EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Sales of veterinary antimicrobial agents in 25 EU/EEA countries in 2011

Third ESVAC report

An agency of the European Union

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

Legal role

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

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

Principal activities

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

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

Guiding principles

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

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About the European Medicines Agency

The European Medicines Agency 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), its former Scientific Advisory Group on Antimicrobials (SAGAM) and the current 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 to promote the continued availability of effective antimicrobials for use in animals, while at the same time acting to minimise risks to animals or man arising from their use.

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

About the report

This third ESVAC report presents data on the sales of veterinary antimicrobial agents from 25 EU/EEA countries, provided at package level according to a standardised protocol and template[2]. Data from Switzerland are included in Annex 9, as, due to confidentiality issues, data from Switzerland could not be delivered in accordance with the ESVAC data-collection form. This report has special emphasis on food-producing animals.

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

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

[1] Available from the Agency's website via: Home > Special topics > Antimicrobial resistance.

[2] Available from the Agency's website via: Home > Regulatory > Veterinary medicines > Antimicrobial resistance > European Surveillance of Veterinary Antimicrobial Consumption.

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Summary

A total of 26 European Union (EU)/European Economic Area (EEA) countries submitted to the European Medicines Agency their 2011 data on sales, at package level, of antimicrobial veterinary medicinal products (VMPs), according to a standardised protocol and using a common template. Greece could not validate its data, due to lack of resources, and these data were therefore not included in the report. The 25 countries included in the ESVAC 2011 data cover approximately 95% of the food-producing animal population in the EU/EEA area.

For four countries, 2011 was the first year for which they had collected data on antimicrobial VMPs; nine countries had collected such data for 2 years, two countries for 3 years and ten countries for more than 5 years.

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

In 21 of the 25 countries, a legal basis existed for the national competent authority to request data on sales or prescription of veterinary antimicrobial agents from the distributors of such products, while in four countries (Ireland, France, the Netherlands and Spain), data were provided to the national competent authority voluntarily.

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

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

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

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

Overall in the 25 countries, approximately 36% of the sales of veterinary antimicrobial agents, in mg/PCU, were for pharmaceutical forms applicable for mass treatment (i.e. premixes) and 56% for forms applicable for group treatment — i.e. oral powders (48%) and oral solutions (8%). The amount accounted for by these three pharmaceutical forms varied considerably between the countries. The proportion of the sales, in tonnes of active ingredient, of antimicrobial VMPs sold as injectable preparations was 7%, and 1% was for local uses (intramammary and intrauterine preparations).

The distribution of sales of the various antimicrobial classes and subclasses by pharmaceutical form varied considerably between the 25 countries. Overall for the 25 countries, 43% of tetracyclines were sold as premixes, 51% as oral powders, 4% as oral solutions and 2% as injectable preparations. For penicillins, premixes accounted for 22%, oral powder for 63%, oral solutions for 2% and injections for 12% of the total sales in the 25 countries. For sulfonamides, premixes accounted for 38%, oral powders for 39%, oral solutions for 18% and injections for 4% in the 25 countries.

Of the sales (in mg/PCU) of 3rd- and 4th-generation cephalosporin preparations, none of the pharmaceutical forms was applicable for group treatment; 83% were injectable preparations and 17% were intramammary preparations. The proportion of fluoroquinolones sold as oral solution was 76% and injections accounted for 24% of the sales aggregated by the 25 countries. Premixes accounted for 33% of the total sales of macrolides in the 25 countries, oral powders for 53%, oral solutions for 8% and injectable preparations for 6%.

Nineteen of the 20 countries that provided sales data to ESVAC in both 2010 and 2011 reported a decrease in sales (range 0.4%–28%) expressed as mg/PCU. For one country, an increase of 3.5% was reported from 2010 to 2011. However, one marketing-authorisation holder failed to report the sales data in 2010; for this company, the reported sales were 21% of the total sales in 2011; provided that the sales for this company were at the same level in 2010, the sales of veterinary antimicrobial agents have actually declined considerably. Overall in the 25 countries, 16% of the decline in the sales of veterinary antimicrobials from 2010 to 2011 was accounted for by premixes, 7% by oral powders and 4% by oral solutions.

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

A large difference in the sales, expressed as mg/PCU, is observed between the most- and least-selling countries (range 3.7–408 mg/PCU). This is in part likely to be due to differences in the composition of the animal population in the various countries (e.g. more pigs than cattle, or a high proportion of veal calves within the cattle population). There may also be considerable variation in terms of daily dose used for the various antimicrobial agents, length of treatment period, or formulations used; this may also in part explain some of the differences between the countries. However, these factors can only partly explain the differences in the sales observed between the 25 countries; other factors also need to be considered. Also, differences in the selection of data source may have an impact, but this is considered to be low.

Of the overall sales in the 25 countries, the largest proportions, expressed as mg/PCU, were accounted for by tetracyclines (37%), penicillins (23%), sulfonamides (11%) and polymyxins (7%). For the antimicrobial classes belonging to the World Health Organization (WHO) list of critically important antimicrobials (CIAs) with highest priority in human medicine, namely 3rd- and 4th-generation cephalosporins, fluoroquinolones and macrolides, the sales for food-producing animals, including horses, accounted for 0.2%, 1.6% and 8%, respectively, of the total sales in the 25 countries in 2011.

The prescribing patterns of the various antimicrobial classes, expressed as mg/PCU, varied substantially between the countries. Notable variations between the countries in the proportion of 3rd- and 4th-generation cephalosporins, fluoroquinolones and macrolides sold were observed, with sales ranging from 0.05% to 0.78%, 0.01% to 13.8% and 0% to 14%, respectively.

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

Of the total numbers of product presentations of antimicrobial VMPs applicable for food-producing animals (including horses) — i.e. product name, pharmaceutical form, strength and pack size (tablets not included) — 81% contained only one active ingredient, 17% contained two active ingredients, 2% contained three active ingredients and 0.2% contained four active ingredients (these were intramammaries).

Overall in the 25 countries, the proportion of the sales in 2011 of antimicrobial VMPs as premixes (for mass treatment), oral powders and oral solutions applicable for group treatment containing two or more active ingredients was relatively low. Of the total sales, 85%, 15% and 0.2% of these pharmaceutical forms contained one, two and three active ingredients, respectively. However, as it is possible to mix more than one premix/oral powder and oral solution into feed or drinking water, respectively, these data do not provide a reliable estimate of treatment through feed or drinking water with two or more active ingredients.

In 2011, the sales according to most-sold pharmaceutical forms of the major antimicrobial classes expressed as mg/PCU for the 25 countries were as follows. Premixes: 55% tetracyclines, 10% penicillins, 10% sulfonamides, 7% polymyxins, 6% macrolides and 6% pleuromutilins; oral powders: 40% tetracyclines, 28% penicillins, 13% sulfonamides and 5% macrolides; oral solutions: 24% tetracyclines, 20% fluoroquinolones, 17% sulfonamides, 11% penicillins, 10% macrolides, 6% polymyxins and 6% pleuromutilins; injectable preparations: 47% penicillins, 21% aminoglycosides, 11% tetracyclines, 5% sulfonamides and 4% macrolides.

Important variations between the sales and sales patterns, expressed in tonnes, of veterinary antimicrobial agents used in companion animals (tablets) were observed. This is in particular the case for the sales of tablets with the combination of penicillins + beta-lactamase inhibitors (tonnes of clavulanic acid not included in the data), which varied between 3% and 100% (5 countries) of the total sales of penicillin tablets. Where sales of penicillins + clavulanic acid tablets accounted for 100% of sales of penicillin tablets, it reflects that such combinations are the only penicillin tablets marketed in the country for companion animals. It has to be noted that, in companion animals, human medicinal products containing antimicrobial agents and injectable veterinary medicinal products containing antimicrobial agents may also be used, and thus the data on sales of tablets should be interpreted with great care.

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

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

Through the terms of reference from the Commission[3], the Agency was requested, among other activities:

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

With regard to the data collection:

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

About ESVAC

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

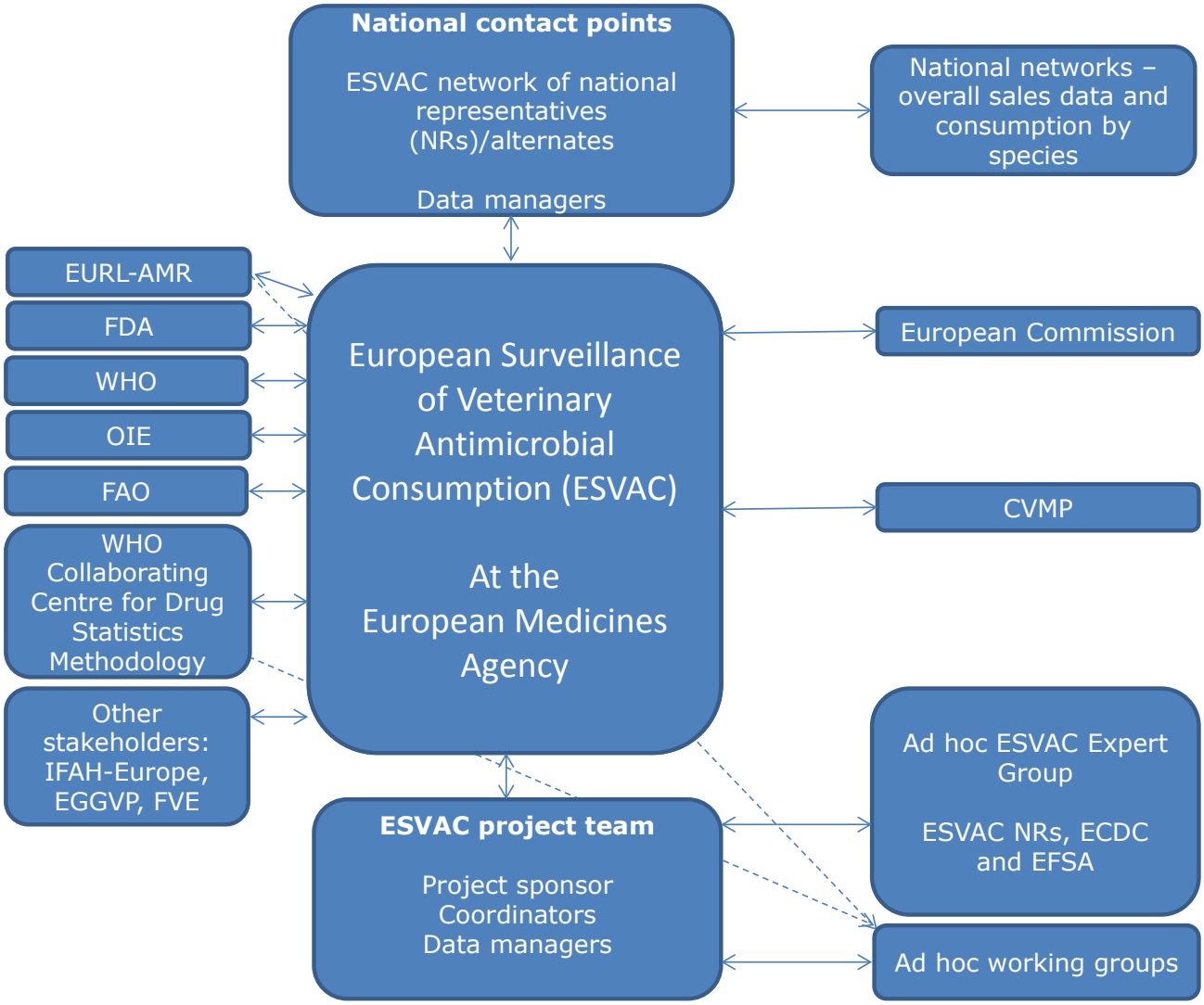
The organisation of the ESVAC project is illustrated in Figure 1.

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

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

[3] SANCO/E2/KDS/rz D(2008) 520915.

Figure 1. Organisation of the ESVAC project



1. Technical notes

1.1. Veterinary antimicrobial agents included in the data sets

To harmonise the veterinary antimicrobial agents to be included in the data sets, the Anatomical Therapeutic Chemical classification system for veterinary medicinal products (ATCvet[4]) was applied (Table 1). This includes all pharmaceutical forms and medicated feed except dermatological preparations (ATCvet group QD) and preparations for sensory organs (ATCvet group QS) (Table 1). The contribution from these groups of antimicrobial agents, in tonnes of active ingredient, to the total amounts is minimal, and therefore the effect of the deviation is negligible.

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

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

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

1.2. Variables reported for each antimicrobial veterinary medicinal product

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

However, when analysing the sales data, it was identified that the categorisation of oral solutions into individual or herd treatment, and of oral powders into individual or herd treatment, differed between the countries. For example, a couple of countries had defined almost all pack sizes of oral powder with pack sizes ranging from 150 g to 20 kg as preparations for individual treatment, although the major proportion was for pack sizes ≥1 kg. For oral powders, 91% of the packages were between 1 kg and 25 kg, and 4% between 0.5 kg and 1 kg. For oral solutions, 93% of the packages were between 1 L and 5 L, and 4.2% between 0.5 L and 1 L. All oral solutions and oral powders have therefore been aggregated to express oral solutions and oral powders for group treatment, respectively, during the analysis of the data, in order to present harmonised data.

In the current report, the term 'group treatment' is used instead of 'herd treatment'.

[4] ATCvet codes: www.whocc.no/atcvet

1.3. Population correction unit

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

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

1.4. Calculation of PCU

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

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

PCU calculation by species, age class and production type

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

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

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

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

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

[5] Available from the Agency's website via: Home > Regulatory > Veterinary medicines > Antimicrobial resistance > European Surveillance of Veterinary Antimicrobial Consumption

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

1.6. Updates of the 2010 data

For six countries — Estonia, Iceland, Ireland, Lithuania, Portugal and Spain — there have been minor revisions of the 2010 data because of identified errors in reported number of packages sold, in calculation of ingredient content, in strengths given and/or missing products. Furthermore, sales in 2010 for fish have been included in the sales data for Norway and Sweden.

PCU data have been updated for three countries; for Norway and Sweden, fish have been included in the PCU. The United Kingdom has replaced the Eurostat statistics by national statistics for both 2010 and 2011, due to deviation of ≥5% between the national data and Eurostat data.

The updated data are presented in this report in Figures 2, 9, 12 and 14, and in Table 5.

1.7. Reporting of the data

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

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

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

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

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

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

Table 2. Summary of information on years collecting data, legal basis for collecting data at national level, national data providers, sources for ESVAC data and characteristics of data by country for 2011

Country	Years collecting data	Legal basis	National data provider to ESVAC	Sources for ESVAC data (approx. no)	Prescription data, sales data or purchase data[1]	Sales between wholesalers and/or MAHs[2] excluded (Yes/No)	Products used on special licence included (Yes/No)
Austria	2 years	Mandatory to report	Austrian Agency for Health and Food Safety	MAHs[2] (n=12); wholesalers (n=6)	Sales to veterinarians	Yes	No
Belgium	>5 years	Mandatory to report	Federal Agency for Medicines and Health Products	Wholesalers (n=25); feed mills (n=59)	Sales to veterinarians and pharmacies; sales from feed mills to farmers	Yes	No
Bulgaria	1 year	Mandatory to report	Bulgarian Food Safety Agency	Wholesalers (n=24)	Sales to veterinarians and pharmacies	Yes	No
Cyprus	1 year	Mandatory to report	Ministry of Agriculture, Natural Resources and Environment - Veterinary Services	Wholesalers (n=21)	Sales to pharmacies and veterinary clinics	Yes	No
Czech Republic	>5 years	Mandatory to report	Institute for State Control of Veterinary Biologicals and Medicines	Wholesalers (n=112); feed mills (n=52),	Sales to veterinarians, pharmacies and farmers; sales by feed mills to farmers	Yes	Yes (only one product with significant consumption in 2011)
Denmark	>5 years	Mandatory to report	Danish Veterinary and Food Administration	VetStat (n=1) obtaining data from pharmacies; wholesalers; veterinarians; feed mills	Prescription data from pharmacies, veterinarians, distributors and feed mills	Not applicable	Yes
Estonia	>5 years	Mandatory to report	State Agency of Medicines	Wholesalers (n=8)	Sales to veterinarians and pharmacies	Yes	Yes
Finland	>5 years	Mandatory to report	Finnish Medicines Agency	Wholesalers (n=3); feed mills (n=1); importers of medicated feed (n=1)	Sales to pharmacies and veterinarians	Yes	Yes
France	>5 years	Not mandatory	National Agency for Veterinary Medicinal Products (Anses-ANMV)	MAHs (n=29)	Sales to veterinarians, farmers, wholesalers and feed mills	Yes	No

[1] Purchase data from e.g. pharmaceutical industry and/or from other countries. [2] MAHs = marketing-authorisation holders. [3] PSUR = periodic safety update reports.

