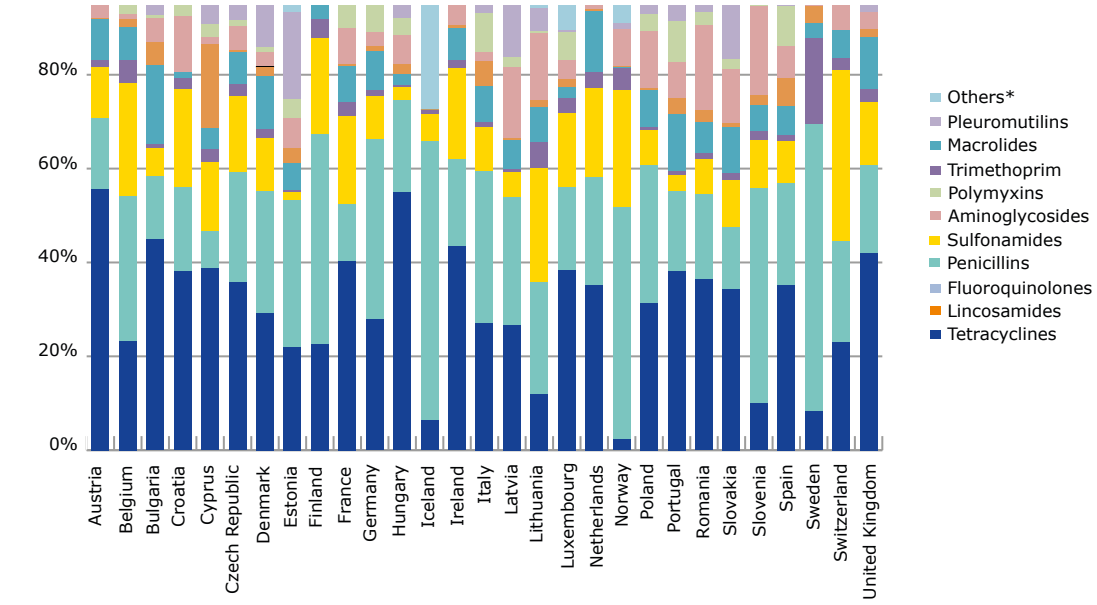
Figure 8. Sales for food-producing species, in mg/PCU, of the various veterinary antimicrobial classes, for 29 European countries, in 2014[1]



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

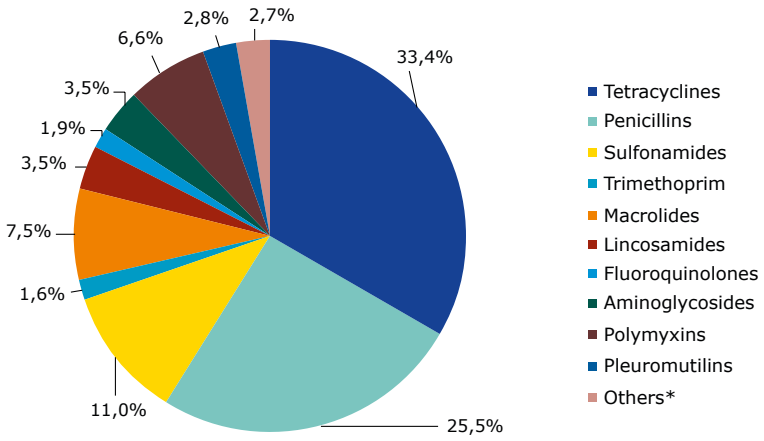
[1] Differences between countries can be partly explained by differences in animal demographics, in the selection of antimicrobial agents, in dosage regimes, in type of data sources, and veterinarians prescribing habits and prices.

Figure 9. Proportion of the total sales of the different veterinary antimicrobial classes, in mg/PCU, in the 29 European countries, for 2014



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

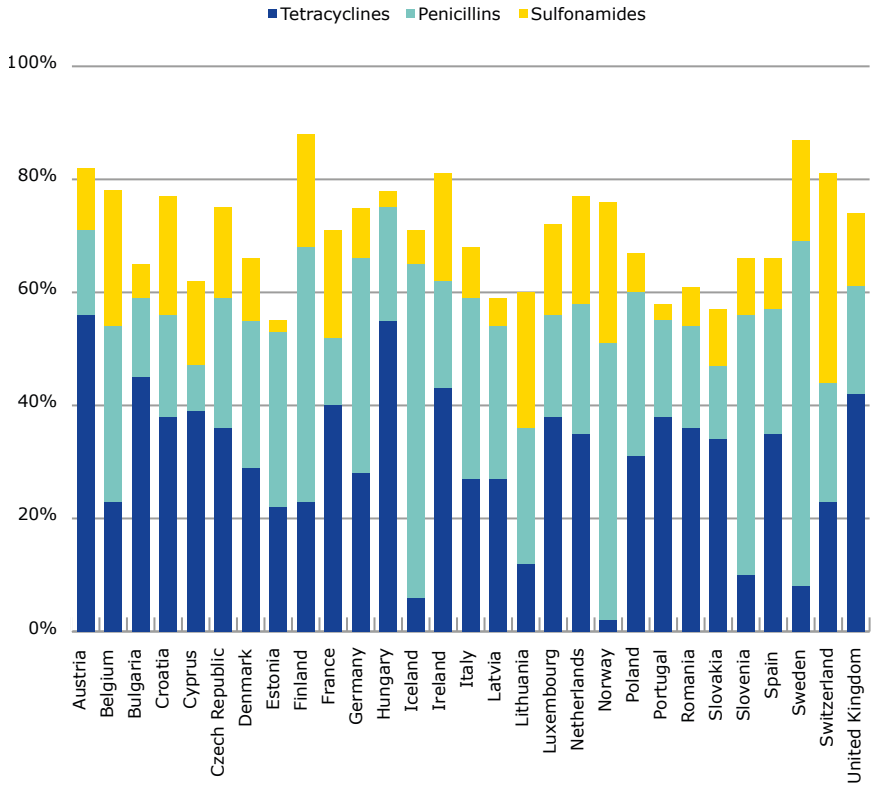
Figure 10. Sales of antimicrobial agents by antimicrobial class as percentage of the total sales for food-producing species, in mg/PCU, aggregated by 29 European countries, for 2014



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

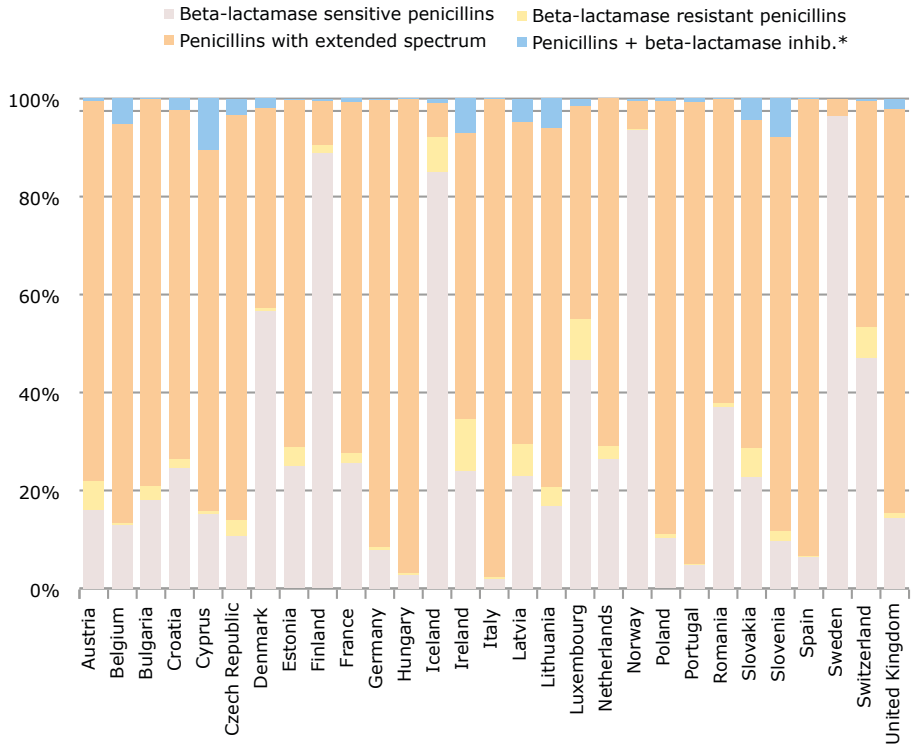
For all 29 countries, the sales of tetracyclines, penicillins and sulfonamides, in mg/PCU, accounted for 69.9 % of the total sales in 2014 (Figure 10). Of the overall sales in the 29 countries, 0.08 % were accounted for by 1st- and 2nd-generation cephalosporins, 0.16 % were for 3rd- and 4th-generation cephalosporins, 0.94 % were for amphenicols, and 0.41 % for other quinolones.

Figure 11. Sales of tetracyclines, penicillins and sulfonamides as a percentage of the total sales for food-producing species, in mg/PCU, in 29 European countries, for 2014



The percentage of sales of penicillins attributed to the various subclasses differed substantially between the 29 countries (Figure 12). In the Nordic countries, where the proportion of sales of penicillin are typically high, beta-lactamase-sensitive penicillins[14] accounted for the major part of penicillins sold (range: 56.6% – 96.4%), in (Figure 11). For countries other than the Nordic ones, penicillins with an extended spectrum accounted for the major proportion of penicillins sales.

Figure 12. Distribution of the sales, in mg/PCU, of penicillins by subclass for food-producing species, in 29 European countries, for 2014



* Note: In the ATCvet system classified as combinations of penicillins that include beta-lactamase inhibitors.

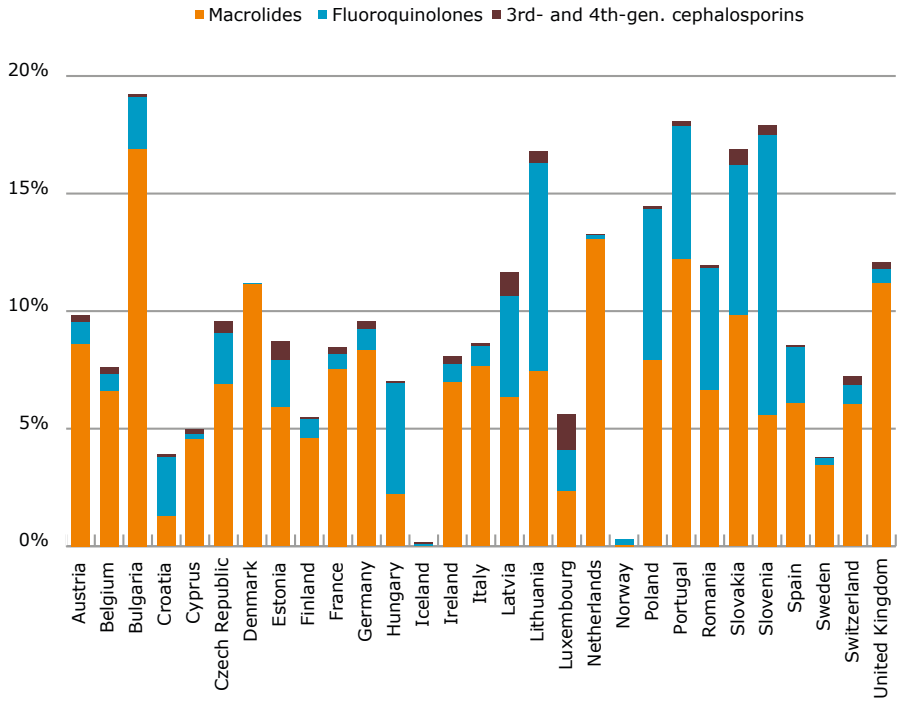
The substances included in each of the categories in the above figure are detailed in Table A15. Penicillins plus beta-lactamase inhibitors refer to penicillins in combination with clavulanic acid.

The proportion of critically important antimicrobials (CIAs) with the highest priority in human medicine, as defined by the WHO — 3rd- and 4th-generation cephalosporins, fluoroquinolones and macrolides — sold in 2014 varied substantially between the 29 countries, ranging from 0.01% to 1.5%, 0.01% to 11.9%, and 0% to 16.9%, respectively (Figure 13). The total sales, in mg/PCU, of these classes/subclasses in the 29 EU/EEA countries are shown in Figures 61–63.

Overall, in the 29 countries, the sales (mg/PCU) of 3rd- and 4th-generation cephalosporins, fluoroquinolones and macrolides accounted for 0.2%, 1.9% and 7.5%, respectively, of the total sales of antimicrobial VMPs in 2014.

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

Figure 13. Proportion of the total sales of macrolides, fluoroquinolones and 3rd- and 4th-generation cephalosporins for food-producing species, in mg/PCU, for 29 European countries, in 2014[1]



[1] No sales of macrolides in Iceland.

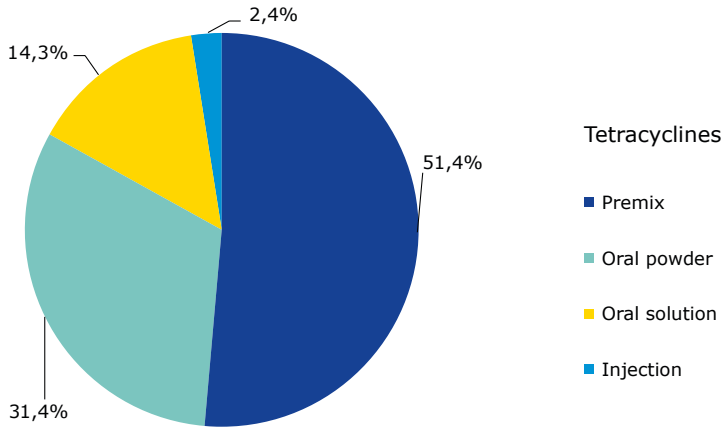
The total sales, in mg/PCU, of these classes/subclasses in the 29 countries are shown in Figures 63–65, and for fluoroquinolones and 3rd- and 4th-generation cephalosporins in Chapter 2.8.2. that present country-specific data across years.

2.4.1. Distribution of sales for the most-sold antimicrobial classes and the most important CIAs by pharmaceutical form, aggregated by the 29 European countries

2.4.1.1. Tetracyclines

The overall sales of tetracyclines for the 29 countries, divided into pharmaceutical forms, are shown in Figure 14. In addition, 0.5% were sold as intramammary preparations, intrauterine preparations and boluses.

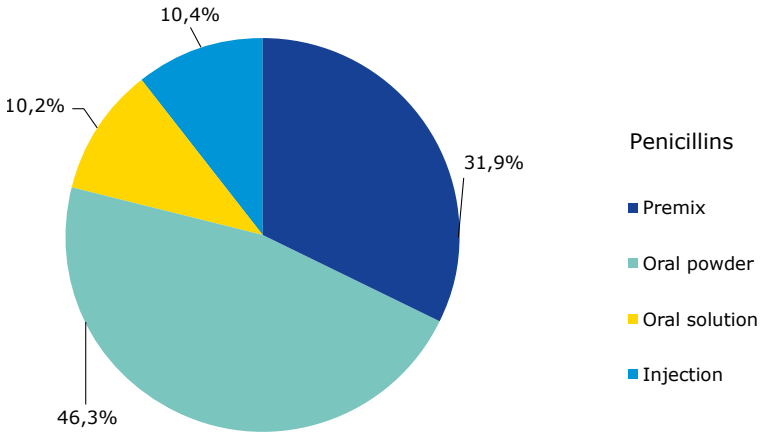
Figure 14. Distribution of sales of tetracyclines for food-producing animals, in mg/PCU, by the major pharmaceutical forms sold, aggregated by the 29 European countries, for 2014



2.4.1.2. Penicillins

The overall sales of penicillins in the 29 countries, divided into pharmaceutical forms, are shown in Figure 15. In addition, 1.1% was accounted for by intramammary preparations and 0.2% by boluses and intrauterine preparations.

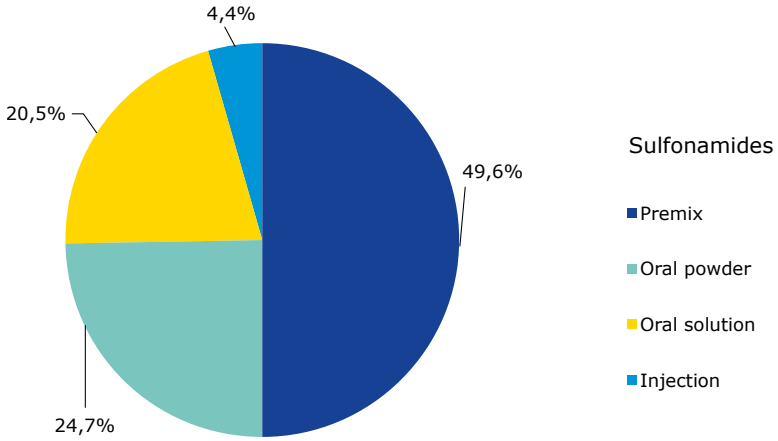
Figure 15. Distribution of sales of penicillins for food-producing animals, in mg/PCU, by the major pharmaceutical forms sold, aggregated by the 29 European countries, for 2014



2.4.1.3. Sulfonamides

The overall sales of sulfonamides in the 29 countries, stratified into pharmaceutical forms, are shown in Figure 16. Other pharmaceutical forms, i.e. intramammary preparations, intrauterine preparations and oral pastes, accounted for 0.8%.

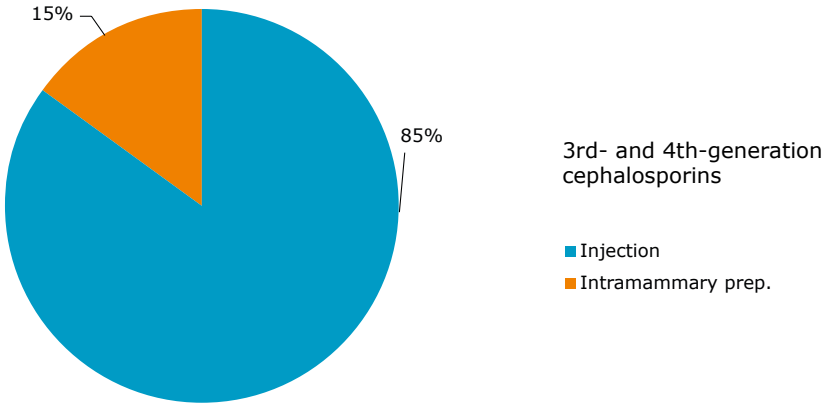
Figure 16. Distribution of sales of sulfonamides for food-producing animals, in mg/PCU, by the major pharmaceutical forms sold, aggregated by the 29 European countries, for 2014



2.4.1.4. 3rd- and 4th-generation cephalosporins

The pharmaceutical forms of 3rd- and 4th-generation cephalosporins are sold as injections and intramammary preparations (Figure 17).

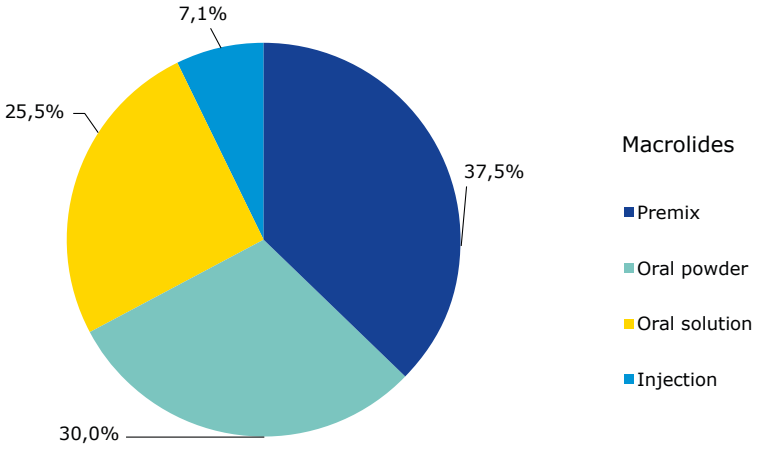
Figure 17. Distribution of sales of 3rd- and 4th-generation cephalosporins for food-producing animals, in mg/PCU, by pharmaceutical form sold, aggregated by the 29 European countries, for 2014



2.4.1.5. Macrolides

The overall sales of macrolides by pharmaceutical form in the 29 countries are shown in Figure 18. In addition, 0.04 % of the macrolides were sold as intramammary preparations.

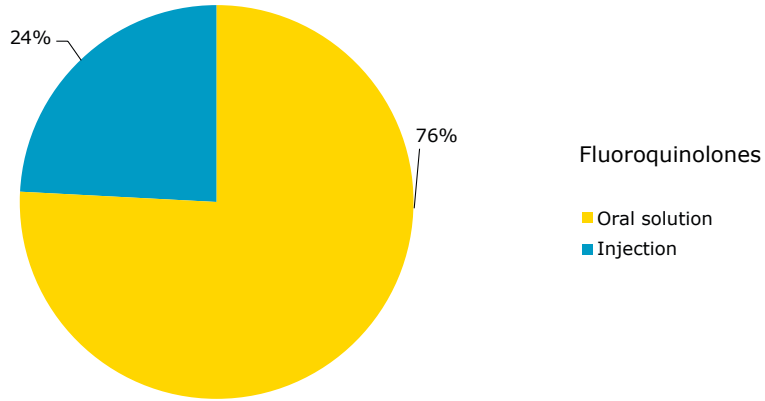
Figure 18. Distribution of sales of macrolides for food-producing animals, in mg/PCU, by pharmaceutical form sold, aggregated by the 29 European countries, for 2014



2.4.1.6. Fluoroquinolones

The overall sales of fluoroquinolones for the 29 countries, stratified into pharmaceutical forms, are shown in Figure 19. In addition, 0.01 % was sold as boluses and oral pastes.

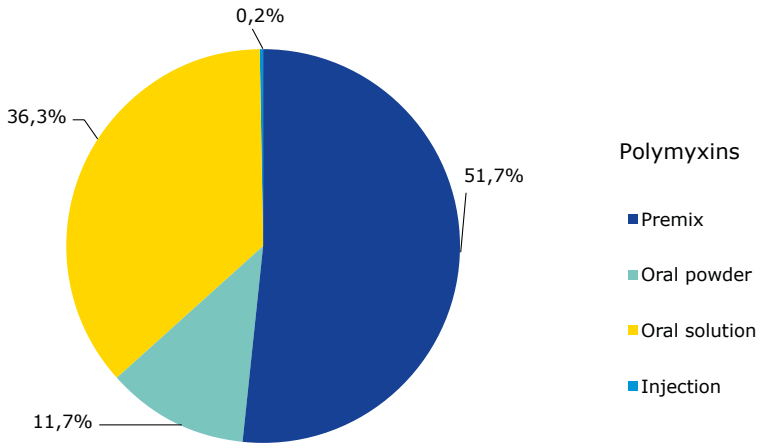
Figure 19. Distribution of sales of fluoroquinolones for food-producing animals, in mg/PCU, by the major pharmaceutical forms sold, aggregated by the 29 European countries, for 2014



2.4.1.7. Polymyxins

The overall sales of polymyxins for the 29 countries, divided into pharmaceutical forms, are shown in Figure 20. In 2014, the only polymyxin sold was colistin. In addition, 0.02 % of polymyxins were sold as boluses, oral pastes, intramammary and intrauterine preparations.

Figure 20. Distribution of sales of polymyxins for food-producing animals, in mg/PCU, by the major pharmaceutical forms sold, aggregated by the 29 European countries, for 2014



Colistin and the mcr-1 gene

Following the discovery of a colistin horizontally transferable resistance mechanism (MCR-1) in China, the Agency has provided the European Commission with advice on the use of colistin products in animals within the EU and the development of resistance and possible impact on human and animal health. This advice includes an analysis of colistin's toxicity, susceptibility testing, activity and resistance mechanisms, risk profile (based on the consumption patterns and epidemiology), and risk management options.

In human medicine, use of colistin has historically been limited to topical use due to its systemic toxicity. In the last decade, increasing numbers of hospital outbreaks of carbapenemase-producing enterobacteriaceae and other multidrug-resistant bacteria have forced clinicians to reintroduce systemic treatment using colistin as a last-resort alternative in healthcare settings. As a consequence of growing carbapenem-resistance, the use of colistin has been growing rapidly in southern European regions, leading to increasing selective pressure.

Colistin is a polymyxin that has been in regular use in veterinary medicine for decades. It is of therapeutic importance for the treatment of Gram-negative gastrointestinal infections in certain food-producing species. It is predominantly administered as group treatment using oral administration. In 2013, colistin represented more than 99 % of the sales of the polymyxins in the 26 EU/EEA countries; in 2014, the only polymyxin reportedly sold was colistin. In 2014, polymyxins were the fifth most-sold antimicrobial class, accounting for 6.6 % of total antimicrobials sales in the 29 European countries.

The Agency advice indicates that use of colistin in both human and veterinary medicine must be rationalised and reserved for clinical conditions. The main recommendations are that colistin sales for use in animals should be reduced to the lowest level possible and that it should be added to the AMEG list for a higher-risk category

(category 2) which currently includes fluoroquinolones and 3rd- and 4th-generation cephalosporins. Extended spectrum penicillins and aminoglycosides have been included provisionally in category 2, pending risk profiling (http://www.ema.europa.eu/docs/en_GB/document_library/Scientific_guideline/2016/07/WC500211080.pdf).

ESVAC sales data has supported the development of the Agency's advice on colistin, including setting targets for reduced sales for use in animals. These data will be important for the future assessment of the impact of national risk mitigation measures to reduce sales of colistin for animal use.

The advice concludes:

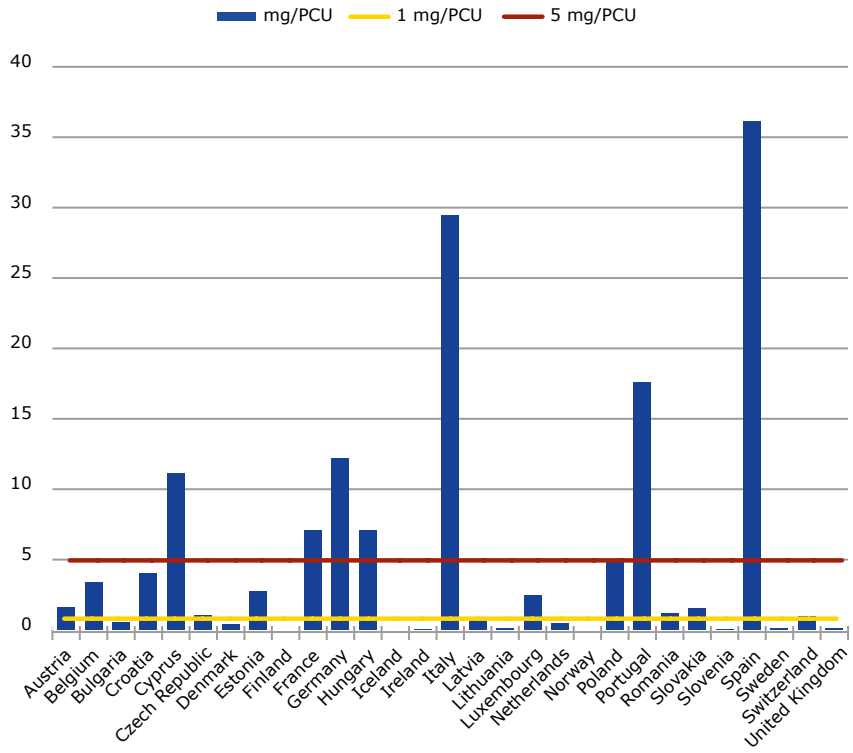
"Considering the rapidly increasing importance of colistin for treatment of critically ill human patients, all countries should strive to reduce the use of polymyxins as much as possible.

For the current "high and moderate consumers" the target and desirable levels are set at 5 mg/PCU and 1 or below 1 mg/PCU, respectively, based on the observations on the level of sales in other ESVAC participating countries. Meanwhile more information should be gathered to determine the lowest level of colistin use that can be achieved while maintaining animal welfare without increasing the use of fluoroquinolones and 3rd- and 4th-generation cephalosporins or the overall use (mg/PCU) of antimicrobials.

The targets for reduction in sales of colistin should be achieved in a period of 3 to 4 years."

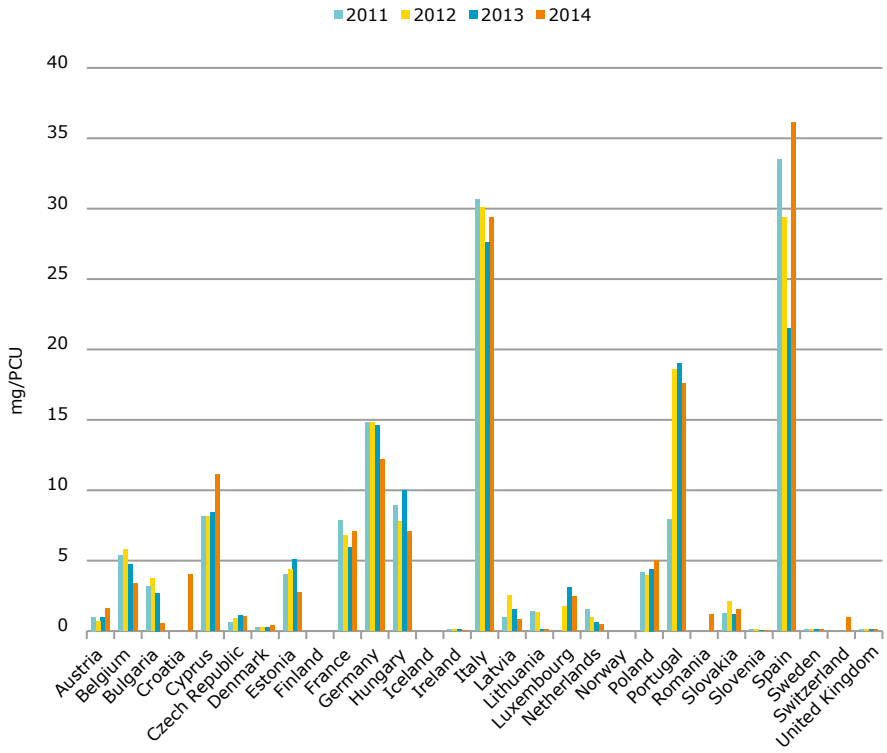
Sales of colistin, in mg/PCU, in 2014 (ESVAC data), including the 5 and 1 mg/PCU levels through the ESVAC collection of data, is shown in Figure A1.

Figure A1. Sales of colistin for use in food-producing animals, in mg/PCU, in 2014, including the 5 and 1 mg/PCU levels[1]



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

Figure A2. Sales of polymyxins[1] for use in animals, in mg/PCU, in 29 European countries, from 2011 to 2014[2]



[1] In 2014 the only polymyxin sold was colistin.

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

2.5. Distribution of sales for food-producing animals — overall and by antimicrobial class and pharmaceutical form

2.5.1. Distribution of sales of antimicrobials for food-producing animals by country

Figure 21. Spatial distribution of overall sales of all antimicrobials for food-producing animals, in mg/PCU, for 29 countries, for 2014

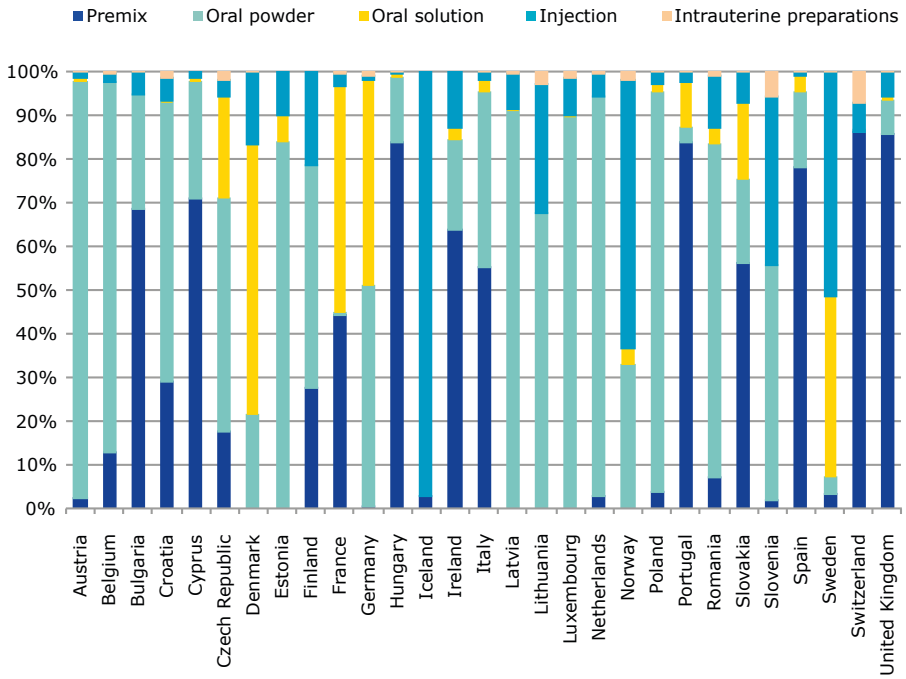
2.5.2. Distribution of sales of antimicrobials by class and forms by country

There was considerable variation in the distribution of sales, in mg/PCU, in terms of antimicrobial classes and pharmaceutical forms among the participating countries.

2.5.2.1. Tetracyclines

Figure 22. Spatial distribution of sales of tetracyclines for food-producing animals, in mg/PCU, by country, for 2014

Figure 23. Distribution of sales by pharmaceutical forms of tetracyclines, in mg/PCU, by country, for 2014[1]



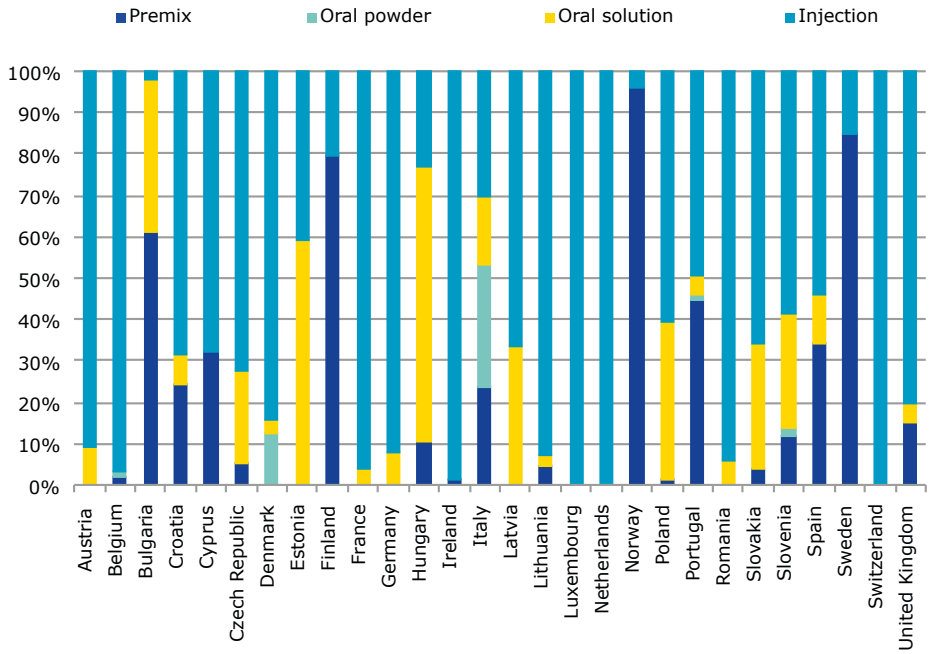
[1] In addition, negligible amounts were sold as boluses, intramammary preparations and/or oral pastes in some countries.

2.5.2.2. Amphenicols

Figure 24. Spatial distribution of sales of amphenicols, in mg/PCU, by country, for 2014[1]

[1] No sales in Iceland.

Figure 25. Distribution of sales by pharmaceutical form of amphenicols, in mg/PCU, by country, for 2014[1]

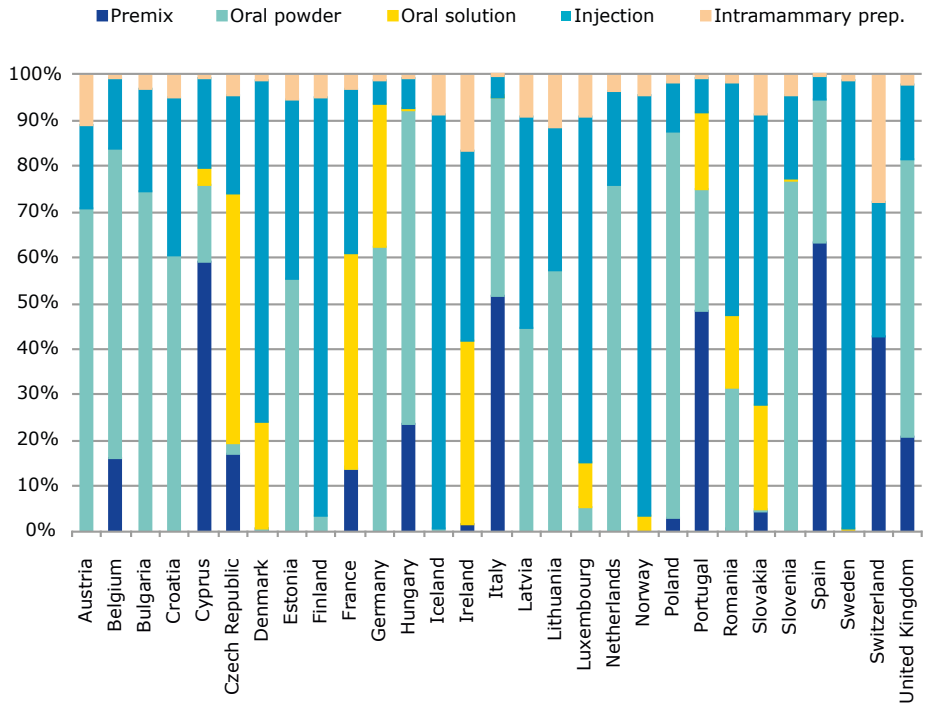


[1] No sales in Iceland.

2.5.2.3. Penicillins

Figure 26. Spatial distribution of sales of penicillins for food-producing animals, in mg/PCU, by country, for 2014

Figure 27. Distribution of sales by pharmaceutical form for penicillins, in mg/PCU, by country, for 2014[1]



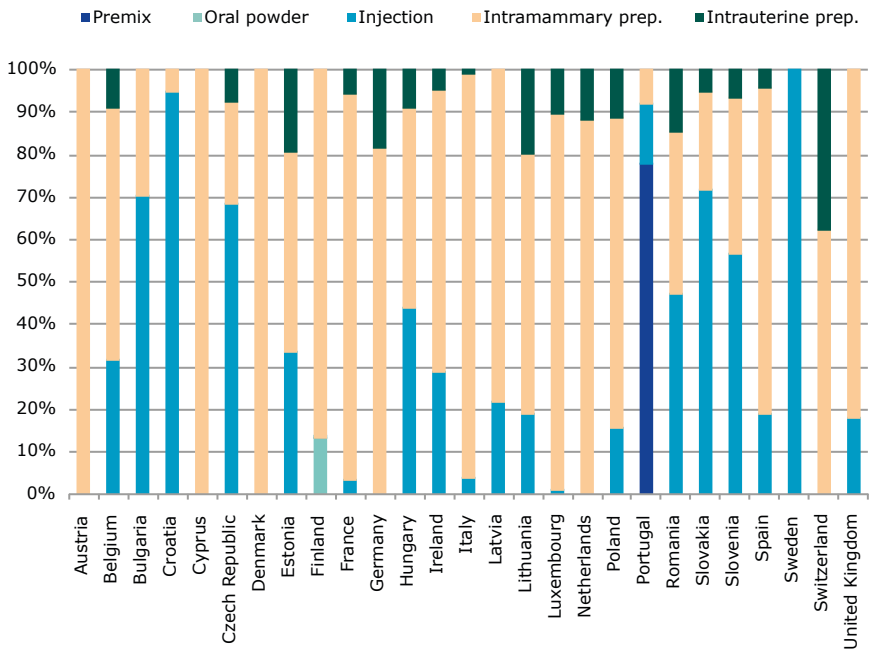
[1] In addition, negligible amounts were sold as boluses, intrauterine preparations and/or oral pastes in some countries.

2.5.2.4. 1st- and 2nd-generation cephalosporins

Figure 28. Spatial distribution of sales of 1st- and 2nd-generation cephalosporins, in mg/PCU, by country, for 2014[1]

[1] No sales in Iceland, Norway.

Figure 29. Distribution of sales by pharmaceutical form for 1st- and 2nd-generation cephalosporins, in mg/PCU, by country, for 2014[1,2]

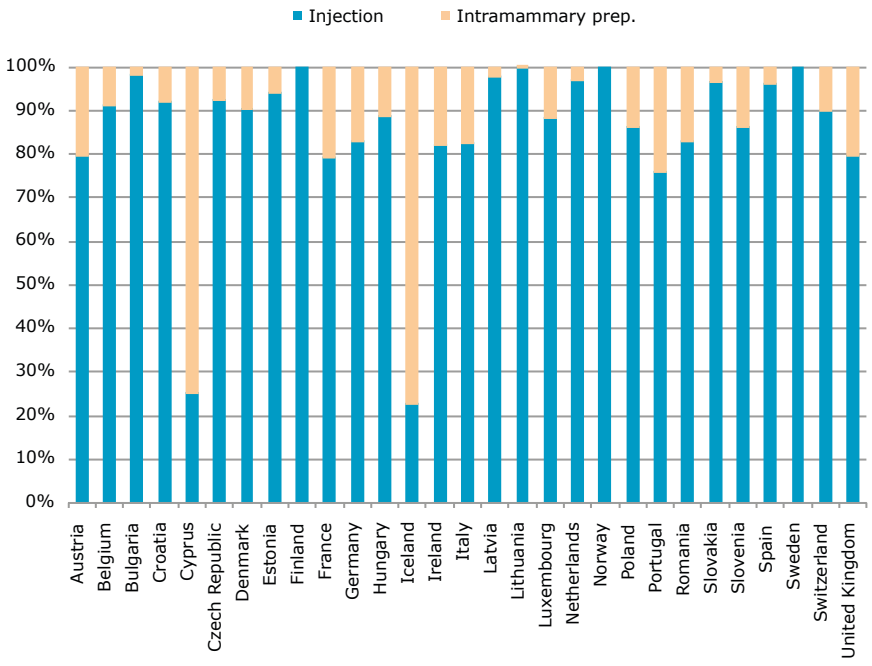


[1] No sales in Iceland, Norway.
[2] In addition, negligible amounts were sold as oral pastes in some countries.

2.5.2.5. 3rd- and 4th-generation cephalosporins

Figure 30. Spatial distribution of sales of 3rd- and 4th-generation cephalosporins, in mg/PCU, by country, for 2014

Figure 31. Distribution of sales by pharmaceutical form for 3rd- and 4th-generation cephalosporins, in mg/PCU, by country, for 2014[1]

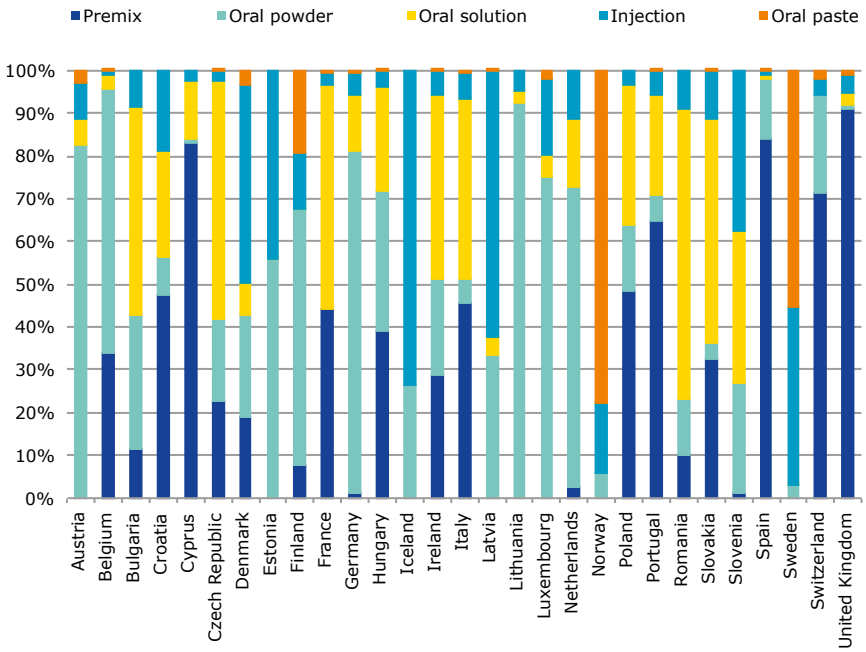


[1] Sales < 1 kg in Iceland and Norway.