Country	Years collecting data	Legal basis	National data provider to ESVAC	Sources for ESVAC data (approx. no)	Prescription data, sales data or purchase data[1]	Sales between wholesalers and/or MAHs[2] excluded (Yes/No)	Products used on special licence included (Yes/No)
Germany	1 year	Mandatory to report	Federal Office of Consumer Protection and Food Safety	MAHs (n=38); wholesalers (n=16); PSUR[3] data for premix	Sales to veterinarians	Yes	No
Hungary	>5 years	Mandatory to report	National Food Chain Safety Office Directorate of Veterinary Medicinal Products	Wholesalers (n=54); wholesalers other countries (n=2)	Sales to veterinarians and feed mills	Yes	No
Iceland	2 years	Mandatory to report	Icelandic Medicines Agency	Wholesalers (n=2)	Sales by wholesalers to veterinarians and pharmacies	Yes	Yes
Ireland	3 years	Not mandatory	Irish Medicines Board	MAHs (n=61)	Sales to pharmacies or veterinarians	Yes	No
Italy	2 years	Mandatory to report	Italian Ministry of Health	MAHs (n=48)	Sales to wholesalers, pharmacies, feed mills, and farms authorised to produce medicated feed for self-consumption	Yes	No
Latvia	2 years	Mandatory to report	Food and Veterinary Service	Wholesalers (n=24)	Sales to pharmacies, veterinarians and farmers	Yes	No
Lithuania	2 years	Mandatory to report	State Food and Veterinary Service	Wholesalers (n=29)	Sales to pharmacies, veterinarians and farmers	Yes	No
Netherlands	>5 years	Not mandatory	Federation of the Dutch Veterinary Pharmaceutical Industry (FIDIN)	MAHs (n=17)	Sales to veterinarians	Yes	No
Norway	>5 years	Mandatory to report	Norwegian Veterinary Institute	Wholesalers (n=5)	Sales to pharmacies, veterinarians and feed mills	Yes	Yes
Poland	1 year	Mandatory to report	Ministry of Agriculture and Rural Development	Wholesalers (n=127)	Sales to veterinarians	Yes	Yes

[1] Purchase data from e.g. pharmaceutical industry and/or from other countries. [2] MAHs = marketing-authorisation holders. [3] PSUR = periodic safety update reports.

Country	Years collecting data	Legal basis	National data provider to ESVAC	Sources for ESVAC data (approx. no)	Prescription data, sales data or purchase data[1]	Sales between wholesalers and/or MAHs[2] excluded (Yes/No)	Products used on special licence included (Yes/No)
Portugal	2 years	Mandatory to report	Portuguese National Authority for Animal Health	Wholesalers (n=75)	Sales to retailers, veterinarians, farmers, producer organisations, veterinary clinics and feed mills	Yes	No
Slovakia	1 year	Mandatory to report	Institute for State Control of Veterinary Biologicals and Medicaments	Wholesalers (n=59)	Purchase data	Not applicable	No
Slovenia	2 years	Mandatory to report	Administration of the Republic of Slovenia for Food Safety, Veterinary Sector and Plant Protection (AFSVSPP)	Wholesalers (n=11)	Sales to pharmacies and veterinarians	Yes	Yes
Spain	3 years	Not mandatory	Spanish Agency for Medicines and Health Products	MAHs (n=37)	Sales to wholesalers and retailers, i.e. veterinary organisations and pharmacies	Yes	No
Sweden	>5 years	Mandatory to report	National Veterinary Institute and Swedish Board of Agriculture	Apotekens Service AB (n=1) obtaining data from pharmacies	Dispensed prescriptions	Not applicable	Yes
United Kingdom	>5 years	Mandatory to report	Veterinary Medicines Directorate	MAHs (n=62)	Sales to veterinarians and veterinary pharmacies	Yes	No

[1] Purchase data from e.g. pharmaceutical industry and/or from other countries. [2] MAHs = marketing-authorisation holders. [3] PSUR = periodic safety update reports.

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 25 countries included in the ESVAC 2011 data cover approximately 95% of the food-producing animal population measured as PCU in the EU/EEA countries.

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

Overall, pigs, cattle, poultry and sheep/goats accounted for 34%, 32%, 13% and 12%, respectively, of the PCU in the 25 countries.

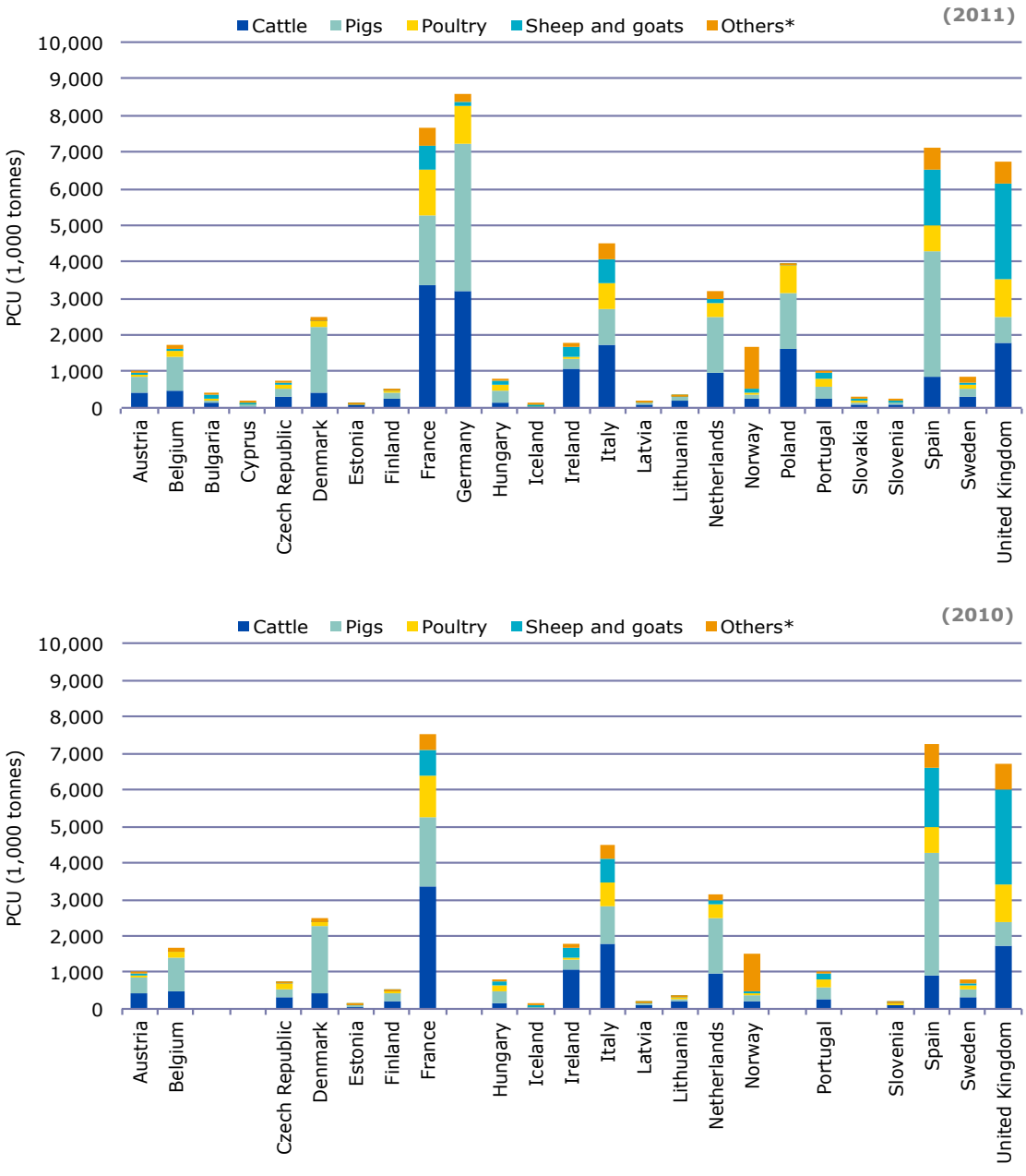
Table 3. Estimated PCU (in 1,000 tonnes) of the population of food-producing species[1] (including horses), by country, for 2011

Country	Cattle	Pigs	Poultry	Sheep/ goats	Fish	Rabbits	Horses	Total
Austria	440	392	80	35			29	977
Belgium	491	931	159	17	1	4	93	1,695
Bulgaria	137	62	44	94	6		56	399
Cyprus	18	56	14	32	5	0.2	3	127
Czech Republic	293	222	139	16	21	10	31	732
Denmark	402	1,836	120	13	35		72	2,479
Estonia	61	34	10	5	0		4	114
Finland	224	182	62	11	11		30	520
France	3,376	1,902	1,219	688	234	55	170	7,643
Germany	3,169	4,033	1,045	146	21	0.4	185	8,600
Hungary	142	314	170	89	20	1	30	767
Iceland	19	6	5	47	5		31	114
Ireland	1,050	265	79	289	44		42	1,770
Italy	1,701	989	695	680	204	33	195	4,497
Latvia	111	33	15	6	1	0.002	5	171
Lithuania	213	70	41	5	3	0.04	6	337
Netherlands	974	1,508	387	101	44	3	169	3,186
Norway	228	126	64	102	1,145		15	1,680
Poland	1,610	1,551	739	18			11	3,929
Portugal	239	348	206	185	9	8	22	1,016
Slovakia	104	58	49	34	1		2	247
Slovenia	101	25	36	10	0.1	0.02	9	182
Spain	877	3,383	708	1,527	274	89	277	7,135
Sweden	323	221	82	52	12		145	835
United Kingdom	1,767	717	1,012	2,664	170		395	6,724
Total 25 countries	**18,069**	**19,264**	**7,180**	**6,866**	**2,266**	**201**	**2,026**	**55,872**

[1] Animal categories included: see Annex 3.

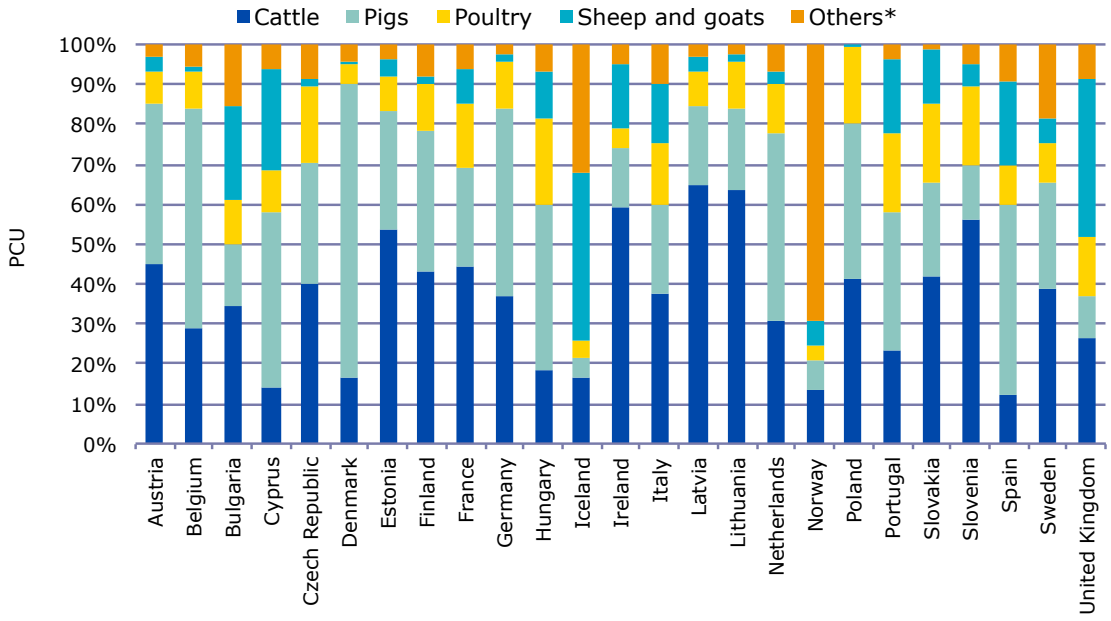
A minor decrease in the PCU from 2010 to 2011 was observed for 10 of the 20 countries reporting data for both years (range 0.2%–3.1%), and for 9 countries a minor increase was seen (0.2%–3.7%) (Figure 2; Table 5). For one country (Norway), an increase of 9.3% of the PCU was reported; this was due to increased production of farmed fish.

Figure 2. PCU (in 1,000 tonnes) of the various food-producing animal species, including horses, by country, for 2011 and 2010[1]



[1] 2010 data have been updated to include fish for Norway and Sweden, and use of national statistics for the UK. * Horses and, for some countries, fish and/or rabbits.

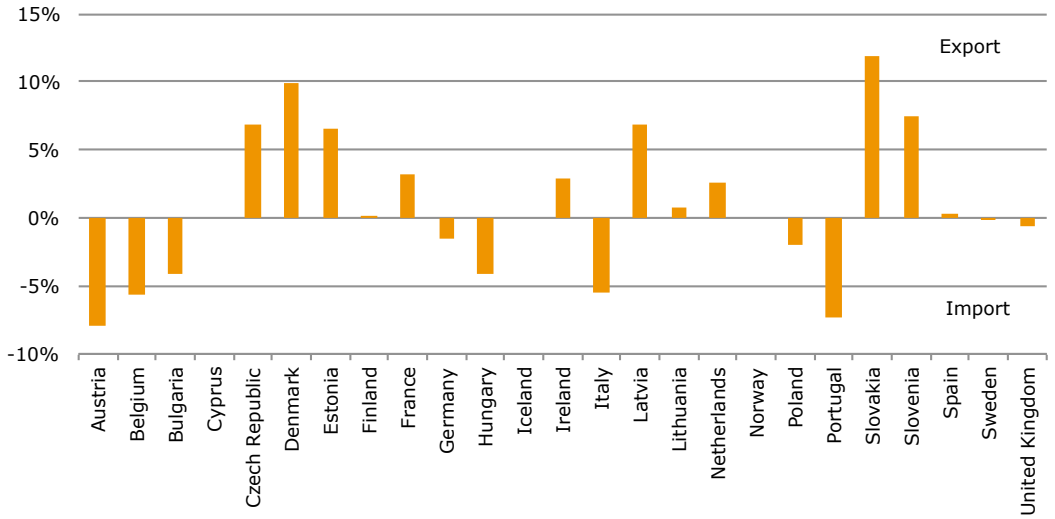
Figure 3. Distribution of PCU (1,000 tonnes), by food-producing animal species, including horses, by country, for 2011



* Horses and, for some countries, fish and/or rabbits.

The percentage of the total PCU accounted for by the net export or import of animals for slaughter and/or fattening is shown in Figure 4. Of the 25 countries, 6 countries had a net export of animals for slaughter and/or fattening to other Member States that accounted for ≥ 5% of the PCU.

Figure 4. Net export and net import[1], as a percentage of the total PCU, of animals for fattening or slaughter in another Member State, for 2011



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

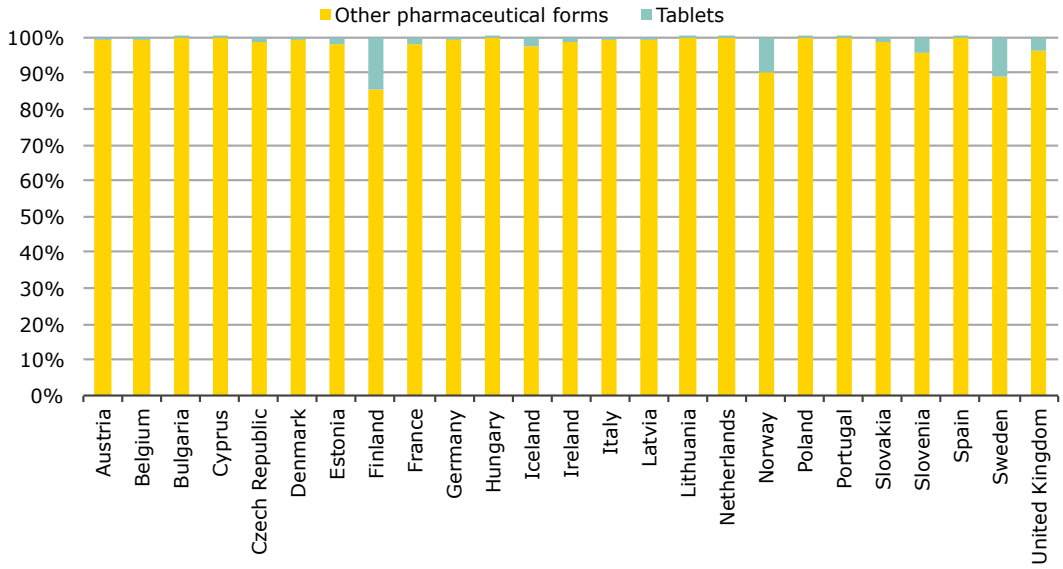
2.2. Overall sales of veterinary antimicrobial agents

The overall national sales data provided covered sales for use almost solely in companion animals (mainly tablets) and food-producing animals, including horses (all other pharmaceutical forms). Injectable veterinary antimicrobial agents are also used in companion animals, but due to minor use, in terms of weight of active ingredient, such sales are included in the statistics for food-producing animals. Except for Finland, Norway and Sweden, where tablets accounted for 14.4%, 9.7% and 10.6%, respectively, sales of tablets, and therefore use in companion animals, accounted for a minor proportion of the total sales of veterinary antimicrobial agents in 2011 (Table 4; Figure 5). Overall in the 25 countries, the sales, in tonnes, of tablets represented 0.7% of the total sales.

Table 4. Distribution of overall sales, in tonnes of active ingredient, split into tablets (used in companion animals) and all other pharmaceutical forms (used mainly in food-producing animals, including horses), by country, for 2011

	Tablets		All other pharmaceutical forms		Total
Country	**Tonnes**	**% of overall sales**	**Tonnes**	**% of overall sales**	**Tonnes**
Austria	0.2	0.5	53.2	99.5	53.4
Belgium	1.5	0.5	297.0	99.5	298.6
Bulgaria	0.1	0.2	41.6	99.8	41.7
Cyprus	0.04	0.1	51.8	99.9	51.8
Czech Republic	0.8	1.2	60.7	98.8	61.4
Denmark	1.0	0.9	105.5	99.1	106.5
Estonia	0.1	1.8	7.5	98.2	7.7
Finland	2.1	14.4	12.4	85.6	14.4
France	17.1	1.9	895.7	98.1	912.8
Germany	7.6	0.4	1,818.7	99.6	1,826.3
Hungary	0.1	0.1	147.5	99.9	147.5
Iceland	0.02	2.5	0.7	97.5	0.7
Ireland	1.0	1.2	87.5	98.8	88.5
Italy	9.2	0.5	1,662.7	99.5	1,671.9
Latvia	0.04	0.7	6.0	99.3	6.0
Lithuania	0.04	0.3	14.0	99.7	14.0
Netherlands	1.1	0.3	362.9	99.7	364.0
Norway	0.7	9.7	6.2	90.3	6.8
Poland	1.7	0.4	471.2	99.6	472.9
Portugal	0.4	0.2	163.8	99.8	164.2
Slovakia	0.1	1.2	10.9	98.8	11.0
Slovenia	0.4	4.5	7.8	95.5	8.2
Spain	1.5	0.1	1,779.2	99.9	1,780.7
Sweden	1.3	10.6	11.3	89.4	12.7
United Kingdom	13.4	3.7	344.0	96.3	357.4
Total 25 countries	**62**		**8,420**		**8,481**

Figure 5. Distribution of sales, in tonnes of active ingredient, split into tablets (used almost solely in companion animals) and all other pharmaceutical forms (used mainly in food-producing animals, including horses), by country, for 2011



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

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

Figure 6. Distribution of sales of veterinary antimicrobial agents for food-producing animals (including horses), in mg per population correction unit (mg/PCU), by pharmaceutical form, by country, for 2011

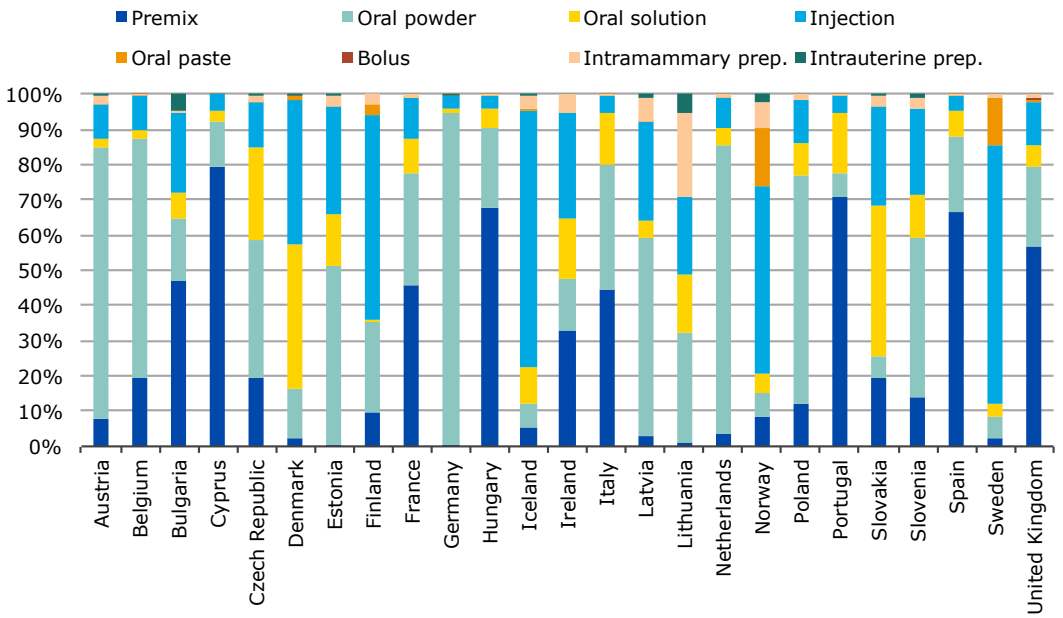


Figure 7. Oral solutions, oral powders and premixes as percentages of total sales, in mg per population correction unit (mg/PCU), of veterinary antimicrobial agents for food-producing animals (including horses), by country, for 2011

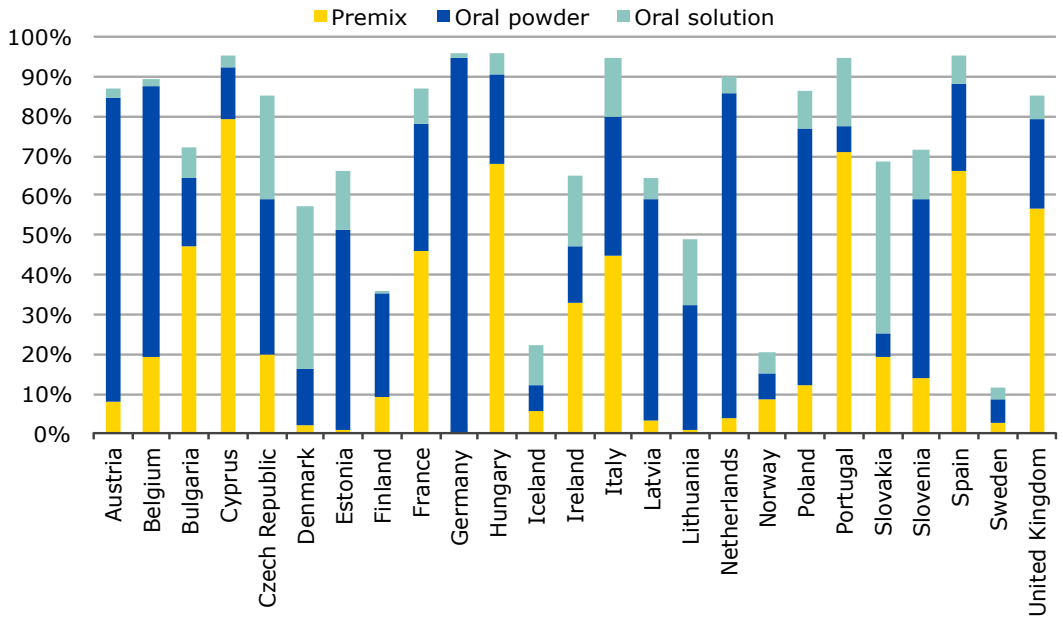
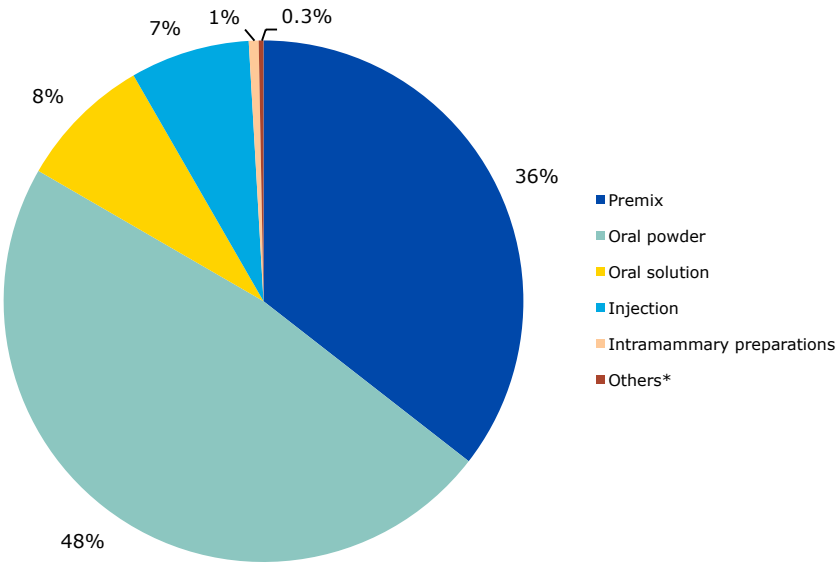


Figure 8. Distribution of sales, in mg/PCU, of the various pharmaceutical forms of veterinary antimicrobial agents for food-producing animals (including horses) aggregated by the 25 EU/EEA countries for 2011



* Oral paste, bolus and intrauterine preparations.

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

Although a minor proportion of the oral powders and oral solutions are applicable for treatment of an individual animal or a very limited number of animals, the sales figures for these forms are reasonable estimates of group treatment.

Aggregated by the 25 countries, the sales in mg/PCU of premixes accounted for 36% of the overall sales, while 48% were for oral powders, 8% for oral solutions and 7% for injectable preparations.

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

The sales of veterinary antimicrobial agents, expressed as mg sold per population correction unit (PCU), varied from 3.7 mg/PCU to 408 mg/PCU between the 25 countries. Also, the sales patterns of the antimicrobial classes varied substantially between the 25 countries (Tables 5 and 6; Figure 9).

Table 5. Sales, in tonnes of active ingredient, of veterinary antimicrobial agents marketed mainly for food-producing animals[1] (including horses), population correction unit (PCU) and sales in mg/PCU, by country, for 2010[2] and 2011

Country	Sales (tonnes) for food-producing animals		PCU (1,000 tonnes)		% change PCU	mg/PCU		% change mg/PCU
	2010	2011	2010	2011	2010-2011	2010	2011	2010-2011
Austria	63	53	994	977	-1.8%	63	54	-13%
Belgium	299	297	1,660	1,695	2.1%	180	175	-3%
Bulgaria		42		399			104	
Cyprus		52		127			408	
Czech Republic	71	61	755	732	-3.1%	94	83	-12%
Denmark	119	106	2,503	2,479	-1.0%	47	43	-10%
Estonia	7.6	7.5	115	114	-1.1%	66	66	-0.4%
Finland	13	12	517	520	0.6%	25	24	-4%
France	997	896	7,538	7,643	1.4%	132	117	-11%
Germany		1,819		8,600			211	
Hungary[3]	206	147	768	767	-0.2%	268	192	-28%
Iceland	0.9	0.7	113	114	0.8%	7.2	6.3	-13%
Ireland	96	87	1,779	1,770	-0.5%	54	49	-9%
Italy	1,928	1,663	4,514	4,497	-0.4%	427	370	-13%
Latvia	6.6	6.0	165	171	3.7%	40	35	-12%
Lithuania	16	14	342	337	-1.5%	48	42	-14%
Netherlands	461	363	3,155	3,186	1.0%	146	114	-22%
Norway	6.3	6.2	1,537	1,680	9.3%	4.1	3.7	-11%
Poland		471		3,929			120	
Portugal	181	164	1,020	1,016	-0.3%	178	161	-9%
Slovakia[4]		11		247			44	
Slovenia	8.4	7.8	181	182	1.0%	46	43	-6%
Spain[5]	1,746	1,779	7,248	7,135	-1.6%	241	249	3.5%
Sweden	13	11	832	835	0.3%	15.2	13.6	-11%
United Kingdom	456	344	6,714	6,724	0.2%	68	51	-25%

[1] Tablets excluded as almost solely used in companion animals; injectable antimicrobial VMPs can also be used in companion animals; a few other products may solely be used in companion animals, but as the proportional use is minor, these are included in the sales for food-producing animals. [2] Data for Estonia, Iceland, Ireland, Lithuania, Portugal and Spain are updated. [3] Import data for 2010. [4] Import data for 2011.
[5] Substantial underreporting was identified for 2010, indicating that the sales have actually decreased from 2010 to 2011 (see Section 2.4.1).