2.5.2.6. Sulfonamides

Figure 32. Spatial distribution of sales of sulfonamides, in mg/PCU, by country, for 2014

Figure 33. Distribution of sales by pharmaceutical form for sulfonamides, in mg/PCU, by country, for 2014[1]

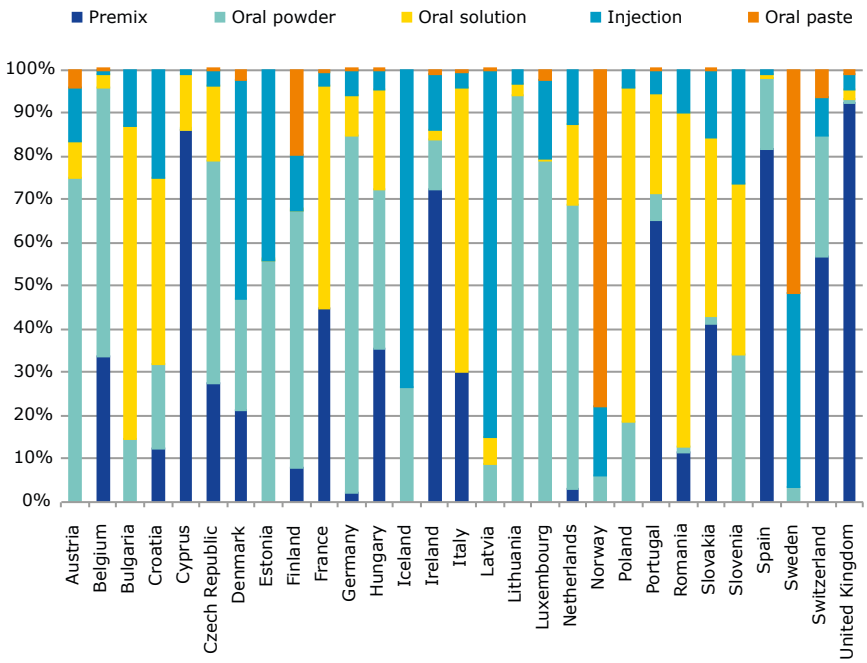


[1] In addition, negligible amounts were sold as bolus, intramammary and/or intrauterine preparations in some countries.

2.5.2.7. Trimethoprim

Figure 34. Spatial distribution of sales of trimethoprim, in mg/PCU, by country, for 2014

Figure 35. Distribution of sales by pharmaceutical form for trimethoprim, in mg/PCU, by country, for 2014[1]



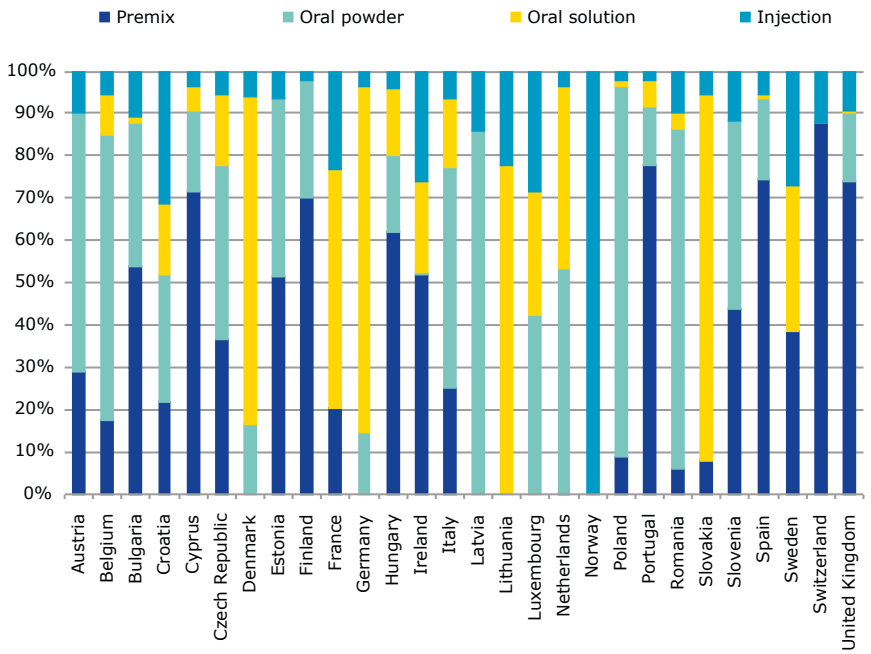
[1] In addition, negligible amounts were sold as intramammary preparations and/or boluses in some countries.

2.5.2.8. Macrolides

Figure 36. Spatial distribution of sales of macrolides, in mg/PCU, by country, for 2014[1]

[1] No sales in Iceland.

Figure 37. Distribution of sales by pharmaceutical form for macrolides, in mg/PCU, by country, for 2014[1,2]



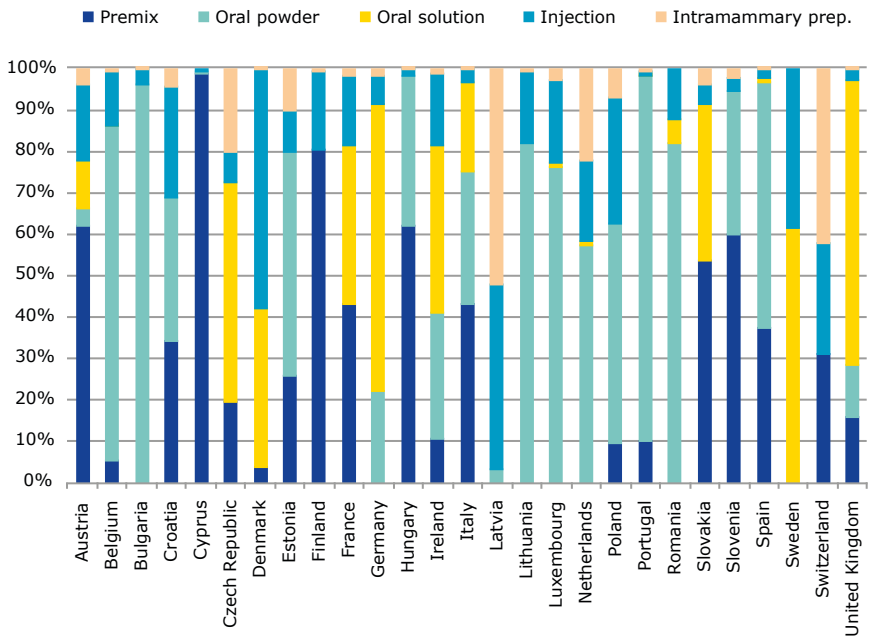
[1] No sales in Iceland.
[2] In addition, negligible amounts were sold as intramammary preparations in some countries.

2.5.2.9. Lincosamides

Figure 38. Spatial distribution of sales of lincosamides, in mg/PCU, by country, for 2014[1]

[1] No sales in Iceland, Norway.

Figure 39. Distribution of sales by pharmaceutical form for lincosamides, in mg/PCU, by country, for 2014[1]

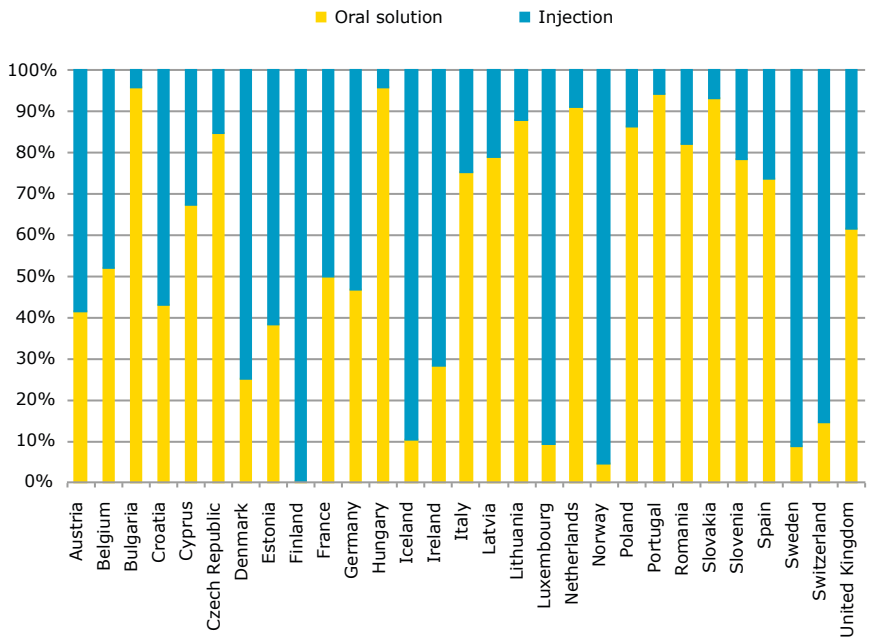


[1] No sales in Iceland and Norway.

2.5.2.10. Fluoroquinolones

Figure 40. Spatial distribution of sales of fluoroquinolones, in mg/PCU, by country, for 2014

Figure 41. Distribution of sales by pharmaceutical form for fluoroquinolones, in mg/PCU, by country, for 2014[1,2]



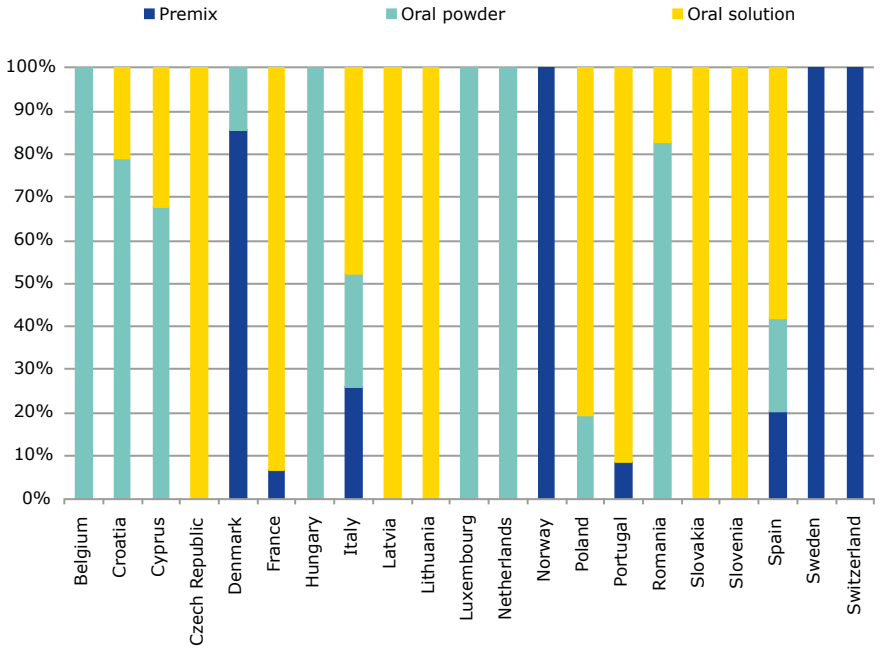
[1] In addition, negligible amounts were sold as boluses in some countries.
[2] Sales < 1 kg in Iceland

2.5.2.11. Other quinolones

Figure 42. Spatial distribution of sales of other quinolones, in mg/PCU, by country, for 2014[1]

[1] No sales in Austria, Bulgaria, Estonia, Finland, Germany, Ireland and the United Kingdom.

Figure 43. Distribution of sales by pharmaceutical form for other quinolones, in mg/PCU, by country, for 2014[1,2]

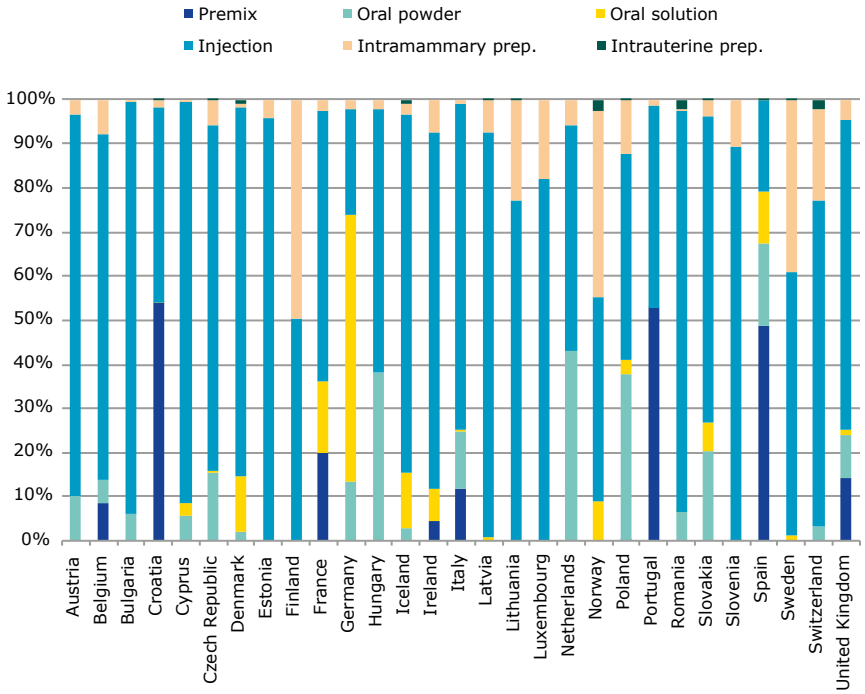


[1] No sales in Austria, Bulgaria, Estonia, Finland, Germany, Iceland, Ireland and the United Kingdom.
[2] In addition, negligible amounts were sold as injections, boluses and/or oral pastes in some countries.

2.5.2.12. Aminoglycosides

Figure 44. Spatial distribution of sales of aminoglycosides, in mg/PCU, by country, for 2014

Figure 45. Distribution of sales by pharmaceutical form for aminoglycosides, in mg/PCU, by country, for 2014

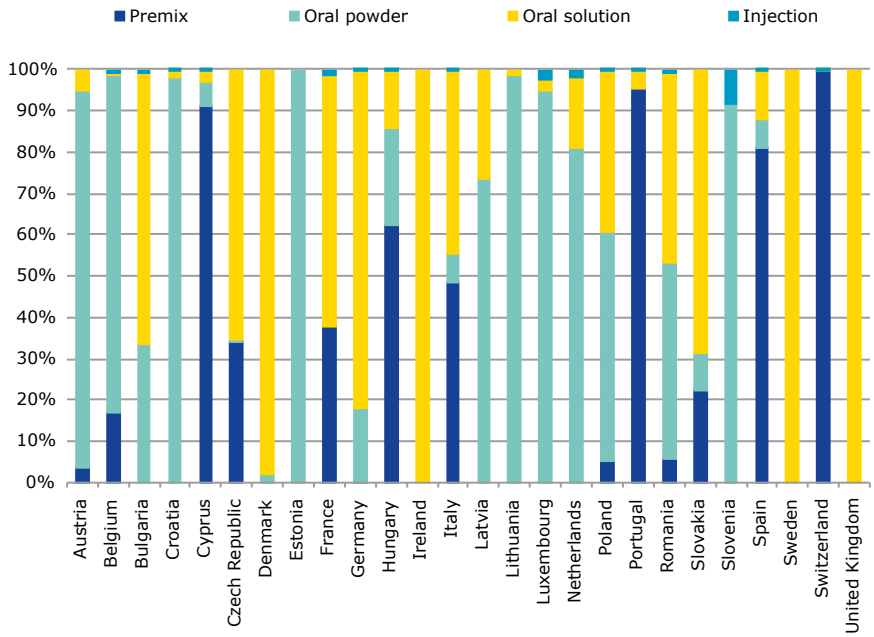


2.5.2.13. Polymyxins

Figure 46. Spatial distribution of sales of polymyxins, in mg/PCU, by country, for 2014[1]

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

Figure 47. Distribution of sales by pharmaceutical form for polymyxins, in mg/PCU, by country, for 2014[1,2]



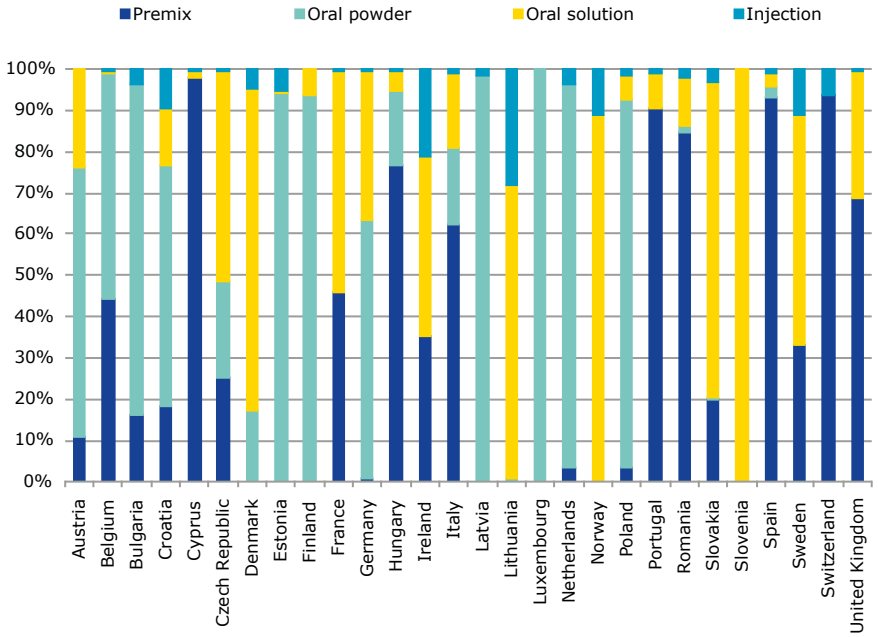
[1] No sales in Finland, Iceland and Norway.
[2] In addition, negligible amounts were sold as boluses, oral pastes, intramammary and/or intrauterine preparations in some countries.

2.5.2.14. Pleuromutilins

Figure 48. Spatial distribution of sales of pleuromutilins, in mg/PCU, by country, for 2014[1]

[1] No sales in Iceland.

Figure 49. Distribution of sales by pharmaceutical form for pleuromutilins, in mg/PCU, by country, for 2014[1]



[1] No sales in Iceland.

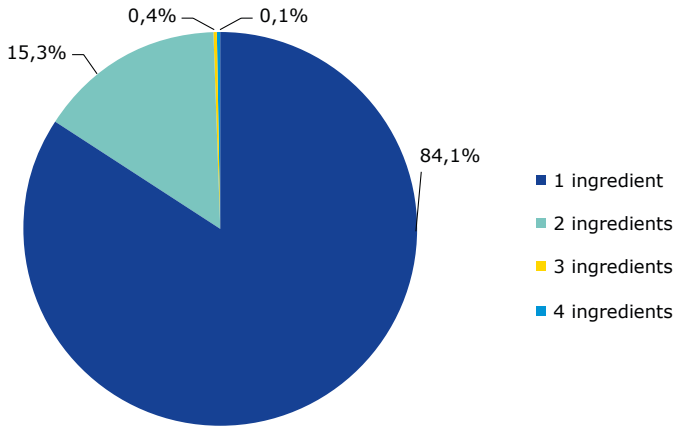
2.6. Distribution of single- and multiple-ingredient products of veterinary antimicrobial agents

Of the 8,432 product presentations (tablets excluded) for which sales were reported — i.e. product name, form, strength and pack size — 80.8 % contained only one active ingredient, 16.9 % contained two active ingredients, and 2.2 % contained three active ingredients (Annex 1, Table A7). In addition, 0.2 % (n=16) of the product presentations contained four active ingredients. Sales of products with three active ingredients were accounted for almost solely by products for individual treatment (intramammary and intrauterine preparations), and sales of products containing four active ingredients were only accounted for by intramammary preparations.

For all 29 countries, 88 % of the product presentations of antimicrobial VMPs were for animal group treatment in the form of premixes, oral powders and oral solutions. From these, 83.2 % contained one active ingredient, 15.4 % two active ingredients and 1.3 % three active ingredients (Annex 1, Table A8).

Across the 29 countries, of the total sales of premixes, oral powders and oral solutions, in tonnes of active ingredient, 84.1 %, 15.3 % and 0.4 % were accounted for by products containing 1, 2 and 3 active ingredients, respectively (Figure 50).

Figure 50. Percentage of sales, in tonnes of active ingredient, of premixes, oral powders and oral solutions containing 1, 2, 3 and 4 antimicrobial agents, in 2014

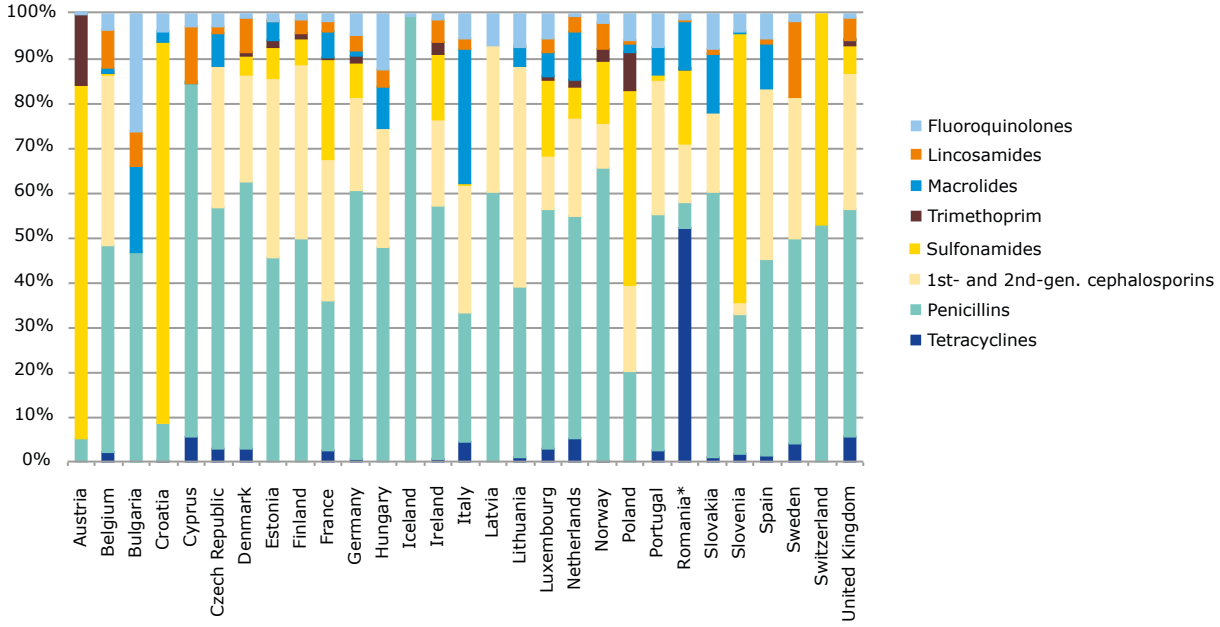


2.7. Estimates of sales of tablets by veterinary antimicrobial class for companion animals

Tablets are excluded from the dataset used to report sales for food-producing animals based on the assumption that tablets are used almost solely for companion animals. Figure 51 shows the distribution of tablet sales, in tonnes of active ingredient, by antimicrobial class and country, for 2014. The sales patterns for tablets varied substantially between countries, but in general the most-sold tablets contained penicillins (mainly in combination with a beta-lactamase inhibitor, see Figure 52).

Antimicrobial medicinal products marketed for human use can also be used in companion animals, in application of Article 10 of Directive 2001/82/EC, as amended, 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 pharmacy sales and not on the reimbursement of physicians' prescriptions, as provided by insurance companies. Therefore, the data presented in Figure 51 only covers sales of tablets containing antimicrobials marketed for veterinary use and should be interpreted as such. In the current report, all injectable veterinary antimicrobial products are included in the sales data for food-producing animals, but some of the injectable preparations are also used in companion animals while some are only marketed for companion animals.

Figure 51. Distribution of sales of tablets, in tonnes of active ingredient, by antimicrobial class (reported according to the ATCvet hierarchical system), by country, for 2014[1]



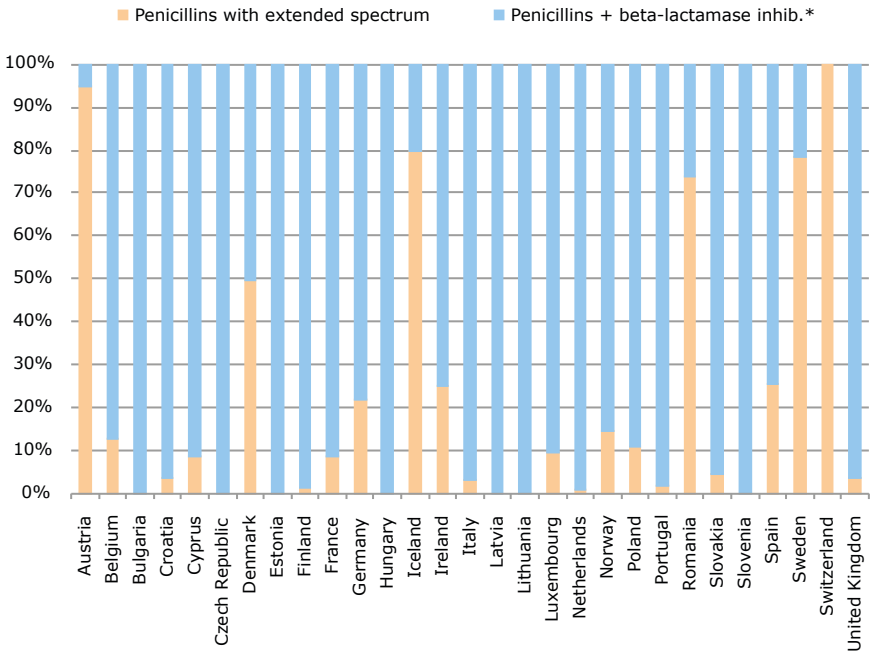
* In Romania 43% (1.75 tonnes) of tablets sold were indicated for poultry.

[1] Small amounts of aminoglycosides, amphenicols, polymyxins and other antibacterials (classified as such in the ATCvet system) were sold in some countries, but are not included in this figure. No sales of VMP tablets containing other quinolones and 3rd- and 4th-generation cephalosporins were reported.

Aggregated by 29 countries, penicillins (38 %), 1st- and 2nd-generation cephalosporins (27 %), sulfonamides (13 %) and macrolides (7 %) were the most-sold antimicrobial classes of tablets.

The sales of penicillins available as tablets varied significantly by subclasses in the 29 countries (Figure 52.). Combinations of penicillins with beta-lactamase inhibitors represented 15 % to 100 % (in seven countries) of the total sales of penicillin tablets (sales of clavulanic acid inhibitors are not included in the data).

Figure 52. Distribution of sales (by weight of active ingredient) of tablets containing penicillins by subclass, by country, in 2014



* Note: In the ATCvet system classified as combinations of penicillins that include penicillin + beta-lactamase inhibitors.

2.8. Changes over time (2011-2014)

Chapter 2.8.1 describes the overall changes observed between 2011 and 2014 for the 25 countries which delivered data for these years, and focuses on the most-sold classes and the CIAs with the highest priorities for human medicine.

Chapter 2.8.2. reflects on the categorisation of antimicrobial agents made by the EMA Antimicrobial Advice ad hoc Expert Group (AMEG), in terms of their public health importance in Europe[15]. Category 2 includes veterinary antimicrobials for which the risk to public health is estimated to be higher; fluoroquinolones and 3rd- and 4th-generation cephalosporins are included but not, for example, macrolides. The recently published advice to add colistin to the list of substances in AMEG category 2[16] (higher risk) is addressed in chapter 2.4.1.7.

2.8.1. All countries

2.8.1.1. Changes by PCU

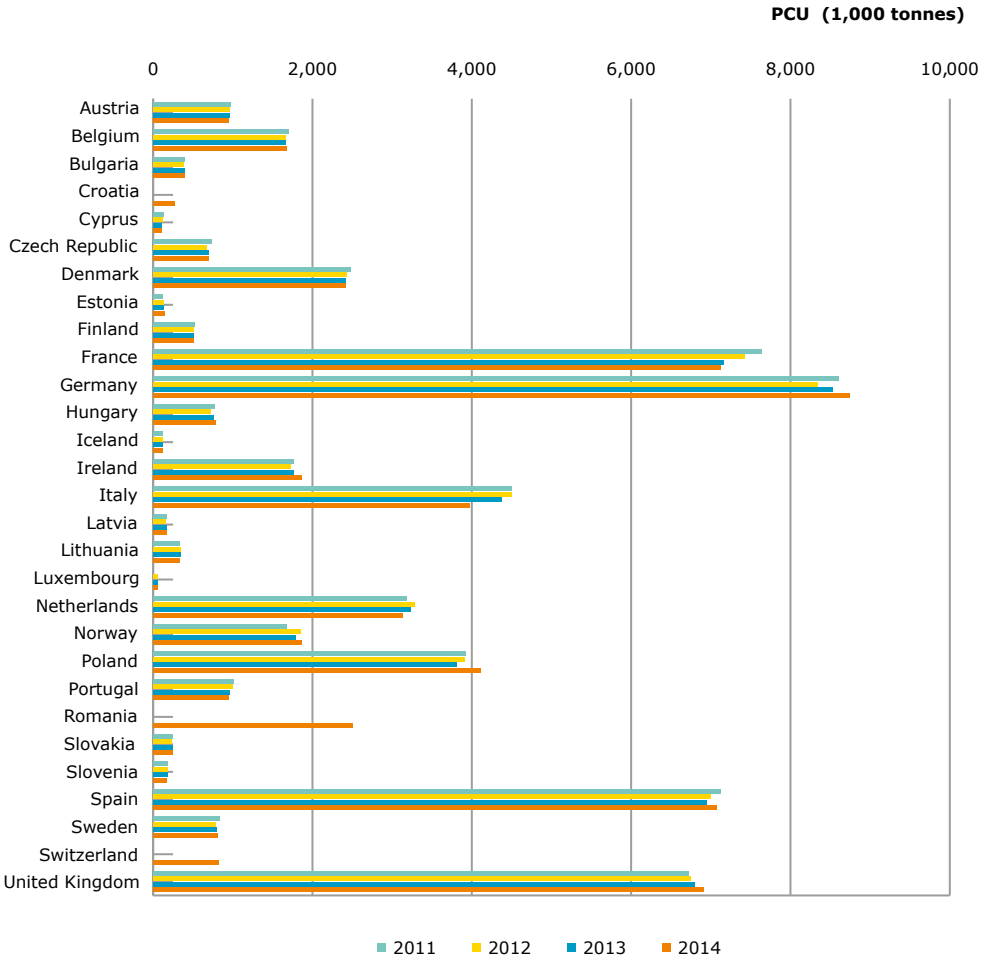
From 2011 to 2014, the PCU (estimated weight at treatment of livestock and slaughtered animals) was relatively stable for most countries (Figure 53).

For two of the 25 countries (Estonia and Norway) that delivered data for these four years, an increase of more than 10 % was observed in the PCU, while for two countries (Cyprus and Italy) a decrease of more than 10 % was seen (see Chapter 2.8.2. for more detailed information).

[15] Available on the EMA website (http://www.ema.europa.eu/docs/en_GB/document_library/Other/2014/07/WC500170253.pdf) via Home > Veterinary regulatory > Antimicrobial resistance > Use of antibiotics in animals

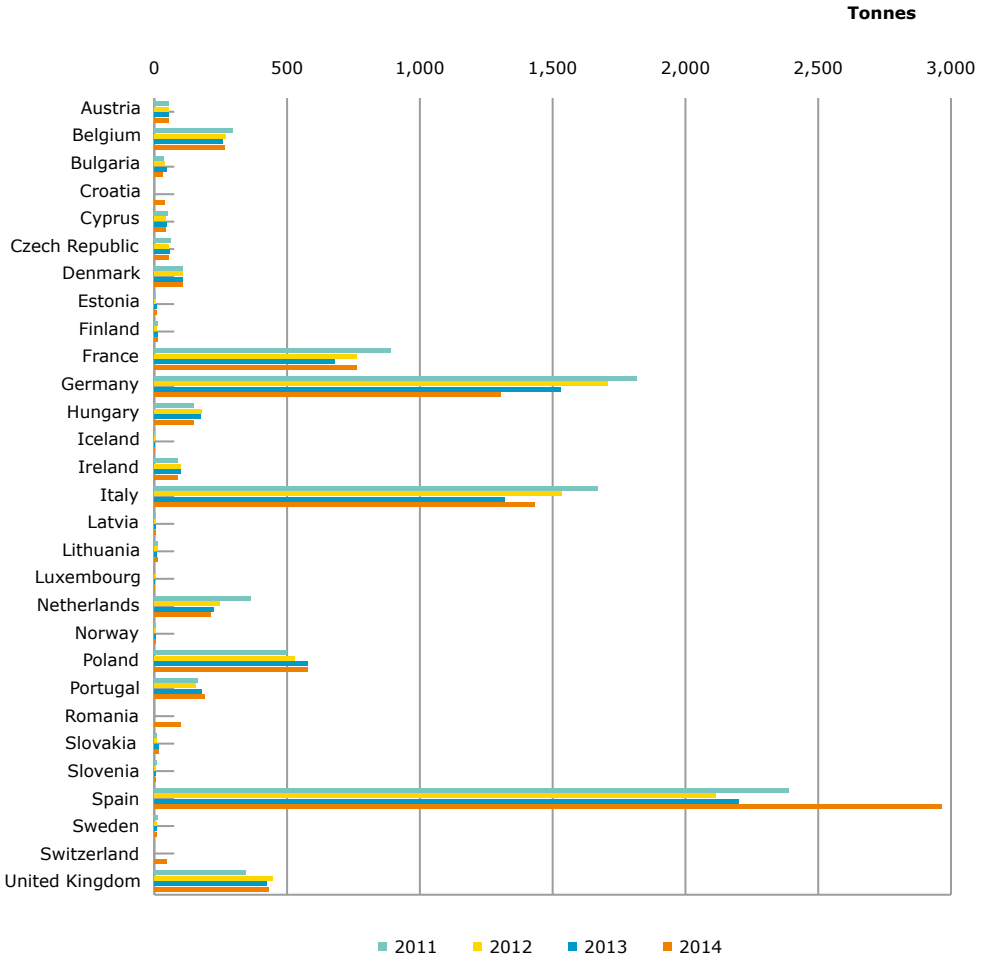
[16] Available on the EMA website (http://www.ema.europa.eu/docs/en_GB/document_library/Scientific_guideline/2016/07/WC500211080.pdf) via Home > Veterinary regulatory > Antimicrobial resistance > Use of antibiotics in animals

Figure 53. Population correction unit (PCU) for food-producing animals, in 1,000 tonnes, by country, between 2011 to 2014, in 29 European countries



2.8.1.2. Changes in sales of tonnes of active ingredients

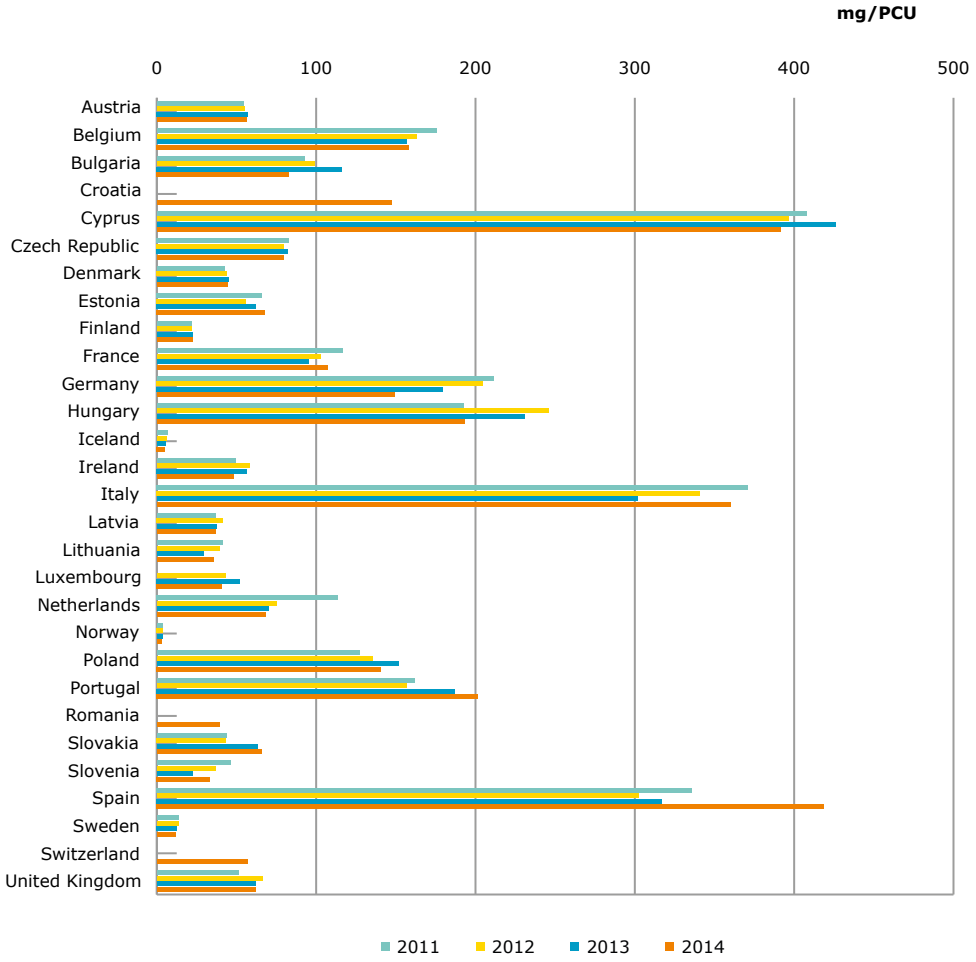
Figure 54. Sales, in tonnes of active ingredients, of veterinary antimicrobials for food-producing animals, between 2011 to 2014, in 29 European countries[1-7]



[1] Correction of sales data published in ESVAC 2013 report is described in chapter 1.5.2. [2] Under-reported for Bulgaria for 2011 and 2012 as several wholesalers failed to report data. [3] Strength reported as base for most VMPs for 2011 -2012 for the Czech Republic; for 2013 and 2014, strength reported as in the label of the VMPs. [4] Strength reported as base for some VMPs for 2011–2012 for the Netherlands; for 2013 and 2014, strength reported as in the label of the VMPs. [5] For Slovakia, for 2011 and 2012, the data only represents antimicrobial VMPs imported by wholesalers; for 2013 and 2014, data represents all sales from wholesalers to end-users (veterinarians, pharmacies, producers of medicated feeding stuffs and farmers, obtained by import and from national manufacturers). [6] For Spain, under-reporting has been identified for 2011 to 2013 (underestimates). [7] For the UK, high sales of certain tetracycline-containing products late in 2010 was probably used in 2011 and thus the use has been underestimated for 2011. For more details see chapter 2.8.2.

2.8.1.3. Changes in mg/PCU

Figure 55. Total sales of veterinary antimicrobial agents for food-producing species, in mg/PCU, from 2011 to 2014, for 29 European countries[1-7]

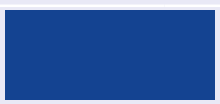


[1] Correction of sales data and/or PCU data published in ESVAC 2012 report is described in chapter 1.5. [2] Under-reported for Bulgaria for 2011 and 2012 as several wholesalers failed to report data. [3] Strength reported as base for most VMPs for 2011-2012 for the Czech Republic; for 2013 and 2014, strength reported as in the label of the VMPs. [4] Strength reported as base for some VMPs for 2011–2012 for the Netherlands; for 2013 and 2014, strength reported as in the label of the VMPs. [5] For Slovakia, for 2011 and 2012, the data only represents antimicrobial VMPs imported by wholesalers; for 2013 and 2014, data represents all sales from wholesalers to end-users (veterinarians, pharmacies, producers of medicated feeding stuffs and farmers, obtained by import and from national manufacturers). [6] For Spain, under-reporting for the years 2011 to 2013 has been identified (underestimated). [7] For the UK, high sales of certain tetracycline-containing products late in 2010 was probably used in 2011 and thus the use has been underestimated for 2011. For more details see chapter 2.8.2.

During the period 2011 to 2014, a drop of more than 5% (range 8% to 40%) in the sales (mg/PCU) was observed for nine countries (Table 8). For five countries, an increase of more than 5% is seen (range 11% to 51%); for one country (Spain) an increase of 51% was observed from 2011 to 2014, but the data-collection system changed for 2014 data and thus the increase observed is therefore artificial.

Table 8. Annual sales of veterinary antimicrobial agents for food-producing species, in mg/PCU, for 29 European countries[1], from 2011 to 2014

Country	2011	2012	2013	2014	2014	Trends 2011-2014
Austria	54.5	54.9	57.2	56.3		57.2 54.5
Belgium	175.3	163.1	156.6	158.3		175.2 156.6
Bulgaria[2]	92.6	98.9	116.1	82.9		116.1 82.9
Croatia				147.2		
Cyprus	407.6	396.5	425.8	391.5		425.8 391.5
Czech Republic[3]	83.0	79.8	82.2	79.5		83.0 79.5
Denmark	42.6	44.1	44.9	44.2		44.9 42.6
Estonia	66.0	56.1	62.2	68.0		68.0 56.1
Finland	21.9	21.8	22.4	22.3		22.4 218
France	116.5	102.7	95.0	107.0		116.5 95.0
Germany	211.5	204.8	179.7	149.3		211.5 149.3
Hungary	192.5	245.8	230.7	193.1		245.8 192.5
Iceland	6.6	5.9	5.3	5.2		6.6 5.2
Ireland	49.5	58.2	56.6	48.0		58.2 48.0
Italy	371.0	341.0	301.6	359.9		3710 3016

Country	2011	2012	2013	2014	2014	Trends 2011-2014
Latvia	36.7	41.5	37.7	36.7		
Lithuania	41.3	39.2	29.1	35.5		
Luxembourg		43.2	52.1	40.9		
Netherlands[4]	113.8	74.9	69.9	68.4		
Norway	3.7	3.8	3.7	3.1		
Poland	127.3	135.2	151.5	140.8		
Portugal	161.8	156.9	187.2	201.6		
Romania				39.2		
Slovakia[5]	43.7	43.3	63.1	65.9		
Slovenia	46.1	37.0	22.4	33.4		
Spain[6]	335.8	302.4	317.1	418.8		
Sweden	13.6	13.5	12.7	11.5		
Switzerland				56.9		
United Kingdom[7]	51.1	66.3	62.1	62.1		

[1] Correction of sales data and/or PCU data published in ESVAC 2013 report is described in chapter 1.5. [2] Under-reported for Bulgaria for 2011 and 2012 as several wholesalers failed to report data. [3] Strength reported as base for most VMPs for 2011–2012 for the Czech Republic; for 2013 and 2014, strength reported as in the label of the VMPs. [4] Strength reported as base for some VMPs for 2011–2012 for the Netherlands; for 2013 and 2014, strength reported as in the label of the VMPs. [5] For Slovakia, the data for 2011 and 2012 represents only imported antimicrobial VMPs by wholesalers; for 2013 and 2014, data represent all sales from wholesalers to end-users (veterinarians, pharmacies, producers of medicated feeding stuffs producers and farmers, obtained by import and from national manufacturers). [6] For Spain, under-reporting the years 2011 to 2013 has been identified. [7] For UK high sales of certain tetracycline-containing products late 2010 that is likely to have been used in 2011 and thus the use is underestimated for 2011. For more details see chapter 2.8.2.

The PCU was stable over the years in question; only a 0.9% reduction of PCU was observed for the 25 countries while the reduction in tonnes sold was 2.9%.

For the period 2011 to 2014, a drop in the sales (in mg/PCU) of more than 5% was observed for 10 of the 25 countries. For the same period, there was an increase in the sales of over 5% in five of the 25 countries (Table 8.).

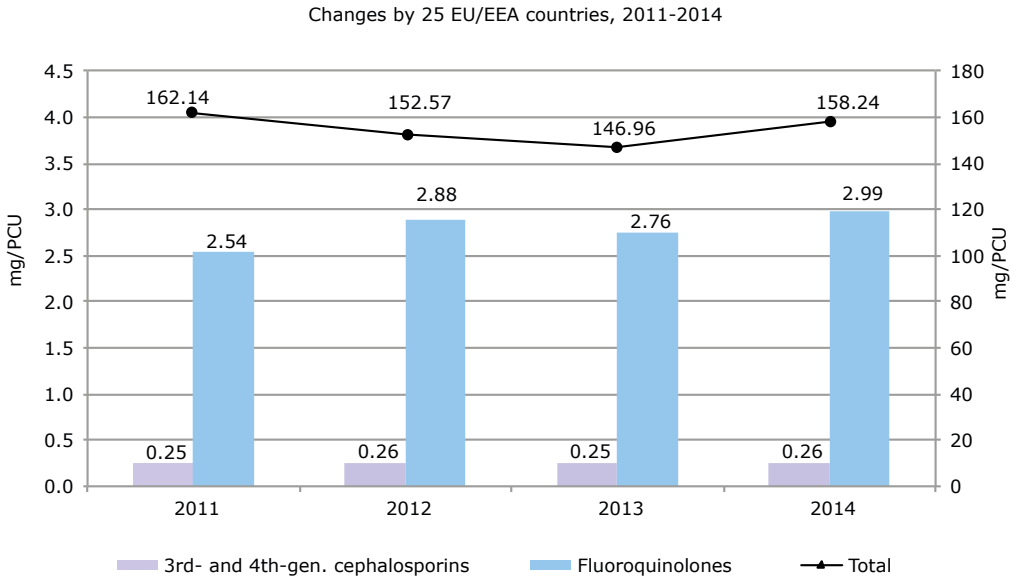
For 25 countries reporting sales data to ESVAC for the years 2011–2014, an overall decrease 2.4% in sales (mg/PCU) was observed. The sales were 162 mg/PCU, 153 mg/PCU, 147 mg/PCU and 158 mg/PCU in 2011, 2012, 2013 and 2014, respectively (Figure 56).

Spain changed its system for collecting sales data in 2014 and it became evident that some of the highest selling VMPs in 2014 had not been reported by MAHs between 2011-2013, despite having been marketed during these years. Thus, the suggestion is that sales data for Spain for 2011 to 2013 has been significantly underestimated. Consumption of antimicrobials in Spain is one of the highest among the European countries participating in ESVAC; therefore, sales aggregated by the 25 countries are not directly comparable, e.g. 2011 and 2014.

By excluding Spain, an overall drop of 12% in sales (mg/PCU) from 2011 to 2014 (from 138 mg/PCU in 2011 to 121 mg/PCU in 2014) was observed in the remaining 24 countries (Austria, Belgium, Bulgaria, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Hungary, Iceland, Italy, Ireland, Latvia, Lithuania, the Netherlands, Norway, Poland, Portugal, Slovakia, Slovenia, Sweden and the United Kingdom).

It should be noted that during these years, countries other than Spain also changed their national data collection systems, e.g. Slovenia in 2013, or have identified under-reporting in some years, e.g. Bulgaria in 2014. This underlines the fact that changes observed over the years should be interpreted with caution.

Figure 56. Changes in total sales and in sales of fluoroquinolones and 3rd- and 4th-generation cephalosporins, for 25 EU/EEA countries[1], from 2011 to 2014 (note the differences in the scales of the Y axes)



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

A 2.4% drop in total sales (mg/PCU) of antimicrobial VMPs was observed in the 25 countries which delivered data for all the years between 2011 and 2014. During this period, the sales of 3rd- and 4th-generation cephalosporins remained stable and there was an 18% increase in the sales of fluoroquinolones (Figure 56).

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

Sales of tetracyclines are shown in Figure 57. The sales of doxycycline are presented separately because of the lower dosing used in the treatment of animals compared to other tetracyclines and the high volume of sales attributed to this class of antimicrobials (Figure 58). Therefore, an increase in the sales of doxycycline could be associated with a decrease in total sales of tetracyclines.

Figure 57. Sales of tetracyclines for food-producing species, in mg/PCU, by 29 European countries, from 2011 to 2014

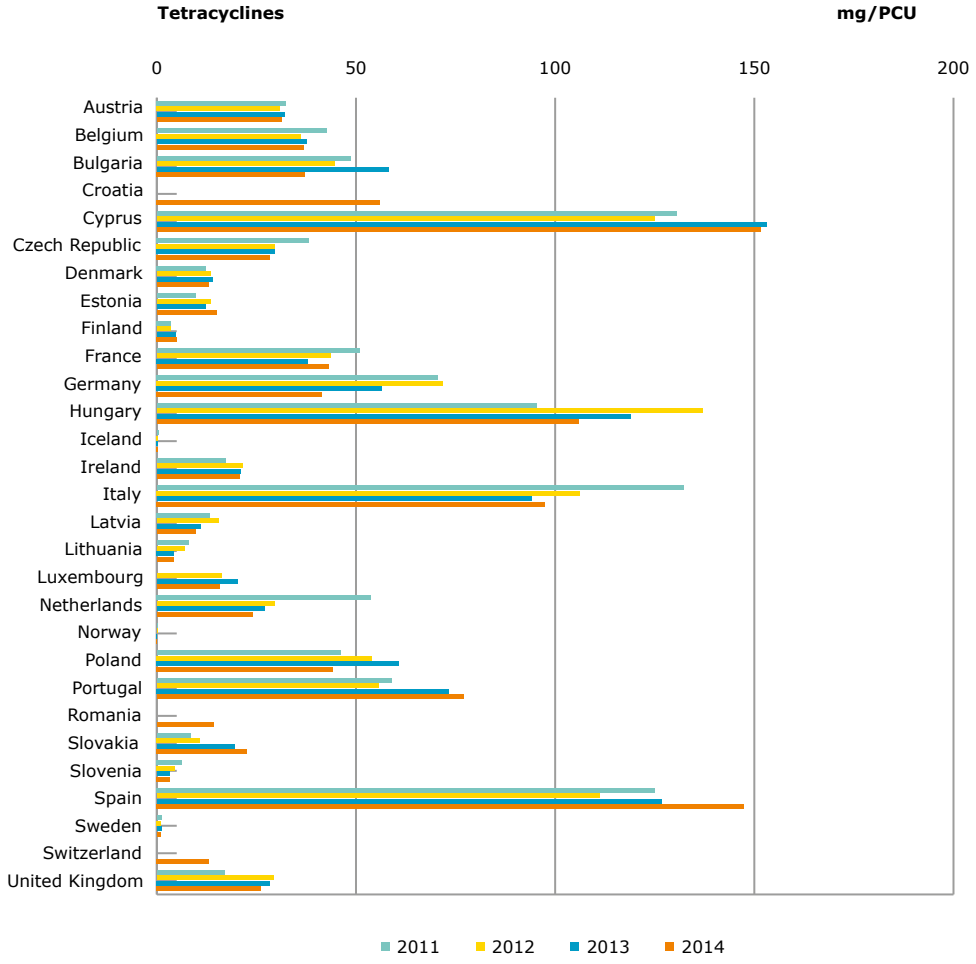
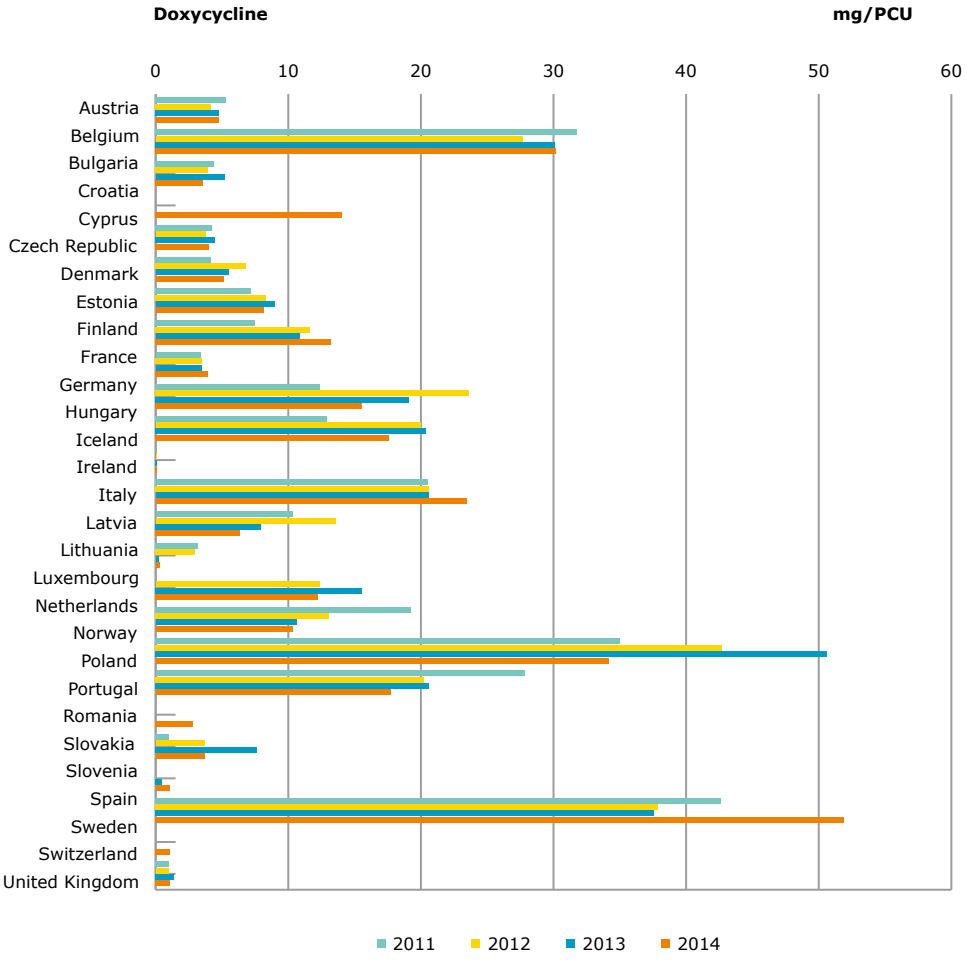


Figure 58. Sales of doxycycline for food-producing species, in mg/PCU, by 29 European countries, from 2011 to 2014[1]



[1] Countries not included in the graph: No sales in Iceland since 2012, and minor sales in 2011; Finland, Norway and Sweden had no sales or they were ≤0.1 mg/PCU; see chapter 2.8.2.

In some countries, it can be seen that the overall sales of tetracyclines have decreased while the sales of doxycycline have either increased or remained stable.

Figure 59. Sales of penicillins for food-producing species, in mg/PCU, by 29 European countries, from 2011 to 2014

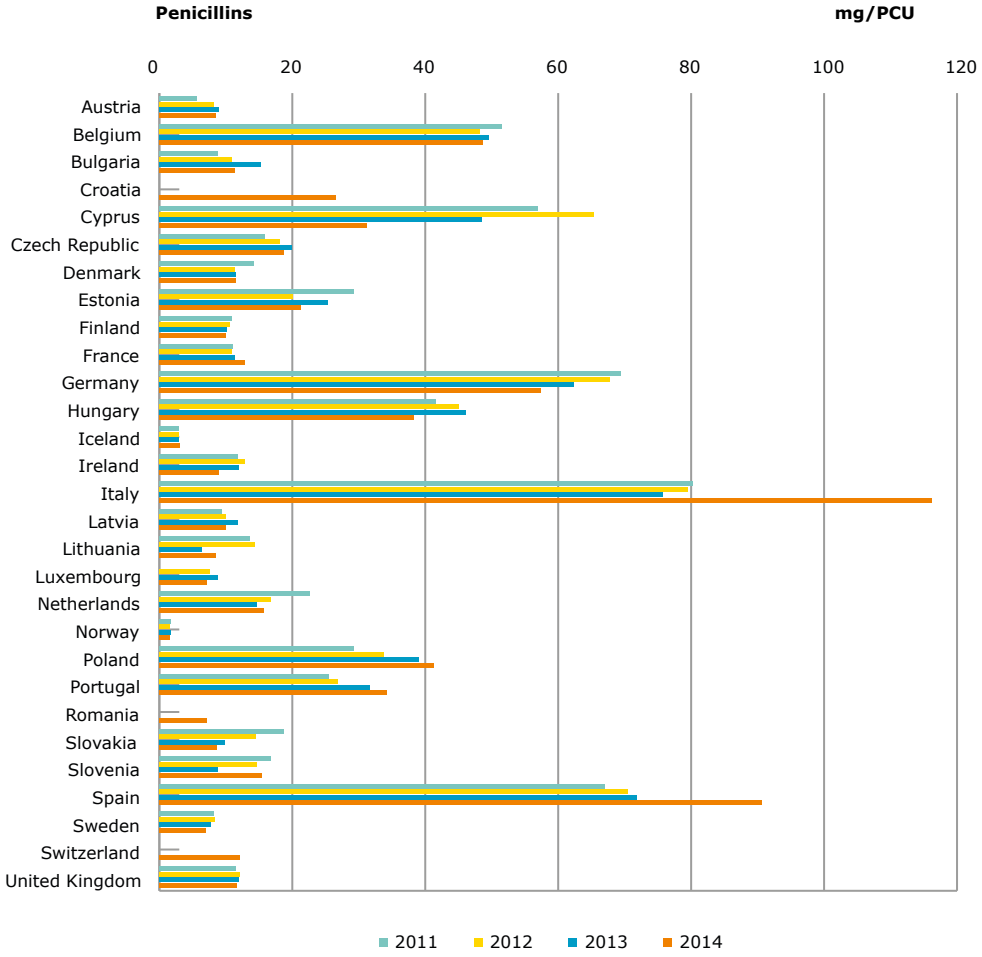
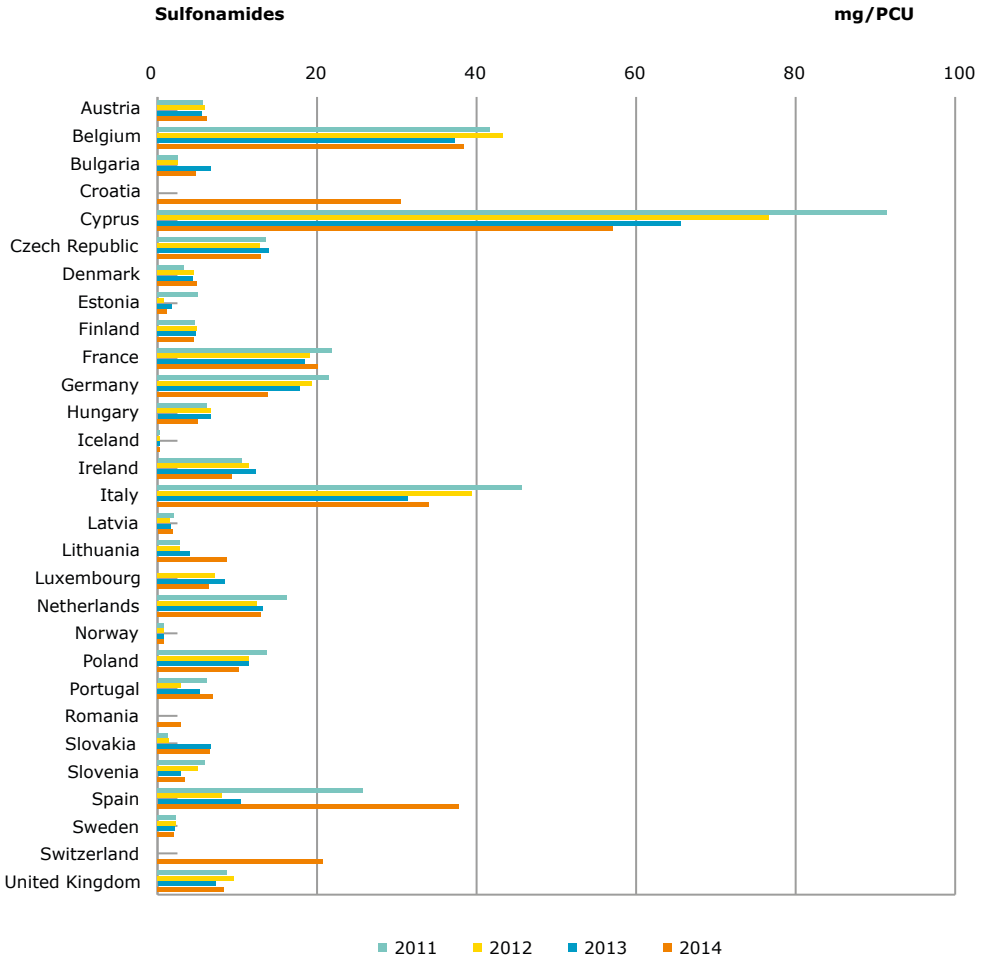


Figure 60. Sales of sulfonamides for food-producing species, in mg/PCU, by 29 European countries, from 2011 to 2014[1]



[1] Negligible sales in Iceland: < 1mg/PCU; see chapter 2.8.2.

Figure 61. Sales of 3rd- and 4th-generation cephalosporins for food-producing species, in mg/PCU, by 29 European countries, from 2011 to 2014

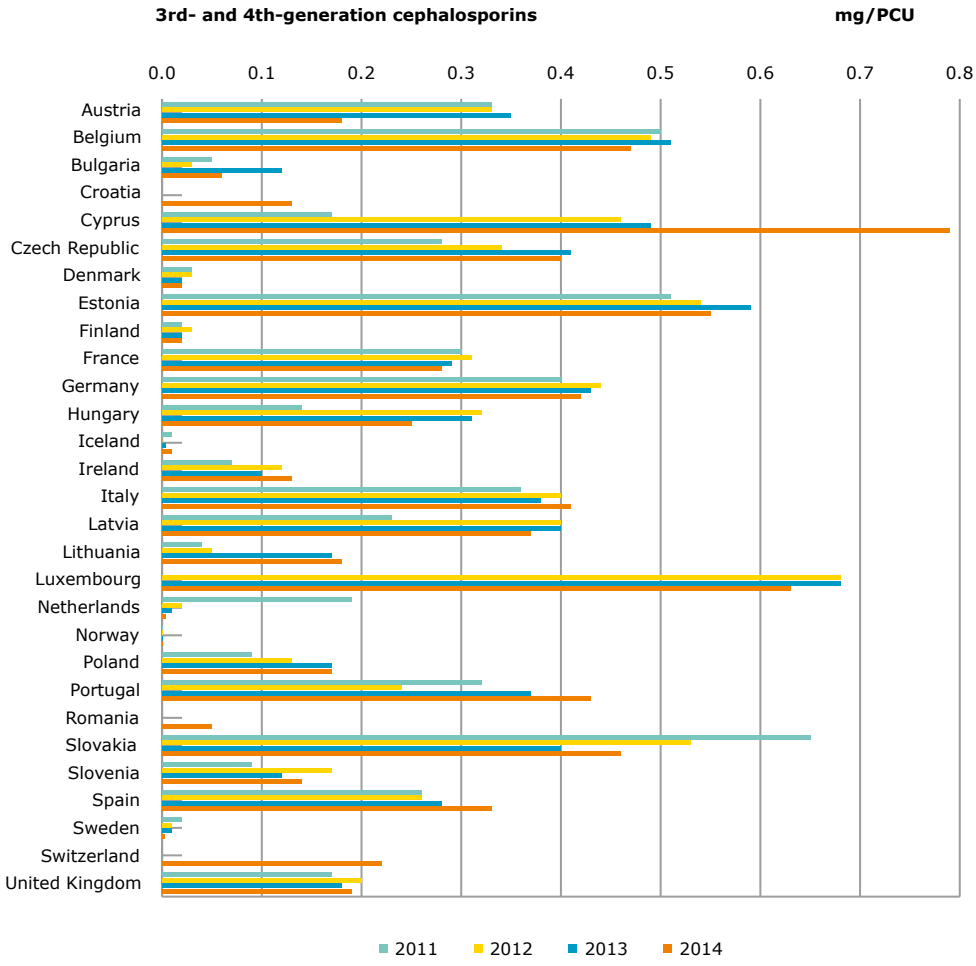
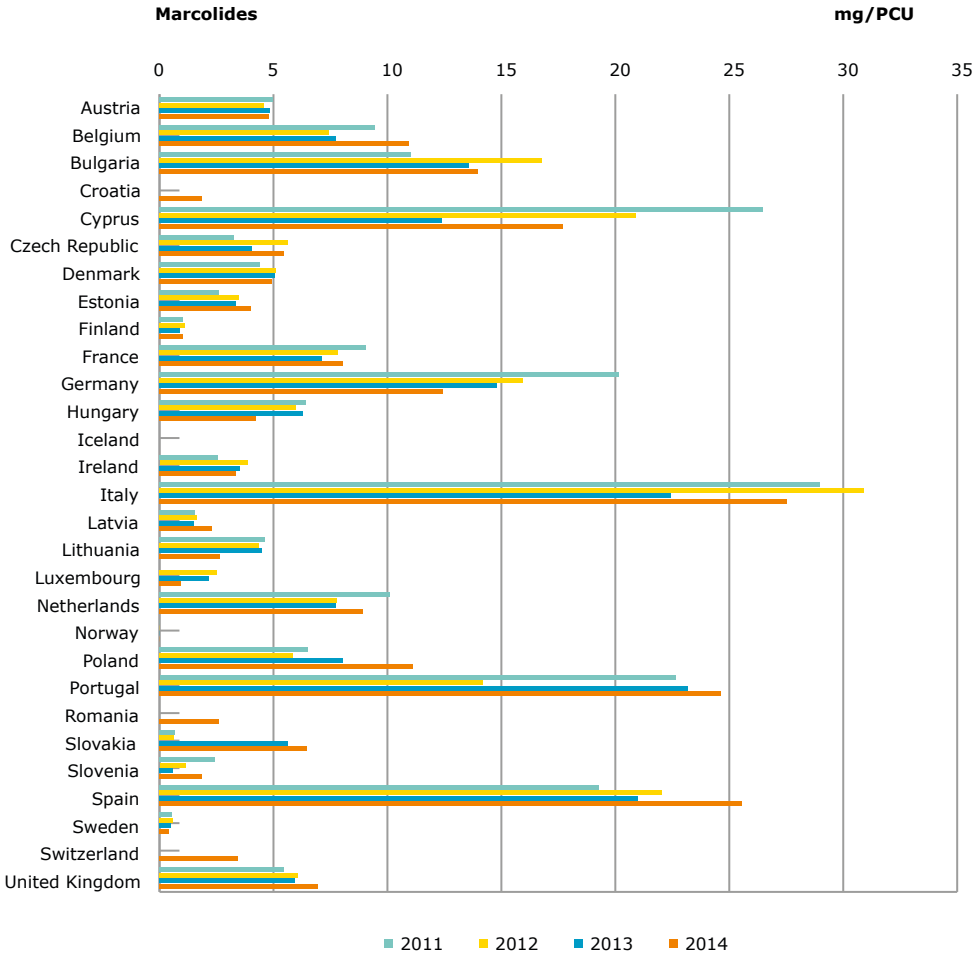
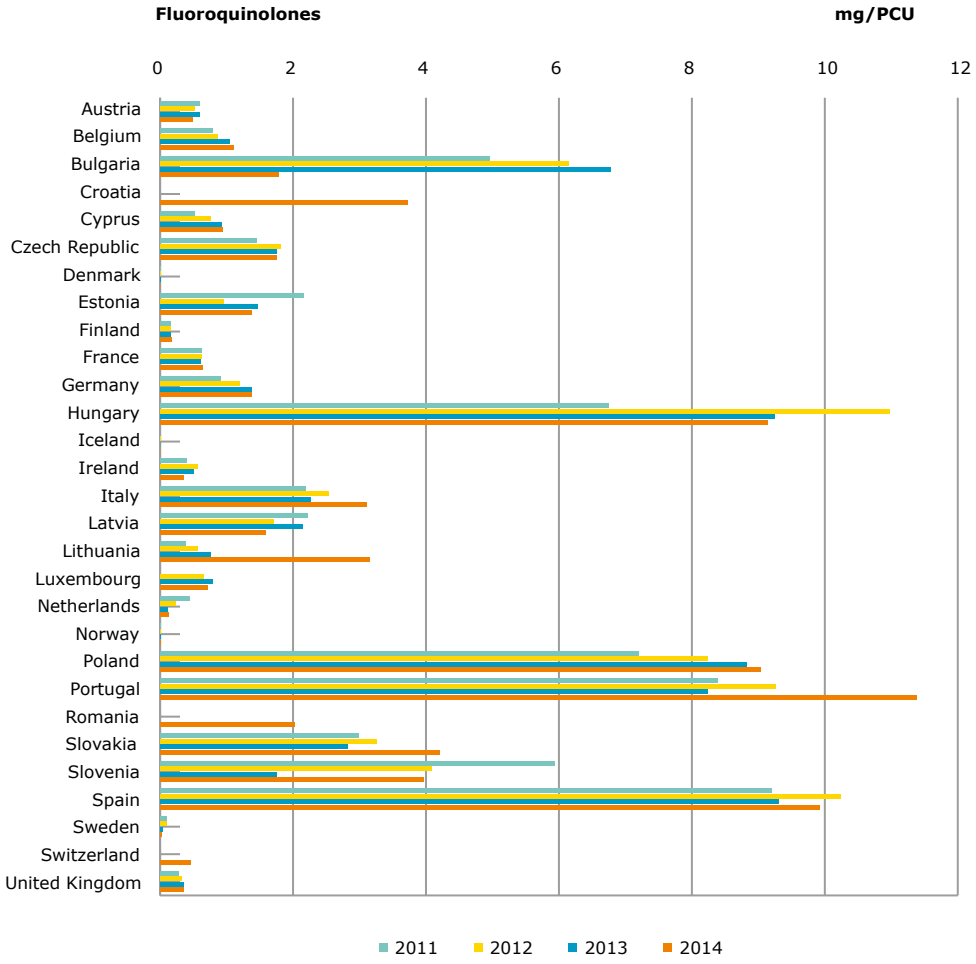


Figure 62. Sales of macrolides for food-producing species, in mg/PCU, by 29 European countries, from 2011 to 2014[1]



[1] No sales in Iceland; negligible sales in Norway; see chapter 2.8.2.

Figure 63. Sales of fluoroquinolones for food-producing species, in mg/PCU, by 29 European countries, from 2011 to 2014[1]

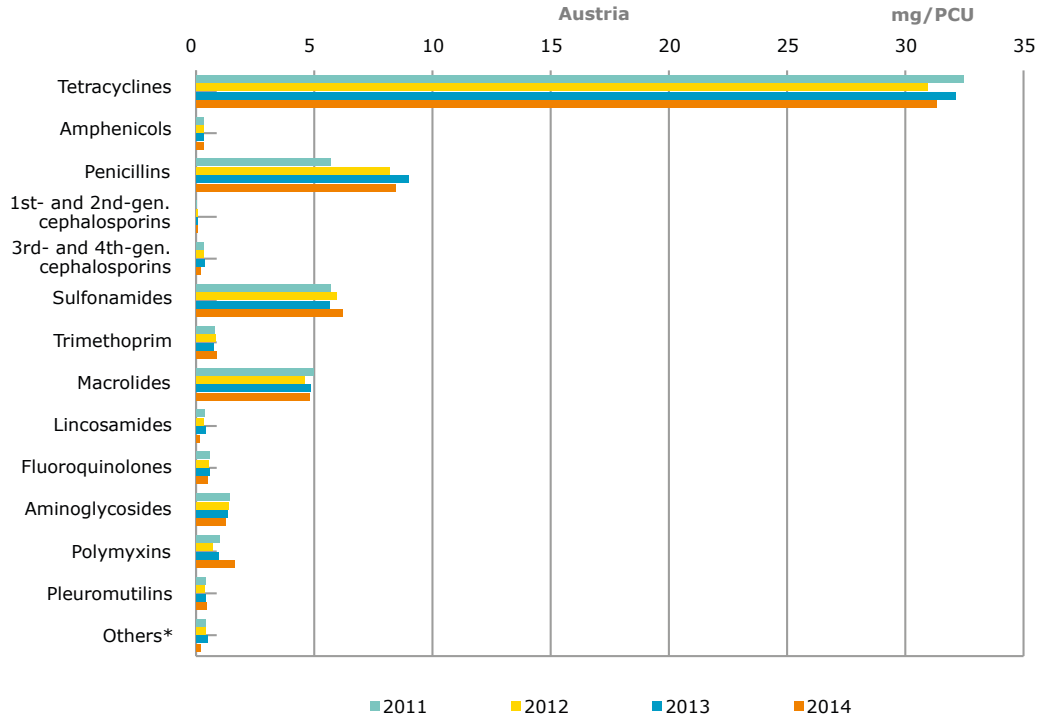


[1] Negligible sales in Denmark, Iceland, Norway and Sweden; see chapter 2.8.2.

2.8.2. Changes by country

Austria

Figure 64. Sales (mg/PCU) by antimicrobial class in Austria, from 2011 to 2014[1]

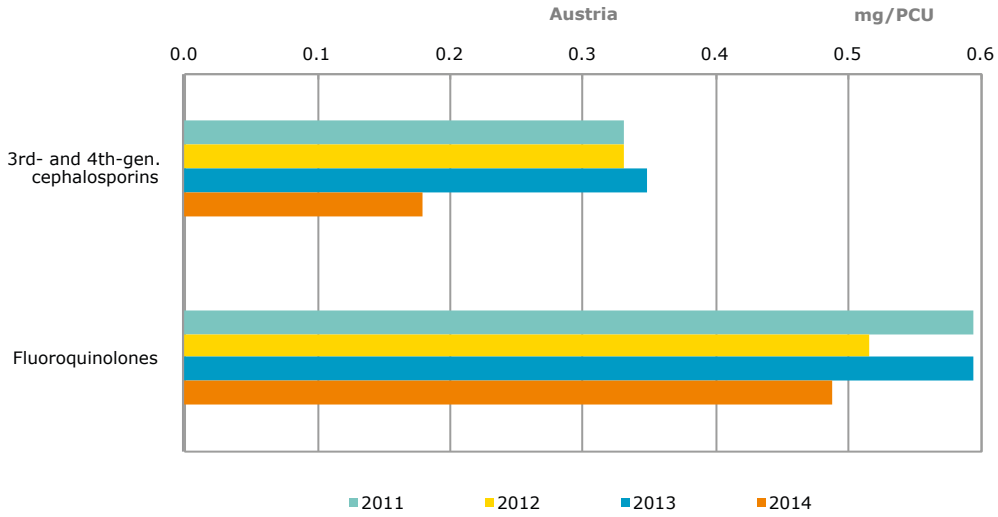


* Other antimicrobials (classified as such in the ATCvet system).

[1] No sales of other quinolones during any of the years.

Overall, a minor increase of 3% was observed in the total annual sales, in mg/PCU, between 2011 and 2014. The sales were dominated by tetracyclines and were stable across this period; the proportion of the total sales accounted for by this class was 56% in 2014. The proportion accounted for by penicillins increased from 10% to 15% during the period 2011 to 2014.

Figure 65. Sales (mg/PCU) of 3rd- and 4th-generation cephalosporins and fluoroquinolones in Austria, from 2011 to 2014

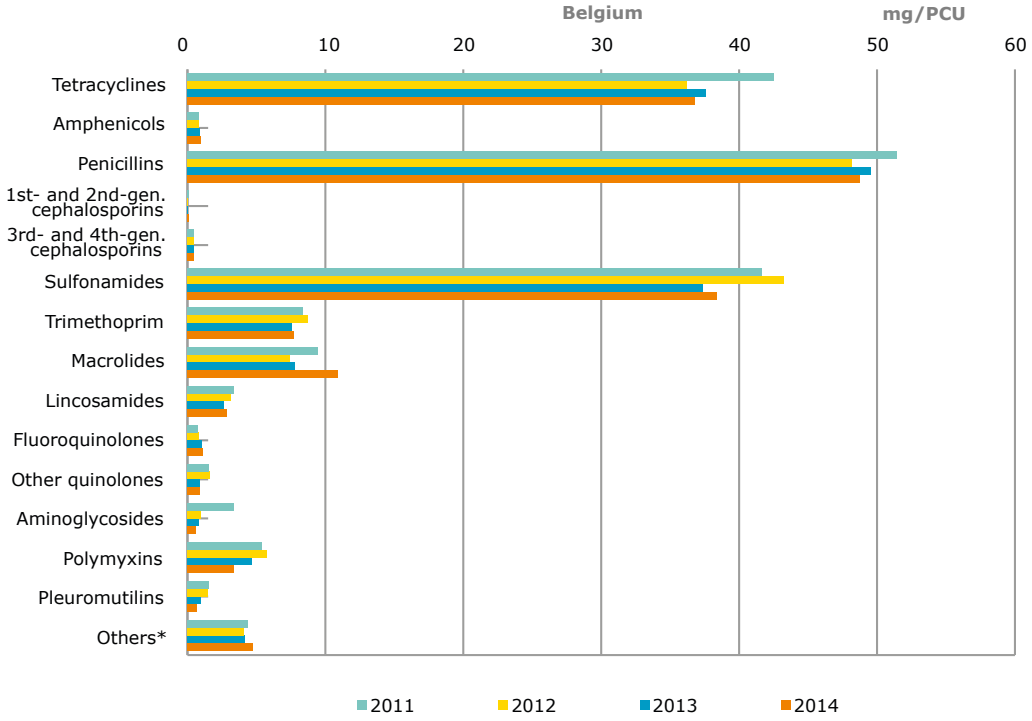


A drop in the sales (mg/PCU) of 3rd- and 4th-generation cephalosporins can be seen. Also, the proportion accounted for by this subclass decreased from 0.6 % of the total sales in 2011 to 0.3 % in 2014. In the same year, the sales of 3rd- and 4th-generation cephalosporins were 0.18 mg/PCU, and average sales across 25 countries were 0.26 mg/PCU (Figure 56).

Sales of fluoroquinolones also fell, although fluctuations were observed during the four-year period; this class accounted for 1.1 % in 2011 and 0.9 % in 2014. In 2014, the sales of fluoroquinolones in Austria were 0.49 mg/PCU, and the average sales for 25 countries were 2.99 mg/PCU (Figure 56).

Belgium

Figure 66. Sales (mg/PCU) by antimicrobial class in Belgium, from 2011 to 2014



* Other antimicrobials (classified as such in the ATCvet system).

From 2011 to 2014, a 10 % decrease in sales (mg/PCU) of veterinary antimicrobial agents was observed in Belgium. There were limited changes in the PCU over these years, so the reduction mainly reflects a fall in the amount of ingredients sold. However, the sales patterns were relatively stable; a minor increase was observed in the proportion accounted for by macrolides, rising from 5 % (9 mg/PCU) to 7 % (11 mg/PCU) from 2011 to 2014.

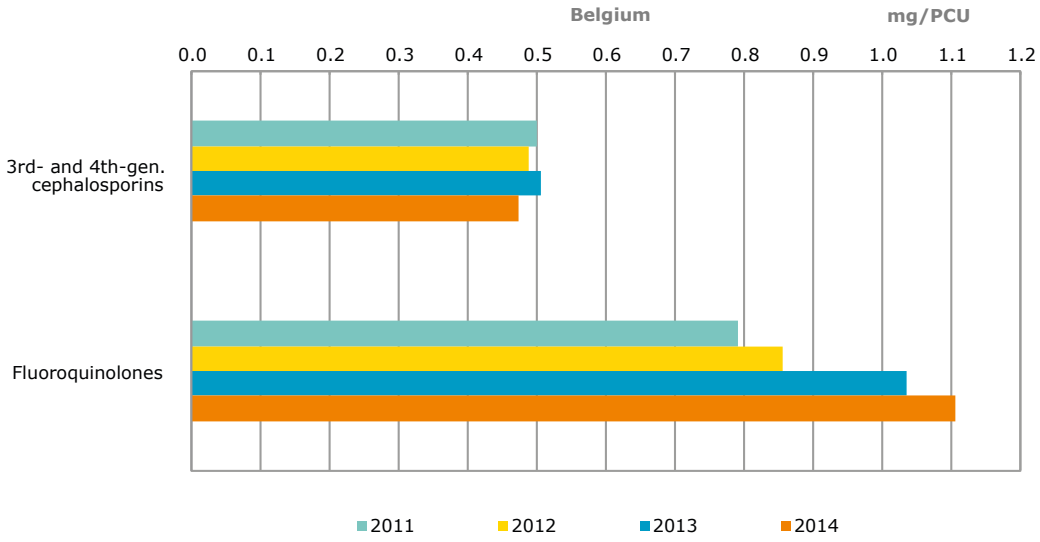
Since September 2013, the use of zinc oxide (ZnO) in therapeutic doses in piglets, administered for two weeks after weaning, is permitted in Belgium. ZnO is the main alternative to colistin used in weaned piglets. In 2014, the use of ZnO increased substantially to 81.964 kg, which corresponds to an estimated treatment of approximately 7 million raised piglets. This was accompanied by a substantial drop (-43.1 %) in the use of polymyxins (almost entirely colistin) from 5.8 mg/PCU in 2012 (when ZnO was not available) to 3.3 mg/PCU in 2014.

Since January 2012, extensive prudent-use campaigns have been set up in Belgium by the AMCRA (Centre of Expertise on Antimicrobial Consumption and Resistance in Animals http://www.amcra.be/en/about-amcra) in the domain of food-producing species such as companion animals and horses.

AMCRA – which comprises various stakeholders such as farmers' organisations, feed manufacturers, the pharmaceutical industry, veterinarians and veterinary associations – became the most important source of recommendations for promoting responsible use to minimise the emergence of resistance. Specific formularies have been developed in which antimicrobial agents are categorised from first to third choice according to species and pathogen and based on pharmacological characteristics and appropriateness of use. Formularies have been published for pigs, poultry, bovines, companion animals and horses, and are adhered to on a voluntary basis (http://www.amcra.be/nl/formularia/formularia).

Awareness campaigns on antibiotic use and resistance are based primarily on the national monitoring programme 'BelVet-SAC' for which the Federal Agency for Medicines and Health Products (FAMHP) collaborates with the Faculty of Veterinary Medicine at Ghent University to collect and analyse data (http://www.fagg-afmps.be/nl/DIERGENEESKUNDIG_gebruik/geneesmiddelen/geneesmiddelen/goed gebruik/Antibiotica). Despite continuous efforts of concerned parties, providing information and rising awareness, the decrease of antimicrobial consumption in 2014 was unsatisfactory. This unfavourable outcome must motivate to maintain sensitisation efforts and also to define more stringent legal measures, e.g. manage centralised data collection system, restrict use of critical important antibiotics, to force stakeholders towards more prudent use of antimicrobials.

Figure 67. Sales (mg/PCU) of 3rd- and 4th-generation cephalosporins and fluoroquinolones in Belgium, from 2011 to 2014

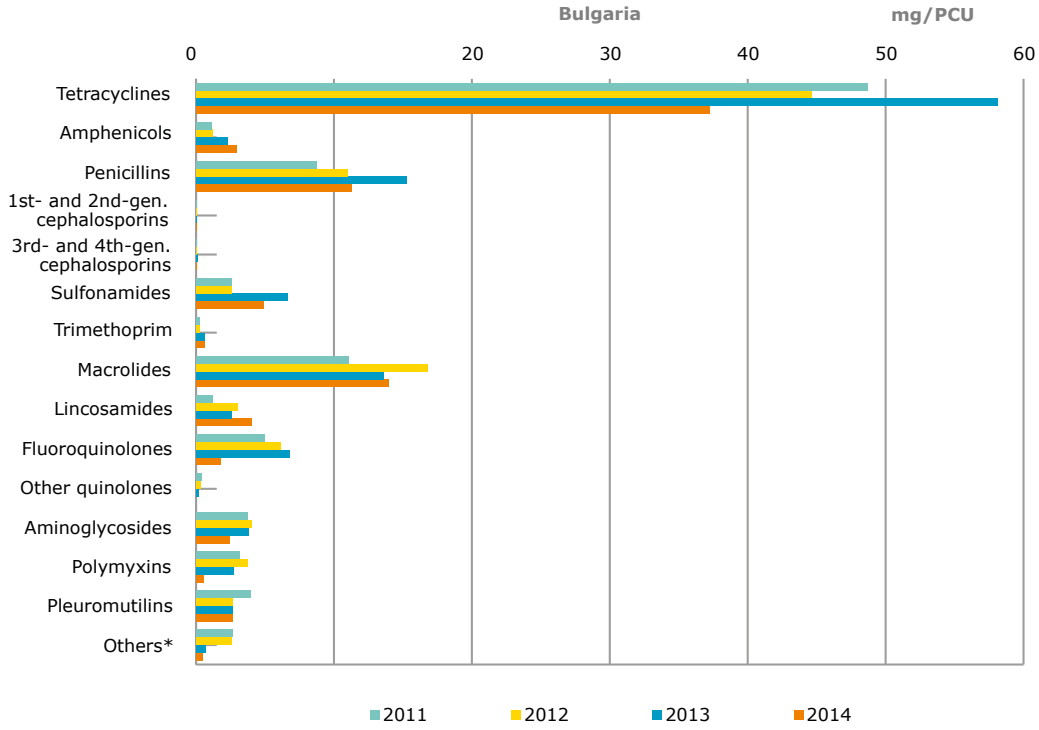


The proportion of sales (mg/PCU) accounted for by 3rd- and 4th-generation cephalosporins was relatively stable across the years from 2011 to 2014, representing 0.3% of total sales. The proportion of the fluoroquinolones increased from 0.5% to 0.7% (Figure 67, Figure 63).

In 2014, sales of 3rd- and 4th-generation cephalosporins were 0.47 mg/PCU; average sales for 25 countries were 0.26 mg/PCU that year. The sales of fluoroquinolones were 1.11 mg/PCU; average sales of fluoroquinolones for 25 countries were 2.99 mg/PCU that year (Figure 56).

Bulgaria

Figure 68. Sales (mg/PCU) by antimicrobial class in Bulgaria, from 2011 to 2014

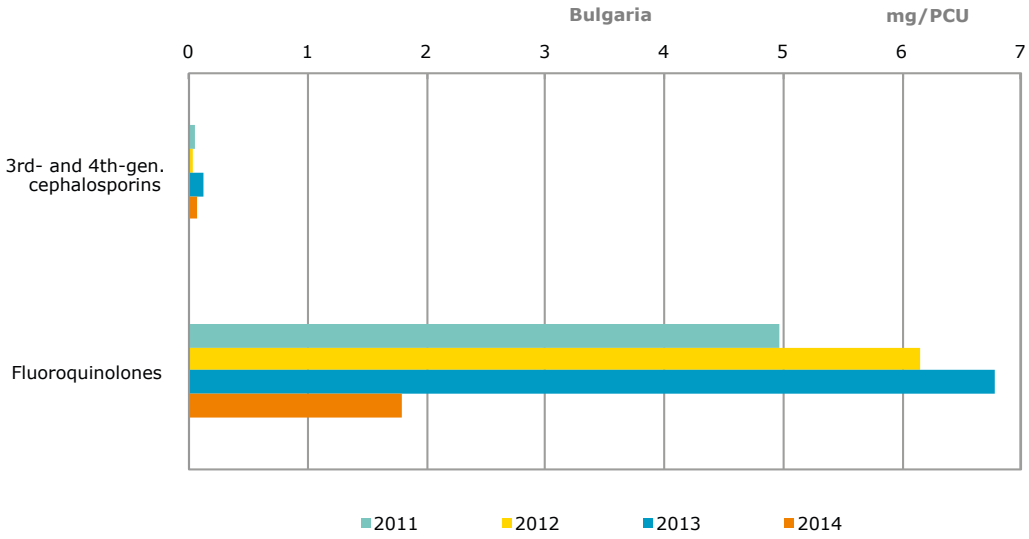


* Other antimicrobials (classified as such in the ATCvet system).

In Bulgaria, only 24 of the 36 wholesalers delivered data for 2011 and 2012 thus sales data for veterinary antimicrobial agents for these years are underestimated. For 2014, 31 wholesalers reported data, and two failed to report any data. No conclusion can be drawn as to whether there was an increase or decrease in the sales (mg/PCU) of veterinary antimicrobial agents or whether or not there was any change in the sales patterns for 2013 and 2014 compared to the previous two years (2011 and 2012).

Tetracyclines, macrolides and penicillins were the most-sold classes between 2011 and 2014.