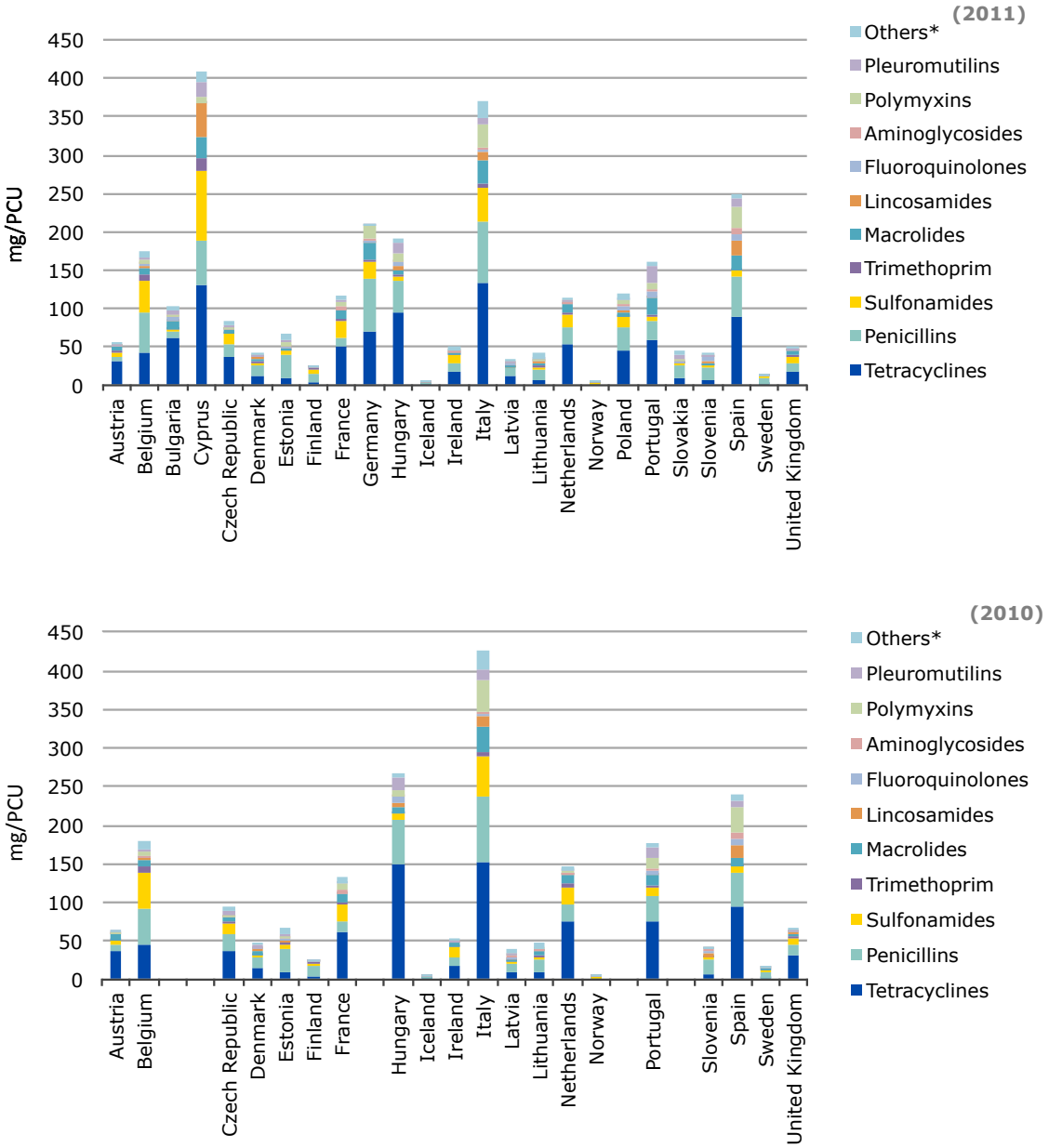
Overall in the 25 countries, 16% of the decline in the sales of veterinary antimicrobial agents from 2010 to 2011 was accounted for by premixes, 7% by oral powders and 4% by oral solutions.

Table 6. Percentages of sales for food-producing animals (including horses), in mg per population correction unit (mg/PCU), of the various veterinary antimicrobial classes, by country, for 2011

Country	Tetracyclines	Amphenicols	Penicillins	1-2 gen. cephalosporins	3-4 gen. cephalosporins	Sulfonamides	Trimethoprim	Macrolides	Lincosamides	Fluoroquinolones	Other quinolones	Aminoglycosides	Polymyxins	Pleuromutilins	Others*	Total mg/PCU
Austria	59.6	0.6	10.4	0.1	0.6	10.5	1.4	9.1	0.6	1.1		0.6	1.8	0.8	2.8	54.5
Belgium	24.3	0.5	29.3	0.05	0.3	23.8	4.8	5.4	1.9	0.5	0.9	0.5	3.1	0.9	3.9	175.2
Bulgaria	57.9	1.1	8.4	0.03	0.05	2.4	0.2	10.6	1.1	4.8	0.4	0.5	3.0	3.8	5.6	104.3
Cyprus	32.0	0.2	14.0	0.001	0.04	22.4	4.4	6.5	10.7	0.1	0.4	0.2	2.0	4.7	2.5	407.6
Czech Republic	46.1	0.5	19.4	0.3	0.3	16.0	1.1	4.0	0.4	1.8	0.3	0.3	0.7	4.6	4.3	82.8
Denmark	29.1	0.9	33.5	0.1	0.1	7.7	1.3	10.4	2.3	0.0	0.3	0.6	0.4	8.6	4.7	42.6
Estonia	14.8	0.2	44.3	0.7	0.8	7.6	1.8	4.0	1.6	3.3		1.1	6.1	5.1	8.6	66.0
Finland	14.9	1.0	53.4	0.3	0.1	19.6	3.9	4.3	0.8	0.7		0.2		0.6	0.2	23.8
France	44.0	0.5	9.5	0.2	0.3	18.6	2.8	7.7	0.6	0.5	0.7	3.1	6.7	0.8	4.1	117.2
Germany	33.4	0.3	32.8	0.02	0.2	10.2	1.6	9.5	0.9	0.4		1.9	7.0	0.9	0.7	211.5
Hungary	49.6	1.2	21.5	0.3	0.1	3.2	0.7	3.3	2.0	3.5	0.1	0.3	4.6	7.5	2.0	192.4
Iceland	5.6		44.8		0.2	3.0	0.6		0.7	0.1	5.3	11.8		0.1	27.9	6.3
Ireland	34.7	1.6	23.9	0.8	0.1	21.3	1.9	5.2	0.4	0.8		1.7	0.2	0.04	7.3	49.4
Italy	35.7	0.9	21.7	0.1	0.1	12.2	1.5	7.8	3.4	0.6	2.5	0.7	8.2	2.2	2.4	369.7
Latvia	38.2	0.04	26.0	0.2	0.7	4.6	1.2	4.5	1.9	3.7	0.02	1.5	2.8	5.3	9.3	35.0
Lithuania	19.1	1.0	33.4	2.5	0.1	6.6	1.5	11.1	1.9	0.9	0.5	3.4	3.4	2.3	12.2	41.5
Netherlands	47.2	0.7	20.0	0.03	0.2	14.3	2.6	8.9	0.3	0.4	1.0	1.5	1.4	0.3	1.2	113.9
Norway	3.6	5.6	46.2		0.02	23.3	4.3	0.02		0.3	3.4	0.7		1.8	10.8	3.7
Poland	38.1	0.8	24.0	0.2	0.1	11.4	0.7	5.4	0.9	6.0	0.1	1.9	3.5	1.2	5.8	119.9
Portugal	36.5	0.9	15.4	0.1	0.2	3.8	0.8	14.0	0.6	5.2	0.3	1.7	4.9	12.9	2.7	161.2
Slovakia	19.2	0.8	42.4	0.9	1.5	3.0	0.6	1.5	0.3	6.8	0.8	0.3	2.8	12.0	7.0	43.9
Slovenia	14.7	4.1	38.9	0.4	0.2	7.0	1.9	5.7	4.7	13.8	0.2	1.4	0.3	0.8	6.0	43.2
Spain	35.9	0.5	21.2	0.03	0.1	2.5	0.4	7.6	7.5	3.4	0.01	3.8	10.5	4.4	2.1	249.4
Sweden	9.1	0.4	60.9		0.1	16.7	3.0	4.0		0.8	0.01	0.6	0.7	1.2	2.5	13.6
United Kingdom	33.2	0.8	22.5	0.2	0.3	17.0	3.4	10.7	1.6	0.6		0.8	0.3	3.6	5.2	51.2

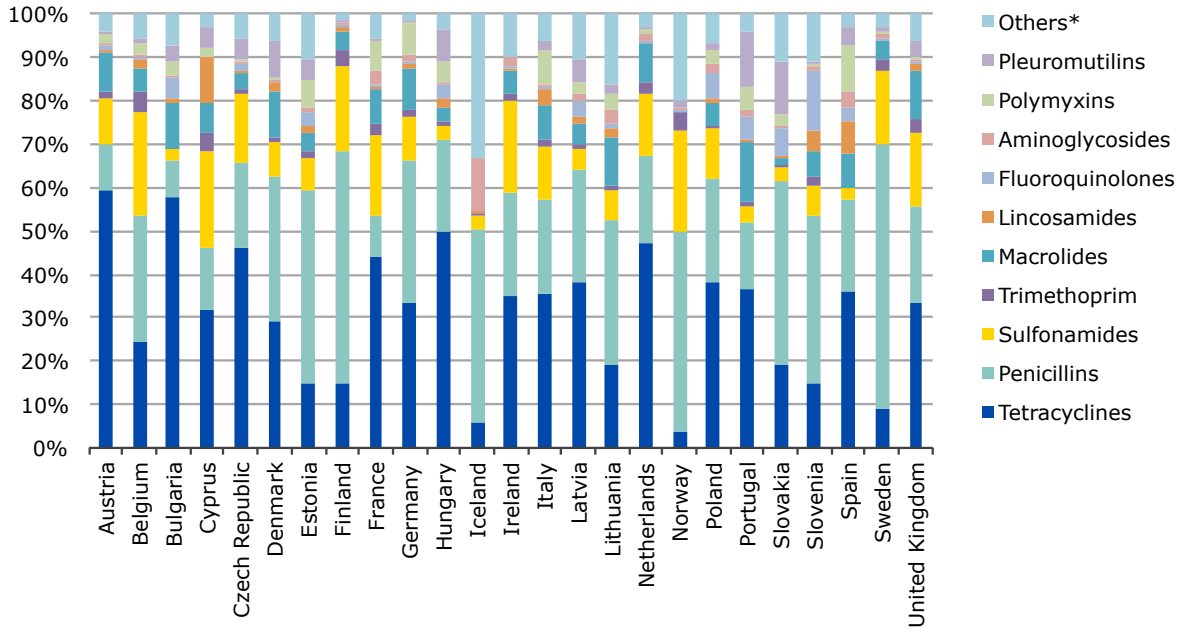
* Bacitracin, paromycin and spectinomycin (classified as 'Others' in the ATCvet system).

Figure 9. Sales for food-producing species, including horses, in mg/PCU, of the various veterinary antimicrobial classes, by country[1], for 25 countries in 2011 and for 20 countries in 2010



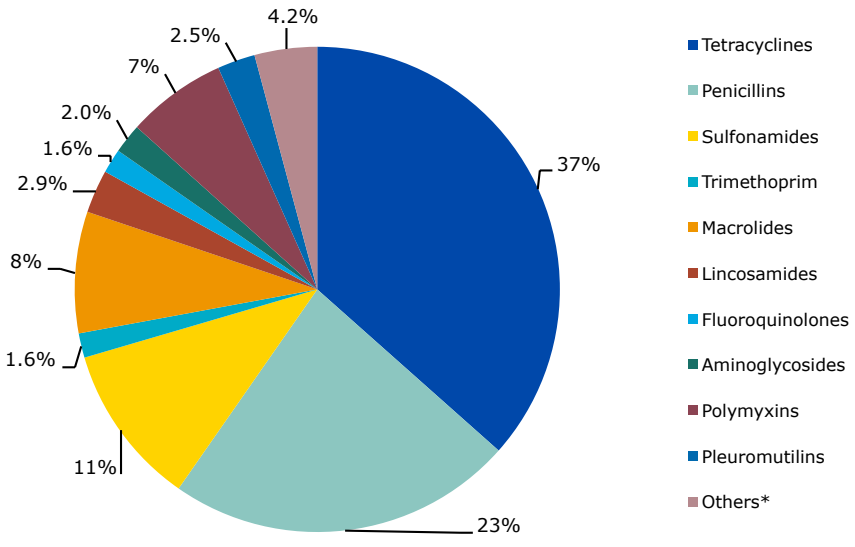
[1] Differences between countries can partly be explained by differences in animal demographics, in the selection of antimicrobial agents, in dosage regimes and in type of data sources, among other factors. * Amphenicols, cephalosporins, other quinolones and other antibacterials (classified as such in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

Figure 10. Proportion of the total sales of the different veterinary antimicrobial classes, in mg/PCU, by country, for 2011



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

Figure 11. Sales of antimicrobial agents by antimicrobial class as a percentage of the total sales for food-producing species (including horses), in mg/PCU, aggregated by the 25 countries, for 2011

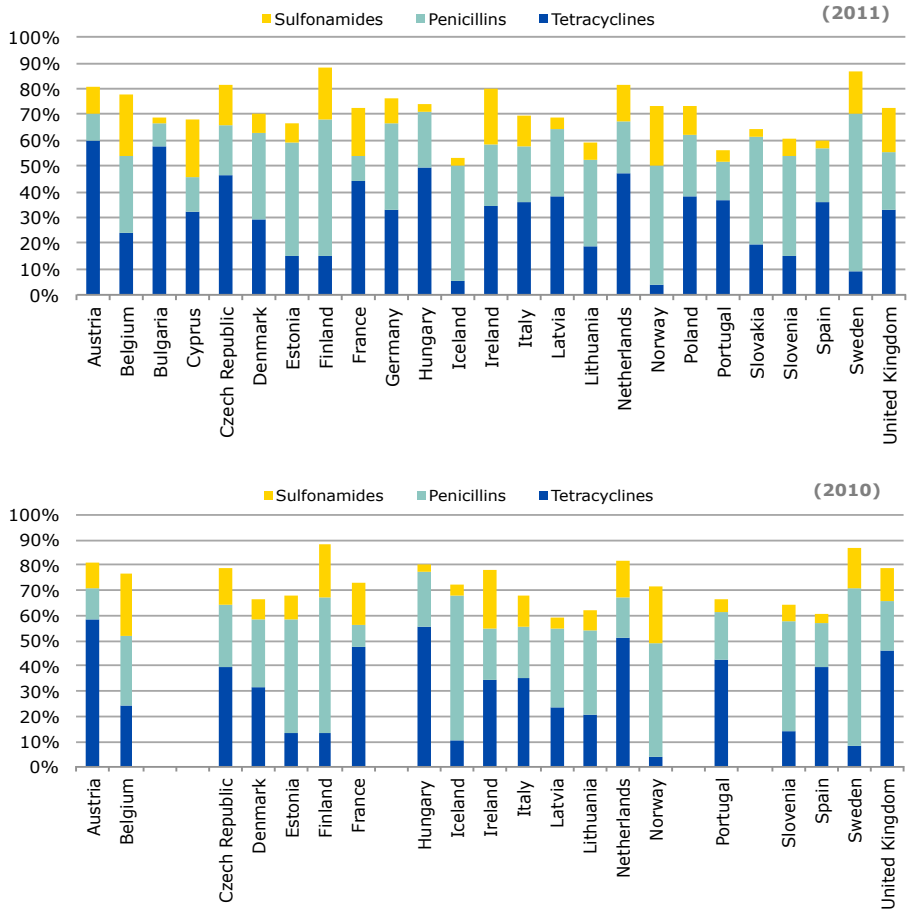


* Amphenicols, cephalosporins and other quinolones.

For all 25 countries, the sales of tetracyclines, penicillins and sulfonamides, in mg/PCU, accounted for more than 71% of the total sales (range 53%–88%) in 2011 (Figure 11).

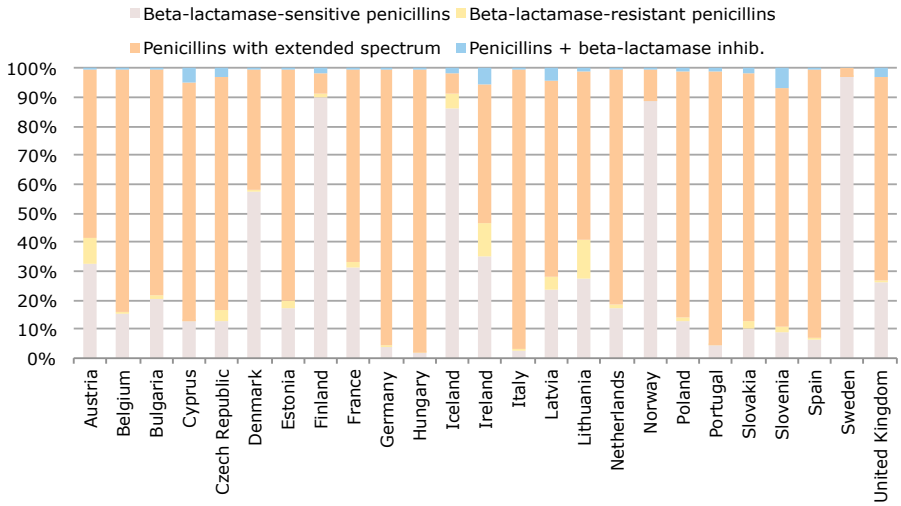
Of the overall sales in the 25 countries, 0.1% was accounted for by 1st- and 2nd-generation cephalosporins, 0.2% was for 3rd- and 4th-generation cephalosporins, 0.6% was for amphenicols and 0.7% for other quinolones.

Figure 12. Sales of tetracyclines, penicillins and sulfonamides as a percentage of the total sales for food-producing species (including horses), in mg/PCU, by country, for 2010 and 2011



The percentage of sales of penicillins attributed to the various subclasses differed substantially between the 25 countries (Figure 13); in the Nordic countries, the proportion of beta-lactamase-sensitive penicillins accounted for the majority of penicillins sold, while for other countries it was penicillins with extended spectrum that accounted for the majority of sales.

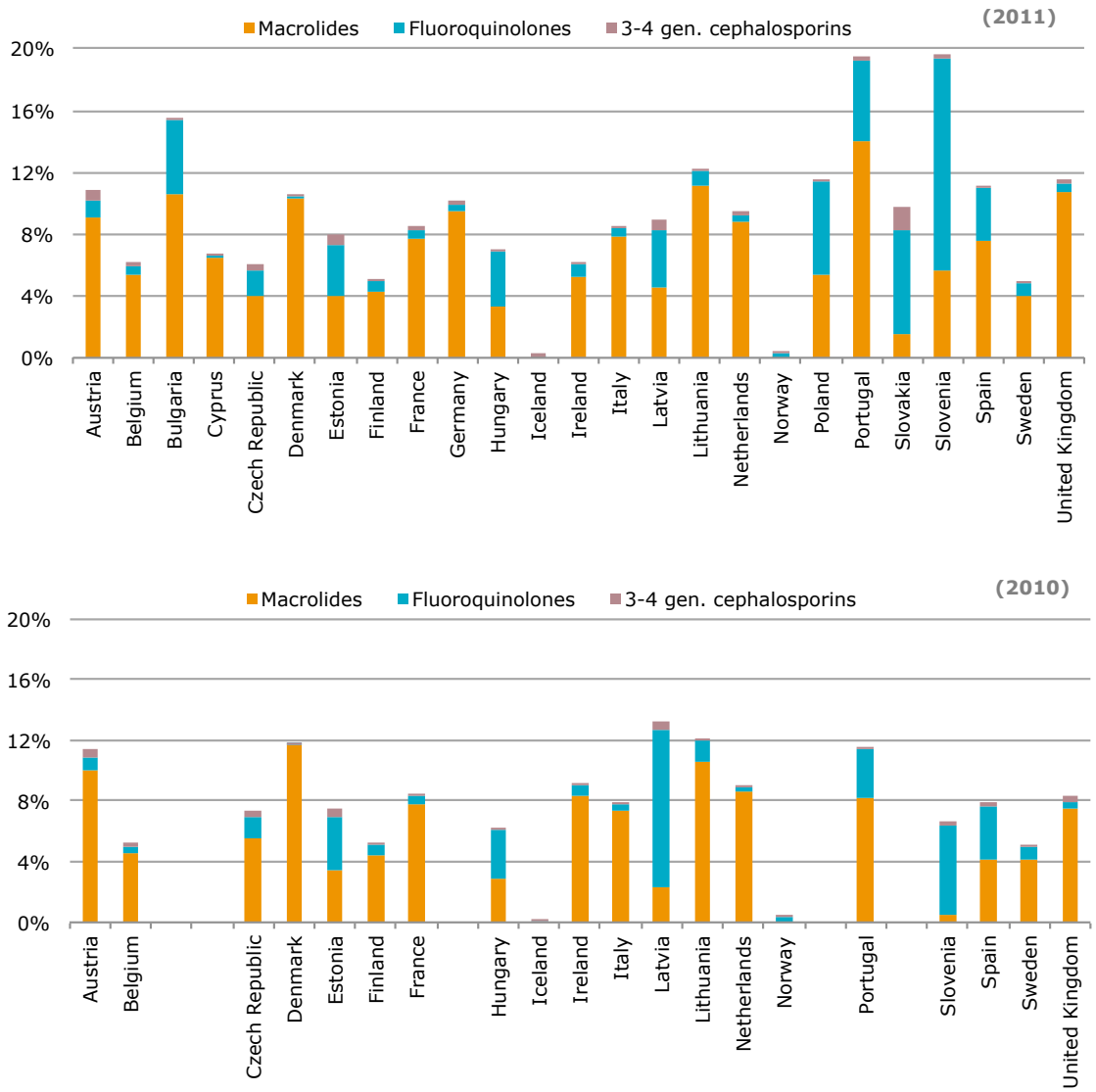
Figure 13. Distribution of sales in mg/PCU of penicillins, by subclass, for food-producing species, including horses, by country, for 2011



The proportion sold of the critically important antimicrobials (CIAs) with the highest priority in human medicine — 3rd- and 4th-generation cephalosporins, fluoroquinolones and macrolides — in the different countries in 2011 varied substantially, ranging from 0.05% to 0.78%, 0.01% to 13.8%, and 0% to 14%, respectively (Figure 14).

Overall in the 25 countries, the sales (mg/PCU) of these CIAs accounted for 0.2%, 1.6% and 8%, respectively, of the total sales of antimicrobial VMPs in 2011.

Figure 14. Percentages of the total sales of macrolides, fluoroquinolones and 3rd- and 4th-generation cephalosporins for food-producing species, including horses, in mg/PCU, by country, for 25 countries in 2011 and 20 countries in 2010



2.4.1. Explanations for observed changes in sales and sales patterns, 2010–2011

Nineteen of the 20 countries that reported sales in both 2010 and 2011 reported a decrease in sales, in mg/PCU, within a range of 0.4% to 28%, while for one country, an increase from 2010 to 2011 is observed (3.5%) (Table 5; Figure 9). The proportion accounted for by the various antimicrobial classes changes notably for several countries. The countries collecting data on sales of veterinary antimicrobial agents for the first time in 2010 might not yet have established a stable system, and this may explain part of the observed changes in the sales or sales patterns.

Austria

A decline in the sales (in mg/PCU) of 13% from 2010 to 2011 was observed, and the major part of the reduction was for penicillins, tetracyclines, macrolides and sulfonamides. The sales patterns were relatively stable. Most of the reduction can be explained by a decrease in the sales of five products from two companies (the selling of one of these products was stopped in May 2011). In general, a decrease in number of products on the market from 2010 to 2011 was observed. Thus, the observed change may be due to changes in the market situation.

Belgium

The sales, in mg/PCU, declined by 3% from 2010 to 2011; the proportion accounted for by the various antimicrobial classes remained stable.

Czech Republic

From 2010 to 2011, a decline in sales (in mg/PCU) of 12% (and a 14% decline in tonnes) is seen in the Czech Republic. This is mainly accounted for by penicillins (with extended spectrum), macrolides and pleuromutilins. The sales of tetracyclines and sulfonamides, two of the most-selling classes, remained stable in mg/PCU, while the proportion of sales of these two classes increased by 6% and 2.3%, respectively.

The overall decrease can be explained by a decrease in the use of premixes, as these are mainly used in pigs, for which a decrease in the population was observed from 2010 to 2011. Since the most frequently used premixes in pigs contain amoxicillin, chlortetracycline, sulfonamides, macrolides or pleuromutilins, this could explain the change in the sales patterns of penicillins, macrolides and pleuromutilins. The decrease in sales of penicillins may also partly have been caused by a decrease in the poultry population, as amoxicillin is relatively frequently used in poultry (via medicated water).

Approximately 12% of the overall decrease (mg/PCU) in sales from 2010 to 2011, during which total PCU decreased by approximately 3%, can in addition to the fact mentioned above be explained by changes in the PCU stratification: decreases in pig (-7.5%) and poultry (-4.8%) populations (as target group for mass medication), and increases in populations of cattle, sheep, horses and goats (as target groups for individual or small group medication).

Regarding the increase in the proportion accounted for by tetracyclines and sulfonamides, it should be noted that the products containing ingredients from these classes are used in the whole spectrum of the target species. Moreover, sulfonamides are used not only for bacterial-disease treatment and prevention, but also against coccidia in a lot of animal species, including sheep and goats. The proportional increase in sales of tetracyclines and sulfonamides can thus reflect a slight increase in the population of species other than pigs and poultry, i.e. sheep, goats and fish.

Denmark

In Denmark, a 10% reduction in sales (in mg/PCU) from 2010 to 2011 is observed. This is mainly accounted for by tetracyclines, penicillins and pleuromutilins, but also macrolides and sulfonamides. The proportion accounted for by the major antimicrobial classes remained relatively stable. The substantial decrease in sales is primarily explained by the introduction of the 'yellow card' in pig production. The yellow card works as follows: based on the total consumption of antimicrobial agents in pigs in Denmark, measured as prescribed numbers of defined daily doses animals (DDDA)/100 pigs per day, a maximum limit value is set up per age group. For sows, this value is currently 5.2, for weaners, 28, and for slaughter pigs, 8. If just one of the different age groups on a farm exceeds the limit, the farmer will as a first step be asked for an explanation, and if the reply is not satisfactory, will receive a fine of approximately 1,100 euro. They will then have 9 months to bring the consumption of antimicrobial agents down under the maximum limit. If they do not succeed, they will receive another fine and further restrictions, such as a reduction in the number of animals.

Estonia

A 0.4% decrease in sales (in mg/PCU) from 2010 to 2011 is observed. The proportion accounted for by the various antimicrobial classes remained stable.

Finland

From 2010 to 2011, a 4% decrease in sales of veterinary antimicrobial agents (in mg/PCU) was seen. The proportion accounted for by the various antimicrobial classes remained stable.

France

An 11% decrease in sales (in mg/PCU) was observed from 2010 to 2011, mainly accounted for by tetracyclines, macrolides, polymyxins and sulfonamides. The results from 2011 confirm the trend in sales seen in previous years.

The sales in weight of active ingredient do not accurately reflect their use because of the differences in potency and dosing between different antimicrobial agents, and thus a decrease in sales volume does not necessarily correspond to a decrease in exposure to antimicrobial agents. To more precisely quantify animal exposure to antimicrobial agents, the French authority has assessed the weight of animals treated with antimicrobial agents by taking into account the dosing. The weight of animals treated with the various antimicrobial classes is obtained by dividing the sales volume expressed in weight of active ingredient by the amount of active ingredient required to treat one kilogram of body weight (daily dose multiplied by the duration of treatment). By use of this method, the estimated exposure to antimicrobial agents, including all routes of administration and species combined, showed an increase between 1999 (start of the monitoring of antibiotic sales) and 2007, and since then there has been a steady decline; from 2010 to 2011, the exposure fell by 3.7%, and by 15.3% over the past five years.

However, this overall trend must be qualified according to target species and antimicrobial classes. The exposure to tetracyclines decreased for all species, and the exposure to macrolides decreased for all species except cattle. Over the past five years, exposure to 3rd- and 4th-generation cephalosporins has increased by 9.4%, while exposure to fluoroquinolones has increased by 7.0%. After a period of sharp increase in animal exposure to these two classes of antimicrobial agents, an inflection can be seen in the exposure development curve, indicating a trend towards stabilisation.

Some sectors (especially the pig and rabbit sectors) that have taken measures to promote the prudent use of antimicrobial agents experienced greater reductions in exposure. Following an initiative in the pig sector to voluntarily restrict the use of newer-generation cephalosporins, exposure of pigs to this class of antimicrobial agents fell by 51.8% between 2010 and 2011.

Hungary

In 2011, the sales (in mg/PCU) of veterinary antimicrobial agents were 28% lower than reported for 2010. The decrease is mainly accounted for by a reduction in the reported sales of tetracyclines and penicillins, which represent 76% and 71% of the sales in 2010 and 2011, respectively. However, the data reported for 2011 represent sales from wholesalers to end-users, such as veterinarians and farmers, while the 2010 data were based on import/purchase data. A possible explanation for the apparent decrease could be that the importers (wholesalers) did not sell all the veterinary antimicrobial products the same year as they were imported, and this would in particular affect the most-selling products, i.e. tetracyclines and penicillins. The 2010 data, therefore, most likely represent an overestimate, and the real decline in the reported sales from 2010 to 2011 may be considerably lower.

Minor changes in the prescribing patterns from 2010 to 2011 are seen, but since the data cannot be regarded as comparable, this change may be artificial.

Iceland

A 13% decrease in sales (in mg/PCU) is observed from 2010 to 2011. This was caused by a minor reduction in the sales of many of the products, and for some products, the sales are clearly declining. However, no definite conclusion as to what caused these changes can be reached for the time being.

Ireland

A decline in sales (in mg/PCU) of 9% from 2010 to 2011 was observed, and the major part of the reduction was for macrolides, sulfonamides and tetracyclines. The prescribing patterns were relatively stable. The reduced sales are possibly explained by increased competition in the marketplace. With over one hundred new product presentations authorised in 2011, a shift to the use of other active substances that are used in lower doses may account for the change.

Italy

In Italy, a decline in sales (in mg/PCU) of 13% from 2010 to 2011 is observed, and the decline is reported for almost all classes; however, the major part was for tetracyclines, polymyxins, sulfonamides and pleuromutilins. The prescribing patterns were relatively stable. The reduced sales are likely to have been caused by the following factors:

- Since 2009, a continuous improvement of the information and of the training system related to rational and prudent use of veterinary medicinal products has taken place.
- In 2009, the Ministry of Health launched awareness campaigns against prophylactic use of antimicrobial agents in breeding plants. Training courses were held in collaboration with the National Reference Laboratory for Antimicrobial Resistance, IZSLT, in Rome. An online training course on veterinary medicines surveillance and pharmacovigilance, which also included basic principles of prudent use of antimicrobial agents in livestock productions, was published in the Italian Veterinarians Federation's journal.
- In 2010, an information system was activated that involved reporting to the Ministry of Health the prescription volumes by the Italian regions, in order to estimate the total number of prescriptions issued throughout each Italian region, divided by animal category (farm animals, companion animals, stocks, medicated feed, cascade) and species (number of average annual prescriptions per species). This survey allows the local competent authorities to identify during a particular year the most problematic sectors where antimicrobial resistance has to be tackled in the following year.

Latvia

In Latvia, a decline of 12% in sales (in mg/PCU) from 2010 to 2011 is observed, and this decrease is seen for most of the antimicrobial classes, except for tetracyclines, macrolides and pleuromutilins, for which notable increases are seen. The changes can be explained by the following:

- Animal husbandry in Latvia is intensifying; the average number of animals on a farm (herd) is increasing, but the total number of disease outbreaks has not increased. This might be due to the use of disease-prevention methods.
- Activation of sales by wholesalers: more educational seminars for farmers on the use of medicines; advertising; etc.

For tetracyclines, relatively considerable changes are observed for sales of a doxycycline oral powder used in pig and poultry farming. For macrolides, relatively considerable changes are seen in the sales of tylosin oral powder, which is used for pigs and cattle (including for Pasteurella infections; according to laboratory data, some increase in positive results for cattle was shown in 2011). For pleuromutilins, relatively considerable changes are observed in the sales of tiamulin oral powders, which are used for pigs, poultry and rabbits.

Lithuania

An apparent 14% decrease in sales (in mg/PCU) from 2010 to 2011 was seen in Lithuania, and this is accounted for by all antimicrobial classes. The sales patterns remained relatively stable.

The decrease is mainly accounted for by a reduction in the reported sales of tetracyclines, penicillins and sulfonamides. However, the data reported for 2010 included sales between wholesalers. The 2010 data therefore represent an overestimate, and thus the real decline in the reported sales from 2010 to 2011 is lower.