Figure 69. Sales (mg/PCU) of 3rd- and 4th-generation cephalosporins and fluoroquinolones in Bulgaria, from 2011 to 2014



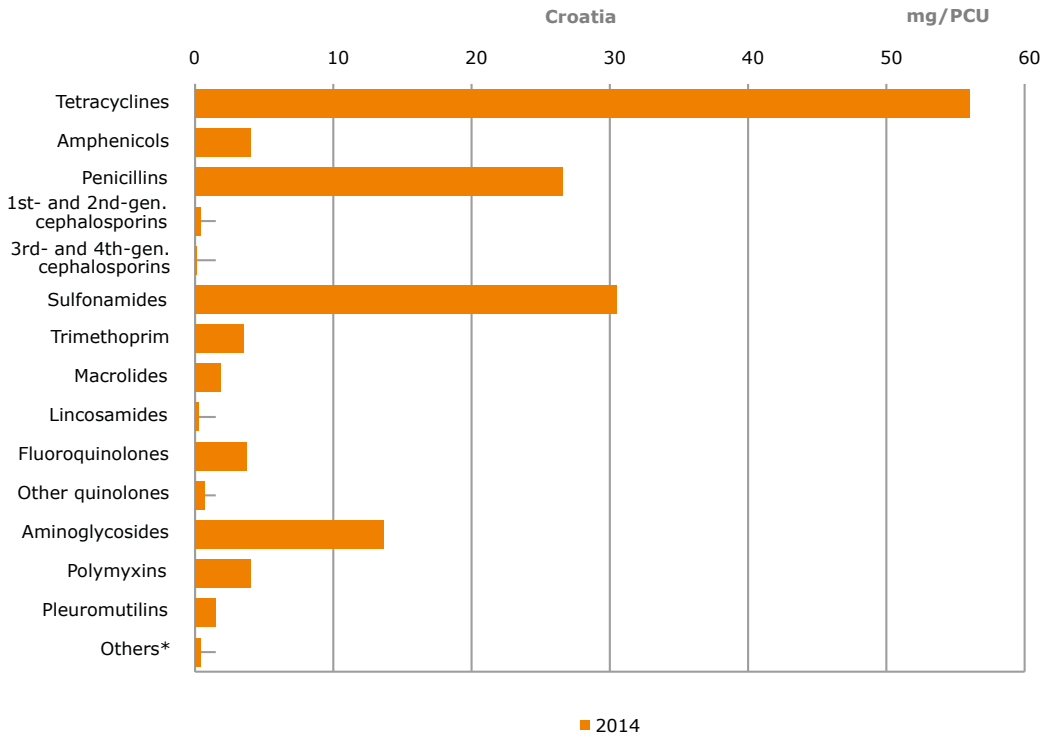
Although underestimated for 2011 and 2012, the observed sales of 3rd- and 4th-generation cephalosporins were low in Bulgaria. In 2014, the sales of 3rd- and 4th-generation cephalosporins were 0.06 mg/PCU, while the average sales for 25 countries was 0.26 mg/PCU (Figure 56).

In 2013, when all the wholesalers reported data, the sales of fluoroquinolones were 6.78 mg/PCU, while in 2014, when two of the 33 wholesalers failed to report data, the corresponding figure was 1.79 mg/PCU. Despite the existing market changes, the reduction in sales of fluoroquinolones could be explained by the under-reporting of sales data. In 2014, the average sales for 25 countries were 2.99 mg/PCU (Figure 56).

For the reasons explained above, conclusions cannot be drawn as to whether or not there was an increase in the sales of 3rd- and 4th-generation cephalosporins or fluoroquinolones from 2011 to 2013. In 2014, the number of wholesalers failing to report data was only two out of 33 (i.e. higher coverage than in 2011 and 2012) which could indicate a reduction in sales of fluoroquinolones from 2013 to 2014.

Croatia

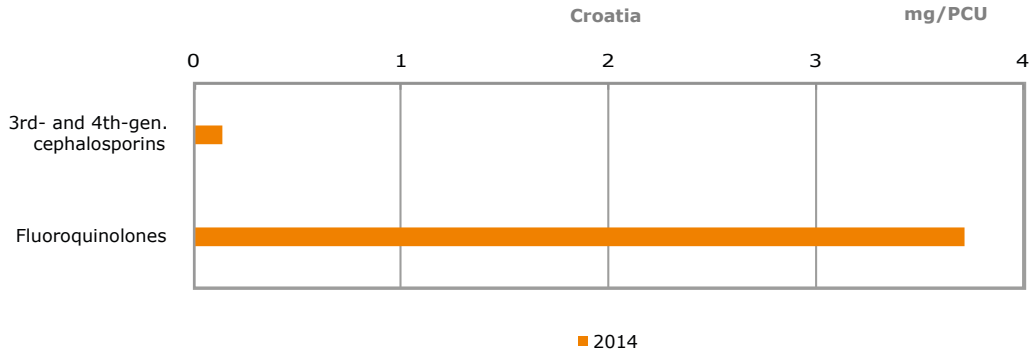
Figure 70. Sales (mg/PCU) by antimicrobial class in Croatia, in 2014



* Other antimicrobials (classified as such in the ATCvet system).

In 2014, tetracyclines, sulfonamides and penicillins were the most-sold classes accounting for 38 %, 21 % and 18 %, respectively, of the total sales of antimicrobials (mg/PCU) for food-producing species, including horses.

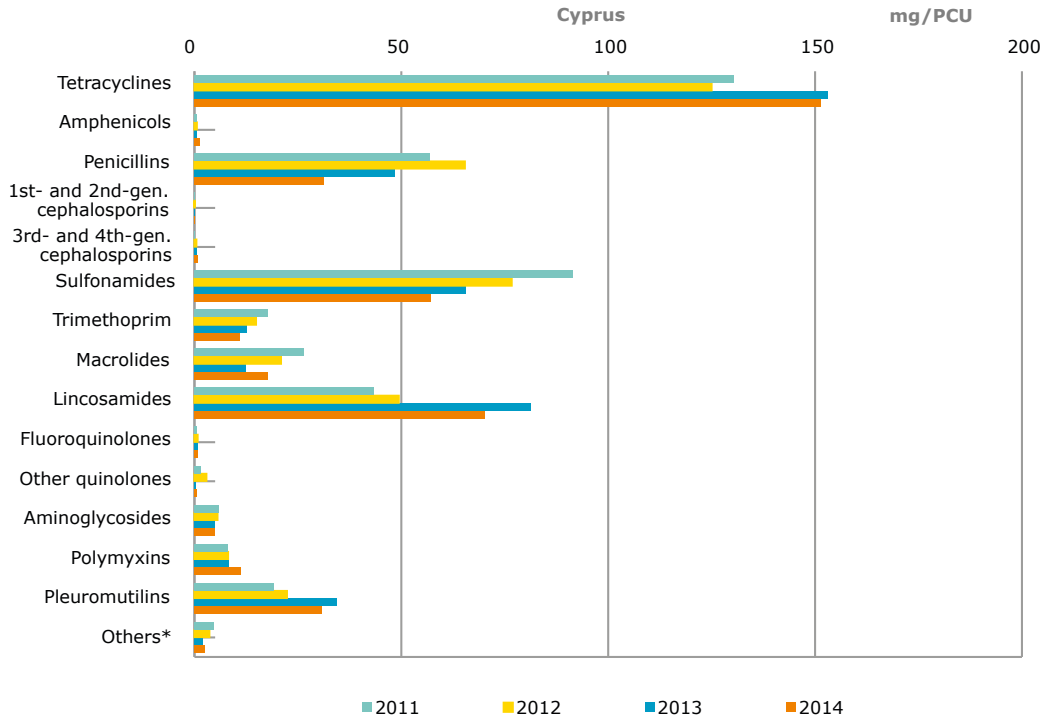
Figure 71. Sales (mg/PCU) of 3rd- and 4th-generation cephalosporins and fluoroquinolones in Croatia, in 2014



In Croatia, the sales (mg/PCU) of 3rd- and 4th-generation cephalosporins and fluoroquinolones represented 0.1% and 2.5%, respectively, of total sales in 2014. In the same year, sales of 3rd- and 4th-generation cephalosporins were 0.13 mg/PCU; the average sales for 25 countries were 0.26 mg/PCU (Figure 56). Sales of fluoroquinolones were 3.72 mg/PCU; the average sales for 25 countries were 2.99 mg/PCU (Figure 56).

Cyprus

Figure 72. Sales (mg/PCU) by antimicrobial class in Cyprus, from 2011 to 2014



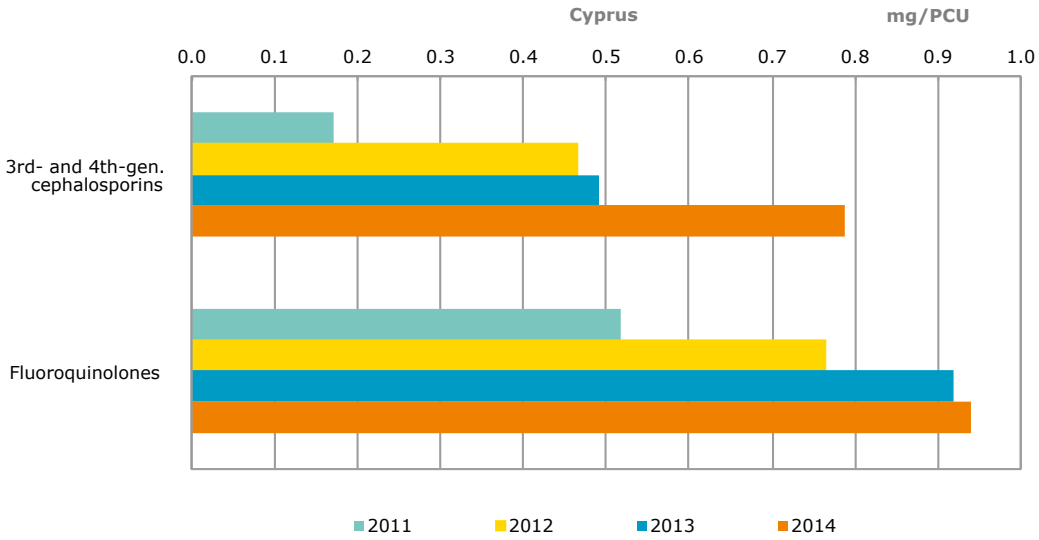
* Other antimicrobials (classified as such in the ATCvet system).

The annual sales, in mg/PCU, of veterinary antimicrobials in Cyprus fluctuated during the period 2011 to 2014, with a fall of 4 % being observed. It should be noted that in contrast to the 2011 data, the 2012, 2013 and 2014 antimicrobial products used on special licence were also included in the dataset. Thus, the sales for 2011 may have been slightly underestimated. Notably, PCU data for fish were only available for 2011, accounting for 5 % of the PCU. Providing that the production of farmed fish was at the same level in 2014 as for 2011, it would have added approximately 5 % to the denominator and thus there would have been a higher reduction in sales from 2011 to 2014. Furthermore, the proportion of goats in Cyprus is relatively high compared to other countries participating in ESVAC. This has a significant effect on the magnitude of PCU for Cyprus since living goats are not included in the PCU calculation for the ESVAC. Based on the national statistics for the number of goats in Cyprus and an average treatment weight of about 45 kg, the living goat PCU would have added 11.4 thousand tonnes to the PCU. If goats had been included in the PCU, the total annual sales, in mg/PCU, would have been approximately 8 %-9 % lower.

The prescribing patterns have changed considerably from 2011 to 2014; in particular, sales of penicillins and sulfonamides has decreased while a substantial increase is observed for tetracyclines (Figure 72). Sales of lincosamides also increased during this period, although a decline can be seen from 2013 to 2014.

In order to lower the sales of antimicrobial agents in Cyprus, the VMPs section of the veterinary services is: (a) gradually updating the labelling of the newer antimicrobial classes to include the so-called 'responsible use' warnings, in line with EU risk-management decisions; (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 as well as continuing to raise awareness of antimicrobial resistance among veterinarians so that they have the right information to make responsible decisions when prescribing antimicrobial agents.

Figure 73. Sales (mg/PCU) of 3rd- and 4th-generation cephalosporins and fluoroquinolones in Cyprus, from 2011 to 2014



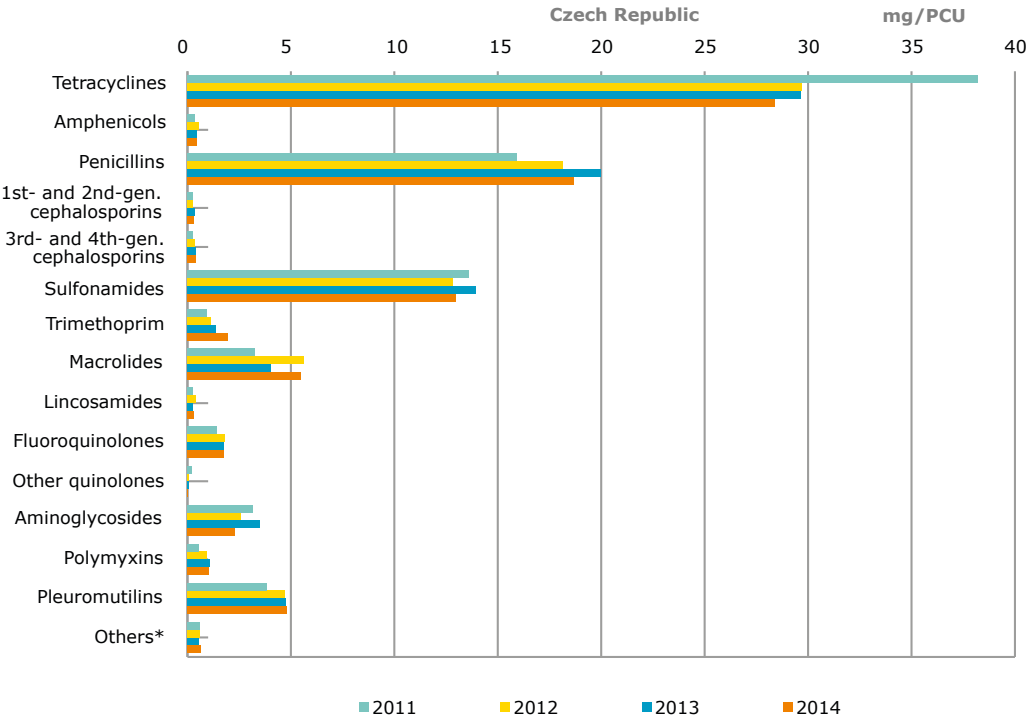
Sales (mg/PCU) of both 3rd- and 4th-generation cephalosporins and fluoroquinolones increased from 2011 to 2014.

In 2011, the 3rd- and 4th-generation cephalosporins accounted for 0.04% of total sales; in 2014, this figure was 0.2%. In the same year (2014), sales of 3rd- and 4th-generation cephalosporins were 0.79 mg/PCU, while the average sales for 25 countries were 0.26 mg/PCU (Figure 56).

For fluoroquinolones, the sales accounted for 0.13% and 0.24% of total sales in 2011 and 2014, respectively. In 2014, sales of fluoroquinolones were 0.94 mg/PCU, while the average sales for 25 countries were 2.99 mg/PCU (Figure 56).

Czech Republic

Figure 74. Sales (mg/PCU) by antimicrobial class in the Czech Republic, from 2011 to 2014



* Other antimicrobials (classified as such in the ATCvet system).

From 2011 to 2014, total sales (mg/PCU) fell by 4 % in the Czech Republic: sales were 15 % lower in 2014 compared to 2010. Notably, for 2011 and 2012, the strength for the major part of the antimicrobials VMP were provided as the base. To ensure complete harmonisation with the data from the other countries participating in the ESVAC, which typically provide the strength as it appears in the label of the VMP, the strengths for the VMP presentations for the Czech Republic was changed to that appearing in the label for 2013 and 2014 data. Thus, an increase of 6.5 % was observed for the total volume measured in tonnes in 2013, compared to 2012 data — this figure is considered to be artificial. If 2013 data had been reported as the base, sales would have been approximately 2 % higher (in total tonnes) compared to that in 2012 (calculated as the base).

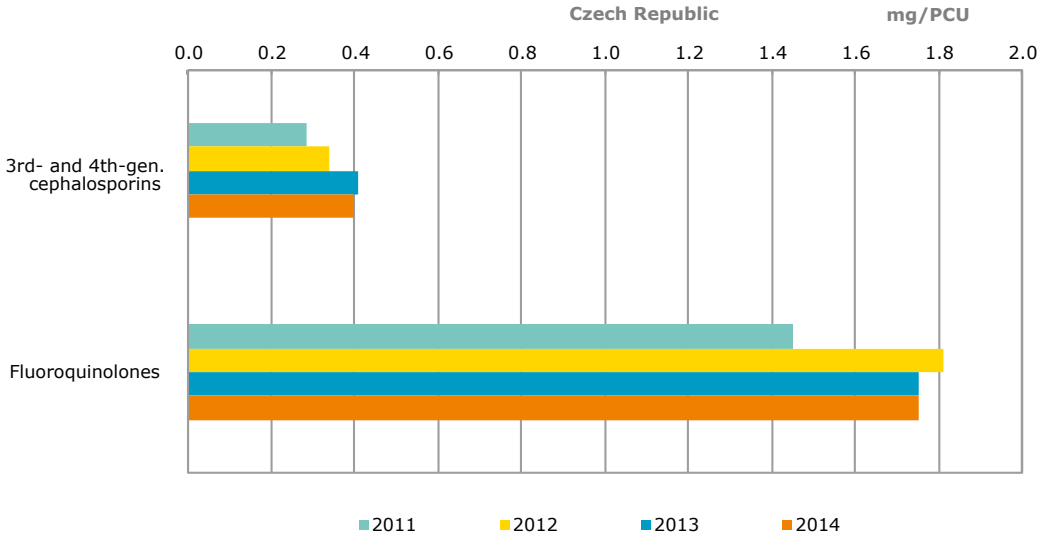
During 2011 to 2014, the largest decreases (in mg/PCU) were observed for tetracyclines — the most-sold class; however, for 2012 to 2013, the fall in sales for tetracyclines stagnated. For penicillins, the second most-sold class, an increase in sales was observed (compared to 2011). The sales of sulfonamides and macrolides fluctuated.

Further analysis of the datasets showed some remarkable changes in sales which indicate that more in-depth analyses are needed to identify the real changes in sales patterns. Selected aspects connected with certain trends in the use of antimicrobials should also be mentioned — for example, there is a close link with the stratification of the animal population, and a decrease in sales and the consumption of premixes (which also continued in 2014), closely reflecting the status of the pig population and certain measures (e.g. continuing repopulation, introduction of the new farming technologies) in the pig-farming sector. The poultry farming sector, despite an improvement in biosecurity measures

and fall in fluoroquinolone consumption (2012–2013), is continuing to work on improving the quality of one-day-old chicks, including imported animals, which is slowing down the decrease in fluoroquinolones (e.g. use of enrofloxacin), when comparing the data from 2013–2014. In some pharmaceutical forms, trends in sales can be more clearly linked to measures such as intramammary VMPs used in mastitis in cattle and a stepwise decline in consumption influenced, for example, by the introduction of 'in-house' ready-to-use tests and a growing number of farms using them, better husbandry hygiene measures and an improved feed balance.

The working group on antimicrobials set up by the Ministry of Agriculture in 2013 sets the priorities that could help to reduce the need to use antimicrobials and should finally result in lower consumption.

Figure 75. Sales (mg/PCU) of 3rd- and 4th-generation cephalosporins and fluoroquinolones in the Czech Republic, from 2011 to 2014

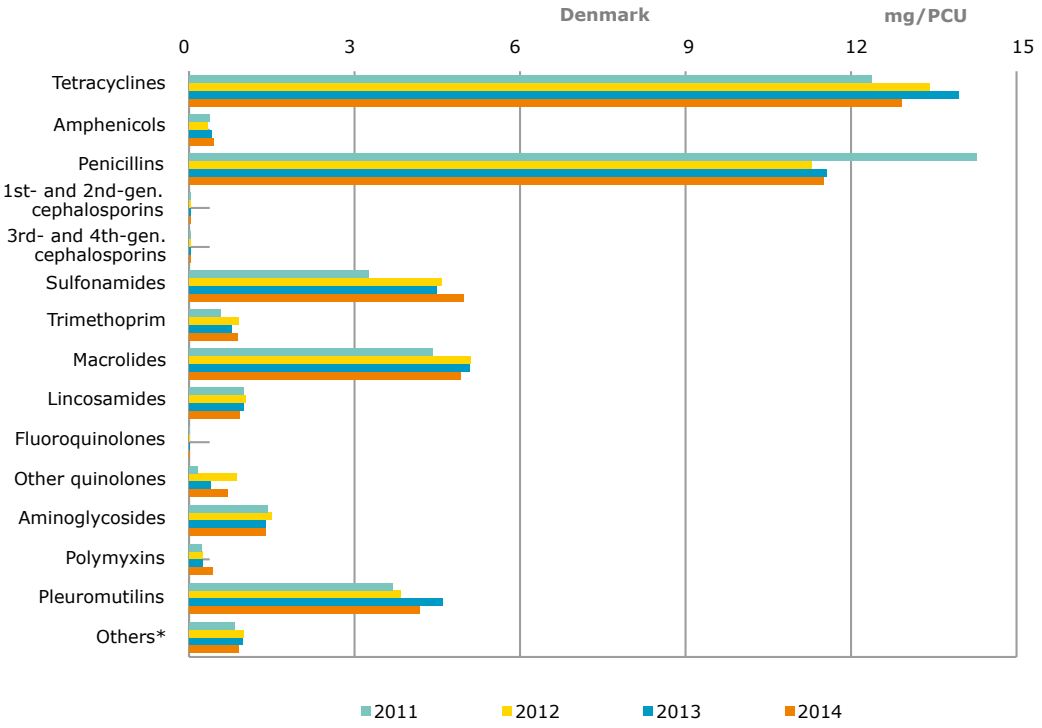


The sales (mg/PCU) of 3rd- and 4th-generation cephalosporins increased slightly during the period, accounting for 0.3% of total sales in 2011and rising to 0.5% in 2014. In 2014, sales of 3rd- and 4th-generation cephalosporins were 0.40 mg/PCU, while the average sales for 25 countries were 0.26 mg/PCU (Figure 56).

The sales (mg/PCU) of fluoroquinolone VMP increased slightly over the period, accounting for 1.7% of total sales in 2011; in 2014, the figure was 2.2%. Also in 2014, sales of fluoroquinolones were 1.75 mg/PCU, while the average sales for 25 countries were 2.99 mg/PCU (Figure 56).

Denmark

Figure 76. Sales (mg/PCU) by antimicrobial class in Denmark, from 2011 to 2014



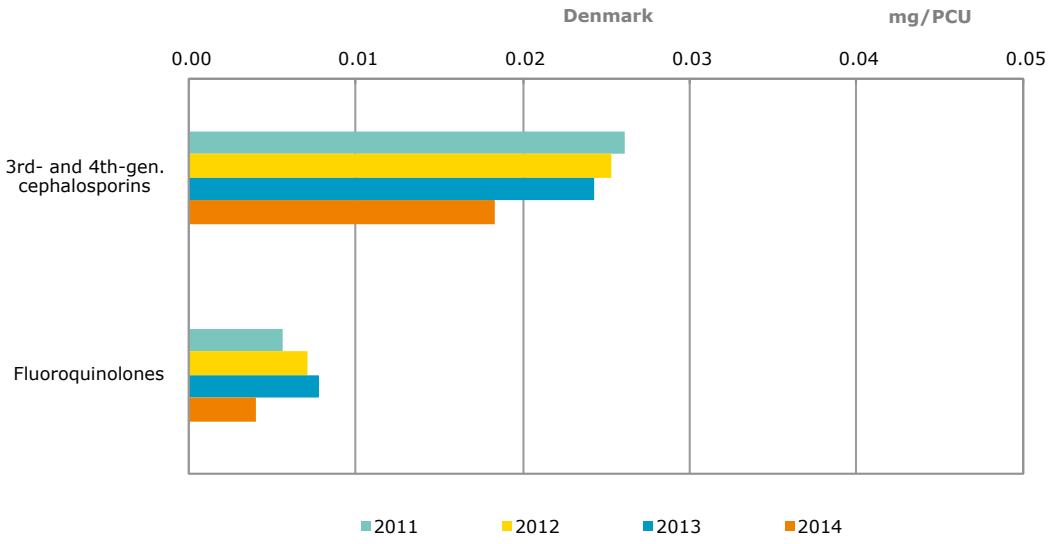
* Other antimicrobials (classified as such in the ATCvet system).

From 2011 to 2014, the overall sales (mg/PCU) of veterinary antimicrobial agents fell by 4 %; sales in 2014 were 6 % lower than in 2010. This is mainly due to new regulations directed towards the 5–10 % of pig producers using most of the antimicrobial agents.

The most-sold classes of antimicrobial VMPs in Denmark were tetracyclines and penicillins; in 2014, these classes accounted for 29 % and 26 %, respectively, of total sales.

The sales of macrolides accounted for approximately 11 % of total sales in 2014. From 2011 to 2014, the consumption of macrolides in food-producing animals increased by 11 %. Approximately 90 % of the macrolides (mostly tylosin) were used in pigs, but there are no obvious explanations for the increase in the consumption of macrolides.

Figure 77. Sales (mg/PCU) of 3rd- and 4th-generation cephalosporins and fluoroquinolones in Denmark, from 2011 to 2014

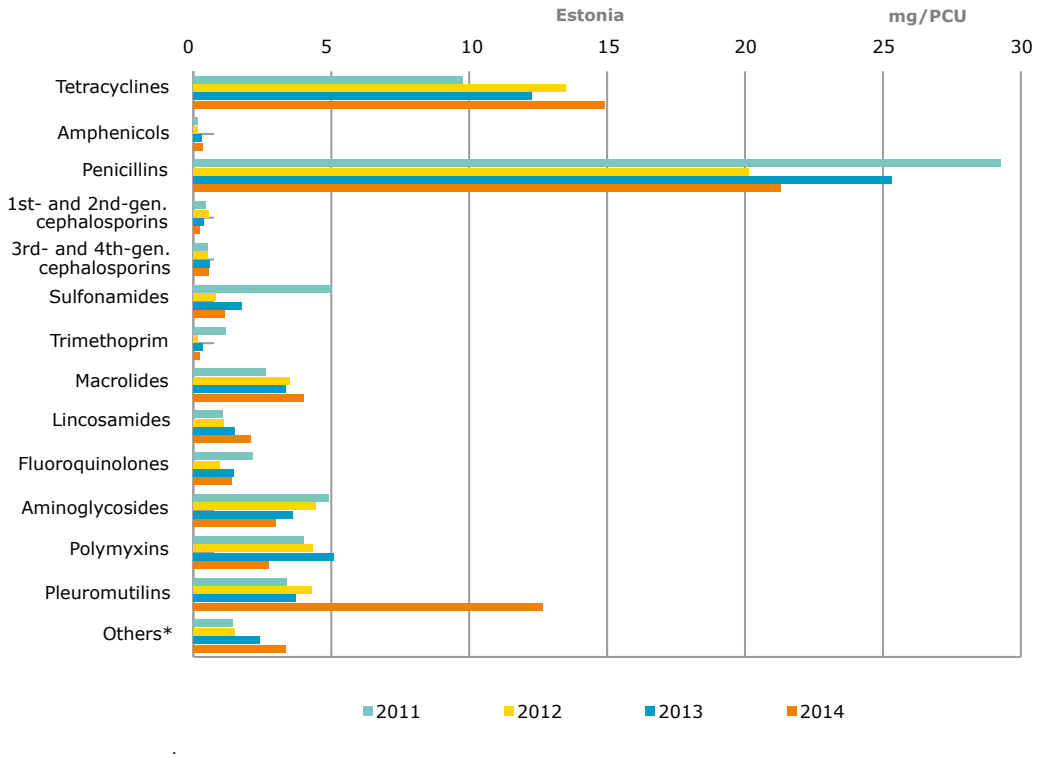


In 2011, the 3rd- and 4th-generation cephalosporins accounted for 0.06 % of total sales; in 2014, this figure was 0.04 %, which is relatively low. In 2014, sales of 3rd- and 4th-generation cephalosporins were 0.02 mg/PCU, while the average sales for 25 countries were 0.26 mg/PCU (Figure 56). From 2011 to 2014, the total sales of 3rd- and 4th-generations fell by 30 %; compared to 2010, the decrease is 66 %, which is mainly due to a voluntary agreement with the industry.

Sales (mg/PCU) of fluoroquinolones for food-producing animals are generally low in Denmark, accounting for just 0.01 % of total sales in 2014. In 2014, sales of fluoroquinolones were 0.004 mg/PCU, while the average sales for 25 countries were 2.99 mg/PCU (Figure 56). From 2011 to 2014, the total sales of fluoroquinolones fell by 72 %. The reason for these rather low figures is the strictly regulated use in production animals.

Estonia

Figure 78. Sales (mg/PCU) by antimicrobial class in Estonia, from 2011 to 2014



* Other antimicrobials (classified as such in the ATCvet system)

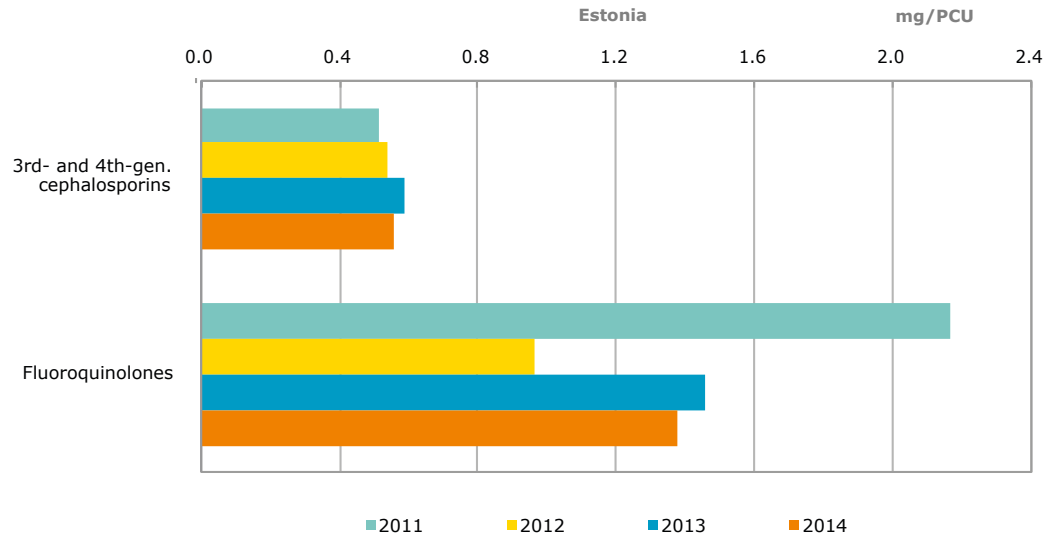
The sales of veterinary antimicrobial agents (mg/PCU) in Estonia fluctuated slightly during the period 2011 to 2014; an increase of 3 % from 2011 to 2014 which is the same as the change from 2010 to 2014.

As is apparent in Figure 78, the sales patterns changed during the period. Penicillins and tetracyclines were the most-sold classes. The proportion accounted for by penicillins decreased from 44 % to 31 % of total sales from 2011 to 2014; a corresponding increase, from 15 % to 22 %, was observed for tetracyclines. The fall in sales of sulfonamides combined with trimethoprim may be related to an increase in sales of tetracyclines during this period — which are all authorised products — while sulfonamides and trimethoprim combination products for oral use are not, so special permission is required for their use.

The sales of pleuromutilins (mg/PCU) almost doubled during the study period. The observed increase in sales of pleuromutilins in 2014 compared to previous years is explained by extensive outbreaks of swine dysentery and higher morbidity of unknown aetiology in many large pig farms in Estonia during that year. Notably, since the second quarter of 2015, sales of tiamulin have been at the same level as for 2012 and 2013.

As Estonia is a small country, changes in the treatment strategy on one or two major farms or outbreaks such as that described above may significantly influence the sales patterns.

Figure 79. Sales (mg/PCU) of 3rd- and 4th-generation cephalosporins and fluoroquinolones in Estonia, from 2011 to 2014

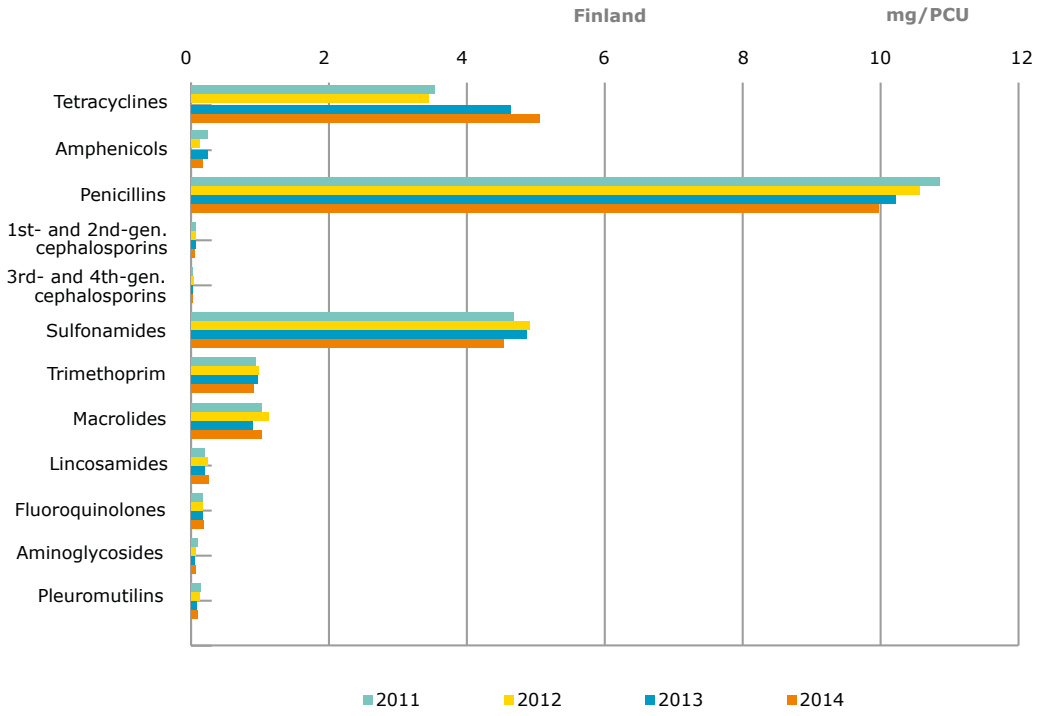


From 2011 to 2014, overall sales (mg/PCU) of 3rd- and 4th-generation cephalosporins were relatively stable. In both 2011 and 2014, the 3rd- and 4th-generation cephalosporins accounted for 0.8 % of total sales. In 2014, sales of 3rd- and 4th-generation cephalosporins were 0.55 mg/PCU, while the average sales for 25 countries were 0.26 mg/PCU (Figure 56).

The sales of fluoroquinolones decreased between 2011 and 2014; however, fluctuations in the sales are observed. In 2011 the fluoroquinolones accounted for 3.3 % of the total sales; in 2014 this figure was 2.0 %. In 2014, sales of fluoroquinolones were 1.38 mg/PCU; the average sales for 25 countries were 2.99 mg/PCU that year (Figure 56).

Finland

Figure 80. Sales (mg/PCU) by antimicrobial class in Finland, from 2011 to 2014[1,2]



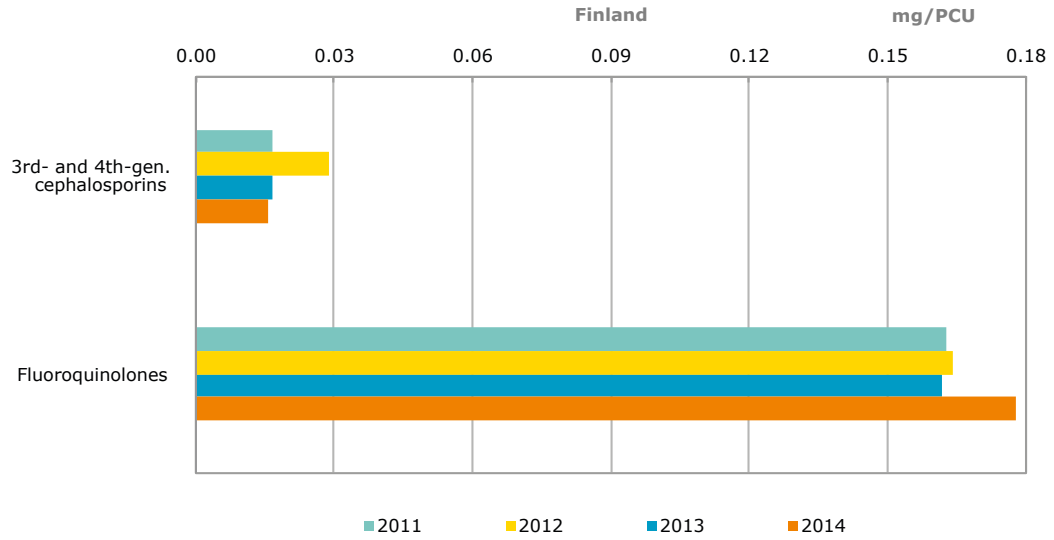
[1] No sales of other quinolones and polymyxins in any of the years.
[2] Penicillins: minor deviations in mg/PCU (and respectively in total mg/PCU) compared to the previous reports. Changes are due to corrected package data for some penicillin products for 2010–2013.

From 2011 to 2014, the total annual sales of antimicrobials for food-producing animals remained stable (22 mg/PCU). Likewise, the total population of food-producing animals (measured as PCU) also remained stable although there were notable changes for some species. The number of sows fell significantly from 2011 to 2014 (-17%) and there was also a fall in the number of slaughtered pigs (-9%). At the same time, the number of slaughtered broilers increased by 12%.

The proportion accounted for by the various antimicrobial classes also remained quite stable, although some changes in the sales of the two major antimicrobial classes were seen. Sales of penicillins decreased by 0.9 mg/PCU from 2011 to 2014 which could be partially explained by the lower number of sows and slaughtered pigs. From 2011 to 2014, the increase in sales of tetracyclines was 1.5 mg/PCU and is assumed to be mainly the result of the increased use in fur animals.

Penicillins were the most sold antimicrobials for food-producing species (45% of total sales in 2014) followed by tetracyclines (23 %) and sulfonamides (20%). In 2014, the proportion of beta-lactamase-sensitive penicillins accounted for more than 89% of the sales of all penicillins (Figure 12) and 81% of penicillins sold were injectable preparations (Figure 27).

Figure 81. Sales (mg/PCU) of 3rd- and 4th-generation cephalosporins and fluoroquinolones in Finland, from 2011 to 2014



Sales (mg/PCU) of 3rd- and 4th-generation cephalosporins and fluoroquinolones remained low during the study period. In 2014, sales of 3rd- and 4th-generation cephalosporins were 0.02 mg/PCU, while the average sales for 25 countries were 0.26 mg/PCU (Figure 56). A minor increase in the sales is observed for fluoroquinolones for 2014. In 2014, sales of fluoroquinolones were 0.18 mg/PCU, while the average sales for 25 countries were 2.99 mg/PCU (Figure 56). During the observation period, both classes were only available as injectable products for food-producing animals.

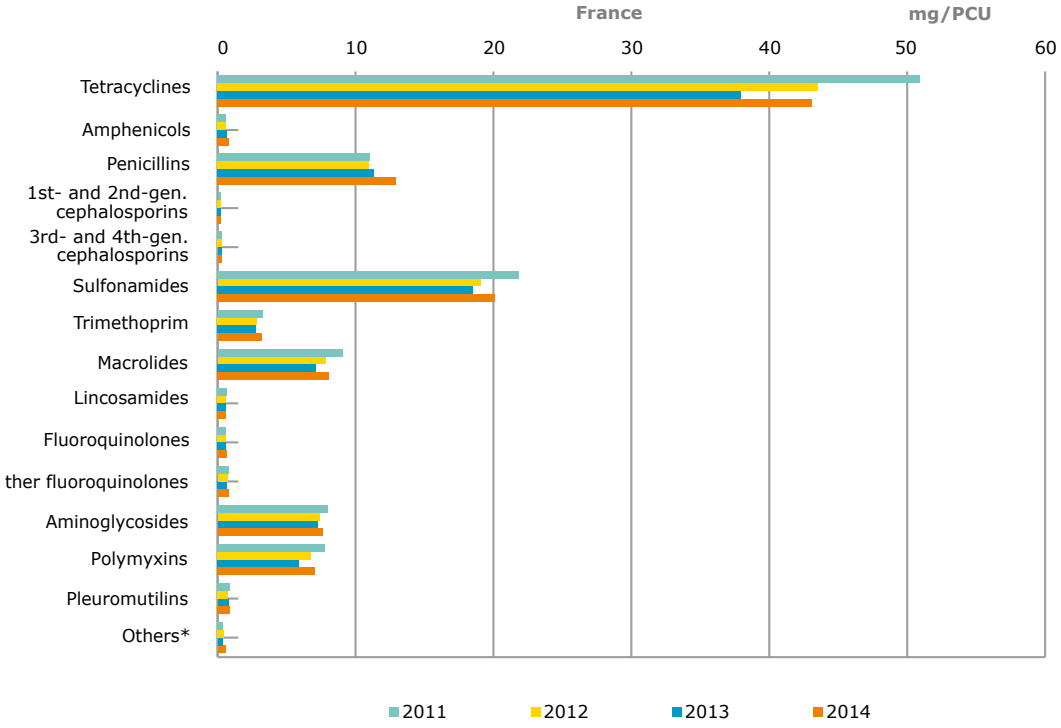
The national legislation restricts the use of 3rd- and 4th-generation cephalosporins to the target species and indications approved in the summary of product characteristics (i.e. use under the cascade is not allowed). In 2012, supervision was targeted at products for this subclass and consequently their sales dropped significantly. In addition, according to the legislation, the 3rd- and 4th-generation cephalosporins, fluoroquinolones and extended spectrum or long-acting macrolides, cannot be used as the first-line treatment and their use must always be based on microbiological diagnosis, bacterial sensitivity testing and/or epidemiological knowledge (first-line treatment has not been effective).

Prudent-use guidelines have been available in Finland since 1996 and have been updated three times, the last time in spring 2016[17]. Specific guidance on possible outbreaks is also given, for example, by the Animal Health ETT (a national association promoting the health and welfare of food-producing animals, i.e. by coordinating national animal healthcare).

[17] https://www.evira.fi/tietoa-evirasta/julkaisut/elaimet/oppaat/mikrobilaakkeiden-kayttosuositukset-elainten-tarkeimpiin-tulehdus--ja-tartuntatauteihin/ (in Finnish)

France

Figure 82. Sales (mg/PCU) by antimicrobial class in France, from 2011 to 2014

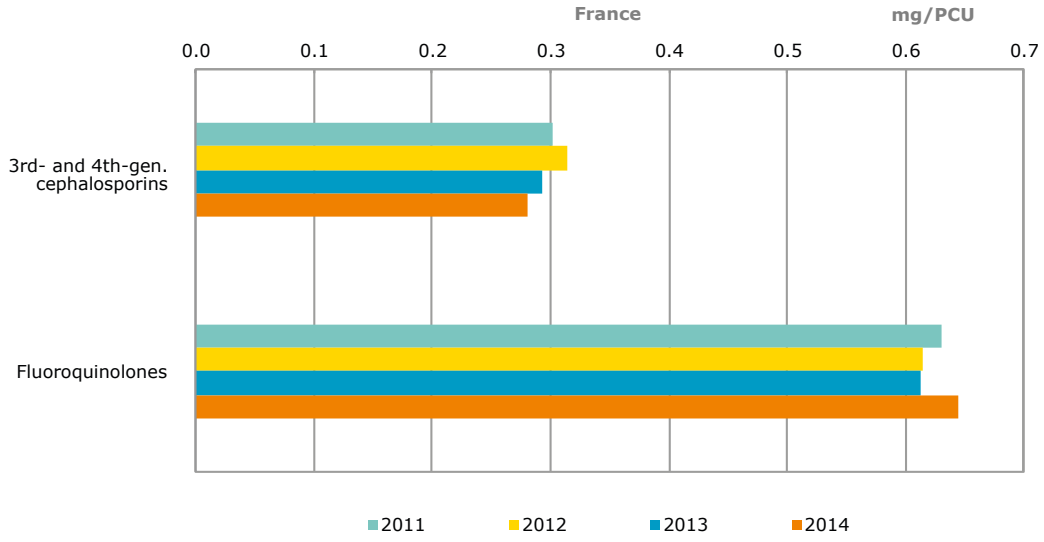


* Other antimicrobials (classified as such in the ATCvet system).

In France, the total sales (mg/PCU) of antimicrobial agents fell by 18.5% between 2011 and 2013, but rose in 2014. This increase can be explained by the publication of a new French law that includes a number of measures for antimicrobials. In 2014, stocks of antimicrobials products were made by stakeholders involved in the sales/delivery of antimicrobials, which was confirmed by the 2015 French results that show a considerable drop in antimicrobials sales.