Netherlands

In the Netherlands, a decrease of 22% in sales (in mg/PCU) from 2010 to 2011 is observed. This is the result of efforts of the major production sectors, which, in 2010, agreed with the government to set reduction targets for the use of antimicrobial agents in animal production: -20% for 2011 and -50% for 2013, with reference to 2009. The reduction achieved affects most of the main antimicrobial classes. The highest reduction percentage was achieved for tetracyclines (-28%), while reduction in the sales of sulfonamides and trimethoprim were just above the average (-24%). Reductions in the sales of 3rd- and 4th-generation cephalosporins, fluoroquinolones and macrolides were a little bit below the average (16%–19%). In contrast, sales of penicillins remained almost constant. Tetracyclines are most commonly used in pig and veal production, the two species accounting for about 80% of the use of antimicrobial agents in Dutch animal production.

A further decrease of 20-25% in total sales has been observed from 2011 to 2012.

Norway

From 2010 to 2011, an 11% decrease in sales (in mg/PCU) was seen. The sales patterns were relatively stable during these two years. The reduced consumption is almost solely caused by a reduction in sales of antimicrobial agents for use in farmed fish (from 0.649 tonnes to 0.549 tonnes).

Portugal

From 2010 to 2011, a decrease in sales (in mg/PCU) of 9% is seen in Portugal. The greatest decrease observed is for tetracyclines, polymyxins and penicillins; but at the same time, the sales of macrolides, pleuromutilins and fluoroquinolones have increased. Since the dosage of macrolides and fluoroquinolones, for example, is lower than that of tetracyclines, the numbers of animals treated have not decreased as much as sales in tonnes.

The Directorate-General for Food and Veterinary Medicine (DGAV) assumes that the decrease in sales in the year 2011 may, among other reasons, be related to economic conjecture in the country, which could have led to a decreased number of holdings, partially consequent to changes in working capital in order to comply with the legislation in force and in the framework of the plan of cross-compliance, but does not dispose of any other sustainable data or information to determine concrete and reliable causes for that decrease. The deviation in sales may also be related to an increased number of generics recently authorised in the market, but no accurate data are available to confirm this.

Slovenia

In Slovenia, the sales (in mg/PCU) declined by 6% from 2010 to 2011. However, the proportion accounted for by the various antimicrobial classes varied substantially between those two years, and in particular for beta-lactamase-resistant penicillins, fluoroquinolones and lincosamides. The proportion accounted for by fluoroquinolones increased in 2011, compared to 2010. This is explained by problems with *Escherichia coli* in parent broiler flocks in a single poultry farm in 2011 that imported the animals from another Member State. In the progeny of this particular flock, the problem of *E. coli* persisted. As therapy, from among the antimicrobial agents appropriate and available, only enrofloxacin was effective.

Spain

In Spain, a 3.5% increase in sales (in mg/PCU) from 2010 to 2011 is reported; the sales data show a moderate change in the proportion of sales of penicillins with extended spectrum, macrolides and polymyxins. For 2010, it was identified that one marketing-authorisation holder (MAH) failed to report the sales data; for this company, the reported sales represented 21% of total sales (in tonnes) for 2011. Consequently, the sales of veterinary antimicrobial agents reported for 2010 represent an underestimate. Provided that the sales for this MAH were at the same level in 2010, the sales in Spain in 2011 would have been approximately 16% lower than in 2010. The observed changes in the sales patterns are partly due to the underreporting of sales from this single MAH.

Sweden

From 2010 to 2011, an 11% decrease in the sales of veterinary antimicrobial agents (in mg/PCU) is reported. The proportion accounted for by the various antimicrobial classes was similar in both years. A decreasing trend in sales of some classes and formulations for group treatment has been observed since the beginning of the 1990s, and of most classes since 2007. The decline in sales from 2010 to 2011 is more prominent, and is primarily explained by decreased sales of beta-lactamase-sensitive penicillins. This in turn is explained by decreased incidence of treatment of dairy cows, and by a somewhat lower completeness in the capture of sales of products sold with special license.

United Kingdom

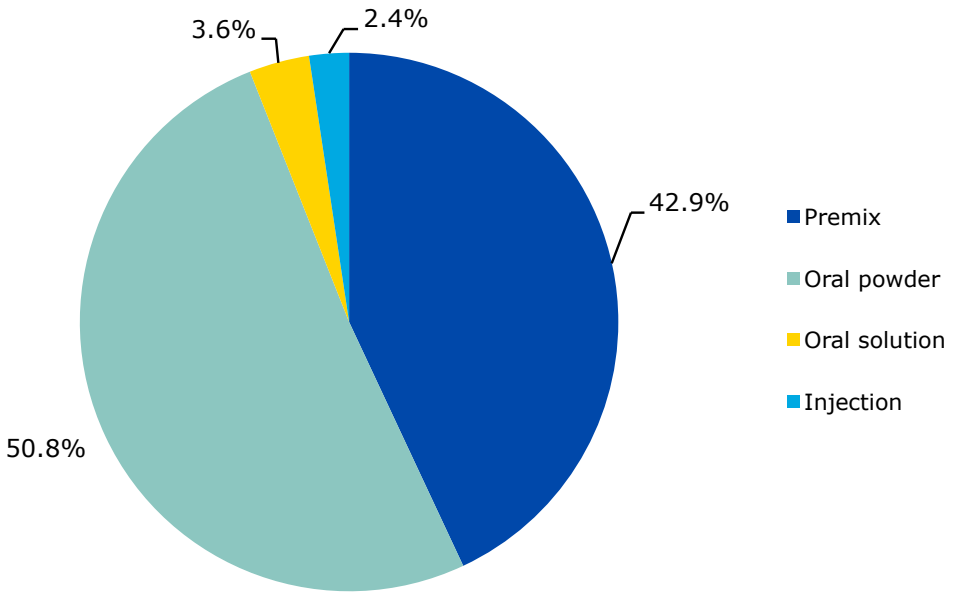
From 2010 to 2011, a 25% decrease in the sales of veterinary antimicrobial agents (in mg/PCU) was observed in the United Kingdom. A reduction was observed for all classes, but in particular for tetracyclines and penicillins with extended spectrum. The proportion accounted for by the various antimicrobial classes varies between the years, and specifically for tetracyclines, sulfonamides and macrolides. The predominant decline was in tetracycline sales. One explanation for this could be altered product-purchasing behaviour in anticipation of a change of marketing-authorisation holder(s) for certain tetracycline-containing products. This drop in sales is therefore not considered to necessarily be reflective of a change in actual use of this antimicrobial class.

2.4.2. Distribution of sales for the most-selling antimicrobial classes and the most important CIAs, by pharmaceutical form, aggregated by the 25 EU/EEA countries

2.4.2.1. Tetracyclines

The overall sales of tetracyclines for the 25 countries, stratified into pharmaceutical forms, are shown in Figure 15. In addition, 0.3% were sold as intramammary preparations, intrauterine preparations and bolus.

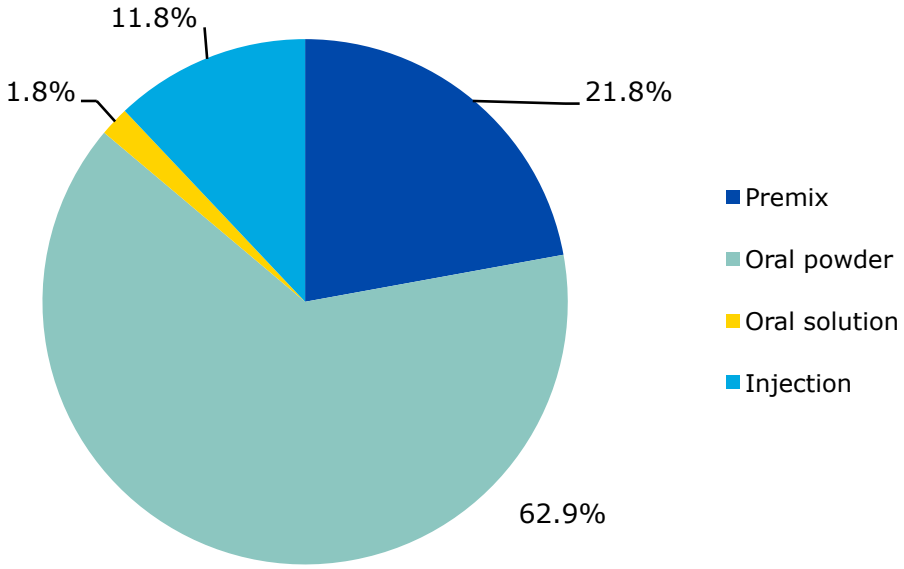
Figure 15. Distribution of sales of tetracyclines for food-producing animals (including horses), in mg/PCU, by the major pharmaceutical forms sold, aggregated by the 25 EU/EEA countries for 2011



2.4.2.2. Penicillins

The overall sales of penicillins for the 25 countries, stratified into pharmaceutical forms, are shown in Figure 16. In addition, 1.5% were accounted for by intramammary preparations, and 0.1% for bolus and intrauterine preparations.

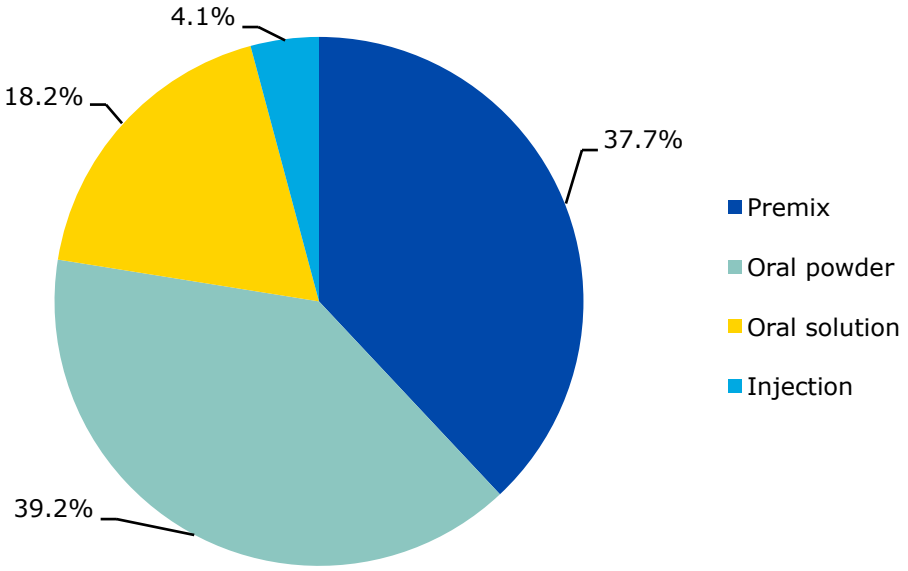
Figure 16. Distribution of sales of penicillins for food-producing animals (including horses), in mg/PCU, by the major pharmaceutical forms sold, aggregated by the 25 EU/EEA countries for 2011



2.4.2.3. Sulfonamides

The overall sales of sulfonamides for the 25 countries, stratified into pharmaceutical forms, are shown in Figure 17. Other pharmaceutical forms, i.e. intramammary preparations, intrauterine preparations and oral paste, accounted for 0.8%.

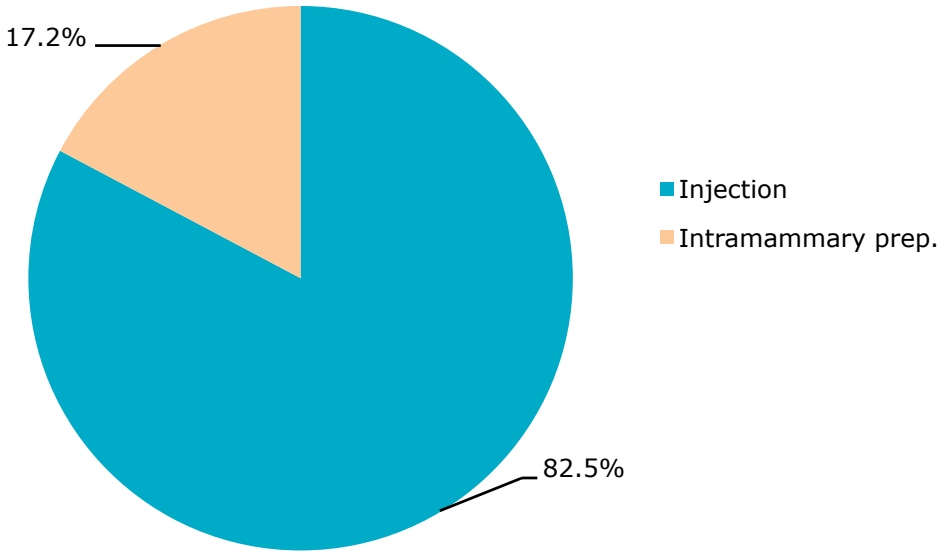
Figure 17. Distribution of sales of sulfonamides for food-producing animals (including horses), in mg/PCU, by the major pharmaceutical forms sold, aggregated by the 25 EU/EEA countries for 2011



2.4.2.4. 3rd- and 4th-generation cephalosporins

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

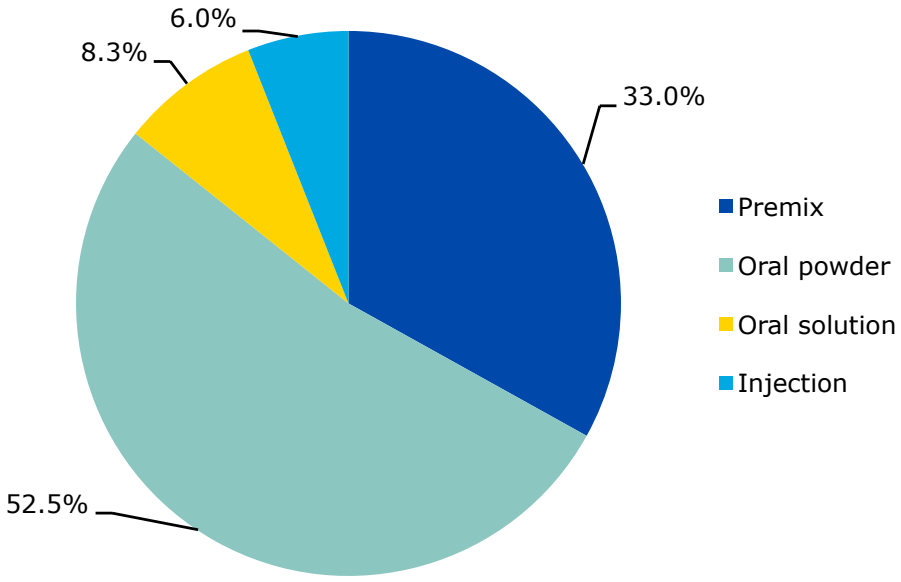
Figure 18. Distribution of sales of 3rd- and 4th-generation cephalosporins for food-producing animals (including horses), in mg/PCU, by pharmaceutical form sold, aggregated by the 25 EU/EEA countries for 2011



2.4.2.5. Macrolides

The overall sales of macrolides for the 25 countries, stratified into pharmaceutical forms, are shown in Figure 19. In addition to the forms shown, 0.2% of the macrolides were sold as intramammary and intrauterine preparations.