The 2014 results cannot be considered as a proxy of the usage in antimicrobials as the increase in tonnage linked to the stocks made does not correspond to an increase in use.

Figure 83. Sales (mg/PCU) of 3rd- and 4th-generation cephalosporins and fluoroquinolones in France, from 2011 to 2014



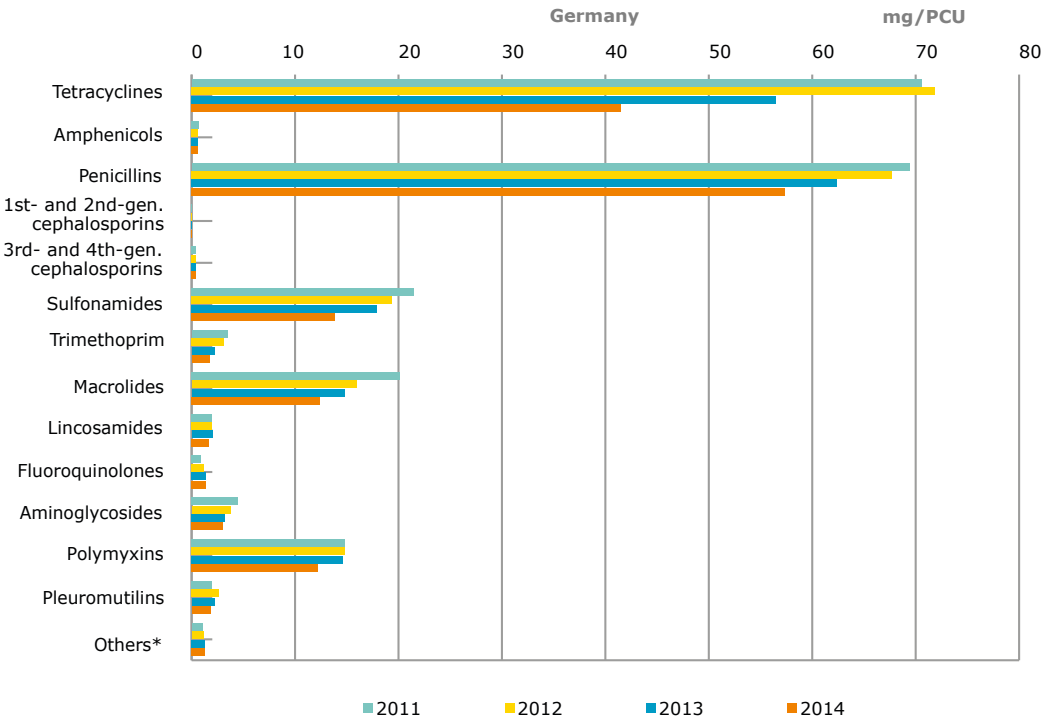
The sales (mg/PCU) of 3rd- and 4th-generation cephalosporins (mg/PCU) and fluoroquinolones were relatively stable from 2011 to 2014.

Both in 2011 and 2014, the 3rd- and 4th-generation cephalosporins accounted for 0.3% of total sales. In 2014, sales of 3rd- and 4th-generation cephalosporins were 0.28 mg/PCU, while the average sales for 25 countries were 0.26 mg/ PCU (Figure 56).

Fluoroquinolones accounted for 0.5% of the total sales in 2011; in 2014, this figure was 0.6%. In 2014, sales of fluoroquinolones were 0.64 mg/PCU, while the average sales for 25 countries were 2.99 mg/PCU (Figure 56).

Germany

Figure 84. Sales (mg/PCU) by antimicrobial class in Germany, from 2011 to 2014[1]

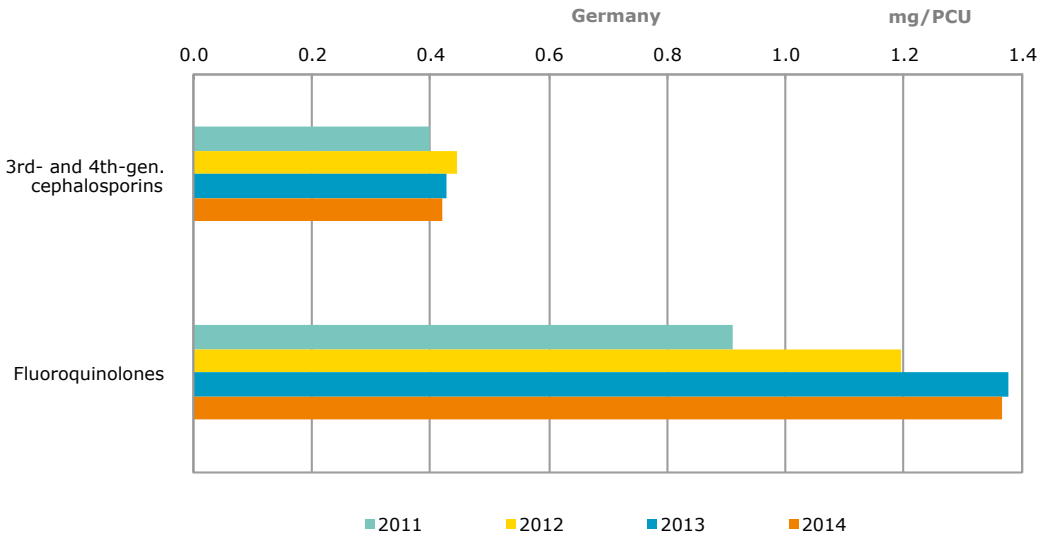


* Other antimicrobials (classified as such in the ATCvet system).
[1] No sales of other quinolones in any of the years.

From 2011 to 2014, a 29 % decrease in the overall sales (in mg/PCU) of veterinary antimicrobial agents was observed in Germany. The greatest fall was noted for tetracyclines, penicillins, macrolides and sulphonamides.

Of total sales, the proportion of penicillins fell from 38 % to 33 %, from 2011 to 2014, while for tetracyclines there total sales dropped from 33 % to 28 %. For macrolides, a decrease in the sales (mg/PCU) was observed; the proportion of sales of macrolides was 10 % in 2011 while in 2014 it fell to 8 %.

Figure 85. Sales (mg/PCU) of 3rd- and 4th-generation cephalosporins and fluoroquinolones in Germany, from 2011 to 2014

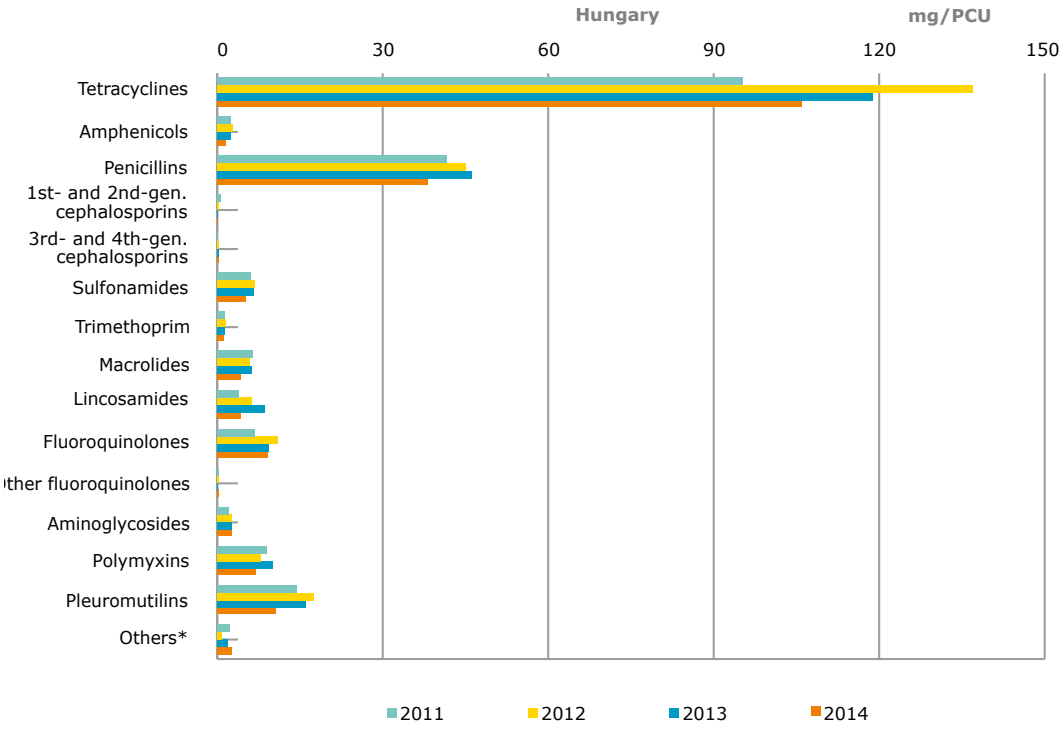


Sales, in mg/PCU, of 3rd- and 4th-generation cephalosporins were relatively stable during the period 2011 to 2014. In 2011, the 3rd- and 4th-generation cephalosporins accounted for 0.2 % of total sales; for 2014, this figure was 0.3 %. In 2014, sales of 3rd- and 4th-generation cephalosporins were 0.42 mg/PCU, while the average sales for 25 countries were 0.26 mg/PCU (Figure 56).

Sales of fluoroquinolones rose by 50 % from 2011 to 2014, mainly due to an increase in the sales of enrofloxacin. In 2011, fluoroquinolones accounted for 0.4 % of total sales, while in 2014 this figure was 0.9 %. Also in 2014, sales of fluoroquinolones were 1.37 mg/PCU, while the average sales for 25 countries were 2.99 mg/PCU (Figure 56).

Hungary

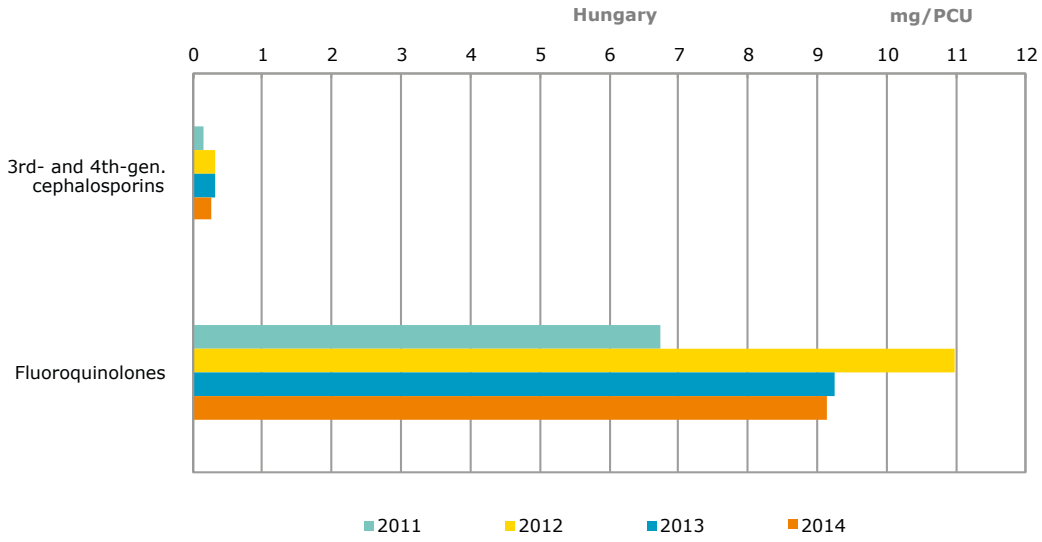
Figure 86. Sales (mg/PCU) by antimicrobial class for in Hungary, from 2011 to 2014



* Other antimicrobials (classified as such in the ATCvet system).

The total sales (mg/PCU) fluctuated during 2011 to 2014 (Table 8); in 2011 and 2014, sales were similar with only a 0.3% increase being observed. The most-sold classes were tetracyclines and penicillins across all four years. Of the total sales, the proportion of the sales accounted for by tetracyclines increased from 50% to 55%, from 2011 to 2014; while for penicillins there was a corresponding fall from 22% to 20% of total sales. For macrolides, a decrease in the sales (mg/ PCU) was observed; the proportion of sales of macrolides was 3.3% in 2011 while in 2014 this figure was 2.2%.

Figure 87. Sales (mg/PCU) of 3rd- and 4th-generation cephalosporins and fluoroquinolones in Hungary, from 2011 to 2014



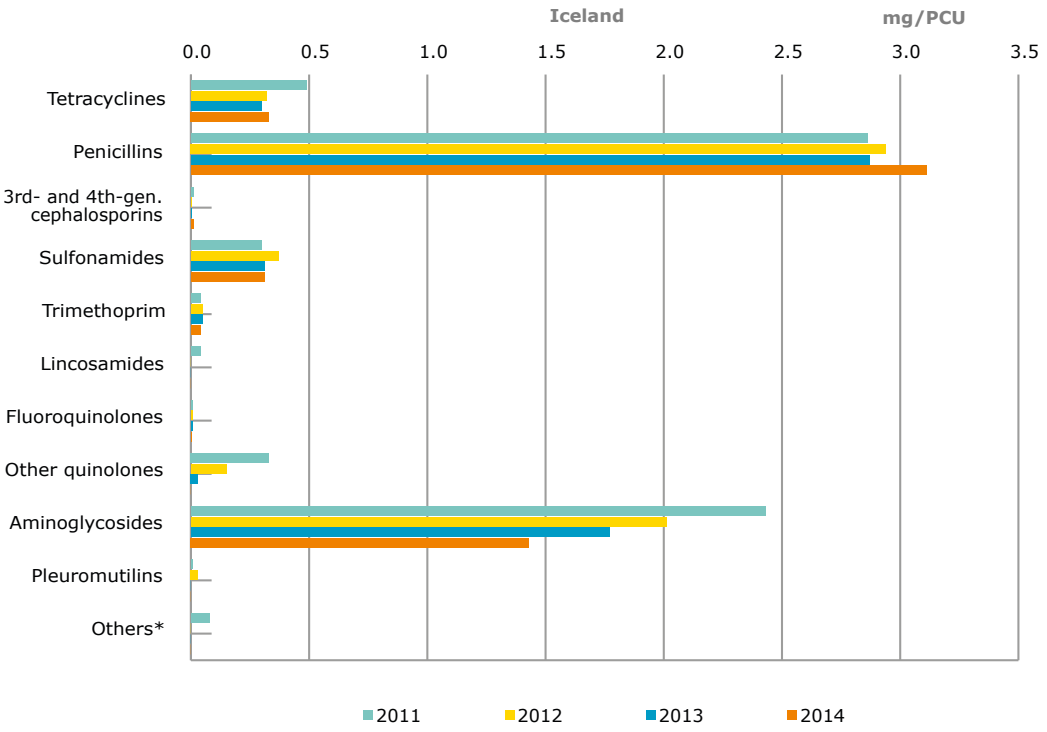
In Hungary, the sales (mg/PCU) of 3rd- and 4th-generation cephalosporins and fluoroquinolones fluctuated during the period 2011 and 2014; across the study period, an increase has been observed for both classes.

In 2011, the 3rd- and 4th-generation cephalosporins accounted for 0.07% of total sales; for 2014, this figure was 0.13%. In 2014, sales of 3rd- and 4th-generation cephalosporins were 0.25 mg/PCU, while the average sales for 25 countries were 0.26 mg/PCU (Figure 56).

The proportion of total sales for fluoroquinolones was 3.5% and 4.7%, respectively, in 2011 and 2014. In 2014, sales of fluoroquinolones were 9.14 mg/PCU, while the average sales for 25 countries were 2.99 mg/PCU (Figure 56).

Iceland

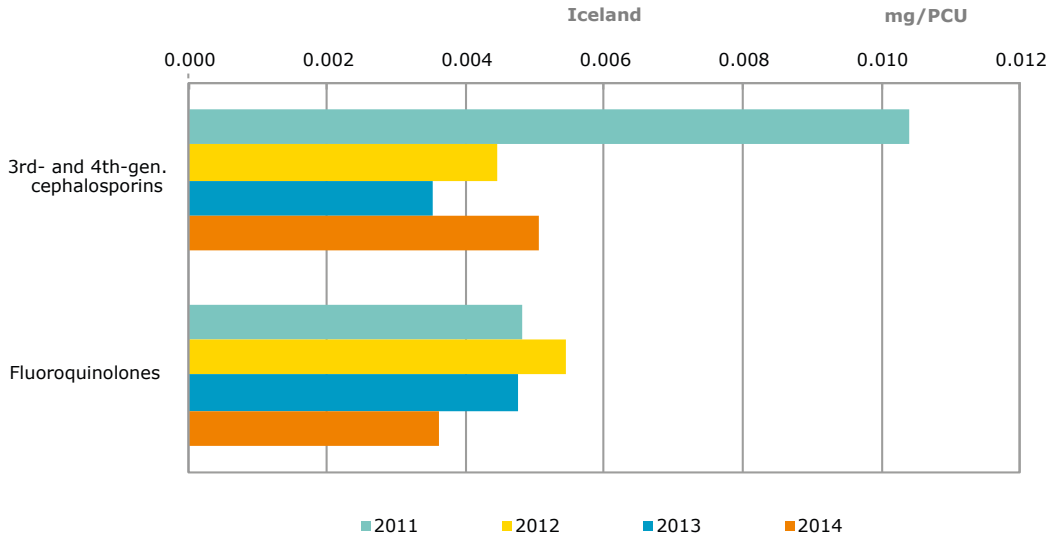
Figure 88. Sales (mg/PCU) by antimicrobial class in Iceland, from 2011 to 2014[1]



* Other antimicrobials (classified as such in the ATCvet system).
[1] No sales of amphenicols, macrolides and polymyxins in any of the years.

A gradual drop of 21% in sales, in mg/PCU, was observed from 2011 to 2014 (Table 8); compared to 2010, sales had declined by 27% in 2014. The decrease from 2011 was caused by a reduction in the sales of several products, in particular aminoglycosides and tetracyclines. However, no definite conclusion can be reached for the time being as to what caused these changes, although there is an increased general awareness of the importance of responsible use of antimicrobials.

Figure 89. Sales (mg/PCU) of 3rd- and 4th-generation cephalosporins and fluoroquinolones in Iceland, from 2011 to 2014



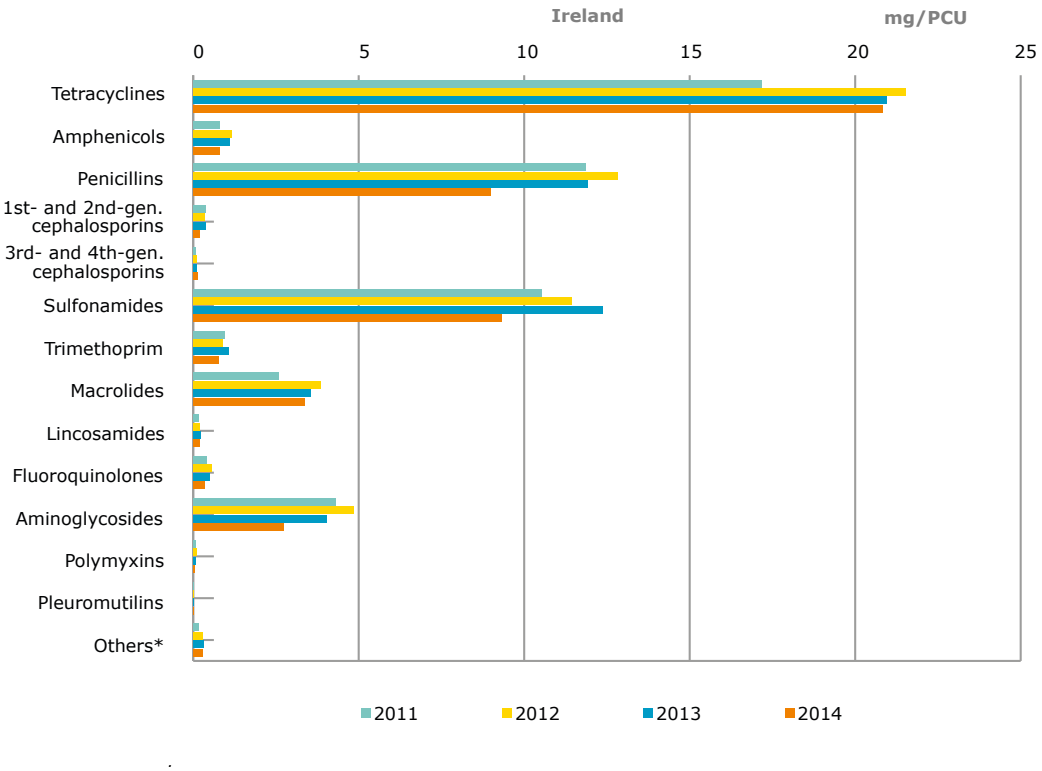
Sales (mg/PCU) of 3rd- and 4th-generation cephalosporins and fluoroquinolones in Iceland are very low.

The sales, in mg/PCU, of 3rd- and 4th-generation cephalosporins declined by 51% during 2011 to 2014. In 2011, the 3rd- and 4th-generation cephalosporins accounted for 0.2% of total sales; for 2014, this figure was 0.1%. In 2014, sales of 3rd- and 4th-generation cephalosporins were 0.05 mg/PCU, while the average sales for 25 countries were 0.26 mg/PCU (Figure 56).

For fluoroquinolones, the sales fell by 25% from 2011 to 2014. In 2011, fluoroquinolones accounted for 0.07% of the total sales both in 2011 and 2014. In 2014, sales of fluoroquinolones were 0.004 mg/PCU, while the average sales for 25 countries were 2.99 mg/PCU (Figure 56).

Ireland

Figure 90. Sales (mg/PCU) by antimicrobial class in Ireland, from 2011 to 2014

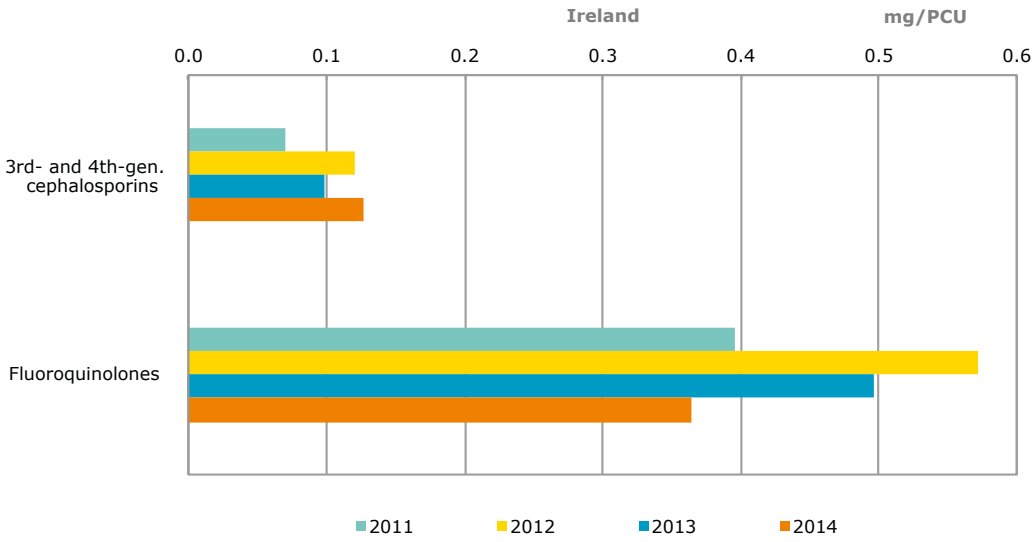


* Other antimicrobials (classified as such in the ATCvet system)

Overall sales (mg/PCU) of veterinary antimicrobial agents in Ireland fell by 3 % from 2011 to 2014; sales were 11 % lower in 2014 compared to 2010. The sales fluctuated across the study period; in 2011, 2012, 2013 and 2014, the observed sales were 49 mg/PCU, 58 mg/PCU, 57 mg/PCU and 48 mg/PCU, respectively. Penicillins accounted for the largest part of the observed decrease; the proportion accounted for by this class has dropped from 24 % to 19 %. In parallel, sales of tetracyclines increased; in 2011, this class accounted for 35 % of the total sales, whereas in 2014 the figure was 43 %. Sales of macrolides also increased during this period.

As noted previously, large fluctuations in sales data from year to year can be attributed to the changing sales patterns in a small number of products. This, coupled with, market volatility and seasonal factors may have contributed to the changes observed.

Figure 91. Sales (mg/PCU) of 3rd- and 4th-generation cephalosporins and fluoroquinolones in Ireland, from 2011 to 2014

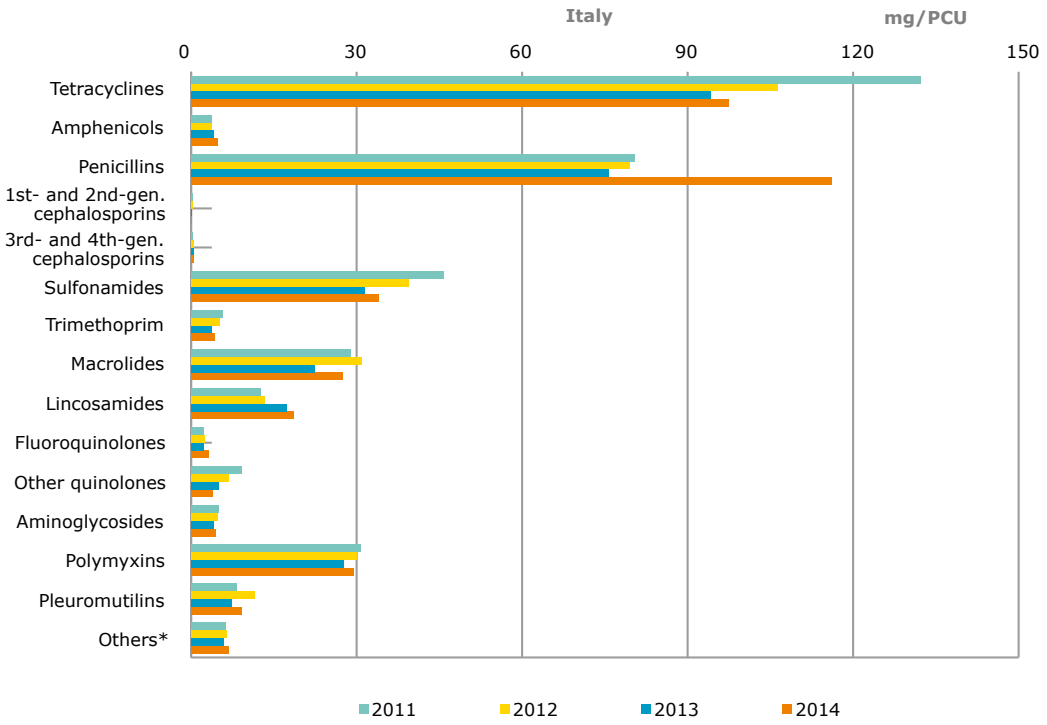


Overall, the sales (mg/PCU) of 3rd- and 4th-generation cephalosporins increased during 2011 to 2014, although sales fluctuated. In 2011, this subclass accounted for 0.1% of the total sales; in 2014, this figure was 0.3%. In 2014, sales of 3rd- and 4th-generation cephalosporins were 0.13 mg/PCU, while the average sales for 25 countries were 0.26 mg/PCU (Figure 56).

Sales of fluoroquinolones fluctuated across the period, peaking in 2012; they were 8% lower in 2014 compared to 2011. The sales of fluoroquinolones were 0.36 mg/PCU in 2014, while the average figure for 25 countries was 2.99 mg/PCU (Figure 56).

Italy

Figure 92. Sales (mg/PCU) by antimicrobial class in Italy, from 2011 to 2014



* Other antimicrobials (classified as such in the ATCvet system).

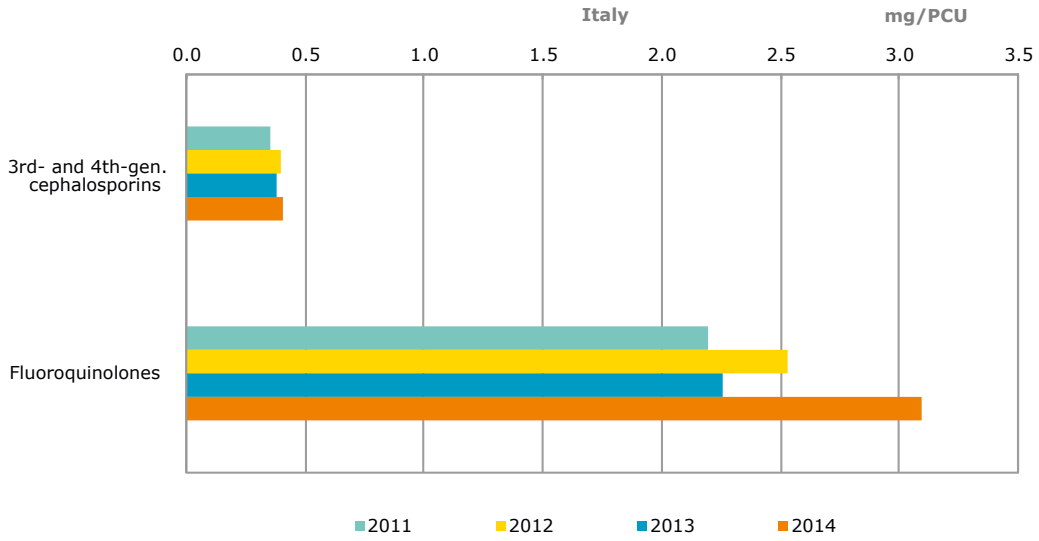
Overall, there was a 3 % drop in sales, expressed as mg/PCU, during the period 2011 to 2014; however, sales in 2014 were 16 % lower compared to 2010. This fall appears to be correlated mainly with a progressive decline in sales of tetracyclines and sulfonamides. The lower sales were probably caused by the following factors:

- In 2009, the Ministry of Health launched awareness campaigns[18] against the prophylactic use of antimicrobial agents in breeding farms and for their prudent use in pet animals[19]. Furthermore, an online training course was published on veterinary medicines surveillance and pharmacovigilance[20].
- 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, in 2010 and 2011, training courses were held in collaboration with the National Reference Laboratory for Antimicrobial Resistance in Rome. At the same time, in accordance with Regulation (EC) No 852/2004, the Ministry of Health validated and published species-specific good husbandry practices manuals in which basic principles for medicines management in farms are addressed.

[18] http://www.salute.gov.it/portale/temi/p2_5.jsp?lingua=italiano&area=veterinari&menu=antibiotici (in Italian).
[19] http://www.salute.gov.it/imgs/C_17_opuscoliPoster_234_allegato.pdf (in Italian).
[20] http://www.trentagiorni.it/numeroDettaglio.php?numeriId=3 (in Italian).

- In February 2012, a 'Biosecurity manual and for prudent use of antimicrobials in poultry, pig and rabbit production', addressed to farmers and veterinarians, was developed and published by the Italian authorities[21]. Also, a national 'Guideline for official controls on distribution and use of veterinary medicines' was developed in January 2012 for regional and local official veterinary services to enable them to plan and perform official controls based on the farms' risk categorisation level. In 2015, drafting began of the 'Guidelines for the correct management of livestock in order to reduce the prescription of antibiotics and prevent the risk of resistance' through biosecurity, hygiene and animal welfare indicators.
- In 2015, a testing phase for the use of electronic veterinary prescriptions was initiated.
- In 2013 and 2015, rabbit and poultry production adopted a voluntary plan for the responsible use of veterinary drugs and for the fight against antimicrobial resistance.

Figure 93. Sales (mg/PCU) of 3rd- and 4th-generation cephalosporins and fluoroquinolones in Italy, from 2011 to 2014



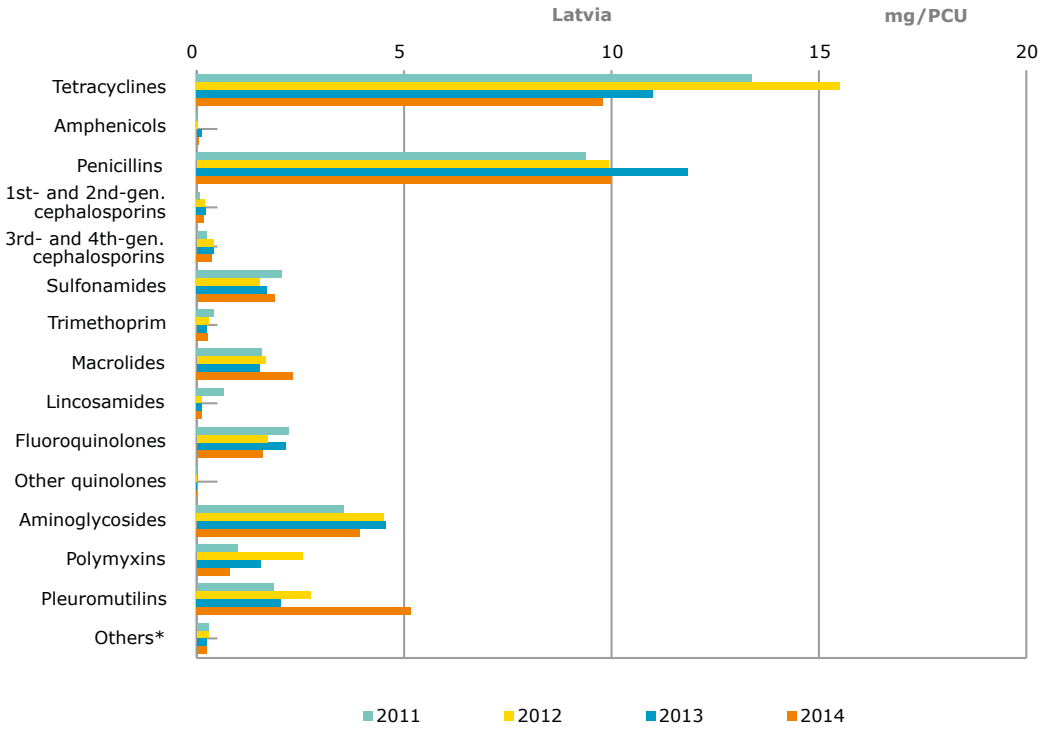
Sales (mg/PCU) of 3rd- and 4th-generation cephalosporins were relatively stable during the period 2011 to 2014, accounting for approximately 0.1% of total sales each year. In 2014, the sales of 3rd- and 4th-generation cephalosporins were 0.41 mg/PCU, while the average figure for 25 countries was 0.26 mg/PCU in the same year (Figure 56).

There was a slight increase in sales of fluoroquinolones over the four-year period; in 2011, this sub-class accounted for 0.6% of total sales while for 2014 the corresponding figure was 0.9%. In 2014, sales of fluoroquinolones were 3.1 mg/PCU, which is close to the average sales in 25 countries in 2014 (2.99 mg/PCU) (Figure 56).

[21] http://www.salute.gov.it/imgs/C_17_pubblicazioni_1683_allegato.pdf (in Italian).

Latvia

Figure 94. Sales (mg/PCU) by antimicrobial class in Latvia, from 2011 to 2014



* Other antimicrobials (classified as such in the ATCvet system).

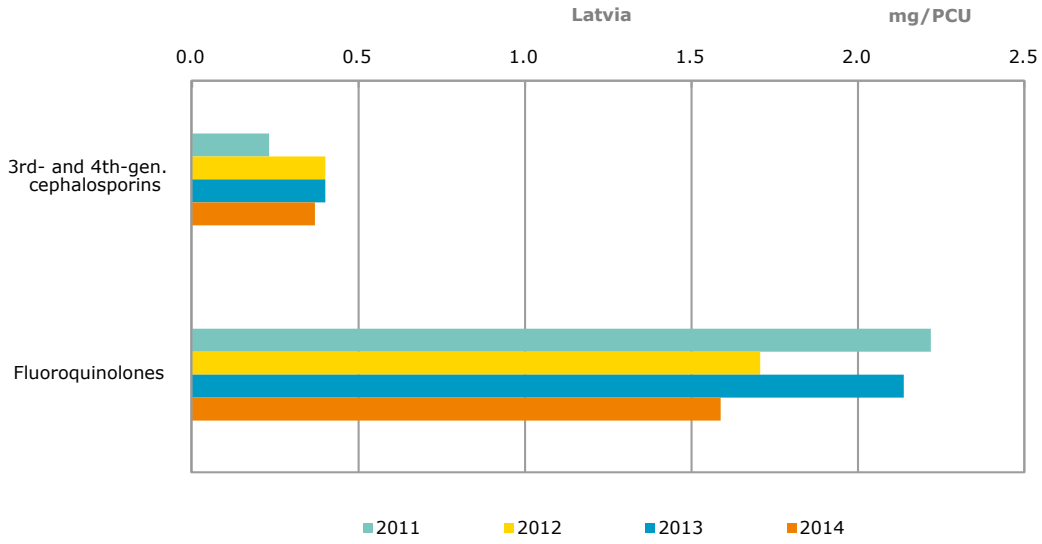
The annual sales (mg/PCU) of antimicrobial VMPs were stable during the period 2011 to 2014; sales in both 2011 and 2014 were 37 mg/PCU. Overall sales declined by 7% from 2010 to 2014, while the proportion accounted for by most of the various antimicrobial classes fluctuated.

Tetracyclines and penicillins are the most-sold classes for all the study years. A peak in sales of tetracyclines was observed for 2012; overall, a drop of 26% in sales of this class is observed from 2011 to 2014. Sales of penicillin VMPs were relatively stable in Latvia, except for 2013 when a peak can be seen.

Sales of pleuromutilins increased from 1.9 mg/PCU to 5.2 mg/PCU from 2011 to 2014, which is almost double the sales of this class during the period. At the moment, no precise data are 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 have been carried out to inform farmers and animal owners, and to give additional information to veterinarians about the prudent use of antimicrobial agents in animals. For example, in 2014, representatives from the Food and Veterinary Service, Institute of Food Safety, Animal Health and Environment BIOR and Veterinary Medicine Faculty in Latvia participated in the seminar 'Prevalence of zoonotic agents in food-producing animals in the population and foodstuffs of animal origin'. A list of first- and second-choice antimicrobial agents is currently being drawn up. During 2014, several training courses were organised for inspectors carrying out inspections of the distribution and use of veterinary medicines, and for veterinary practitioners.

Figure 95. Sales (mg/PCU) of 3rd- and 4th-generation cephalosporins and fluoroquinolones in Latvia, from 2011 to 2014

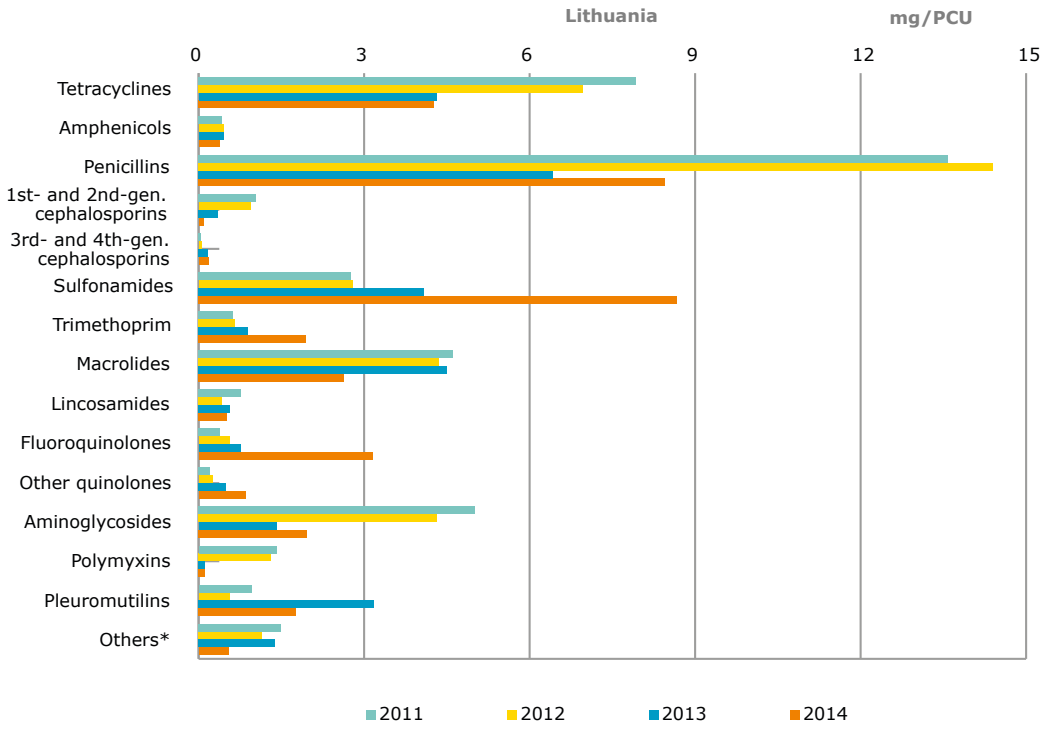


The sales of 3rd- and 4th-generation cephalosporins rose from 0.23 mg/PCU in 2011 to 0.37 mg/PCU in 2014; the average figure for 25 countries was 0.26 mg/PCU in 2014 (Figure 56). In 2011, 3rd- and 4th-generation cephalosporins accounted for 0.6% of total sales, while this figure was 1.0% for 2014.

In Latvia, sales of fluoroquinolones fluctuated during the period 2011 to 2014; however, a decline from 2.2 mg/PCU to 1.6 mg/PCU can be seen during this period. In comparison, average sales in 25 countries were 2.99 mg/PCU in 2014 (Figure 56). Sales of fluoroquinolones accounted for 6.0% of total sales in 2011 and 4.3% in 2014.

Lithuania

Figure 96. Sales (mg/PCU) by antimicrobial class in Lithuania, from 2011 to 2014[1]

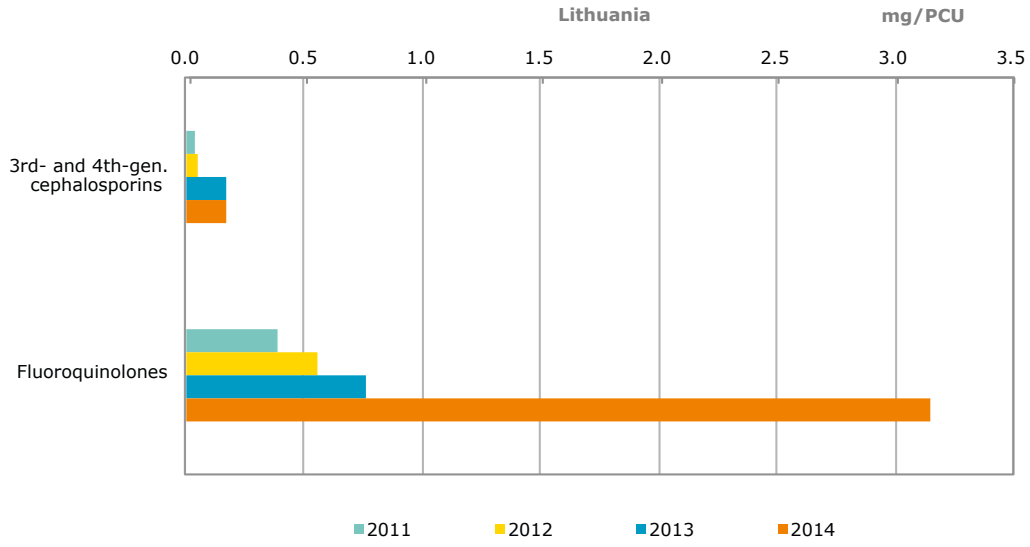


* Other antimicrobials (classified as such in the ATCvet system).
[1] No sales of pleuromutilins in 2010.

From 2011 to 2014, an 8 % drop in sales (in mg/PCU) was seen in Lithuania, accounted for by almost all antimicrobial classes. Exceptions are sulfonamides and trimethoprim and fluoroquinolones for which a substantial increase can be seen. Currently, there is no precise data available that can explain the observed increase in the changes in the sales patterns of veterinary antimicrobial agents in Lithuania. Compared to 2010, sales of antimicrobial VMPs had declined by 21 % by 2014.

The fall during 2011 to 2014 is mainly accounted for by a reduction in the reported sales of tetracyclines and penicillins. In 2011, sales of penicillins accounted for 33 % of the total sales of antimicrobial VMPs while this figure was 28 % in 2014. The corresponding figures for tetracyclines were 19 % and 11 %.