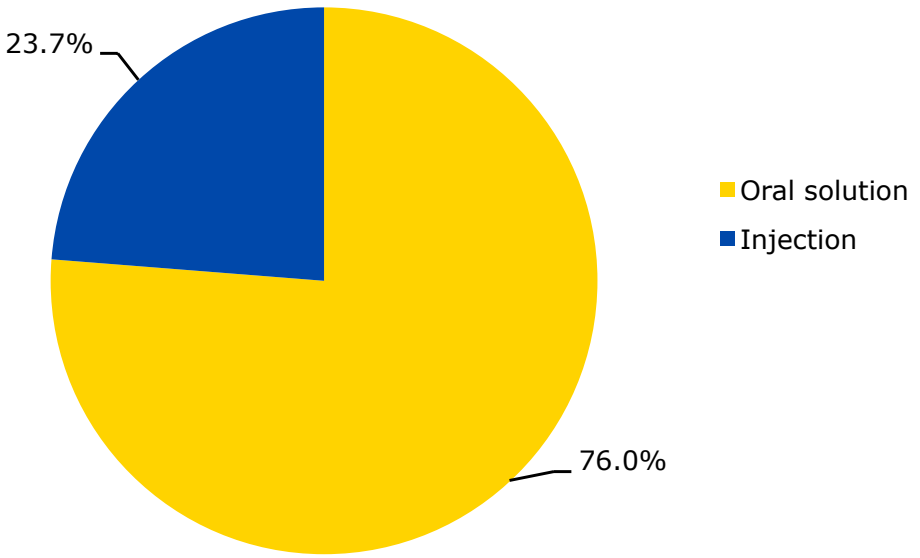
Figure 19. Distribution of sales of macrolides for food-producing animals (including horses), in mg/PCU, by pharmaceutical form sold, aggregated by the 25 EU/EEA countries for 2011



2.4.2.6. Fluoroquinolones

The overall sales of fluoroquinolones for the 25 countries, stratified into pharmaceutical forms, are shown in Figure 20. In addition, 0.3% were sold as premixes, oral powders, oral paste and bolus.

Figure 20. Distribution of sales of fluoroquinolones for food-producing animals (including horses), in mg/PCU, by the major pharmaceutical forms sold, aggregated by the 25 EU/EEA countries for 2011



2.5. Distribution of sales for food-producing animals, including horses, by antimicrobial class and pharmaceutical form for 25 countries

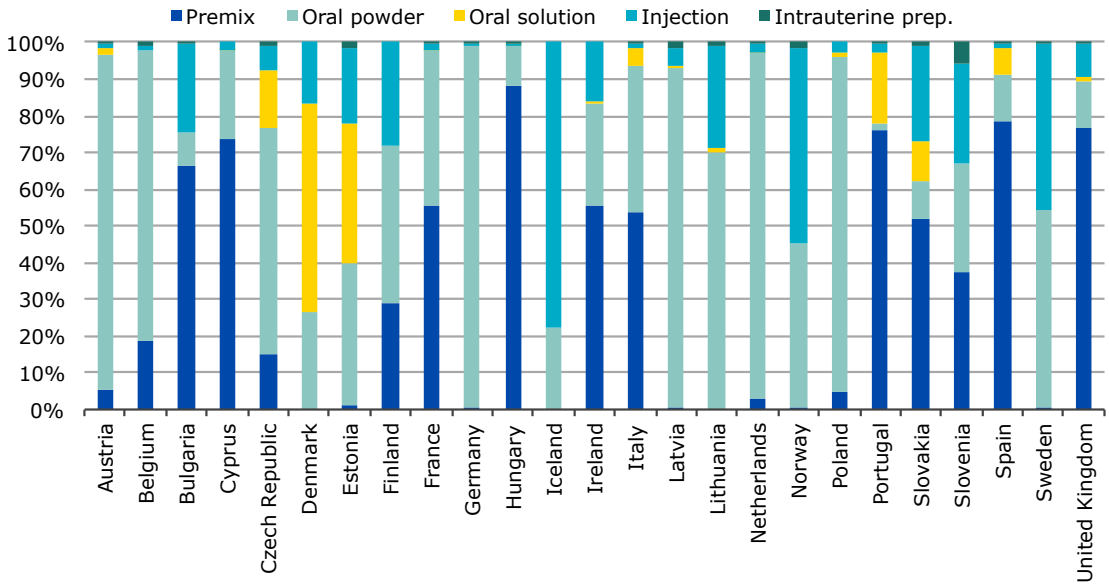
The distribution of sales, in mg/PCU, of the various antimicrobial classes by pharmaceutical form varied considerably for the various classes of antimicrobial agents, both aggregated by 25 EU/EEA countries and between countries.

See the following pages for the distribution per country.

2.5.1. Tetracyclines

Figure 21. Spatial distribution of sales of tetracyclines for food-producing animals, in mg/PCU, in 25 EU/EEA countries, for 2011

Figure 22. Distribution of sales by pharmaceutical form for tetracyclines, in mg/PCU, by country, for 2011[1]

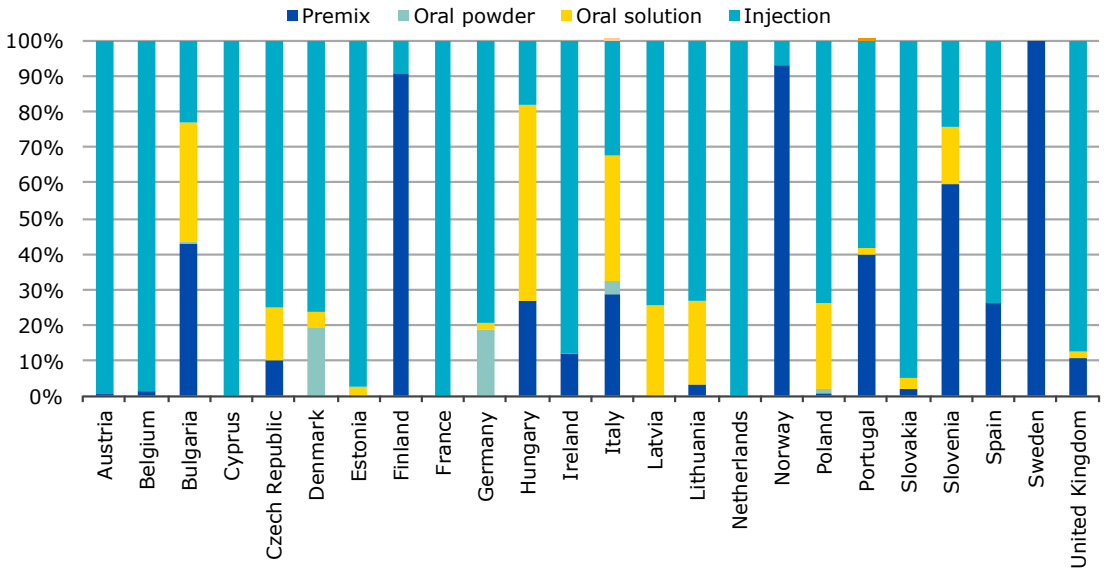


[1] In addition, negligible amounts were sold as bolus, intramammary preparations and/or oral pastes in some countries.

2.5.2. Amphenicols

Figure 23. Spatial distribution of sales of amphenicols, in mg/PCU, in 25 EU/EEA countries, for 2011

Figure 24. Distribution of sales by pharmaceutical form for amphenicols, in mg/PCU, by country, for 2011[1,2]

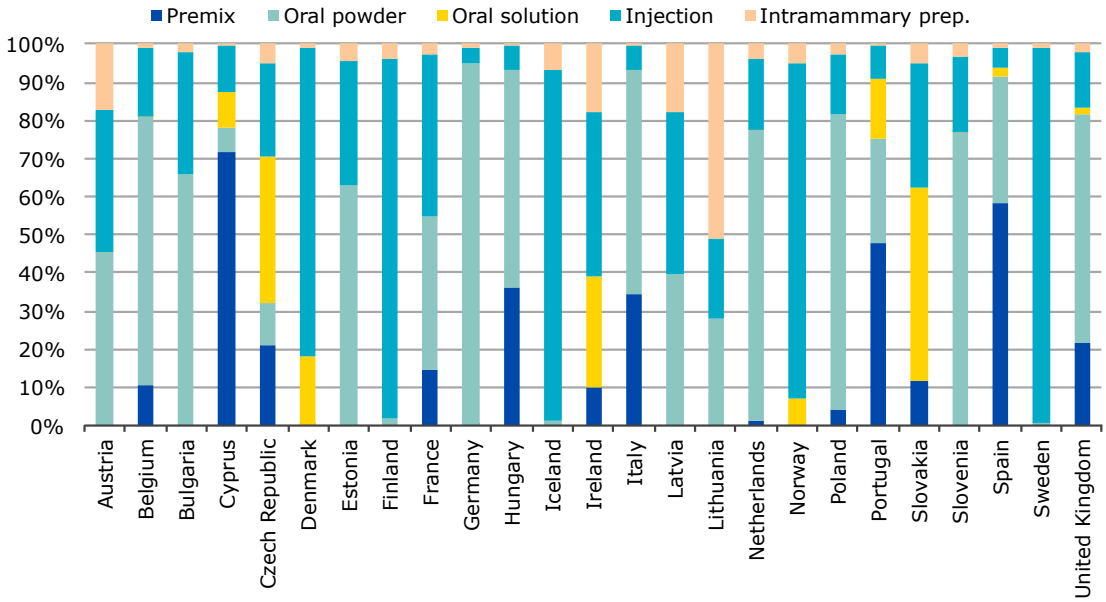


[1] No sales in Iceland. [2] In addition, negligible amounts were sold as intramammary preparations and/or oral pastes in two countries.

2.5.3. Penicillins

Figure 25. Spatial distribution of sales of penicillins for food-producing animals, in mg/PCU, in 25 EU/EEA countries, for 2011

Figure 26. Distribution of sales by pharmaceutical form for penicillins, in mg/PCU, by country, for 2011[1]

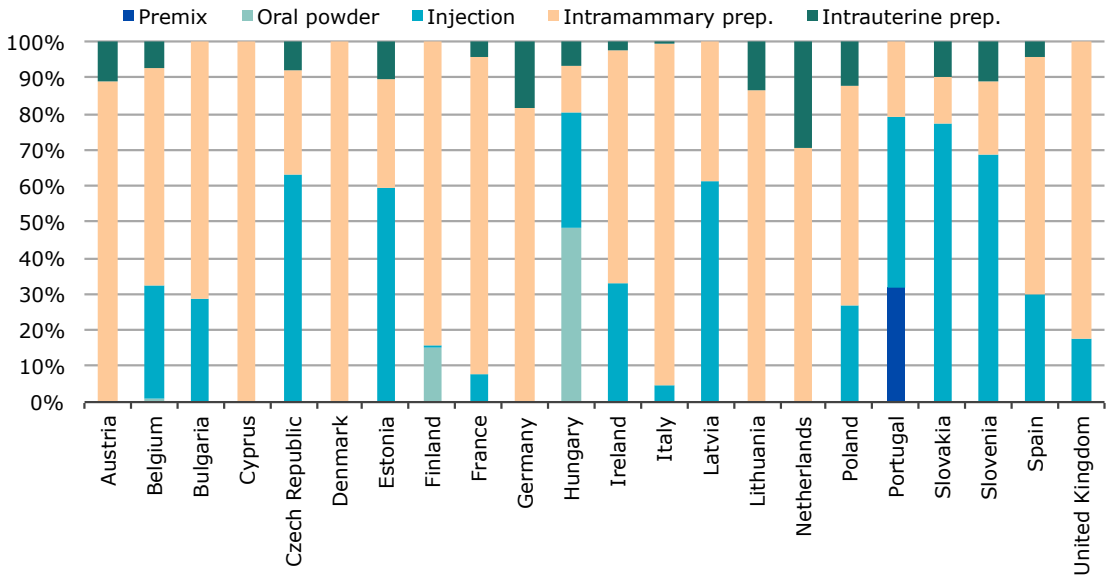


[1] In addition, negligible amounts were sold as bolus, intrauterine preparations and/or oral pastes in some countries.

2.5.4. 1st- and 2nd-generation cephalosporins

Figure 27. Spatial distribution of sales of 1st- and 2nd-generation cephalosporins, in mg/PCU, in 25 EU/EEA countries, for 2011

Figure 28. Distribution of sales by pharmaceutical form for 1st- and 2nd-generation cephalosporins, in mg/PCU, by country, for 2011[1,2]

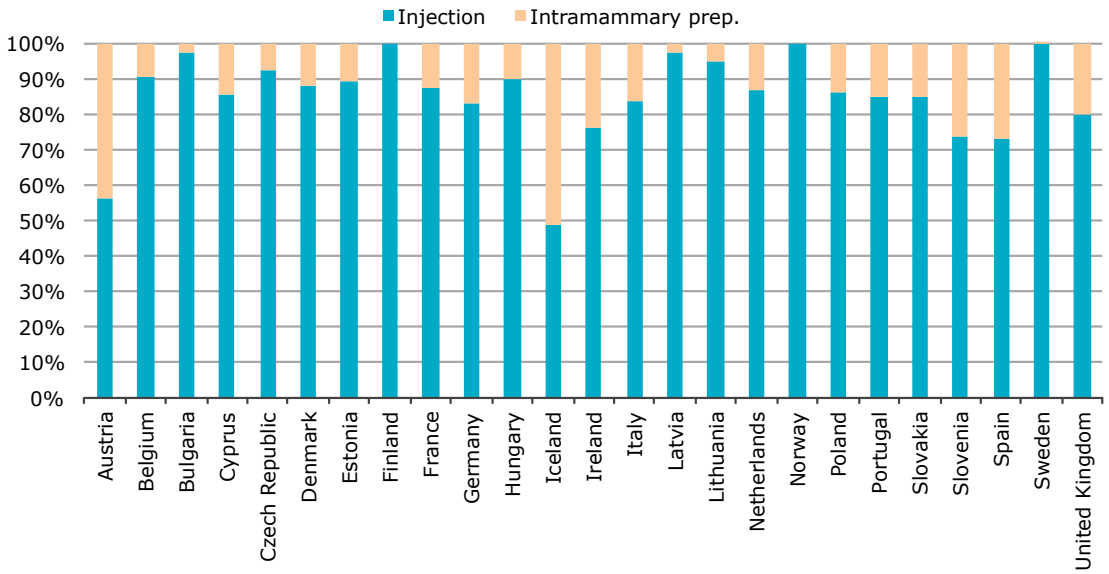


[1] No sales in Iceland, Norway or Sweden. [2] In addition, negligible amounts were sold as oral solution in some countries.

2.5.5. 3rd- and 4th-generation cephalosporins

Figure 29. Spatial distribution of sales of 3rd- and 4th-generation cephalosporins, in mg/PCU, in 25 EU/EEA countries, for 2011

Figure 30. Distribution of sales by pharmaceutical form for 3rd- and 4th-generation cephalosporins, in mg/PCU, by country, for 2011[1]

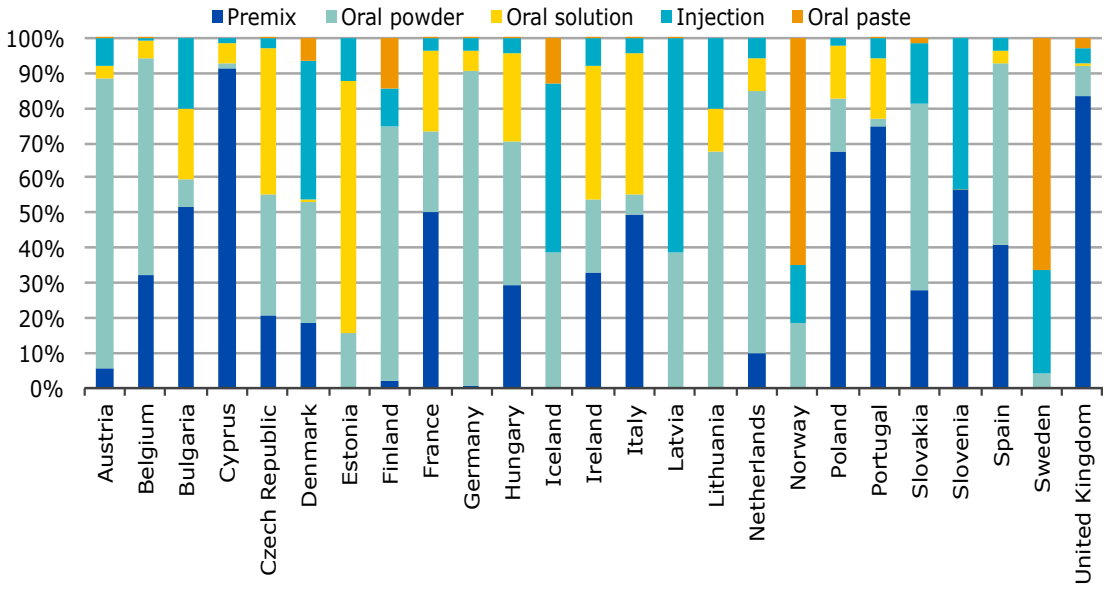


[1] In addition, negligible amounts were sold as oral powder, oral solution and/or intrauterine preparations in some countries.