Figure 97. Sales (mg/PCU) of 3rd- and 4th-generation cephalosporins and fluoroquinolones in Lithuania, from 2011 to 2014

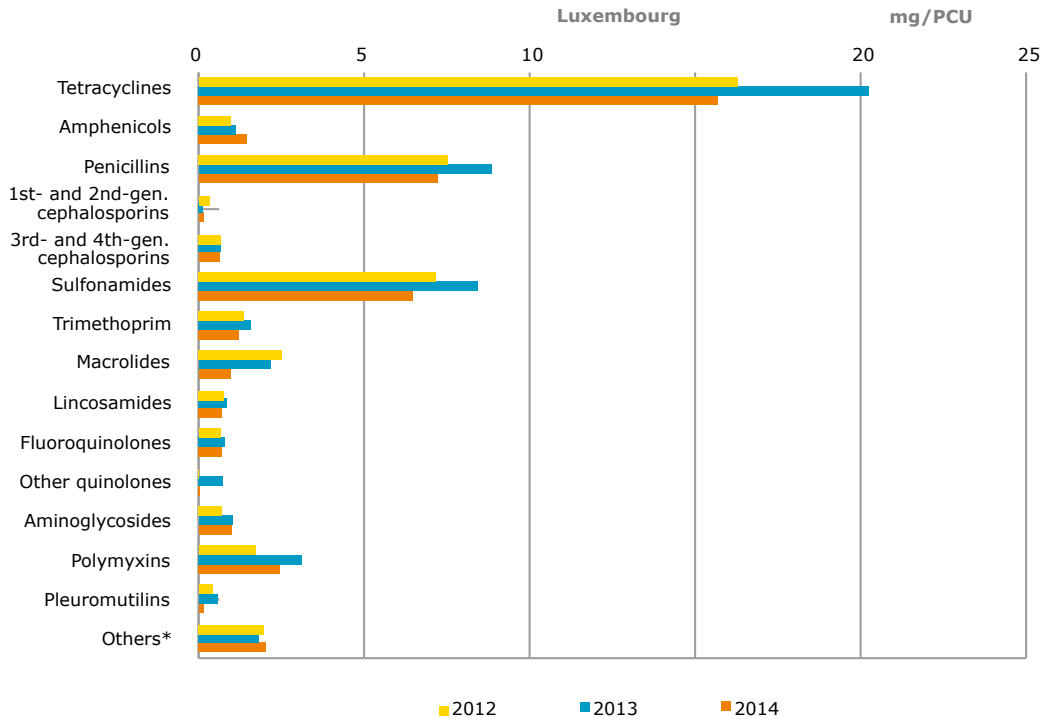


The sales (mg/PCU) of 3rd- and 4th-generation cephalosporins increased from 0.04 mg/PCU to 0.13 mg/PCU from 2011 to 2014. In 2014, the average sales of 3rd- and 4th-generation cephalosporins VMPs were 0.26 mg/PCU across 25 countries (Figure 56). In 2011, sales of this subclass accounted for 0.10 % of total sales, while in 2014 this figure was 0.34 %.

Sales of fluoroquinolones rose during the study period, in particular in 2014. In 2014, sales of fluoroquinolones in Latvia were 3.1 mg/PCU, while the average sales in 25 countries were 2.99 mg/PCU in 2014 (Figure 56).

Luxembourg

Figure 98. Sales (mg/PCU) by antimicrobial class in Luxembourg, from 2012 to 2014

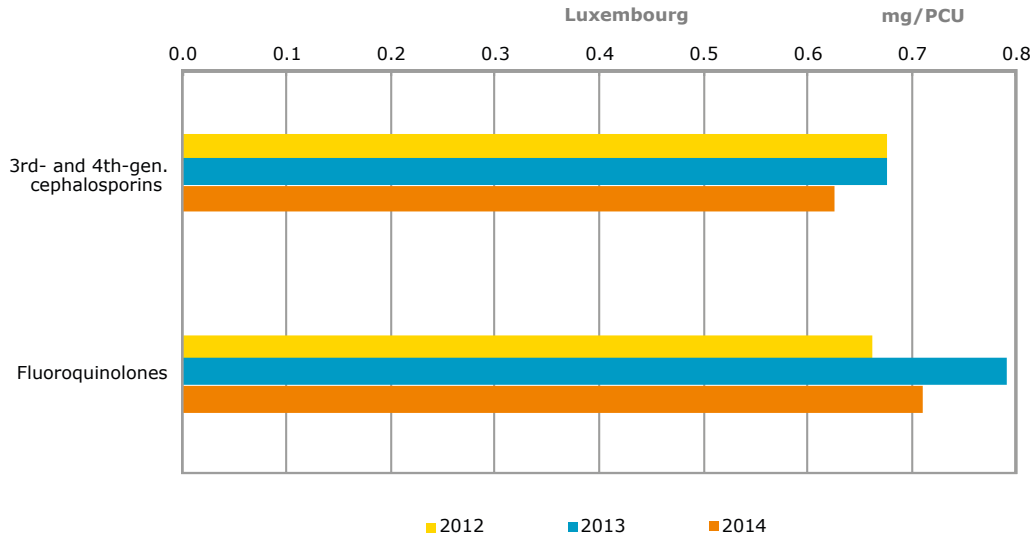


* Other antimicrobials (classified as such in the ATCvet system).

From 2012 to 2014, a 5 % fall in sales (mg/PCU) of antimicrobial VMPs was observed in Luxembourg. The proportion accounted for by the most-sold classes — tetracyclines, penicillins and sulfonamides — was stable from 2011 to 2014, while the proportion for macrolides declined from 5.9 % to 2.4 % of the total sales in this period.

However, these data must be interpreted with caution as Luxembourg is a small country with a small animal population, and any change in treatment strategy by one or two major farms may significantly influence the sales figures.

Figure 99. Sales (mg/PCU) of 3rd- and 4th-generation cephalosporins and fluoroquinolones in Luxembourg, from 2012 to 2014

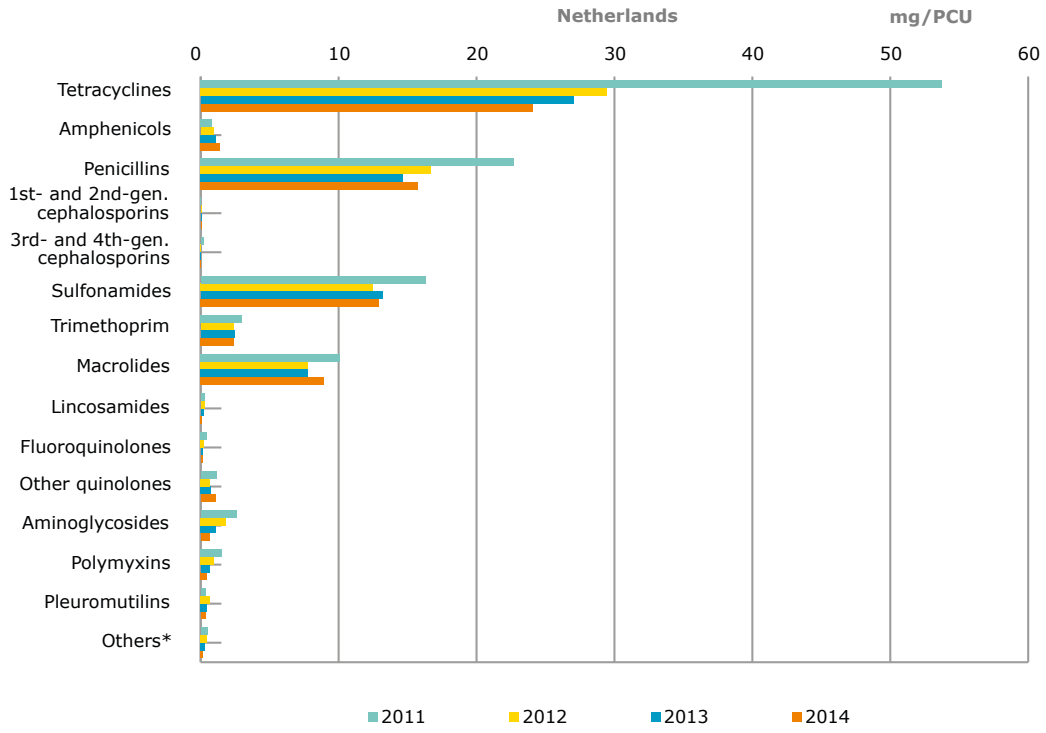


Sales (mg/PCU) of 3rd- and 4th-generation cephalosporins were relatively stable; a slight drop was observed for 2014. In 2012, this subclass accounted for 1.6% of total sales, while in 2014, this figure was 1.5%. In 2014, the sales of 3rd- and 4th-generation cephalosporins VMPs were 0.63 mg/PCU, while average sales for 25 countries in that year were 0.26 mg/PCU (Figure 56).

Sales of fluoroquinolones fluctuated during the study years. In 2014, they were 0.71 mg/PCU, while the average sales for 25 countries in that year were 2.99 mg/PCU (Figure 56).

Netherlands

Figure 100. Sales (mg/PCU) by antimicrobial class for food-producing species, in the Netherlands, from 2011 to 2014



* Other antimicrobials (classified as such in the ATCvet system).

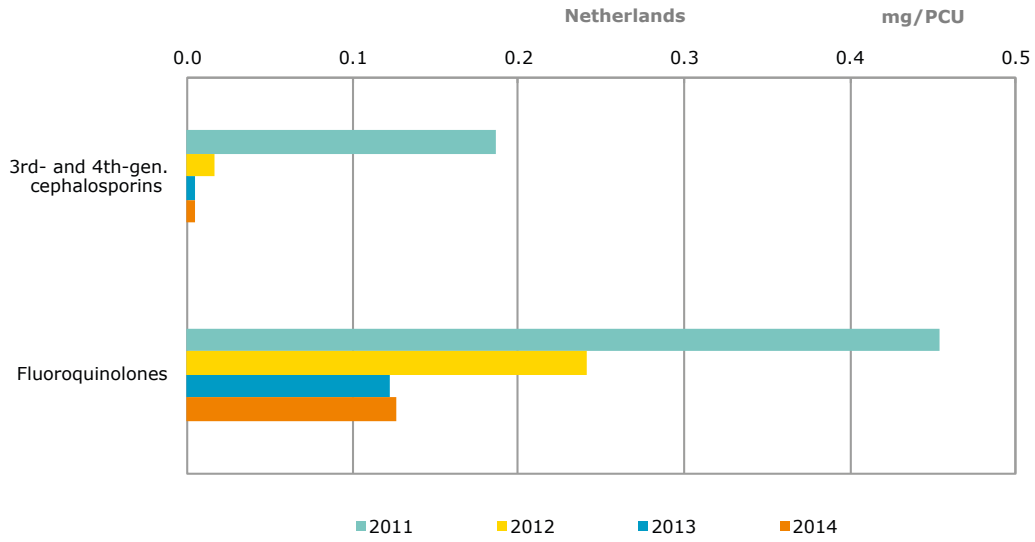
A 35 % drop in sales (in mg/PCU) of veterinary antimicrobial agents was observed from 2011 to 2014; compared to 2010, sales declined by 53 % in 2014. This is the result of efforts by the major production sectors and veterinarians which agreed with the government to set reduction targets in 2010 for the use of antimicrobial agents in animal production: -20 % for 2011 and 50 % for 2013 (in tonnes), all targets with reference to 2009. The data shows that those targets were reached.

The major decline in sales is accounted for by tetracyclines, where a 55 % reduction in the sales (mg/PCU) is seen across the period 2011 to 2014.

In 2012, the government set a new reduction target: -70 % by 2015, with 2009 as the reference year. This target has yet to be reached. From 2009to2015, the use of veterinary antimicrobials was cut by 58.4 %; the Dutch government is maintaining the reduction target of 70 %.

For the ESVAC 2011 and 2012 data (reports), the strength of the VMP presentations were reported as the base for several products. The strengths given for certain VMP presentations were adjusted according to ESVAC standards (as in the VMP label) for 2013 and 2014 to make the data from the Netherlands comparable to data from other countries. If these VMPs had been reported as the base for 2014, the sales would have been slightly lower and the decline in sales slightly higher.

Figure 101. Sales (mg/PCU) of 3rd- and 4th-generation cephalosporins and fluoroquinolones in the Netherlands, from 2011 to 2014



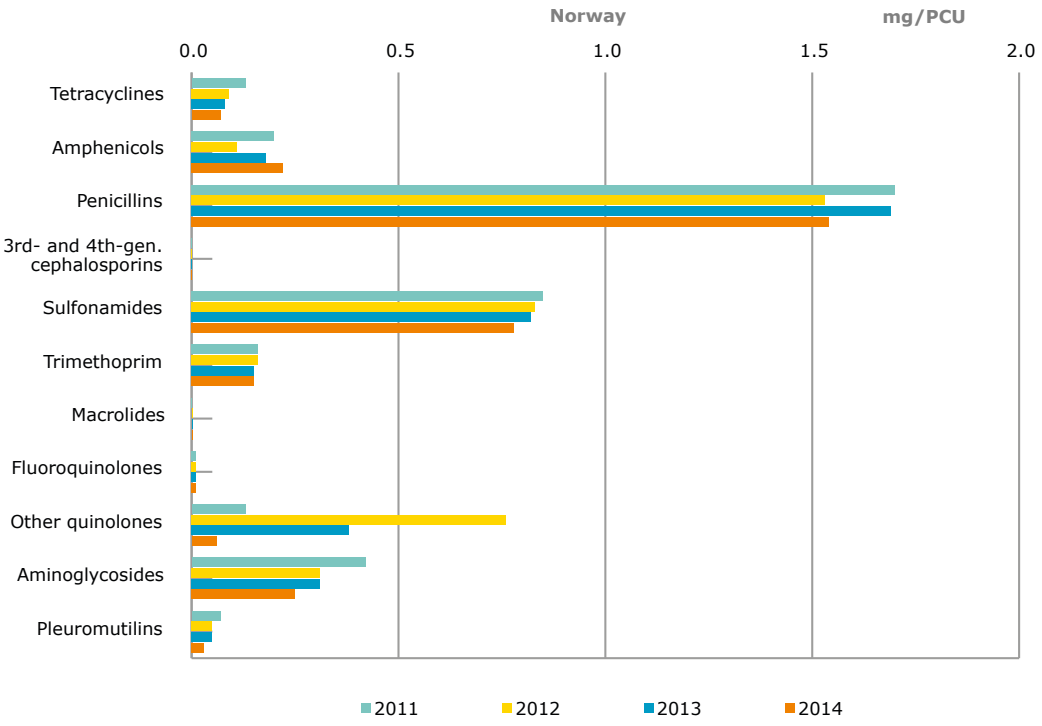
The sales (mg/PCU) of 3rd- and 4th-generation cephalosporins fell by 98 % from 2011 to 2014; in 2011, this subclass accounted for 0.17 % of total sales while for 2014, the figure was 0.01 %. This result was achieved thanks to efforts within private quality-production systems. Private quality systems in the pig sector banned the use of 3rd- and 4th-generation cephalosporins; and in the dairy sector, the systems banned the use of 3rd- and 4th-generation cephalosporins for drying off cows. In 2014, the sales of 3rd- and 4th-generation cephalosporins VMPs were 0.004 mg/PCU, while the average sales for 25 countries in 2014 were 0.26 mg/PCU (Figure 56).

Sales (mg/PCU) of fluoroquinolones decreased by 72 % from 2011 to 2014; in 2011, this subclass accounted for 0.4 % of the total sales, while in 2014 this figure was 0.2 %. In 2014, sales of fluoroquinolones were 0.13 mg/PCU, while the average sales for 25 countries in that year were 2.99 mg/PCU (Figure 56).

In 2012, a legal basis was created for mandatory antimicrobial susceptibility testing before using 3rd- and 4th-generation cephalosporins and fluoroquinolones. It came into force at the beginning of 2013.

Norway

Figure 102. Sales (mg/PCU) by antimicrobial class in Norway, from 2011 to 2014[1]



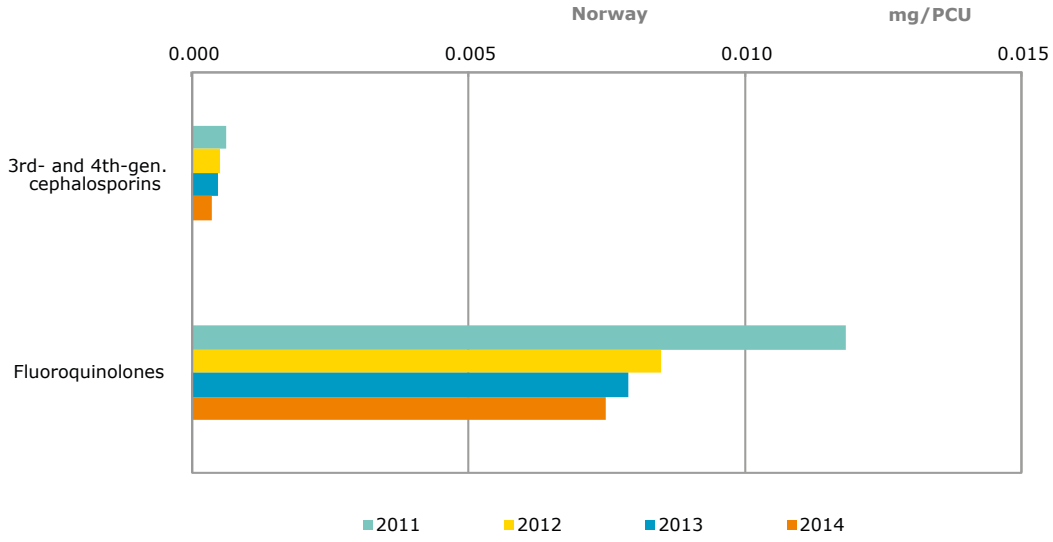
[1] No sales of 1st- and 2nd-generation cephalosporins or polymyxins in any of the years; minor amounts of macrolides sold in 2011, 2012 and 2013 (< 0.002 mg/PCU).

From 2011 to 2014, there was a 15% fall in the sales (mg/PCU) of antimicrobial VMPs in Norway; in 2014, the sales were 24% lower compared to 2010. This was mainly accounted for by lower sales of penicillins, aminoglycosides and sulfonamides for terrestrial animals. Sales of amphenicols and other quinolones fluctuated during the period 2011 to 2014. This is explained by changes in sales in farmed fish as other quinolones and amphenicols are only used in fish.

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

From 1995 to 1999, a 40% reduction was achieved in the sale of antimicrobials for terrestrial animals. Since then, 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). It should be noted that, since 1981, the sales of antimicrobials for use in farmed fish has declined by 97%, while during the same period the production of farmed fish increased more than 100-fold.

Figure 103. Sales (mg/PCU) of 3rd- and 4th-generation cephalosporins and fluoroquinolones in Norway, from 2011 to 2014

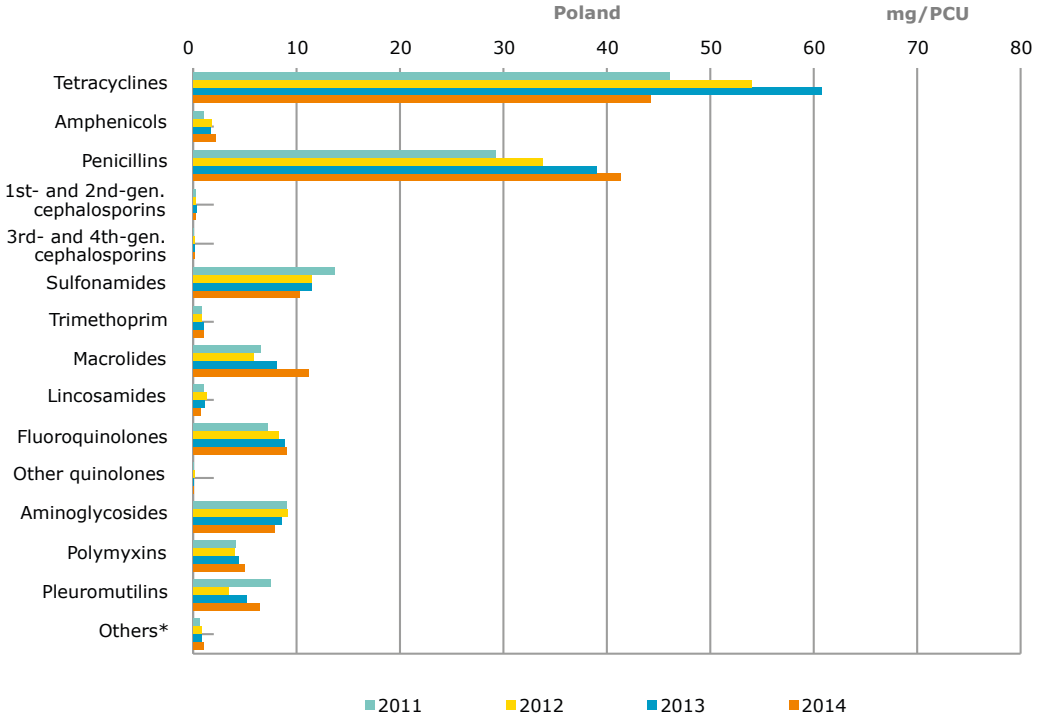


The sales (mg/PCU) of 3rd- and 4th-generation cephalosporins decreased from 2011 to 2014; in 2011, this subclass accounted for 0.02 % of the total sales, while for 2014, this figure was 0.01 %. In 2014, sales of 3rd- and 4th-generation cephalosporins VMPs were 0.004 mg/PCU, while the average sales for 25 countries in that year were 0.26 mg/PCU (Figure 56). It should be noted that intramammary preparations containing 3rd- and 4th-generation cephalosporins are not marketed in Norway.

Sales of fluoroquinolones also fell from 2011 to 2014; in 2011, this subclass accounted for 0.3 % of the total sales, while in 2014, this figure was 0.2 %. In 2014, sales of fluoroquinolones were 0.007 mg/PCU, while the average sales for 25 countries in that year were 2.99 mg/PCU (Figure 56).

Poland

Figure 104. Sales (mg/PCU) by antimicrobial class in Poland, from 2011 to 2014



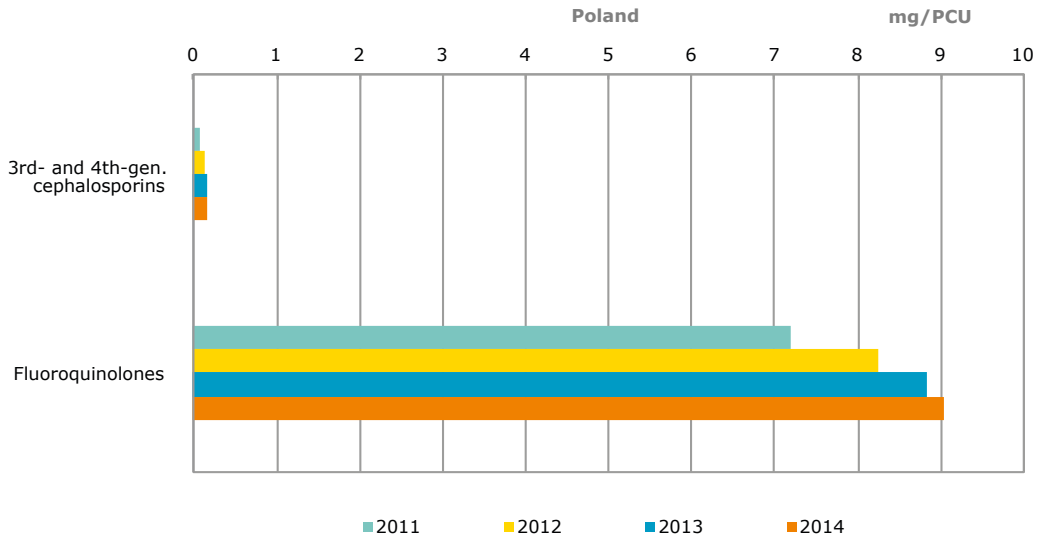
* Other antimicrobials (classified as such in the ATCvet system).

There was an 11 % increase in the sales (mg/PCU) of veterinary antimicrobial agents from 2011 to 2014, mainly related to an increase in sales of penicillins, as well as macrolides.

The two most-sold classes were tetracyclines and penicillins. Sales for tetracyclines accounted for 36 % of total sales in 2011, whereas in 2014 this figure was 31 %; the corresponding figures for penicillins were 23 % to 29 %, indicating a shift in prescribing from tetracyclines to penicillins.

Currently, there is no data available that can explain the observed increase in sales or changes in the sales patterns of veterinary antimicrobial agents in Poland.

Figure 105. Sales (mg/PCU) of 3rd- and 4th-generation cephalosporins and fluoroquinolones in Poland, from 2011 to 2014

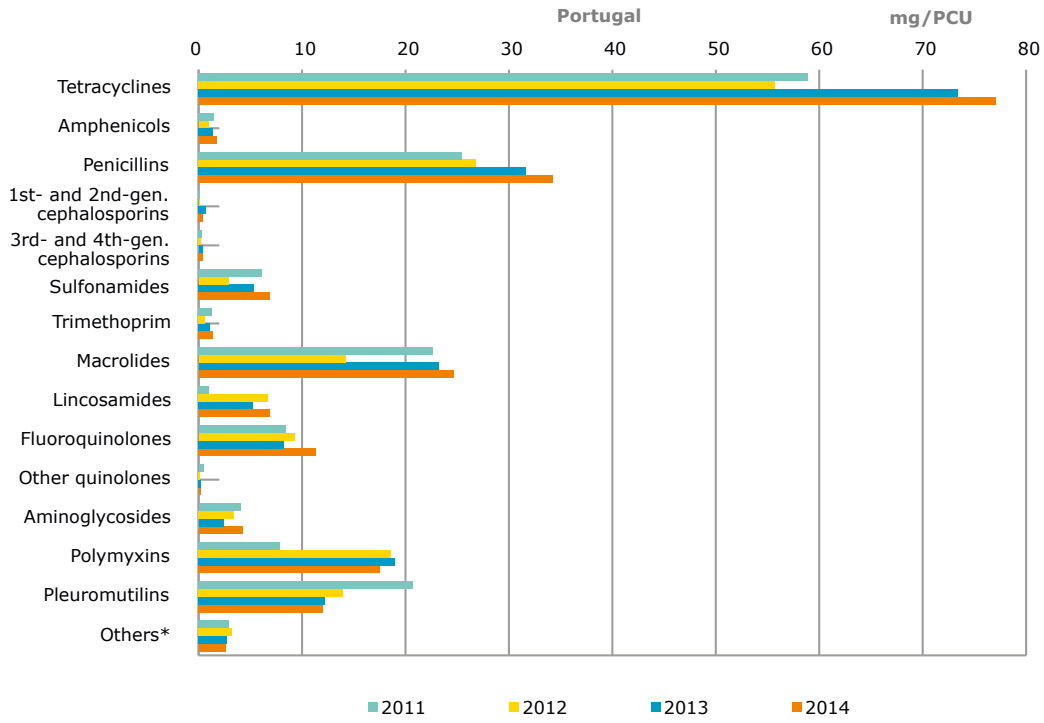


The sales (mg/PCU) of 3rd- and 4th-generation cephalosporins increased slightly from 2011 to 2014; in 2011, this subclass accounted for 0.07% of total sales, while for 2014, this figure was 0.12%. In 2014, the sales of 3rd- and 4th- generation cephalosporins VMPs were 0.17 mg/PCU, while the average sales for 25 countries in that year were 0.26 mg/PCU (Figure 56).

From 2011 to 2014, an increase was observed in the sales (mg/PCU) of fluoroquinolones. In 2011, the proportion of total sales for fluoroquinolones was 5.7%, and in 2014, this figure was 6.4%. In 2014, the sales of fluoroquinolones were 9.4 mg/PCU, while the average sales for 25 countries in that year were 2.99 mg/PCU (Figure 56). This rise might be explained by a 36% increase in the poultry PCU and the relatively high sales for poultry accounting for a relatively high proportion of the total PCU (25% in 2014).

Portugal

Figure 106. Sales (mg/PCU) by antimicrobial class in Portugal, from 2011 to 2014

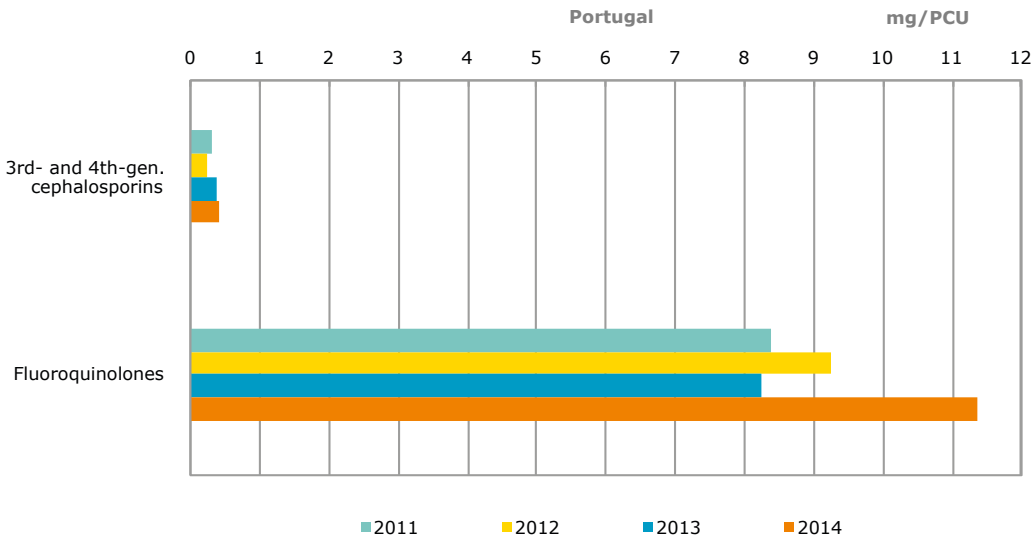


* Other antimicrobials (classified as such in the ATCvet system).

In Portugal, overall sales (mg/PCU) fluctuated during the period 2011 to 2014. An overall increase of 25 % was observed for this period; sales increased by 13 % from 2010 to 2014. The increase from 2011 to 2014 is mainly accounted for by higher sales of tetracyclines, polymyxins, penicillins as well as lincosamides, while a substantial reduction is seen for pleuromutilins.

Analysis of the national situation suggests that the increase in sales of macrolides was due to the rise in the number of new generic veterinary medicinal products as well as a change in the pattern of use of veterinary medicinal products (e.g. decrease in use of oxytetracycline).

Figure 107. Sales (mg/PCU) of 3rd- and 4th-generation cephalosporins and fluoroquinolones in Portugal, from 2011 to 2014



Sales (mg/PCU) of 3rd- and 4th-generation cephalosporins remained relatively stable from 2011 to 2014; this subclass accounted for 0.2% of total sales in 2011 and 2014. In 2014, sales of 3rd- and 4th-generation cephalosporins VMPs were 0.43 mg/PCU, while the average sales for 25 countries in that year were 0.26 mg/PCU (Figure 56).

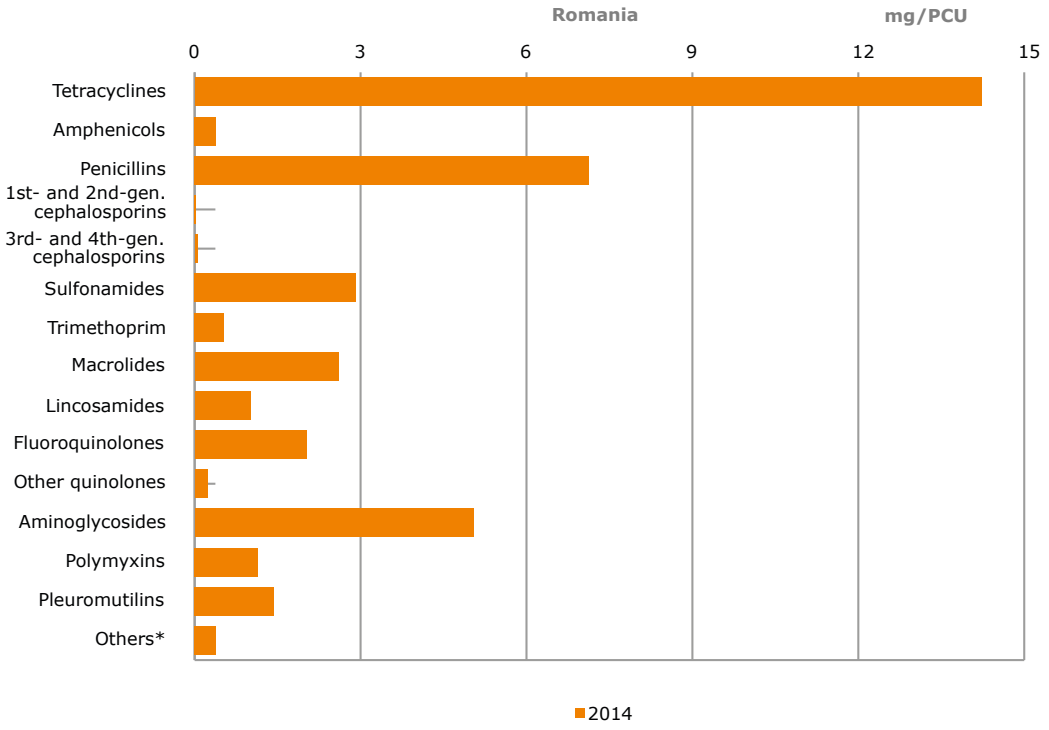
From 2011 to 2014, an increase was observed in the sales (mg/PCU) of fluoroquinolones, which peaked in 2014. In 2011, the proportion of total sales of fluoroquinolones was 5.2%, rising to 5.6% in 2014. This increase is mainly attributed to the availability of several wide spectrum generic VMPs, particularly those containing enrofloxacin. In 2014, the sales of fluoroquinolones were 11.4 mg/PCU, while the average sales for 25 countries in that year were 2.99 mg/PCU (Figure 56.).

In 2014, there was a decrease in sales (mg/PCU) of polymyxins; sales of polymyxins are highlighted as colistin is becoming a last-resort antimicrobial for use in humans and, therefore, subject to further attention when used in animals.

A five-year National Action Plan for the Reduction of Use of Antibiotics in Animals was initiated on 1 January 2014 to promote the prudent use of antimicrobials and to raise awareness about antimicrobial resistance. Conclusions on the performance of the plan cannot be drawn, but sales data from 2014 will be applied to further refine the measures currently being undertaken by the various stakeholders.

Romania

Figure 108. Sales (mg/PCU) by antimicrobial class in Romania, in 2014

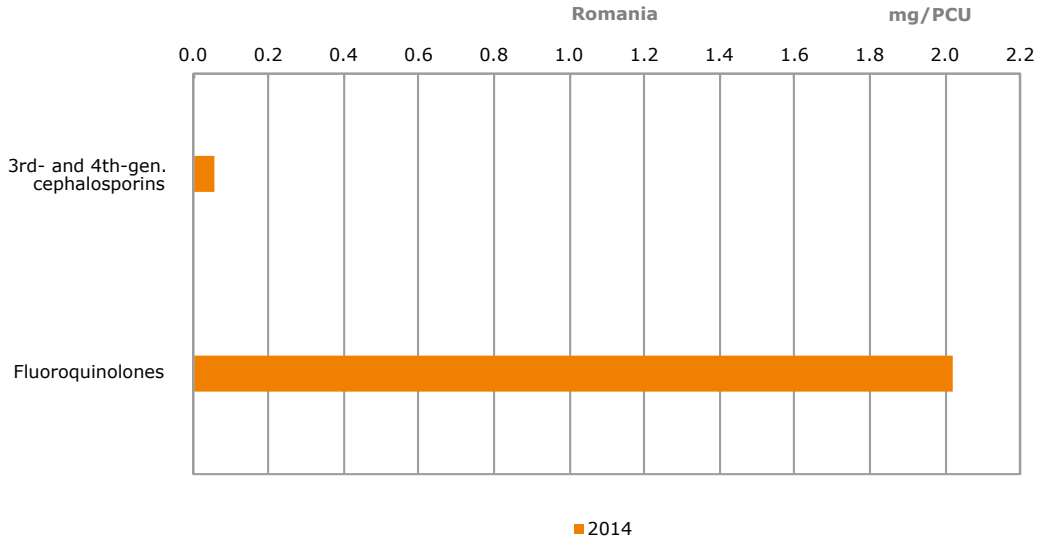


* Other antimicrobials (classified as such in the ATCvet system)

In 2014, sales of veterinary antimicrobial agents were reported to ESVAC for the first time. Data were provided by 37 wholesalers and 11 marketing authorisation holders.

In the same year, the total sales of antimicrobial VMPs in Romania were 39 mg/PCU. The most-sold classes were tetracyclines (36%), penicillins (18%) and aminoglycosides (13%). Sales of macrolides accounted for 6.6% of the total sales. No trends can be disclosed at this stage, as this is the first time Romania has reported sales.

Figure 109. Sales (mg/PCU) of 3rd- and 4th-generation cephalosporins and fluoroquinolones in Romania, in 2014

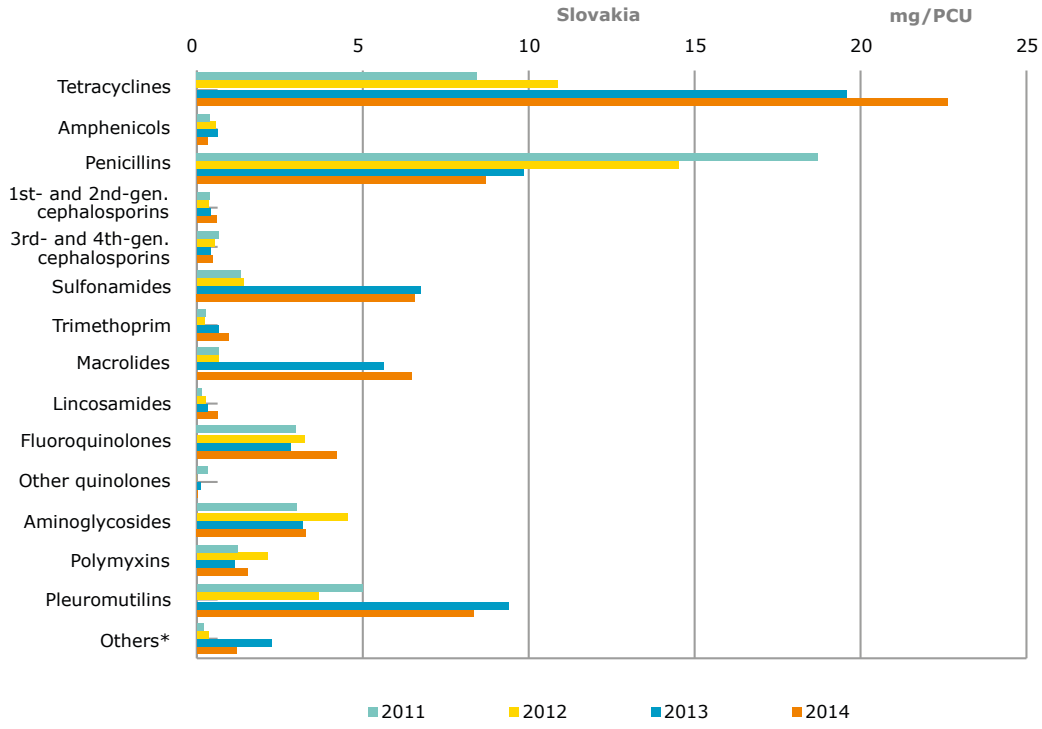


Sales of 3rd- and 4th-generation cephalosporins and fluoroquinolones accounted for 0.1% and 5.2%, respectively, of total sales. In 2014, the sales of 3rd- and 4th-generation cephalosporins VMPs were 0.05 mg/PCU; average sales for 25 countries in that year were 0.26 mg/PCU (Figure 56). Sales for fluoroquinolones were 2.02 mg/PCU, while the average sales for 25 countries in that year were 2.99 mg/PCU (Figure 56).

In 2016, to reduce consumption of antimicrobials and prevent antimicrobial resistance the National Sanitary Veterinary and Food Safety Authority has developed a strategy plus a supporting guide.

Slovakia

Figure 110. Import data by wholesalers (2011 and 2012) and sales to end-users (2013-2014) (mg/PCU) by antimicrobial class for food-producing species, in Slovakia

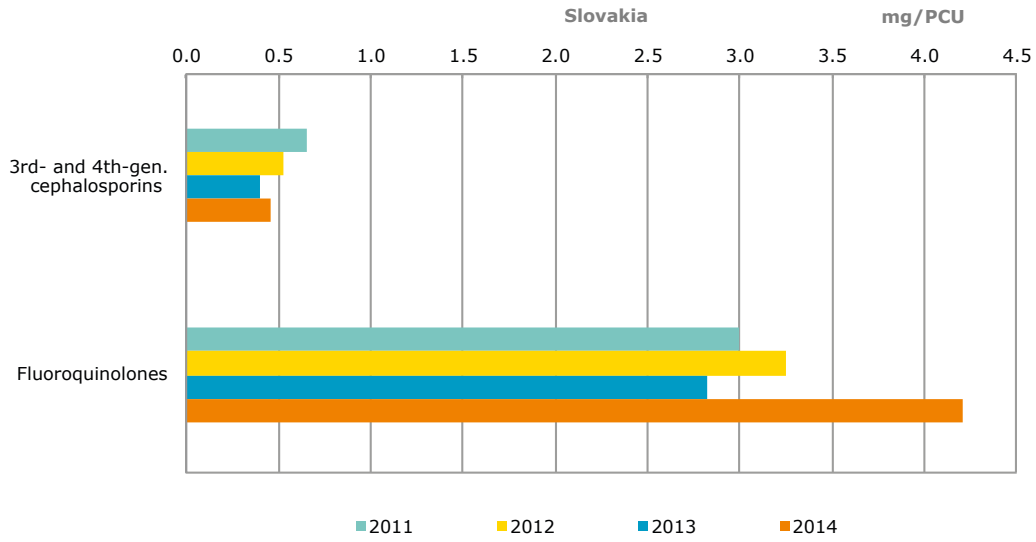


* Other antimicrobials (classified as such in the ATCvet system).

Data for 2011 and 2012 only included imports of antimicrobial VMPs by wholesalers, which implies that sales of antimicrobial VMPs obtained from national manufacturers were not accounted for. For 2013 and 2014, data included sales from wholesalers to end-users (veterinarians, pharmacies, producers of medicated feeding stuffs and farmers) — covering both import data and antimicrobial VMPs produced by national manufacturers. This difference in coverage is thought to be the main explanation for differences in sales between 2011 and 2012 and 2013 and 2014, and that the data reported for 2011 and 2012 are underestimated when compared to 2013 and 2014 data. Thus, the observed increase of 51% from 2011 to 2014 is partly artificial. Slovak manufacturers of veterinary medicinal products mainly produce products with tetracyclines, pleuromutilins, macrolides and sulphonamides, and it is the sale of these veterinary medicinal products which represent the largest difference in consumption data in 2013 and 2014, when compared to previous years.

From 2013 to 2014, for which data is provided from the same sources, a slight increase (4%) in the sales (mg/PCU) can be seen, which is mainly accounted for by tetracyclines.

Figure 111. Import data by wholesalers (2011 and 2012) and sales to end-users (2013-2014) (mg/PCU) of 3rd- and 4th-generation cephalosporins and fluoroquinolones for food-producing species, in Slovakia

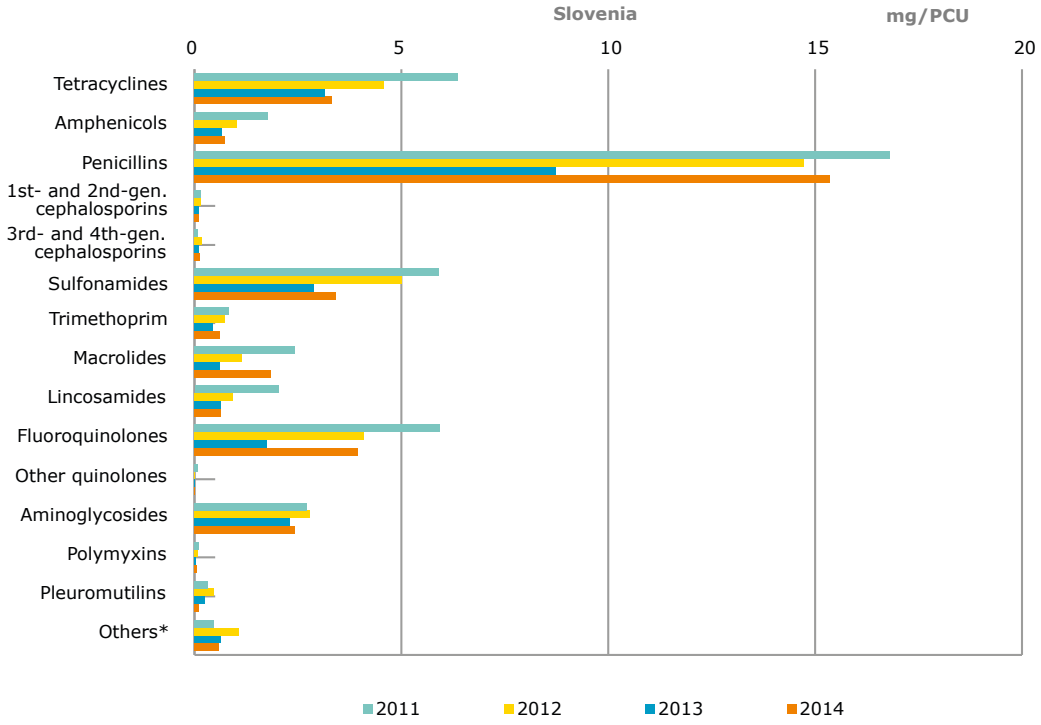


Sales (imports in 2011 and 2012), in mg/PCU, of 3rd- and 4th-generation cephalosporins declined from 2011 to 2014; in 2011, this subclass accounted for 1.5% of total sales; in 2014, this figure was 0.7%. In 2014, the sales of 3rd- and 4th-generation cephalosporins VMPs were 0.46 mg/PCU, while the average sales for 25 countries in that year were 0.26 mg/PCU (Figure 56).

In Slovakia, sales of fluoroquinolones increased during the period 2011 to 2014; in 2011 and 2014, the proportion of the total sales for this subclass accounted for 6.9% and 6.4%, respectively. Since sales of these classes may have been under-reported for 2011 and 2012, the increase might have been slightly overestimated. In 2014, sales of fluoroquinolone VMPs were 4.2 mg/PCU; the average sales for 25 countries in that year were 2.99 mg/PCU (Figure 56).

Slovenia

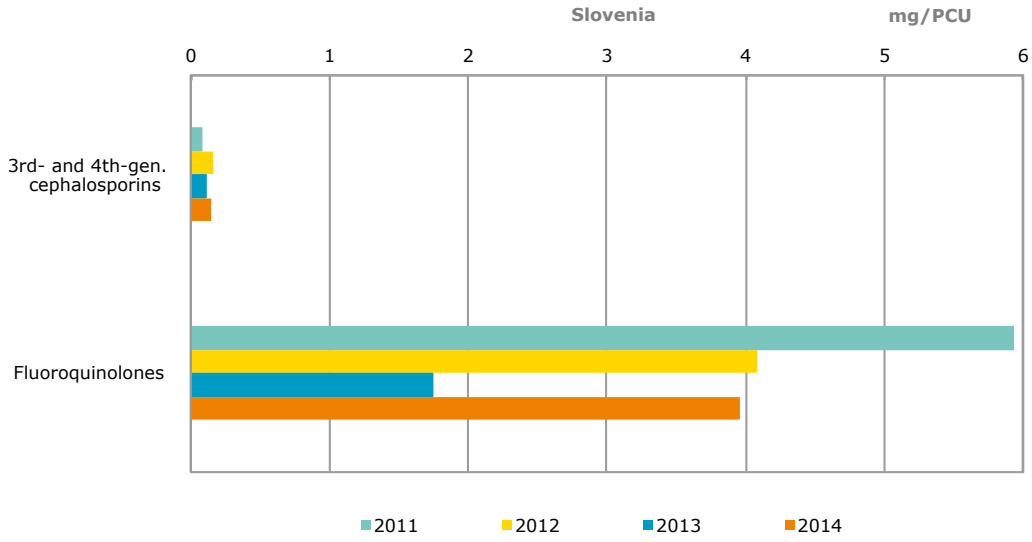
Figure 112. Sales (mg/PCU) by antimicrobial class for food-producing species, in Slovenia, from 2011 to 2014



* Other antimicrobials (classified as such in the ATCvet system).

From 2011 to 2014, there is an overall drop in the sales (mg/PCU) of veterinary antimicrobials from 46 mg/PCU to 33 mg/PCU. This implies a 28% decrease in sales of antimicrobials from 2011 to 2014; compared to 2010, sales in 2014 were 29% lower. The reduction in sales across the study period was accounted for by almost all classes.

Figure 113. Sales (mg/PCU) of 3rd- and 4th-generation cephalosporins and fluoroquinolones for food-producing species, in Slovenia, from 2011 to 2014

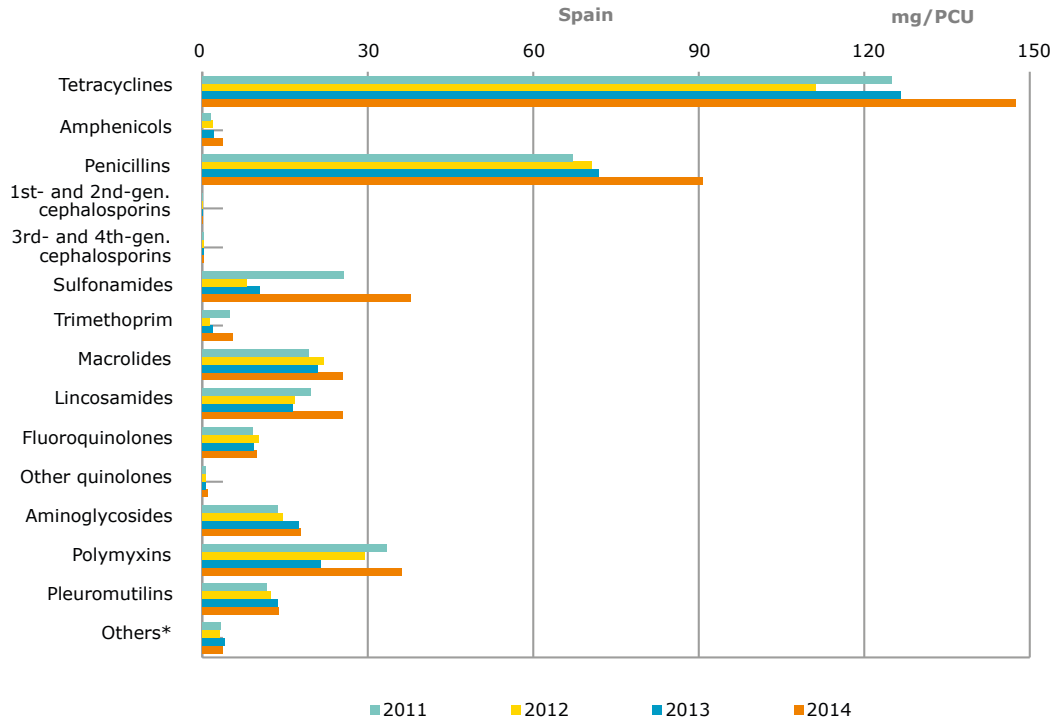


Sales (mg/PCU) of 3rd- and 4th-generation cephalosporins were relatively stable from 2011 to 2014. In 2011, this subclass accounted for 0.2 % of total sales, while for 2014, this figure was 0.4 %. In 2014, sales of 3rd- and 4th-generation cephalosporins VMPs were 0.14 mg/PCU, while the average sales for 25 countries in that year were 0.26 mg/PCU (Figure 56).

In Slovenia, the overall sales of fluoroquinolones fell by a total of 33 % over the period; in 2013, sales of fluoroquinolones was significantly lower compared to the other years. In 2011, fluoroquinolones accounted for 13 % of total sales; the corresponding figure for 2014 was 12 %. In 2014, sales of fluoroquinolone VMPs were 3.96 mg/PCU, while the average sales for 25 countries in that year were 2.99 mg/PCU (Figure 56).

Spain

Figure 114. Sales (mg/PCU) by antimicrobial class in Spain, from 2011 to 2014[1]

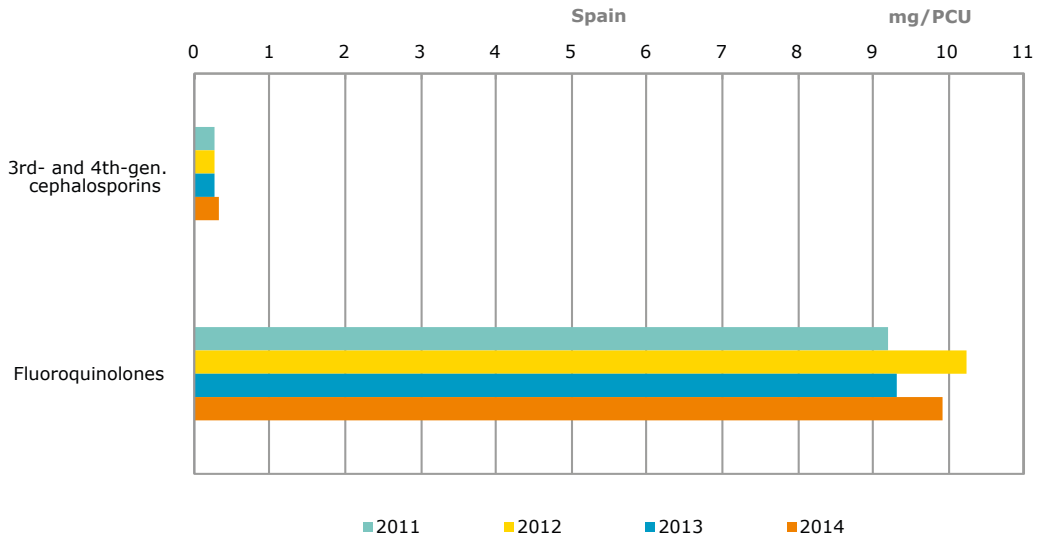


* Other antimicrobials (classified as such in the ATCvet system).
[1] Sales of 1st- and 2nd-generation cephalosporins were low each year (< 0.05% of total sales).

For the period 2011 to 2014, sales (mg/PCU) and sales patterns varied. An overall increase in sales of 25% was observed. The major part of the increase in the sales was accounted for by tetracyclines, penicillins sulfonamides and polymyxins. However, after Spain changed its system for collecting the 2014 data, it was then noted that for certain MAHs, sales of some VMPs identified as high selling (tonnes) in 2014 had not been reported for some MAHs for the previous years (2011–2013), although they had been marketed in these years. Therefore, the suggestion is that the sales data for Spain for 2011 to 2013 represent substantial underestimates.

In 2015, Spain adopted a national five-year plan to combat antimicrobial resistance. Six strategies are included in this common plan for the veterinary and human sectors, aimed at promoting appropriate use, ensuring effective surveillance systems, promoting research and innovation, and the development of a communication and education plan. Nevertheless, more time is needed before conclusions can be drawn on the efficacy of this plan in reducing the sales of antimicrobial agents (http://www.aemps.gob.es/publicaciones/publica/home.htm).

Figure 115. Sales (mg/PCU) of 3rd- and 4th-generation cephalosporins and fluoroquinolones in Spain, from 2011 to 2014

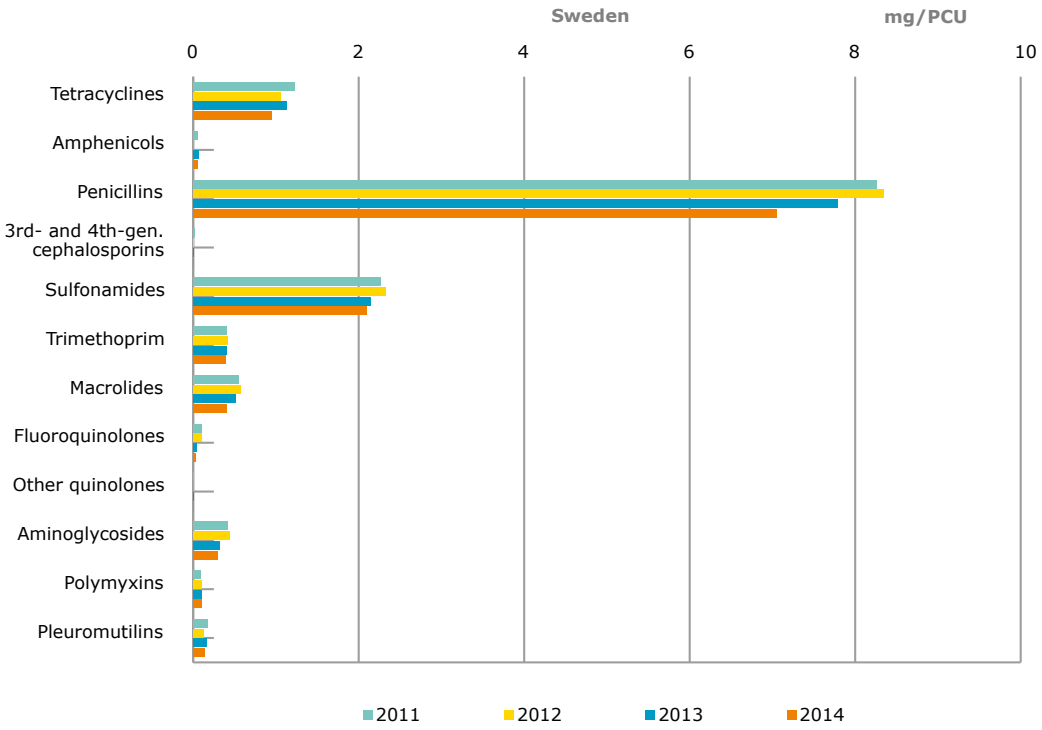


Sales (mg/PCU) of 3rd- and 4th-generation cephalosporins were stable from 2011 to 2014, accounting for 0.8% of the total sales in both years. In 2014, the sales of 3rd- and 4th-generation cephalosporins VMPs were 0.33 mg/PCU, while the average sales for 25 countries in that year were 0.26 mg/PCU (Figure 56).

The sales of fluoroquinolones were relatively stable from 2011 to 2014. In 2011, the sales of fluoroquinolones accounted for 2.7% of total sales, while in 2014, this figure was 2.4%. In 2014, the sales of 3rd- and 4th-generation cephalosporins VMPs were 9.92 mg/PCU, while the average sales for 25 countries in that year were 2.99 mg/PCU (Figure 56).

Sweden

Figure 116. Sales (mg/PCU) by antimicrobial class in Sweden, from 2011 to 2014[1]



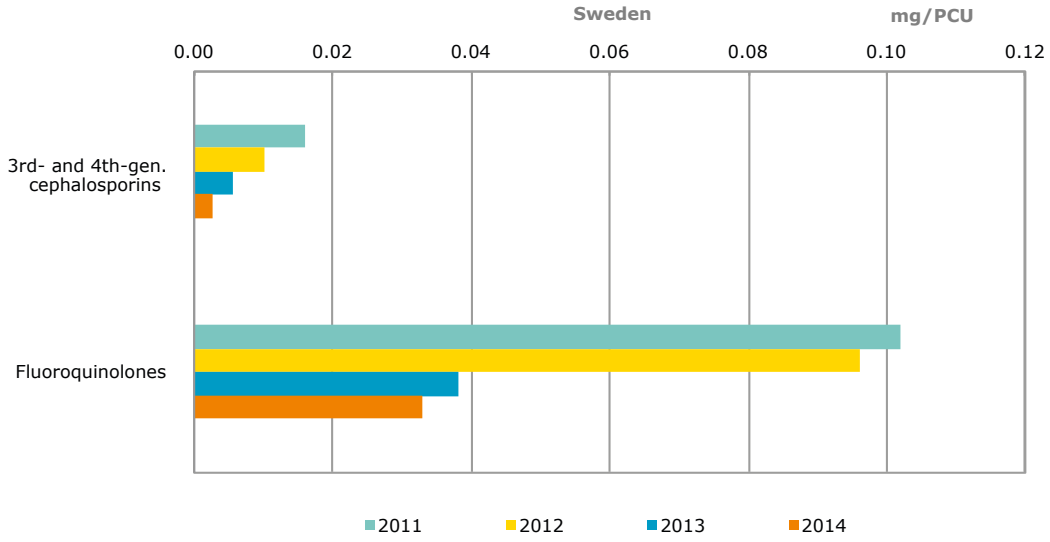
[1] No sales of 1st- and 2nd-generation cephalosporins in any of the years; minor amounts of lincosamides sold in 2012 (not shown in the graph); no sales of other quinolones in 2012 because sales for fish were not available.

From 2011 to 2014, the total sales of antimicrobials for food-producing animals fell from 13.5 mg/PCU to 11.5 mg/PCU. Decreases were noted for most classes, the highest decline in mg/PCU being seen for penicillins. The sales of macrolides dropped by 27 % of total sales expressed as mg/PCU, which is explained by lower sales of products for the group medication of pigs, a trend also noted for other classes (see below).

The Swedish pharmacy market was re-regulated in July 2009, after which some problems were identified concerning a lack of completeness in the sales data. From 2011, products sold under special licence were not fully captured by the system, but from 2012, this was 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 marketing authorisation. This problem is likely to affect products for injection but not the other pharmaceutical forms. For 2014, this was estimated at 5–10 % of the overall sales (see Swedres-Svarm 2014 for more information: www.sva.se). This is being further investigated by the competent authorities.

The fall in overall sales (mg/PCU) from 2011 to 2014 was 15 % and thus larger than the estimated lack of completeness. This means that there is an actual reduction, although its magnitude is uncertain. During the same period, sales of products for the medication of individual animals fell by 13 % and products for group medication by 27 %. The latter is part of a long-term trend since the early 1990s, explained by a change towards medication of individual animals and by the reduced occurrence of relevant diseases. In 2014, sales of products for group medication were 10 % of the total sales. These long-term overall changes are the result of a working model built on continuous collaboration between academia, governmental organisations, advisers in preventive medicine (animal health organisations), 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.

Figure 117. Sales (mg/PCU) of 3rd- and 4th-generation cephalosporins and fluoroquinolones in Sweden, from 2011 to 2014



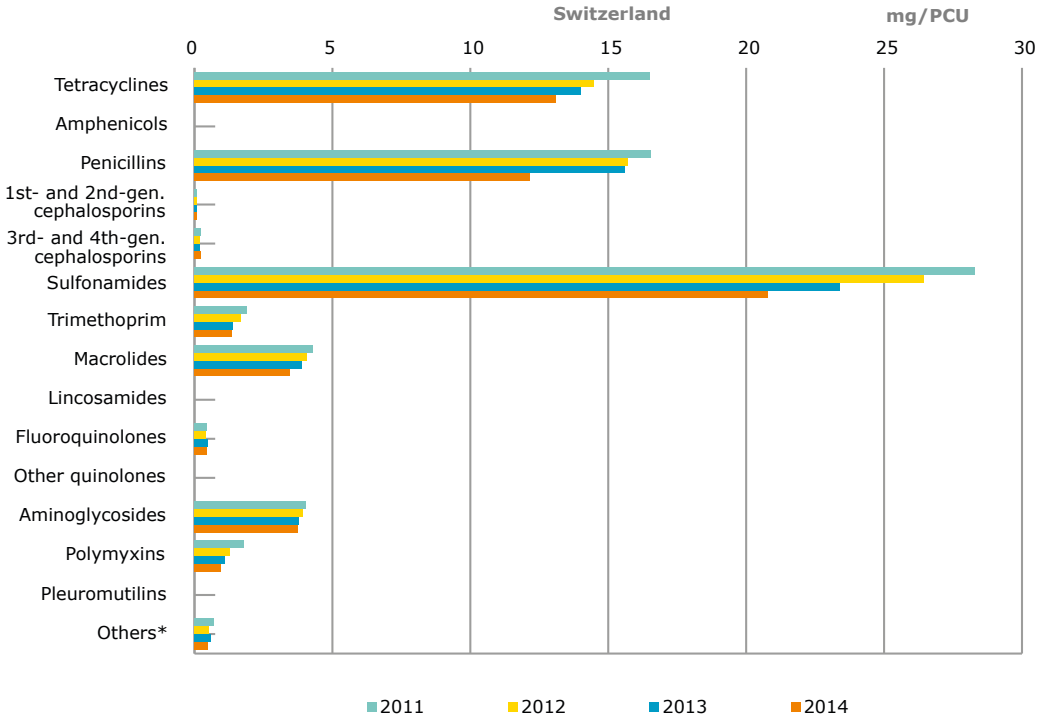
From 2011 to 2014, the sales of 3rd- and 4th-generation cephalosporins and fluoroquinolones, expressed as mg/PCU, decreased substantially by 83 % and 68 %, respectively. In 2011, 3rd- and 4th generation cephalosporins accounted for 0.1 % of the total sales; for 2014, this figure was 0.02 %. The corresponding figures for fluoroquinolones were 0.8 % and 0.3 %, respectively. This trend can probably be explained by increased adherence to the guidance for prudent use of antibiotics in the treatment of animals and by a regulation limiting veterinarians' rights to prescribe this type of antimicrobials (SJVFS 2013:42), which came into force on 1 January 2013.

In 2014, sales of VMPs with 3rd- and 4th-generation cephalosporins were 0.003 mg/PCU, while the average sales for 25 countries in that year were 0.26 mg/PCU (Figure 56).

In 2014, the sales of VMPs with fluoroquinolones were 0.03 mg/PCU, and the average sales for 25 countries in that year were 2.99 mg/PCU (Figure 56).

Switzerland

Figure 118. Sales (mg/PCU) by antimicrobial class in Switzerland, from 2011 to 2014[1]



* Other antimicrobials (classified as such in the ATCvet system).

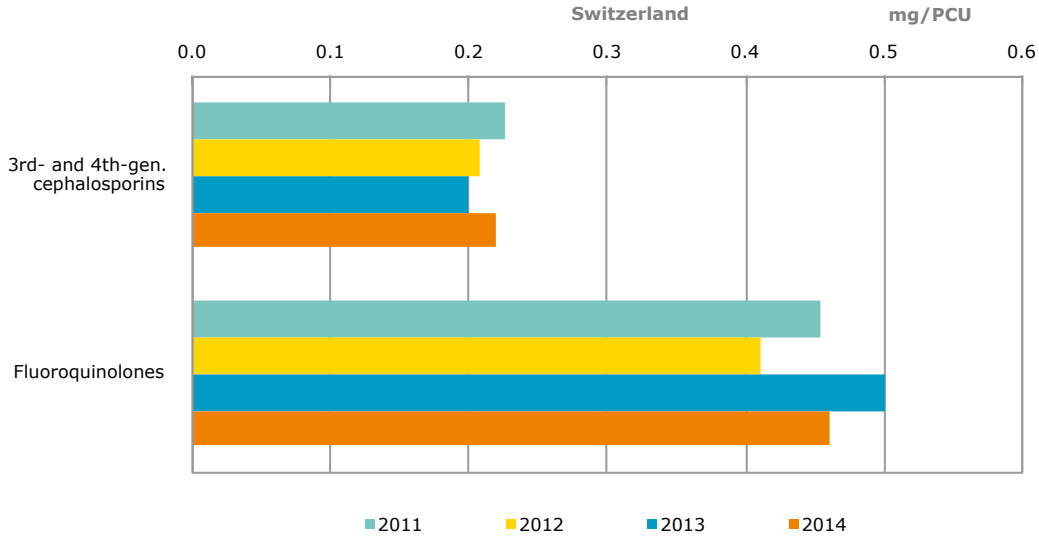
[1] For confidentiality reasons, amphenicols, other quinolones and pleuromutilins are grouped with others and lincosamides are grouped with macrolides. 2Data for 2011–2013 has not been submitted to the ESVAC database but have been retrieved from Annex 9 in previous ESVAC reports.

From 2011 to 2014, total sales in mg/PCU fell by 24 %. This is mainly due to declining sales of sulfonamides (-26.5 %), penicillins (-26.4 %) and tetracyclines (-20.7 %), the three top sellers in all the years under consideration. Among the classes with lower absolute sales figures, there is a 46.6 % reduction in the sales of polymyxins (mainly colistin). For other classes, the sales figures remained stable between 2011 and 2014.

Of the critically important antimicrobial classes with the highest priority for human medicine, sales in mg/PCU of macrolides declined (-20.0 %) whereas they remained stable for 3rd- and 4th-generation cephalosporins and fluoroquinolones.

In the time frame under investigation, there was almost no variation in the total PCU, with a minimal decrease of 0.2 %. However, there is a net decrease of 3.6 % in the number of slaughtered pigs which is compensated for almost exactly by an increase of 16.3 % in the number of slaughtered broilers. As production of the latter in Switzerland uses only small quantities of antimicrobials, the 24 % reduction in total sales expressed as mg/PCU is due to a net reduction in sales of antimicrobials.

Figure 119. Sales (mg/PCU) of 3rd- and 4th-generation cephalosporins and fluoroquinolones in Switzerland, from 2011 to 2014[1]



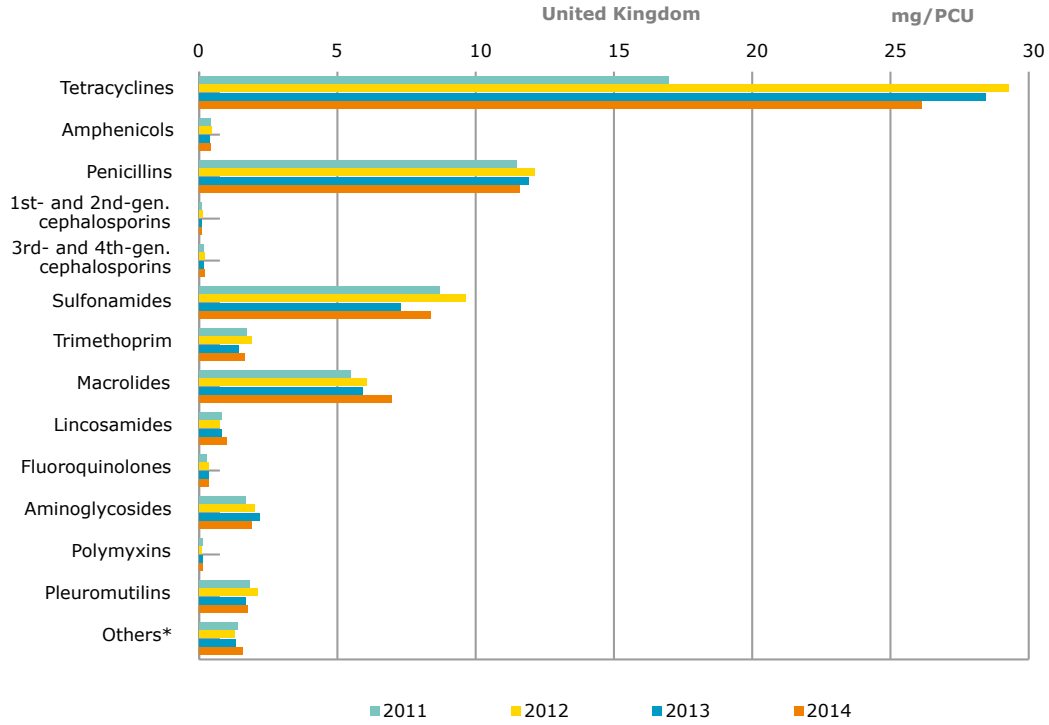
[1] Data for 2011–2013 were not submitted at package level.

Sales (mg/PCU) of 3rd- and 4th-generation cephalosporins were stable from 2011 to 2014, accounting for 0.3% of the total sales in 2011, while this figure was 0.4% in 2014. In 2014, sales of 3rd- and 4th-generation cephalosporins VMPs were 0.22 mg/PCU, and the average sales for 25 countries in that year were 0.26 mg/PCU (Figure 56).

Sales of fluoroquinolones were relatively stable from 2011 to 2014. In 2011, sales of fluoroquinolones accounted for 0.6% of total sales, while in 2014, this figure was 0.8%. In 2014, the sales of fluoroquinolones VMPs were 0.46 mg/PCU, and the average sales for 25 countries in that year were 2.99 mg/PCU (Figure 56).

United Kingdom

Figure 120. Sales (mg/PCU) by antimicrobial class in the United Kingdom, from 2011 to 2014[1]



* Other antimicrobials (classified as such in the ATCvet system).
[1] No sales of other quinolones in any of the years.

From 2011 to 2014, a 22% increase in the sales of veterinary antimicrobial agents (in mg/ PCU) was observed in the United Kingdom, with sales at their lowest level in 2011. One explanation for this could be the altered product-purchasing behaviour in anticipation of a change in marketing authorisation holder(s) for certain tetracycline-containing products, between 2010 and 2011, which led to an increase in sales prior to the change and a subsequent reduction in sales in early 2011. It should be noted that over the period 2010 to 2014, a 9% decline in was observed.

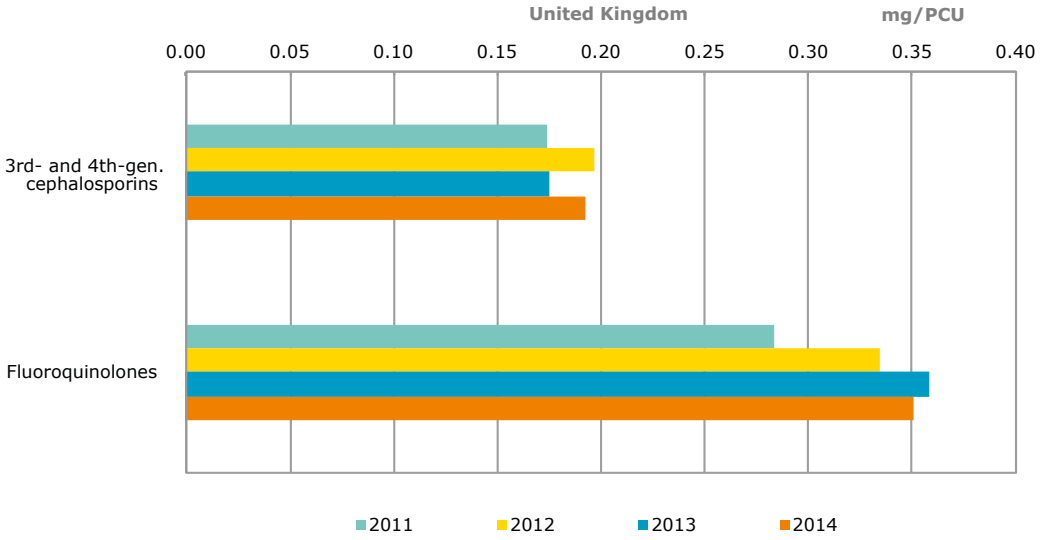
The increase in sales is accounted for by most of the antimicrobial classes although, in particular, there was an increase in sales of tetracyclines as well as macrolides.

Tetracyclines are the most-sold class, accounting for 33% of total sales in 2011; the corresponding figure was 42% in 2014. In parallel, the proportion of penicillins sold fell from 22% in 2011 to 19% in 2014.

A programme for the surveillance of antibiotic consumption is being developed in the UK. In 2015, a review of progress and some preliminary data were published in UK-VARSS[22]. The British Poultry Council (BPC) provided data collected from their members, representing 90% of the commercial meat poultry industry. These data indicated that commercial meat poultry flocks had reduced their use of antibiotics by 33% between 2013 and 2014.

[22] https://www.gov.uk/government/publications/veterinary-antimicrobial-resistance-and-sales-surveillance-2014

Figure 121. Sales (mg/PCU) of 3rd- and 4th-generation cephalosporins and fluoroquinolones in the United Kingdom, from 2011 to 2014



Sales (mg/PCU) of 3rd- and 4th-generation cephalosporins were relatively stable from 2011 to 2014; for all four years this subclass accounted for 0.3% of the total sales.

Sales of fluoroquinolones were stable during the study period and accounted for 0.6% of the total sales in both 2011 and 2014.

In 2014, the sales of 3rd- and 4th-generation cephalosporins VMPs were 0.19 mg/PCU, while the average sales for 25 countries in that year were 0.26 mg/PCU (Figure 56).

In 2014, the sales of fluoroquinolones VMPs were 0.35 mg/PCU, and the average sales for 25 countries in that year were 2.99 mg/PCU (Figure 56).

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 the base, while for the ESVAC the strength is reported as given on the label summary of product characteristics/label of the VMP, which typically is the salt (see references to national reports in Annex 6).

The data sets provided for the ESVAC represent exclusively sales of antimicrobial agents sold as veterinary medicinal products, since antimicrobial growth promoters are not allowed in the ESVAC participating countries.

Dermatological preparations (ATCvet group QD) and preparations for sensory organs (ATCvet group QS) were not included in the data sets. Since, in 2011, these pharmaceutical forms represented, for example, only 0.13% in Denmark, (E. Jacobsen, unpublished data), 0.2% in the Czech Republic (Lucie Pokludová, unpublished data), 0.35% in France (G. Moulin, unpublished data), 0.002% in Norway (www.vetinst.no/eng/Publications/Norm-Norm-Vet-Report) and 0.49% in the United Kingdom (Hannah Reeves, unpublished data) of the total tonnes sold, the annual 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 in companion animals is generally limited to hospitalised animals or perioperative treatments. Data from Denmark and France for 2011 showed that approximately 0.1% and 1.2%, respectively, of the injectable antimicrobial VMPs sold 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 NCs/alternates in 2011 to be approximately 0.01%, 1%, 3%, 9% and 10% of the total sales, respectively[23]. 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 significantly influence 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 among data sources, for example, between wholesalers, and consequently it is assumed that double reporting has been avoided.

In 2014, all countries provided sales data except for Denmark and Sweden which submitted prescription data.

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, as amended, 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 made it possible for all the participating countries to identify all distributors of antimicrobial VMPs in their country, and consequently 100% data-source coverage could be obtained. 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 29 countries.

In the current report, data presented on sales of veterinary antimicrobial agents for companion animals are based solely 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 those countries with a high number of dogs and cats. Furthermore, injectable antimicrobial

[23] EMA/ESVAC. 2011. European Medicines Agency, European Surveillance of Veterinary Antimicrobial Consumption (ESVAC). Sales of veterinary antimicrobial agents in 25 EU/EEA countries in 2011: http://www.ema.europa.eu/docs/en_GB/document_library/Report/2013/10/WC500152311.pdf

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 underestimated, while the data on sales for food-producing animals are slightly overestimated. 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, 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.

Dosing of the various antimicrobial agents between and within classes, as well as between animal species, varies substantially, sometimes by several orders, as reflected by the DDDvet and DCDvet values published by EMA in 2016[24]. For example, the dose for a whole treatment (DCDvet) with an oral fluoroquinolone VMP may be 10–40 mg/kg between cattle, pigs and poultry, while with an oral tetracycline VMP this may vary between 110 and 280 mg/kg. This implies that a given weight of active ingredient of fluoroquinolone sold can be used to treat several times as many animals as the same weight of active ingredient of a 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, a 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 across the countries should be done with great care.

The proportion of sales of small packages of oral powders and oral solutions sufficient for treatment of only a single or a few animals is very low compared to those applicable for group treatment, and oral solutions and oral powders are typically used for group treatment. Thus, the data presented in this report on sales of oral powder and oral sales are considered to be a reasonable estimate of sales of these forms for group treatment.

Product information requested in the ESVAC template includes the 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

The PCU was stable over the years; only a 0.9% reduction of PCU was observed for the 25 countries, while the reduction in tonnes sold was 2.9%.

In 25 countries reporting sales data to ESVAC for the years 2011–2014, there was an overall decrease in the sales (mg/PCU) of 2.4%. The sales were 162 mg/PCU, 153 mg/PCU, 147 mg/PCU and 158 mg/PCU in 2011, 2012, 2013 and 2014, respectively (Figure 56).

However, Spain changed its system for collecting data in 2014 data, when it was identified that for certain MAHs, sales of some VMPs identified as high-selling (tonnes) VMPs in 2014 had not been reported for some MAHs for the previous years (2011–2013), although they were marketed during these years. Therefore, the suggestion is that the sales data for Spain for 2011 to 2013 represent substantial underestimates. The consumption of antimicrobials in Spain is one of the highest among the European countries participating in the ESVAC; sales aggregated by the 25 countries for 2011 and 2014, for example, are therefore not directly comparable.

By excluding Spain, a 12% fall in the sales (mg/PCU) was observed between 2011 (138 mg/PCU) and 2014 (121 mg/PCU) in the remaining 24 countries (Austria, Belgium, Bulgaria, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Hungary, Iceland, Italy, Ireland, Latvia, Lithuania, the Netherlands, Norway, Poland, Portugal, Slovakia, Slovenia, Sweden and the United Kingdom).

[24] Available at the European Medicines Agency website (www.ema.europa.eu) via Home > Veterinary regulatory >Antimicrobial resistance (http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/general/general_content_001493.jsp&mid=WC0b01ac0580a2fcf5)

The sales (mg/PCU) of 3rd- and 4th-generation cephalosporins in 25 countries, that provided data for the years 2011-2014, remained stable during this period, while an increase of 18% was observed for the fluoroquinolones (Figure 56.). The sales (mg/PCU) of polymyxins (mostly colistin) in these 25 countries decreased by 9%.

From 2011 to 2014, a drop of more than 5% (range 8% to 40%) in the sales (mg/PCU) was observed for nine countries (Table 8.). For five countries, an increase of more than 5% was observed (range 11% to 51%). The country with an increase in sales of 51% changed its data collection system between 2011 and 2014, consequently these data should be interpreted with a great care.

Tentative explanations provided by some of the countries (see Chapter 2.8.2) for the decline in sales include, among others, the implementation of responsible-use campaigns, changes in animal demographics, restrictions on use, increased awareness of the threat of antimicrobial resistance, and/or the setting of targets. The reduced sales of veterinary antimicrobials in some countries indicate that there is potential for a decline in other countries, too.

A large difference in the sales, expressed as mg/PCU, was observed between the most- and least-selling countries. This is likely to be partly due to differences in the composition of the animal population in the various countries (e.g. more pigs than cattle). Furthermore, differences in the production system may play an important role. Amongst other factors, 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 must also be considered. Differences in the selection of data source — i.e. prescriptions, sales data or purchase data — may have an impact, although this is considered to be low.

In 2014, the prescribing patterns for the various veterinary antimicrobial classes, expressed as mg/PCU, varied substantially between the countries. Notable variations were observed between the different countries in the proportion of the sales accounted for by the CIAs with the highest priority in human medicine — 3rd- and 4th-generation cephalosporins, fluoroquinolones and macrolides, with proportions ranging from 0.01% to 1.5%, 0.01% to11.9%, and 0% to 16.9%, respectively. Since the major proportion of the sales of these classes/subclasses was accounted for by macrolides, the variations observed between the countries are likely, in part, to reflect difference in the relative proportion of the various animal species and, in particular, differences in pig production (use of macrolides).

Overall, in the 29 countries, the sales (mg/PCU) of 3rd- and 4th-generation cephalosporins, fluoroquinolones, polymyxins (mostly colistin) and macrolides accounted for 0.2%, 1.9%, 6.6% and 7.5%, respectively, of the total sales of antimicrobial VMPs in 2014.

Variations in both the sales patterns and the magnitudes of sales may be due to differences between the countries in the relative proportion of the various food-producing animal species, the availability of veterinary antimicrobial products on the market, prices, animal-production systems and the general situation with regard to infectious diseases. However, these factors cannot fully explain the differences. Other influences, such as the focus on disease prevention by management, vaccines, or implementation of responsible-use campaigns in some countries may also have impacted on the sales patterns.

Another important finding was that the total sales, both in tonnes and in mg/PCU, of veterinary antimicrobial agents in the 29 EU/EEA countries were mainly accounted for by pharmaceutical forms that can be used for mass treatment (premixes) or group treatment (oral powder and oral solution). However, this varies significantly between the countries.

Of the total number of product presentations (i.e. product name, form, strength and pack size) of antimicrobial VMPs applicable for food-producing animals (tablets excluded) sold in 2014, 81.2% contained only one active ingredient, 16.8% contained two active ingredients and 1.9% contained three active ingredients; in addition, 0.2% (n=15) 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.

Considerable variations were observed between the sales and sales patterns, expressed in tonnes, of veterinary antimicrobial agents as tablets used assigned as sold for use in (for companion animals). This is the case in particular for the sales of tablets containing combinations of penicillins + beta-lactamase inhibitors (sales of clavulanic acid not included in the data), which varied between 0% and 100% of the total sales of penicillin tablets. It must be noted that human medicinal products and injectable veterinary products can also be used in companion animals, thus the data on sales of tablets should be interpreted with great care.

Annex 1. Tables

Table A1. Sales, in tonnes of active ingredient, of veterinary antimicrobial agents applicable mainly for food-producing animals by antimicrobial class (presented according to the ATCvet hierarchical system) by country, for 2014 (tablets not included)

Country	Tetracyclines	Amphenicols	Penicillins	1st- and 2nd-gen. cephalosporins	3rd- and 4th-gen. cephalosporins	Sulfonamides	Trimethoprim	Macrolides	Lincosamides	Fluoroquinolones	Other quinolones	Aminoglycosides	Polymyxins	Pleuromutilins	Others[1]	Total tonnes
Austria	29.7	0.3	8.0	0.1	0.2	5.9	0.8	4.6	0.1	0.5		1.2	1.5	0.4	0.2	53.4
Belgium	61.7	1.6	81.8	0.1	0.8	64.4	12.9	18.3	4.8	1.9	1.6	1.0	5.7	1.1	7.9	265.7
Bulgaria	14.6	1.1	4.4	0.01	0.03	1.9	0.3	5.5	1.6	0.7		1.0	0.2	1.0	0.2	32.6
Croatia	15.3	1.1	7.3	0.1	0.04	8.3	1.0	0.5	0.1	1.0	0.2	3.7	1.1	0.4	0.1	40.2
Cyprus	16.2	0.1	3.3	0.001	0.1	6.1	1.2	1.9	7.5	0.1	0.1	0.5	1.2	3.3	0.3	41.7
Czech Republic	20.0	0.3	13.1	0.2	0.3	9.1	1.4	3.8	0.2	1.2	0.02	1.6	0.7	3.4	0.5	55.9
Denmark	31.2	1.1	27.8	0.1	0.04	12.0	2.1	11.9	2.2	0.01	1.7	3.4	1.0	10.1	2.2	106.8
Estonia	2.2	0.1	3.1	0.03	0.1	0.2	0.03	0.6	0.3	0.2		0.4	0.4	1.8	0.5	9.8
Finland	2.6	0.1	5.1	0.03	0.01	2.3	0.5	0.5	0.1	0.1		0.03		0.04		11.4
France	307.0	5.9	92.0	1.8	2.0	143.2	22.7	57.4	4.2	4.6	5.6	54.2	50.3	6.4	4.1	761.5
Germany	362.9	5.1	501.6	0.5	3.7	121.1	15.2	108.7	14.8	12.0		26.6	106.8	16.0	11.0	1,305.8
Hungary	82.5	1.2	29.8	0.1	0.2	4.0	0.9	3.3	3.3	7.1	0.2	2.1	5.5	8.3	2.0	150.4
Iceland	0.04		0.4		0.001	0.04	0.01		0	0.001	0	0.2		0	0	0.6
Ireland[2]	38.9	1.5	16.8	0.4	0.2	17.4	1.4	6.3	0.4	0.7	0	5.1			0.7	89.6
Italy	387.7	18.8	461.9	0.7	1.6	135.3	16.7	109.5	73.6	12.3	15.8	17.6	117.0	36.3	26.8	1,431.6
Latvia	1.7	0.01	1.7	0.03	0.1	0.3	0.05	0.4	0.02	0.3	0.001	0.7	0.1	0.9	0.04	6.3
Lithuania	1.4	0.1	2.8	0.03	0.06	2.9	0.7	0.9	0.2	1.1	0.3	0.7	0.04	0.6	0.2	11.9
Luxembourg	0.8	0.1	0.4	0.01	0.03	0.3	0.1	0.1	0.04	0.04	0.002	0.1	0.1	0.01	0.1	2.1
Netherlands	75.4	4.3	49.3	0.1	0.01	40.5	7.5	28.0	0.4	0.4	3.4	2.0	1.5	1.1	0.5	214.5
Norway	0.1	0.4	2.9		0.001	1.5	0.3	0.004		0.01	0.1	0.5		0.1		5.8
Poland	181.6	9.1	170.0	1.1	0.7	42.2	4.1	45.8	3.2	37.1	0.3	32.4	20.6	26.5	4.0	578.5
Portugal	72.6	1.6	32.2	0.4	0.4	6.5	1.3	23.2	6.5	10.7	0.2	4.0	16.6	11.3	2.5	190.0
Romania	35.6	1.0	17.8	0.1	0.1	7.3	1.3	6.5	2.5	5.1	0.6	12.6	2.9	3.6	0.9	97.9
Slovakia	5.6	0.1	2.2	0.1	0.1	1.6	0.2	1.6	0.2	1.0	0.01	0.8	0.4	2.1	0.3	16.3
Slovenia	0.6	0.1	2.6	0.02	0.02	0.6	0.1	0.3	0.1	0.7	0.001	0.4	0.01	0.02	0.1	5.7
Spain	1,043.0	25.9	641.7	0.4	2.3	267.3	39.2	180.8	179.6	70.2	6.5	127.0	255.5	98.5	26.0	2,963.9
Sweden	0.8	0.1	5.7	0.001	0.002	1.7	0.3	0.3	0.001	0.03	0.001	0.2	0.1	0.1		9.3
Switzerland	10.7	0.2	9.9	0.1	0.2	17.0	1.1	2.8	0.03	0.4	0.001	3.1	0.8	0.2	0.03	46.4
United Kingdom[3]	180.6		80.2	0.7	1.3	57.9	11.4	48.1	6.9	2.4		13.2		12.3	13.6	429.6
Total 29 countries	**2,983.0**	**84.1**	**2,276.6**	**7.3**	**14.6**	**978.7**	**144.6**	**671.5**	**312.8**	**171.8**	**36.4**	**316.4**	**590.9**	**245.8**	**101.9**	**8,935.5**

[1] Bacitracin, paromycin and spectinomycin (classified as 'Other antibacterials' in the ATCvet system).

[2] Polymyxins and pleuromutilins are aggregated with 'Others' for commercial confidentiality reasons.

[3] Polymyxins and amphenicols are aggregated with 'Others' for commercial confidentiality reasons.

Table A2. Distribution of sales, in mg/PCU, of veterinary antimicrobial agents applicable mainly for food-producing animals[1], by administration route/form and country, for 2014

Country	Premix	Oral powder	Oral solution	Injection	Oral paste	Bolus	Intramammary prep.	Intrauterine prep.	Total mg/PCU
Austria	2.4	46.4	1.3	4.9	0.2		1.0	0.2	56.3
Belgium	31.2	110.4	3.1	12.8	0.001	0.1	0.5	0.2	158.3
Bulgaria	35.8	31.2	6.2	9.3			0.3	0.1	82.9
Croatia	40.2	61.6	11.8	31.0	0.03		1.7	0.8	147.2
Cyprus	306.1	52.6	14.9	16.8	0.1	0.1	0.8	0.1	391.5
Czech Republic	15.6	22.7	30.4	8.9	0.02	0.001	1.2	0.6	79.5
Denmark	1.8	5.9	19.8	15.9	0.5	0.007	0.2	0.1	44.2
Estonia	3.2	44.8	1.7	16.4			1.7	0.2	68.0
Finland	2.9	6.5	0.01	11.3	1.1		0.5		22.3
France	37.8	0.1	52.8	15.0	0.1	0.001	1.0	0.2	107.0
Germany	0.4	75.0	65.4	7.0	0.1		0.8	0.6	149.3
Hungary	120.3	51.6	14.1	6.4	0.01		0.4	0.2	193.1
Iceland	0.009	0.1	0.2	4.5	0		0.3	0.1	5.2
Ireland	18.5	6.6	9.5	11.3	0.03	0.3	1.8	0.009	48.0
Italy	169.0	120.4	50.5	19.1	0.2	0.001	0.6	0.3	359.9
Latvia		21.0	1.7	11.8	0.003	0.7	1.5	0.1	36.7
Lithuania	0.02	17.8	7.2	8.1		0.7	1.5	0.2	35.5
Luxembourg	0	25.2	1.6	12.3	0.2	0.1	1.2	0.3	40.9
Netherlands	1.1	51.5	6.5	8.5		0.04	0.6	0.1	68.4
Norway	0.3	0.1	0.1	1.7	0.7		0.2	0.1	3.1
Poland	9.4	99.0	16.3	13.1	0.001		2.7	0.3	140.8
Portugal	138.7	22.6	30.3	9.6	0.005		0.5	0.03	201.6
Romania	2.8	17.7	6.6	11.5	0.02	0.1	0.2	0.3	39.2
Slovakia	18.5	5.5	28.4	12.4	0.01		1.1	0.05	65.9
Slovenia	1.8	15.8	4.9	9.4			1.2	0.2	33.4
Spain	292.1	86.5	22.7	17.2	0.01	0.001	0.3	0.04	418.8
Sweden	0.3	0.1	0.8	8.8	1.4		0.2	0.002	11.5
Switzerland	36.3	5.2	0.1	9.4	0.5	0.01	4.3	1.1	56.9
United Kingdom	40.7	10.5	3.6	6.5	0.1	0.3	0.4	0.01	62.1

[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 2014[1]

Country	Tetracyclines	Amphenicols	Penicillins	Sulfonamides	Trimethoprim	Macrolides	Lincosamides	Other quinolones	Aminoglycosides	Polymyxins	Pleuromutilins	Others[2]	Total mg/PCU premixes
Austria	30%					58.8%	3.6%			2.4%	2.0%	3.6%	2.4
Belgium	15.0%	0.1%	25.0%	41.6%	8.3%	6.1%	0.5%		0.2%	1.8%	0.9%	0.5%	31.2
Bulgaria	71.1%	5.0%		1.6%		21.1%					1.2%		35.8
Croatia	40.2%	2.4%		36.0%	1.1%	1.0%	0.2%		18.2%		0.7%	0.2%	40.2
Cyprus	34.9%	0.1%	6.0%	15.4%	3.1%	4.2%	22.7%			3.3%	9.9%	0.3%	306.1
Czech Republic	32.4%	0.2%	20.5%	19.1%	3.4%	12.8%	0.4%			2.3%	7.8%	1.2%	15.6
Denmark			1.6%	51.3%	10.3%		2.0%	33.2%				1.6%	1.8
Estonia						65.5%	17.3%					17.3%	3.2
Finland	48.4%	4.6%		12.3%	2.5%	24.8%	7.4%						2.9
France	51%		4.7%	23.4%	3.8%	4.4%	0.7%	0.1%	4.0%	7.0%	1.1%	0.2%	37.8
Germany	27%		1.8%	53.8%	10.8%					2.2%	5.0%		0.4
Hungary	73.8%	0.1%	7.5%	1.7%	0.3%	2.2%	2.2%			3.7%	6.8%	1.7%	120.3
Iceland	100%												0.0
Ireland	71.5%	0.05%	0.7%	14.4%	2.9%	9.5%	0.1%		0.7%		0.02%	0.1%	18.5
Italy	31.7%	0.7%	35.5%	9.2%	0.8%	4.1%	4.8%	0.6%	0.3%	8.4%	3.4%	0.7%	169.0
Latvia													0
Lithuania		100%											0.02
Luxembourg													0
Netherlands	58%		0.03%	31.9%	6.4%	2.7%					1.0%		1.1
Norway		78.9%						21.1%					0.3
Poland	16.6%	0.3%	13.3%	52.7%		10.8%	0.8%		0.1%	2.6%	2.3%	0.4%	9.4
Portugal	46.5%	0.6%	12.0%	3.2%	0.7%	13.8%	0.5%	0.01%	1.6%	12.1%	7.8%	1.1%	138.7
Romania	35%		0.9%	10.5%	2.1%	5.7%				2.3%	43.4%		2.8
Slovakia	68.3%	0.1%	2.1%	11.5%	2.1%	2.8%	1.8%			1.8%	9.0%	0.4%	18.5
Slovenia	3.2%	4.9%		1.9%		46.1%	21.9%					21.9%	1.8
Spain	39.4%	0.4%	19.7%	10.9%	1.5%	6.5%	3.3%	0.1%	3.0%	10.0%	4.4%	0.8%	292.1
Sweden	10.9%	18.7%				54.0%		0.1%			16.3%		0.3
Switzerland	31%		14.3%	41.0%	2.1%	8.2%	0.03%	0.01%		2.6%	0.7%	0.03%	36.3
United Kingdom	54.5%	0.2%	5.9%	18.7%	3.7%	12.6%	0.4%		0.7%		3.0%	0.3%	40.7

[1] Negligible amount of cephalosporins sold is 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 2014[1,2]

Country	Tetracyclines	Penicillins	Sulfonamides	Trimethoprim	Macrolides	Lincosamides	Other quinolones	Aminoglycosides	Polymyxins	Pleuromutilins	Others[3]	Total mg/PCU oral powders
Austria	64.4%	12.7%	11.0%	1.4%	6.4%	0.01%		0.3%	3.2%	0.6%	0.01%	46.4
Belgium	28.3%	29.9%	21.5%	4.3%	6.7%	2.1%	0.8%	0.0%	2.5%	0.3%	3.5%	110.4
Bulgaria	31.5%	27.1%	4.9%	0.3%	15.1%	12.5%		0.5%	0.6%	6.8%	0.8%	31.2
Croatia	58.2%	26.1%	4.5%	1.1%	0.9%	0.1%	0.9%	0.1%	6.4%	1.4%	0.2%	61.6
Cyprus	77.0%	9.8%	1.3%	0.04%	6.3%	1.1%	0.7%	0.5%	1.2%		2.1%	52.6
Czech Republic	66.5%	1.9%	10.8%	4.4%	10.0%			1.6%	0.03%	4.9%		22.7
Denmark	47.6%	0.5%	19.5%	3.9%	13.8%		1.7%	0.5%	0.1%	12.3%		5.9
Estonia	27.9%	26.4%	1.4%	0.3%	3.8%	2.5%			6.1%	26.6%	5.0%	44.8
Finland	39.4%	5.2%	41.5%	8.3%	4.3%					1.2%		6.5
France	53.2%	9.2%									37.6%	0.1
Germany	27.9%	47.5%	14.7%	1.9%	2.5%	0.5%		0.5%	2.9%	1.5%	0.04%	75.0
Hungary	30.5%	51.0%	3.2%	0.8%	1.5%	3.0%	0.5%	2.0%	3.3%	3.7%	0.6%	51.6
Iceland		14.3%	45.6%	9.2%				30.8%				0.1
Ireland	66.2%		31.4%	1.3%	0.2%	0.9%						6.6
Italy	32.4%	41.9%	1.6%		11.9%	4.9%	0.9%	0.5%	1.8%	1.4%	1.6%	120.4
Latvia	39.2%	21.2%	3.0%	0.1%	9.5%	0.02%			2.8%	24.2%	0.04%	21.0
Lithuania	16.1%	27.1%	41.9%	9.6%		2.4%			0.7%	0.1%	2.2%	17.8
Luxembourg	55.2%	1.5%	19.2%	3.8%	1.6%	2.1%	0.2%		9.2%	0.6%	6.7%	25.2
Netherlands	42.7%	23.3%	17.6%	3.1%	9.2%	0.1%	2.1%	0.5%	0.7%	0.6%	0.2%	51.5
Norway	29.8%		58.5%	11.6%								0.1
Poland	40.4%	35.3%	1.6%	0.2%	9.8%	0.4%	0.01%	3.0%	2.8%	5.8%	0.7%	99.0
Portugal	11.3%	40.1%	1.9%	0.4%	15.3%	26.8%		0.1%	0.1%		4.0%	22.6
Romania	61.4%	12.5%	2.1%	0.03%	11.8%	4.7%	1.1%	1.8%	3.1%	0.1%	1.4%	17.7
Slovakia	79.7%	0.3%	4.5%	0.3%	0.001%			12.1%	2.6%	0.6%		5.5
Slovenia	10.9%	74.8%	5.6%	1.3%	5.2%	1.4%		0.01%	0.4%		0.3%	15.8
Spain	29.1%	33.0%	6.1%	1.1%	5.7%	17.4%	0.2%	3.9%	3.0%	0.4%	0.1%	86.5
Sweden	30.0%		58.3%	11.7%								0.1
Switzerland	0.1%		90.2%	7.2%				2.5%				5.2
United Kingdom	18.9%	66.7%	0.6%	0.1%	10.7%	1.2%		1.8%			0.003%	10.5

[1] Negligible amount of amphenicols and cephalosporins sold is not included in the table.

[2] France has no sales of oral powder.

[3] Bacitracin, paromomycin 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 2014

Country	Tetracyclines	Amphenicols	Penicillins	Sulfonamides	Trimethoprim	Macrolides	Lincosamides	Fluoroquinolones	Other quinolones	Aminoglycosides	Polymyxins	Pleuromutilins	Others[1]	Total mg/PCU
Austria	27.4%	2.2%		29.7%	5.9%		1.2%	16.2%			6.4%	8.4%	2.5%	1.3
Belgium			0.2%	40.0%	8.0%	32.5%	0.05%	18.4%			0.7%	0.04%	0.2%	3.1
Bulgaria		17.4%		37.9%	7.6%	3.8%		27.7%			5.7%			6.2
Croatia	1.0%	2.5%		63.8%	12.8%	2.7%		13.5%	1.2%	0.001%	0.7%	1.7%		11.8
Cyprus	11.8%		8.5%	51.5%	9.5%	7.1%		4.3%	1.2%	0.9%	2.1%	3.1%		14.9
Czech Republic	21.5%	0.3%	33.5%	23.7%	1.1%	3.0%	0.5%	4.9%	0.1%	0.04%	2.2%	8.0%	1.0%	30.4
Denmark	40.5%	0.1%	13.3%	1.9%		19.4%	1.8%	0.0%		0.9%	2.1%	16.5%	3.6%	19.8
Estonia	55.5%	12.4%		0.1%	0.01%			30.7%				1.3%		1.7
Finland	22.8%			24.1%	4.8%			2.0%				46.2%		0.01
France	42.4%	0.1%	11.6%	20.0%	3.1%	8.6%	0.4%	0.6%	1.4%	2.3%	8.2%	0.9%	0.4%	52.8
Germany	30.1%	0.1%	27.6%	2.8%	0.2%	15.5%	1.8%	1.0%		2.8%	15.3%	1.0%	1.7%	65.4
Hungary	4.2%	7.2%	0.6%	8.8%	1.8%	4.7%		62.1%			6.9%	3.3%	0.4%	14.1
Iceland								0.2%		99.8%				0.2
Ireland	5.9%	0.01%	37.9%	41.4%	0.2%	7.6%	0.9%	1.1%		2.1%	0.7%	0.1%	2.2%	9.5
Italy	5.5%	1.5%	0.1%	28.6%	5.5%	9.0%	7.9%	4.6%	3.7%	0.01%	25.7%	3.3%	4.5%	50.5
Latvia	2.9%	1.0%		4.8%	1.0%			75.2%	0.5%	2.2%	12.5%			1.7
Lithuania		0.1%		2.9%	0.7%	28.5%		38.5%	11.8%		0.02%	17.5%		7.2
Luxembourg[2]	6.0%	0.1%	45.1%	21.3%	0.3%	17.5%	0.5%	4.1%			4.4%		0.8%	1.6
Netherlands	0.1%		0.04%	30.7%	6.9%	59.0%	0.02%	1.8%			1.2%		0.3%	6.5
Norway	2.4%		49.4%					0.3%		20.5%		27.4%		0.1
Poland	4.3%	5.2%		20.6%	4.7%	1.0%		48.1%	0.3%	1.5%	12.0%	2.3%		16.3
Portugal	26.9%	0.3%	19.2%	5.4%	1.1%	5.1%	0.001%	35.5%	0.5%		2.7%	3.5%		30.3
Romania	7.9%	0.4%	17.6%	29.4%	6.0%	1.5%	0.8%	25.1%	0.6%	0.02%	8.1%	2.6%		6.6
Slovakia	13.9%	0.3%	7.1%	12.2%	1.4%	19.7%	0.8%	13.9%	0.1%	0.8%	3.7%	22.5%	3.7%	28.4
Slovenia		4.1%	1.2%	24.3%	4.9%			63.1%	0.1%			2.4%		4.9
Spain	26.6%	1.8%	0.01%	1.7%	0.2%	0.6%	1.4%	32.3%	2.3%	9.2%	18.9%	2.0%	2.9%	22.7
Sweden	52.4%		5.6%	0.01%		18.0%	0.04%	0.4%		0.4%	12.9%	10.3%		0.8
Switzerland						9.4%		89.2%			1.4%			0.1
United Kingdom	6.4%	0.6%	0.04%	6.8%	1.1%	1.7%	18.8%	6.0%		0.7%	3.3%	15.1%	39.6%	3.6

[1] Spectinomycin (classified as 'Other antibacterials' in the ATCvet system).

[2] Insignificant amounts of cephalosporins were sold as oral solutions.

Table A6. Percentage of sales, in mg/PCU, of injection preparations by antimicrobial class (according to ATCvet system) by country, for 2014[1]

Country	Tetracyclines	Amphenicols	Penicillins	1st- and 2nd-gen. cephalosporins	3rd- and 4th-gen. cephalosporins	Sulfonamides	Trimethoprim	Macrolides	Lincosamides	Fluoroquinolones	Aminoglycosides	Pleuromutilins	Others[2]	Total mg/PCU injection prep.
Austria	7.1%	5.9%	31.7%		2.9%	10.8%	2.2%	9.7%	0.5%	5.8%	22.4%		1.0%	4.9
Belgium	5.0%	7.3%	59.3%	0.2%	3.4%	3.1%	0.6%	4.7%	2.9%	4.1%	3.7%	0.04%	5.6%	12.8
Bulgaria	20.0%	0.5%	27.1%	0.2%	0.7%	4.5%	0.9%	15.8%	1.5%	0.7%	24.7%	1.0%	2.3%	9.3
Croatia	9.6%	8.7%	29.7%	1.3%	0.4%	18.3%	2.8%	1.9%	0.2%	6.9%	19.4%	0.4%	0.3%	31.0
Cyprus	12.3%	4.9%	36.1%		1.2%	8.1%	0.6%	3.8%	1.2%	1.8%	26.3%	1.2%	2.2%	16.8
Czech Republic	12.8%	3.7%	45.4%	2.3%	4.1%	3.5%	0.7%	3.2%	0.3%	3.0%	20.2%	0.3%	0.5%	8.9
Denmark	13.3%	2.4%	52.5%		0.1%	14.1%	2.8%	1.8%	3.3%	0.02%	7.3%	1.3%	1.0%	15.9
Estonia	9.0%	0.9%	50.5%	0.5%	3.2%	3.0%	0.6%	1.5%	1.3%	5.2%	17.4%	4.3%	2.6%	16.4
Finland	9.6%	0.3%	81.2%	0.001%	0.1%	5.2%	1.0%	0.2%	0.4%	1.6%	0.3%			11.3
France	9.0%	5.3%	30.9%	0.1%	1.5%	4.3%	0.7%	12.5%	0.7%	2.1%	31.1%	0.02%	1.2%	15.0
Germany	3.8%	7.6%	41.7%		4.9%	10.2%	1.4%	6.0%	1.6%	10.3%	10.4%	0.1%	1.7%	7.0
Hungary	8.6%	5.3%	41.0%	0.8%	3.4%	2.9%	0.7%	2.5%	0.9%	5.7%	25.2%	1.3%	1.4%	6.4
Iceland	7.1%		62.8%		0.03%	3.5%	0.7%			0.1%	25.8%			4.5
Ireland	23.7%	6.9%	32.3%	0.5%	0.9%	4.5%	0.9%	7.7%	0.3%	2.3%	19.5%	0.02%	0.3%	11.3
Italy	9.7%	7.6%	28.8%	0.04%	1.8%	10.6%	0.8%	9.0%	2.8%	4.0%	17.1%	0.4%	7.0%	19.1
Latvia	6.3%	0.2%	39.7%	0.3%	3.1%	9.9%	2.0%	2.8%	0.5%	2.8%	30.6%	0.8%	1.0%	11.8
Lithuania	15.8%	4.4%	32.8%	0.2%	2.2%	4.9%	0.7%	7.3%	1.1%	4.6%	18.7%	6.2%	1.2%	8.1
Luxembourg	10.9%	11.9%	43.7%	0.01%	4.5%	9.1%	1.8%	2.2%	1.2%	5.2%	6.6%		2.4%	12.3
Netherlands	15.4%	16.3%	38.4%		0.1%	17.6%	3.5%	3.8%	0.3%	0.1%	3.9%	0.1%	0.5%	8.5
Norway	2.5%	0.5%	81.4%		0.02%	6.8%	1.4%	0.1%		0.4%	6.7%	0.2%		1.7
Poland	9.6%	10.2%	33.1%	0.3%	1.1%	2.6%	0.3%	1.9%	1.8%	9.3%	28.1%	0.8%	0.9%	13.1
Portugal	19.2%	9.0%	26.4%	0.6%	3.4%	4.0%	0.8%	5.4%	0.7%	6.8%	20.3%	1.1%	2.3%	9.6
Romania	14.9%	3.2%	31.5%	0.1%	0.4%	2.2%	0.4%	2.2%	1.1%	3.1%	39.7%	0.2%	0.9%	11.5
Slovakia	13.3%	1.6%	44.8%	3.4%	3.6%	5.9%	1.2%	2.9%	0.2%	2.2%	18.5%	2.0%	0.5%	12.4
Slovenia	13.0%	4.6%	30.1%	0.6%	1.3%	13.6%	1.7%	2.4%	0.2%	9.0%	23.0%		0.3%	9.4
Spain	6.8%	11.5%	25.8%	0.1%	1.8%	1.9%	0.3%	8.4%	2.7%	15.0%	21.5%	0.7%	3.2%	17.2
Sweden	5.6%	0.1%	78.6%	0.002%	0.03%	9.9%	2.0%	1.2%	0.002%	0.3%	2.0%	0.2%		8.8
Switzerland	8.8%	2.2%	38.7%		2.1%	8.1%	1.3%	4.3%	0.1%	4.2%	29.7%	0.2%	0.2%	9.4
United Kingdom	23.3%	5.0%	29.9%	0.3%	2.4%	5.4%	0.9%	9.7%	0.4%	2.1%	20.6%	0.1%	0.1%	6.5

[1] Negligible amounts of other quinolones and polymyxins are not included in the table.

[2] Paromomycin and spectinomycin (classified as 'Other antibacterials' in the ATCvet system).

Table A7. Number of product presentations (product name, form, strength and pack size) containing 1, 2 and 3 antimicrobial agents1 sold, by country, for 2014 (tablets excluded from the data)

Country	1 ingredient	2 ingredients	3 ingredients	Total number[1]
Austria	206	41	6	253
Belgium	330	55	5	390
Bulgaria	130	39	4	173
Croatia	151	40	6	197
Cyprus	117	34	2	153
Czech Republic	456	92	5	553
Denmark	223	51	7	281
Estonia	123	26	7	156
Finland	68	17	1	86
France	555	163	5	723
Germany	574	57	5	636
Hungary	296	51	7	354
Iceland	21	6	2	29
Ireland	240	48	6	294
Italy	611	139	14	764
Latvia	147	38	12	197
Lithuania	108	32	5	145
Luxembourg	189	52	5	246
Netherlands	214	57	3	274
Norway	60	18	2	80
Poland	502	82	11	595
Portugal	414	65	15	494
Romania	266	77	9	352
Slovakia	302	48	8	358
Slovenia	102	27	2	131
Spain	617	97	6	720
Sweden	94	23	2	119
Switzerland	133	60	37	230
United Kingdom	303	41	5	349
Total 29 countries	**7,552**	**1,576**	**204**	**9,332**

[1] In addition, 16 presentations contained 4 active ingredients, accounting for 0.2% of the product presentations in the 29 countries.

Table A8. 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 sold, by country, for 2014[1]

Country	1 ingredient	2 ingredients	3 ingredients	Total number of product presentations for premixes, oral powders and oral solutions
Austria	74	17	2	93
Belgium	120	26		146
Bulgaria	73	20		93
Croatia	61	20	1	82
Cyprus	51	18		69
Czech Republic	231	42		273
Denmark	86	8	1	95
Estonia	28	5		33
Finland	22	4		26
France	298	85		383
Germany	252	31		283
Hungary	165	22		187
Iceland	6	1		7
Ireland	67	13		80
Italy	351	74	8	433
Latvia	36	6		42
Lithuania	31	6		37
Luxembourg	57	21		78
Netherlands	88	21		109
Norway	23	2		25
Poland	273	34		307
Portugal	162	24	6	192
Romania	141	33	4	178
Slovakia	138	23	4	165
Slovenia	30	13		43
Spain	311	23		334
Sweden	25	2		27
Switzerland	41	15	28	84
United Kingdom	118	13		131
Total 29 countries	**3,359**	**622**	**54**	**4,035**

[1] In addition, 4 preparations contained 4 active ingredients.

Table A9. Sales, in tonnes of active ingredient, of antimicrobial agents sold as premixes, oral powders and oral solutions containing 1, 2 and 3 active ingredients, by country, for 2014[1]

Country	1 ingredient		2 ingredients		3 ingredients		Tonnes (premixes, oral powders and oral solutions)
	Tonnes	%	Tonnes	%	Tonnes	%	
Austria	39.9	84%	5.9	13%	1.6	3%	47.4
Belgium	160.0	66%	82.9	34%			242.9
Bulgaria	25.3	88%	3.5	12%			28.8
Croatia	16.5	76.6%	4.3	19.6%	1.1	4.8%	21.9
Cyprus	30.5	77%	9.3	23%			39.8
Czech Republic	38.9	81%	9.4	19%			48.3
Denmark	57.7	87%	8.7	13%	≤ 0.001	≤ 0.001%	66.4
Estonia	6.4	89%	0.8	11%			7.2
Finland	2.9	61%	1.9	39%			4.8
France	498.8	77%	146.9	23%			645.7
Germany	1,130.7	92%	100.8	8%			1,231.4
Hungary	128.7	89%	16.3	11%			144.9
Iceland	0.03	78%	0.01	22%			0.04
Ireland	55.3	86%	9.1	14%			64.4
Italy	958.1	71%	381.4	28%	12.0	1%	1,351.6
Latvia	3.7	96%	0.2	4%			3.9
Lithuania	5.1	60%	3.3	40%			8.4
Luxembourg	1.0	74%	0.4	26%			1.4
Netherlands	146.3	79%	39.1	21%			185.5
Norway	0.8	88%	0.1	12%			0.9
Poland	474.4	93%	37.9	7%			512.3
Portugal	168.7	93%	11.4	6%	0.4	0.2%	180.5
Romania	55.6	82%	10.9	16%	1.3	2%	67.9
Slovakia	10.5	81%	2.3	18%	0.2	1%	13.0
Slovenia	3.1	82%	0.7	18%			3.9
Spain	2,561.3	90%	278.4	10%			2,839.8
Sweden	0.9	93%	0.1	7%			0.9
Switzerland	8.5	25%	6.8	20%	18.6	55%	34.0
United Kingdom	297.4	78%	81.7	22%			379.0
Total 29 countries	**6,887.3**	**84%**	**1,254.5**	**15%**	**35.1**	**0.4%**	**8,176.9**

[1] In addition, 0.1% of the total sales of premixes, oral powders and oral solutions preparations contained 4 active ingredients, accounting for 9.4 tonnes.

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

Table A10. Variables reported to ESVAC for each antimicrobial veterinary medicinal product, for 2014

	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.
	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.
PRODUCT INFORMATION	**ID**	**Medicinal product package code value** Digit code is 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 × 30; Harmony vet long-acting injection 10 ml.	For validation purposes. To allow, for example, for analysis of use of, for example, long-acting preparations and antimicrobial resistance.
	FORM	**Pharmaceutical form** Bolus (BOLUS), Injection (INJ), Intramammary preparation (INTRAMAM), Intramammary preparation dry cow (INTRAMAM-DC), Oral solution (ORAL SOLU), Oral paste (ORAL PASTE), Oral powder (ORAL POWD), 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 group treatment.
	LONG ACTING	**Long-acting injectable preparations** It refers to injectable preparations that maintain their antimicrobial activity over a long period of time once injected.	Optional.
	PACKSIZE	**Content quantity in package: pack size (numerical only)** e.g. 100 for 100 tablets or 100 intramammary prep.; 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 example, for tablets, capsules, boluses and intramammary prep.).	To allow for calculation of amount of active ingredient in each package/product.
	ATCvet - 5th LEVEL	**ATCvet: Anatomical Therapeutic Chemical (Classification) Veterinary** WHO ATCvet code last version to be used.	Generally, a classification system needs to have a 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 SPC/label: 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 separately.	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 the 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 the 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.
	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.
	TONNES SOLD	**Tonnes sold of active ingredient**	

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

Table A11. 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
Benzylpenicillin (and prodrugs to benzylpenicillin)[4]	1,667	0.00060
Chlortetracycline[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
Framycetin	670	0.00149
Oxytetracycline	870	0.00115
Paromomycin[2]	675	0.00148
Polymyxin B	8,403	0.00012
Spiramycin	3,200	0.00031
Streptomycin	785	0.00127
Tetracycline	982	0.00102
Tobramycin	875	0.00114
Tylosin	1,000	0.00100

[1] WHO 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 A12. Conversion factors used to convert from prodrug content to content of active ingredient[1]

Prodrug	Conversion factor	Active ingredient
Benethamine benzylpenicillin	0.65	Benzylpenicillin
Benzathine benzylpenicillin[2]	0.74	Benzylpenicillin
Cefapirin benzathine	0.41	Cefapirin
Cefalexin benzathine	0.36	Cefalexin
Cloxacillin benzathine	0.43	Cloxacillin
Oxacillin benzathine	0.69	Oxacilline
Penethamate hydriodide	0.63	Benzylpenicillin
Procaine penicillin	0.61	Benzylpenicillin

[1] Martindale (http://www.medicinescomplete.com/mc/martindale/current/141-b.htm?q=procain%20penicillin&t= search&ss=text&p=2#_hit).
[2] Revised (previously 0.39) as an error was identified.

Annex 3. Population correction unit (PCU)

Table A13. Animal categories included in the calculation of the population correction unit (PCU) and data types to be reported

Animal category	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 A14. 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 goats	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

Table A15 includes all the substances for which sales have been reported, divided by class or subclass. Note that in the ESVAC, sales are reported by classes/subclasses independent of whether or not this refers to a single or a combination product — i.e. not by ATCvet classes. An exception to this is combinations of penicillins, incl. beta-lactamase inhibitors which is included as the combination penicillins + beta-lactamase inhibitors reported as such in Figures 13 and 52.

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

Table A15. List of substances reported sold in ESVAC 2011-2014

Class/subclass	Substances		
Tetracyclines			
	Chlortetracycline	Doxycycline	Oxytetracycline
	Tetracycline		
Amphenicols			
	Chloramphenicol[1]	Florfenicol	Thiamphenicol
Penicillins			
Beta-lactamase-sensitive penicillins			
	Benzathine benzylpenicillin	Benzathine phenoxymethylpenicillin	Benzylpenicillin
	Penethamate hydriodide	Phenoxymethylpenicillin	Pheneticillin
	Procaine benzylpenicillin		
Beta-lactamase-resistant penicillins			
	Cloxacillin	Dicloxacillin	Nafcillin
	Oxacillin		
Penicillins with extended spectrum			
	Amoxicillin	Ampicillin	Metampicillin[2]
Combinations of penicillins, incl. beta-lactamase inhibitors			
	Amoxicillin	Ampicillin	
Cephalosporins[4]			
First-generation cephalosporins			
	Cefacetrile	Cefadroxil[2]	Cefalexin
	Cefalonium	Cefapirin	Cefazolin
	Cefalotin		
Third-generation cephalosporins			
	Cefoperazone	Cefovecin[2]	Ceftiofur

Class/subclass	Substances		
Fourth-generation cephalosporins			
	Cefquinome		
Sulfonamides and trimethoprim			
Sulfonamides			
	Formosulfathiazole	Phthalylsulfathiazole	Sulfacetamide
	Sulfachlorpyridazine	Sulfaclozine	Sulfadiazine
	Sulfamonomethoxine	Sulfadimethoxine	Sulfadimidine
	Sulfadoxine	Sulfafurazole	Sulfaguanidine
	Sulfalene	Sulfamerazine	Sulfamethizole
	Sulfamethoxazole	Sulfamethoxypyridazine	Sulfanilamide
	Sulfapyridine	Sulfaquinoxaline	Sulfathiazole
	Sulfazuinoxaline		
Trimethoprim and derivatives			
	Trimethoprim		
Macrolides and lincosamides			
Macrolides			
	Erythromycin	Gamithromycin	Oleandomycin
	Spiramycin	Tildipirosin	Tilmicosin
	Tulathromycin	Tylosin	Tylvalosin
Lincosamides			
	Clindamycin[2]	Lincomycin	Pirlimycin
Aminoglycosides			
	Amikacin[2]	Apramycin	Dihydrostreptomycin
	Framycetin	Gentamicin	Kanamycin
	Neomycin	Streptomycin	
Quinolones			
Fluoroquinolones			
	Danofloxacin	Difloxacin	Enrofloxacin
	Ibafloxacin[2]	Marbofloxacin	Norfloxacin[2]
	Orbifloxacin[2]	Pradofloxacin[2]	
Other quinolones			
	Cinoxacin	Flumequine	Oxolinic acid
Imidazole derivatives			
	Metronidazole[1]		

Class/subclass	Substances		
Pleuromutilins			
	Tiamulin	Valnemulin	
Polymyxins			
	Colistin	Polymyxin B[2]	
Nitrofuran derivatives			
	Furazolidone[1]		
Other antibacterials			
	Bacitracin	Furaltadone[1]	Natamycin
	Nitroxoline	Novobiocin	Paromomycin
	Rifaximin	Spectinomycin	

[1] Included in Table 2 (prohibited substances) of the Annex to Commission Regulation (EU) No 37/2010.

[2] MRLs not established for any food-producing species.

[3] 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 allowed 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 or oral use. Distribution of VMPs for intramammary use or for systemic use (injection) and premixes is restricted to farms that are members of the Austrian Animal Health Service. Sales of VMPs by public pharmacies must be prescribed by a veterinarian; such sales 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: BGBl. II Nr. 83/2014 Veterinär-Antibiotika-MengenströmeVO.

Data sources

Sales data have to be uploaded into the national database by pharmaceutical companies either producing or importing VMPs, and by wholesalers which are assigned by the industry to distribute a product.

Belgium

Distribution of veterinary medicines

In Belgium, all VMPs containing antimicrobial agents are prescription-only medicines. This includes medicated premixes containing 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 via delivery from a pharmacy, on veterinary prescription, or directly from the veterinarian.

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

Note: since 1 June 2014, the Federal Agency of Medicines and Health Products (FAHMP) has imposed a fee per package, according to the active ingredient content, for all veterinary antibiotics on the Belgian market on behalf of the marketing authorisation holders. A higher fee is imposed if it concerns critically important antibiotics such as 3rd- or 4th-generation cephalosporins, quinolones or macrolides.

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 FAHMP 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 it to Belgian farmers.

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

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

Bulgaria

Distribution of veterinary medicines

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

Legal basis for the monitoring of sales

The collection of sales data is based on the national law on veterinary activities, promulgated in the State Gazette (SG), Issue №7/25.01.2013. At the request of the Executive Director of BFSA, in view of pharmacovigilance, the holder of a marketing authorisation for VMP shall provide data on the volume of sales of VMPs. Wholesalers, pharmacies and farmers are obliged to keep records of all sales and purchases, and to deliver these records to the Bulgarian Food Safety Agency on request.

Data sources

Sales data are collected from all manufacturers, importers and wholesalers, which are also either MAHs or official representatives of MAHs in Bulgaria (to avoid double counting, sales of other wholesalers are excluded). The data include the sales to veterinarians, farms and pharmacies.

Croatia

Distribution of veterinary medicines

In Croatia, all antimicrobial veterinary medicinal products (VMPs) are prescription-only medicines. VMPs are dispensed by pharmaceutical companies or wholesalers of VMPs to veterinary practices (surgery, station, hospital), veterinary pharmacies and feed mills. Animal owners can only buy antimicrobial VMPs on veterinary prescription in a veterinary pharmacy.

Large farms have authorised their own veterinary practices for their animals and they can buy premixes on veterinary prescription from a veterinary pharmacy and use them in feed mills. Feed mills should have a record of veterinary prescriptions covering each amount of antimicrobial VMP used.

Legal basis for the monitoring of sales

The collection of sales data by wholesalers is based on the national law, published in the Official Gazette of the Republic of Croatia No: 84/08, 56/13, 94/13 & 15/15.

Data sources

The veterinary antimicrobial agents' sales data are obtained each year from the authorised wholesalers.

Cyprus

Distribution of veterinary medicines

In Cyprus, all VMPs containing antimicrobials are prescription-only medicines. They are dispensed by either pharmacies or veterinary clinics. Veterinarians are only allowed to administer VMPs 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 only administered on prescription by a veterinarian.

Legal basis for the monitoring of sales

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

Data sources

The data on sales of the veterinary antimicrobial agents included 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 VMP 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 the same legal terms as those to which the pharmacies are subject. Both pharmacies and dispensing companies are supplied by pharmaceutical companies and wholesalers. An exemption from the pharmacy/dispensing-company monopoly has been granted for medicated feeds, i.e. feeds into which VMPs formulated as premix are mixed prior to sale. Medicated feed 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. Furthermore, it is mandatory for the veterinarians to report to the VetStat medicines used in their own practices.

Data sources

Data on sales of all prescription medicines at package level from pharmacies, dispensing companies, veterinarians 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 for, 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 from a veterinarian.

Legal basis for the monitoring of sales

Wholesalers are obliged to provide information on the sales of VMPs to the Finnish Medicines Agency in accordance with the Medicines Act (375/1987). Production and imports of medicated feeds 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 pharmacists; 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. A new law published at the end of 2014 makes the provision of data on antimicrobial sales to the competent authority mandatory.

Data sources

The sales data 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 in their care. Veterinarians are supplied with VMPs directly from pharmaceutical companies or wholesalers. Very few animal owners acquire VMPs 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 specific regulation.

Data sources

Data on sales to veterinarians were collected by pharmaceutical companies and wholesalers which 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 on prescription and thus are 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 only supplied by authorised wholesalers. Wholesalers are authorised by the National Food Chain Safety Office, and the retailers are authorised by the local government 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 as it must be possible to control the journey of each batch from the manufacturer to the farmer.

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

Legal basis for the monitoring of sales

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 which 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 they themselves put into circulation (i.e. there is no double reporting).

Iceland

Distribution of veterinary medicines

In Iceland, all antimicrobial VMPs and almost all other VMPs are prescription-only medicines. They 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 feeding stuffs for livestock are produced by feed mills in Iceland.

Legal basis for the monitoring of sales

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

Data sources

The data on sales of 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 only be supplied on prescription. The products are supplied to the trade by wholesalers authorised by the Department of Agriculture, Food and the Marine. In accordance with the prescription of the prescribing veterinarian, the prescribed products can be dispensed either by the veterinarian or by a pharmacist. By way of exception to this rule, intramammary antimicrobial substances can also be dispensed by licensed agricultural merchants. Medicated feeds containing antimicrobials are prepared from authorised premixes, again under veterinary prescription. They are incorporated into the feed under a special authorisation granted by the Department of Agriculture, Food and the Marine. The licences for incorporation are granted either to feed mills or to farms that have the appropriate facilities for inclusion. It should be noted that the sale, supply, or possession of any unauthorised veterinary medicine in Ireland is a criminal offence.

Legal basis for the monitoring of sales

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

Data sources

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

Italy

Distribution of veterinary medicines

In Italy, antimicrobial agents for use in animals are prescription-only medicines. Therefore, their sale to the end-user can only take place upon presentation of a veterinary prescription. The sale of veterinary medicines (including antimicrobial agents) on 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 only be done on 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, under veterinary prescription, and can only be carried out in the presence of a pharmacist.

Farmers, veterinarians, breeding and healthcare facilities may, on request, be authorised by the local competent authority to hold stocks of 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 can be held.

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

Legal basis for the monitoring of sales

The collection of sales data by pharmaceutical companies is based on the national law 193/2006 (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 the 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 obliged to provide information on sales of VMPs to the State Food and Veterinary Service of the Republic of Lithuania, in accordance with national law.

Data sources

Data on sales of antimicrobial VMPs at package level 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 in their care.

Legal basis for the monitoring

Wholesalers, pharmacies, veterinarians and farmers are legally obliged to keep records of all sales. They are legally bound to provide any data or information 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 who 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 are generally dispensed through pharmacies, which are supplied by drug wholesalers. 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 in most other European countries. However, group/flock treatment of livestock with antimicrobial agents is possible, again subject to veterinary prescription, through drinking water or as top dressing on feed.

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 (NIPH).

Data sources

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

Poland

Distribution of veterinary medicines

Most VMPs, including antimicrobial VMPs, are prescription-only medicines. VMPs are distributed by wholesalers to veterinarians. Antimicrobial VMPs are 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 obliged 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 means of an official veterinary prescription. Veterinarians do not sell VMPs, and they may only charge for those they use for treatment of animals under their care. Premixes are distributed through wholesalers or wholesaler-distributors directly to feed mills. Only farmers are receivers from feed mills. Medicated feeds containing antimicrobial premixes also have to be prescribed by a veterinarian and can only be manufactured by officially authorised feed mills.

Legal basis for the monitoring of sales

The collection of sales data is based on the national law no. 148/2008, dated 29 July (Art. 120), amended and reprinted by national law no. 314/2009, dated 28 October.

Data sources

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

Romania

Distribution of veterinary medicines

In Romania, all VMPs containing antimicrobial agents, are prescription-only medicines.

Wholesalers must supply medicinal products only to those authorised to provide retail activities or to those who are legally allowed to purchase medicinal products from wholesalers. Retail distribution of the veterinary medicinal products is performed only by those authorised to carry out such operations in accordance with the national legislation.

Marketing of veterinary medicinal products is carried out according to the veterinary legislation in force, i.e. only through veterinary pharmaceutical establishments which are authorised by the National Sanitary Veterinary and Food Safety Directorate.

Legal basis for the monitoring of sales

The collection of sales data is based on the national law on veterinary activities — Order of the National Sanitary Veterinary and Food Safety President — promulgated in the Official Monitor from 15 October 2015.

The MAHs are obliged to report the sales of the antimicrobials each year before 15 March, and to deliver these records to the Institute for Control of Biological Products and Veterinary Medicines, which reports the data to the ESVAC.

Data sources

For 2014, the sales data were collected from 37 wholesalers and 11 MAHs. The data include the sales to veterinarians, farmers and pharmacies. From 2015, the sales will be collected from MAHs (according to the updated veterinary law).

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 to 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

For 2011 and 2012, import data were collected from all wholesalers licensed in the Slovak Republic; for 2013, data represent sales from wholesalers to end-users.

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.

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' co-operatives) 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 (Hazard Analysis and Critical Control Point principles).

Legal basis for the monitoring of sales

There is a legal basis for mandatory reporting of sales data from the distributors of such products, while monitoring of sales from the MAHs 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 a central database. Until and including 2013, this was an infrastructure company owned by the state, Apotekens Service AB. From 1 January 2014, all activities of that company have been transferred to the Swedish eHealth Agency. All feed mills and farms authorised to mix medicated feed are requested to report their purchases and sales on a yearly basis to the Board of Agriculture.

Data sources

Data on sales at package level were obtained from Apotekens Service AB/the Swedish eHealth Agency.

Switzerland

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. 35 of the Federal Ordinance on Veterinary Medicines, enacted in September 2004. Art. 36 requests the Federal Office of Food Safety and Veterinary Affairs to "specifically establish a statistic about usage of veterinary antimicrobials for the purpose of monitoring resistances". Sales of veterinary antimicrobials are published yearly in the ARCH-VET report[25], covering sales and resistances to veterinary antimicrobials. Note that figures published in the national ARCH-VET report differ from figures in the present report since all ATCvet groups are included in the national report.

Data sources

Data are obtained at package level from the marketing authorisation holders. They are requested by the Swiss Agency for Therapeutic Products (Swissmedic) and processed and analysed by the Federal Office of Food Safety and Veterinary Affairs.

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, meaning that sales figures cannot be further validated. Veterinarians may import VMPs for companion and food-producing animals, including products containing antimicrobial agents, based on a single authorisation valid for one year and delivered by Swissmedic. As these products 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.

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, can only be supplied by a wholesale dealer authorised by the United Kingdom 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 United Kingdom Veterinary Medicines Directorate collects data from those veterinary pharmaceutical manufacturers that hold current United Kingdom marketing authorisations.

[25] ARCH-VET report (extensive version in German only): https://www.blv.admin.ch/dam/blv/de/dokumente/tiere/publikationen-und-forschung/Statistik%20und%20Berichte/archv-vet-2014-gesamt.pdf.download.pdf/ARCH-Vet_2014_2015-10-13_final.pdf

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

Table A16. List of ESVAC national contact points/alternates 2015

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Annex 8. ESVAC sales advisory expert group members and observers

Table A17. List of ESVAC sales advisory expert group members

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Table A18. List of ESVAC sales advisory expert group observers from the European Commission, ECDC and EFSA

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