2.5.6. Sulfonamides

Figure 31. Spatial distribution of sales of sulfonamides, in mg/PCU, in 25 EU/EEA countries, for 2011

Figure 32. Distribution of sales by pharmaceutical form for sulfonamides, in mg/PCU, by country, for 2011[1]

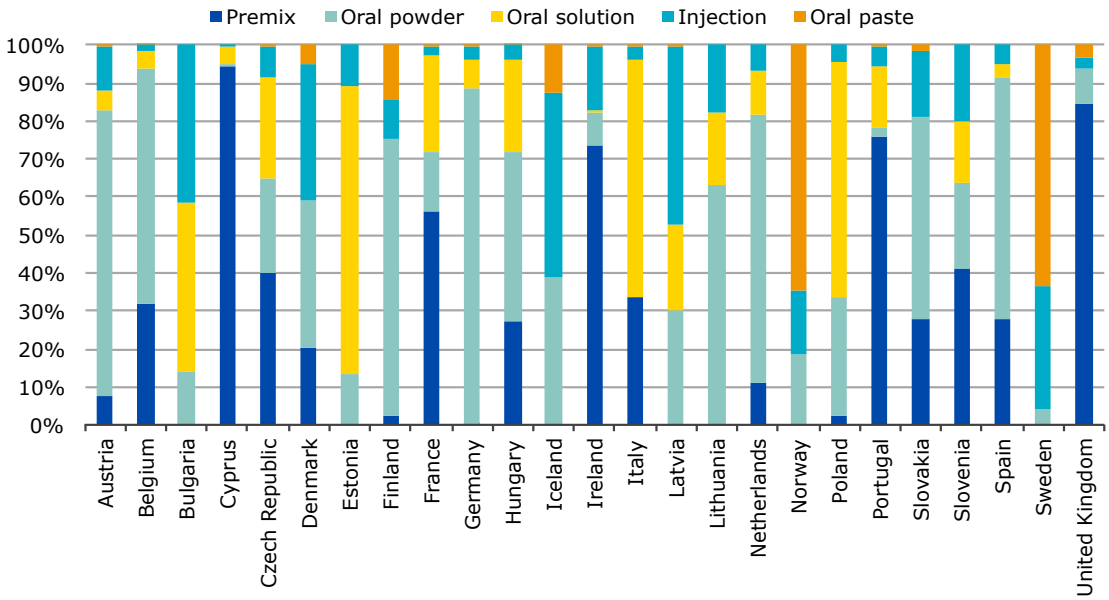


[1] In addition, negligible amounts were sold as bolus, intramammary and/or intrauterine preparations in some countries.

2.5.7. Trimethoprim

Figure 33. Spatial distribution of sales of trimethoprim, in mg/PCU, in 25 EU/EEA countries, for 2011

Figure 34. Distribution of sales by pharmaceutical form for trimethoprim, in mg/PCU, by country, for 2011

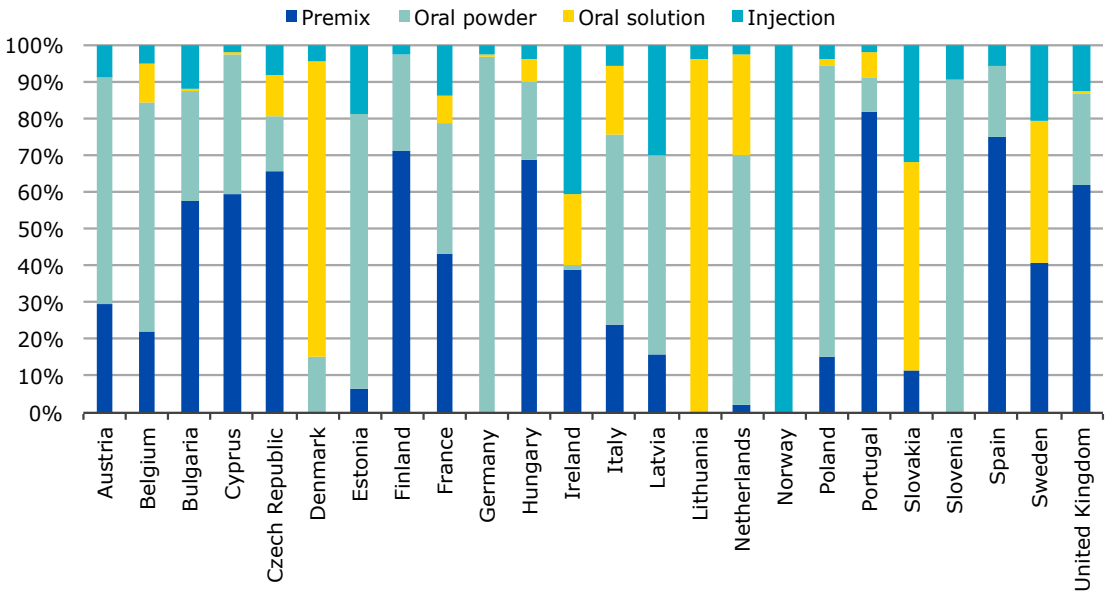


[1] In addition, negligible amounts were sold as intramammary preparations and/or bolus in some countries.

2.5.8. Macrolides

Figure 35. Spatial distribution of sales of macrolides, in mg/PCU, in 25 EU/EEA countries, for 2011

Figure 36. Distribution of sales by pharmaceutical form for macrolides, in mg/PCU, by country, for 2011[1,2]

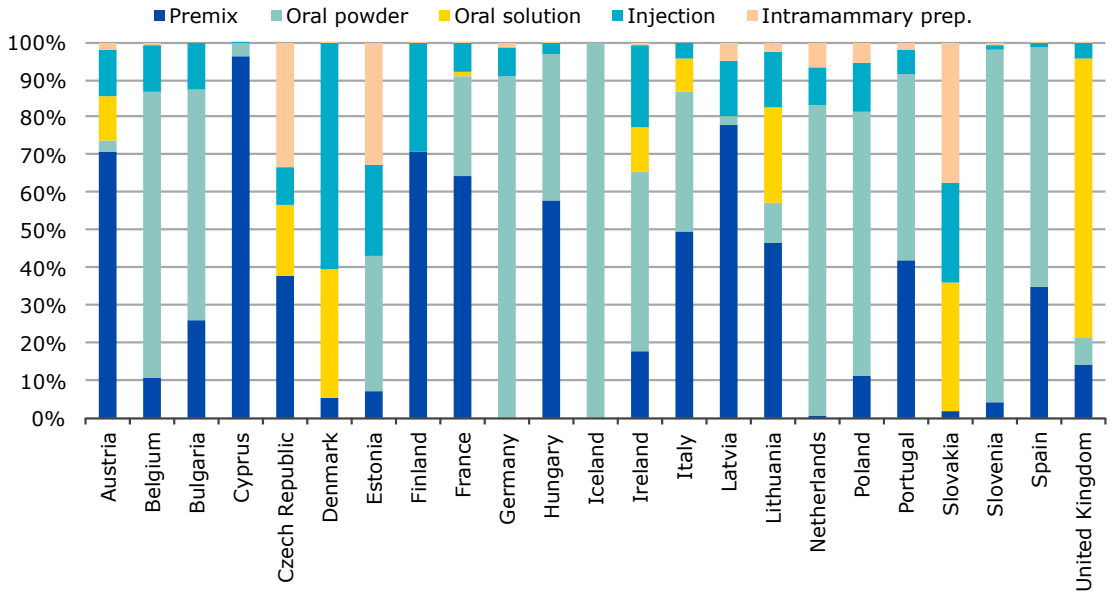


[1] No sales in Iceland. [2] In addition, negligible amounts were sold as intramammary and/or intrauterine preparations in some countries.

2.5.9. Lincosamides

Figure 37. Spatial distribution of sales of lincosamides, in mg/PCU, in 25 EU/EEA countries, for 2011

Figure 38. Distribution of sales by pharmaceutical form for lincosamides, in mg/PCU, by country, for 2011[1]

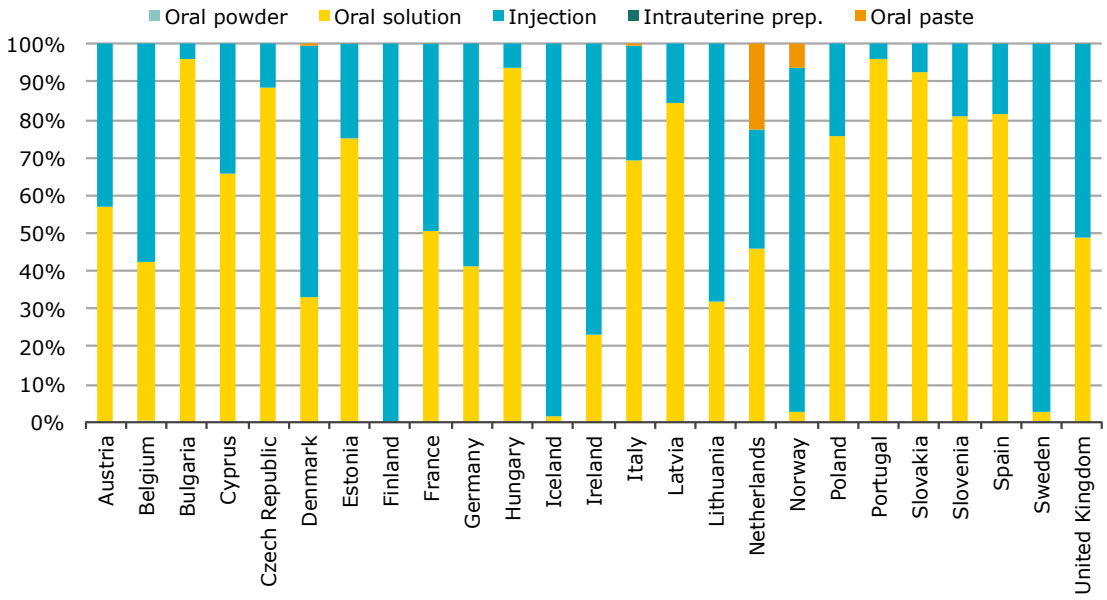


[1] No sales in Norway or Sweden.

2.5.10. Fluoroquinolones

Figure 39. Spatial distribution of sales of fluoroquinolones, in mg/PCU, in 25 EU/EEA countries, for 2011

Figure 40. Distribution of sales by pharmaceutical form for fluoroquinolones, in mg/PCU, by country, for 2011[1]

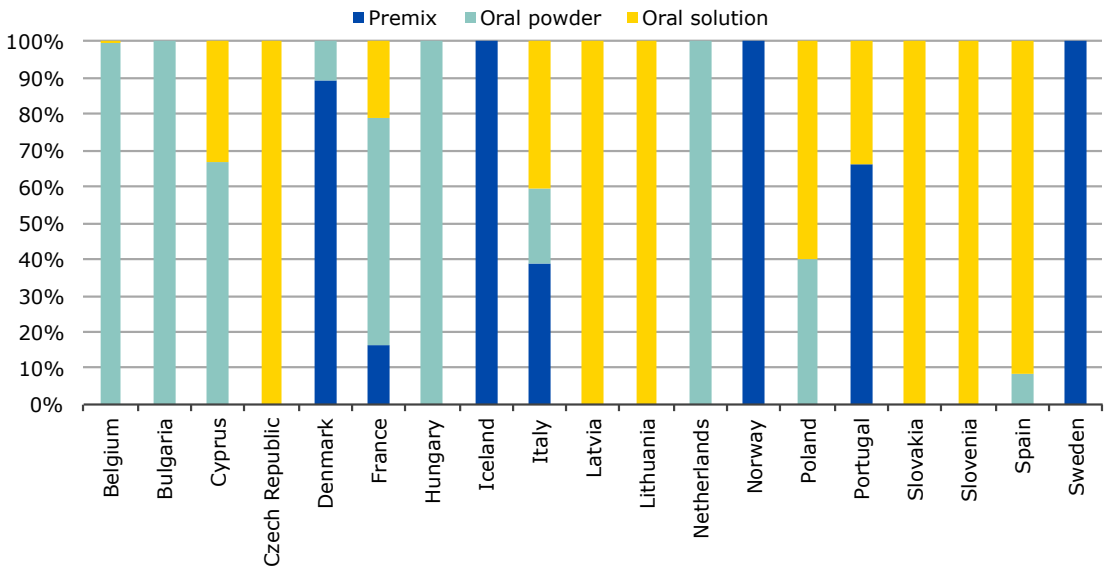


[1] In addition, negligible amounts were sold as bolus and/or oral powder in some countries.

2.5.11. Other quinolones

Figure 41. Spatial distribution of sales of other quinolones, in mg/PCU, in 25 EU/EEA countries, for 2011

Figure 42. Distribution of sales by pharmaceutical form for other quinolones, in mg/PCU, by country, for 2011[1,2]

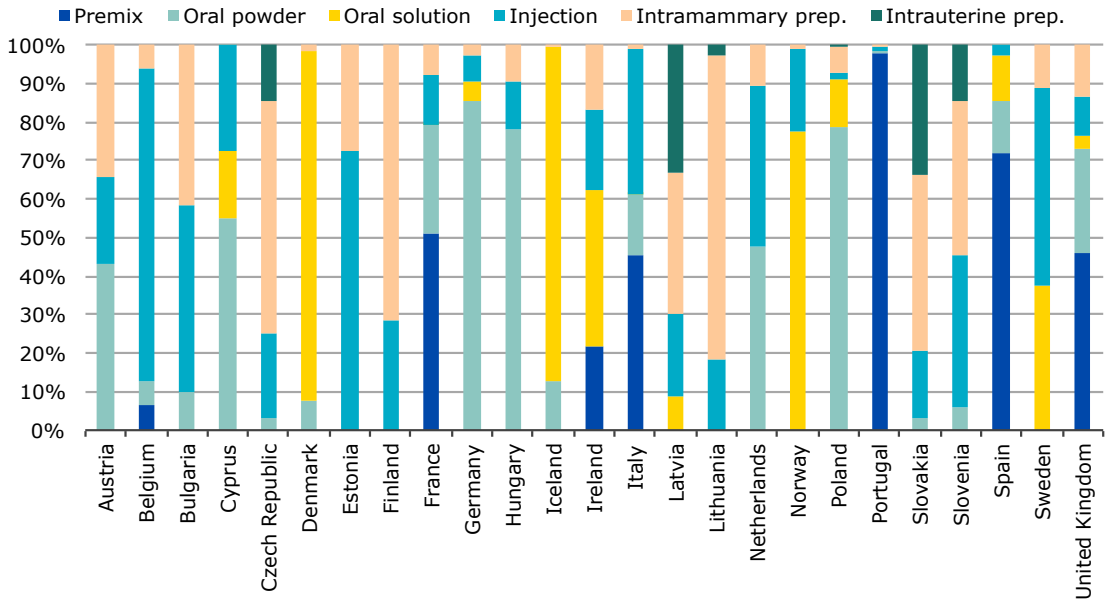


[1] No sales in Austria, Estonia, Finland, Germany, Ireland or the United Kingdom. [2] In addition, negligible amounts were sold as injection, intramammary preparations and/or oral paste in some countries.

2.5.12. Aminoglycosides

Figure 43. Spatial distribution of sales of aminoglycosides, in mg/PCU, in 25 EU/EEA countries, for 2011

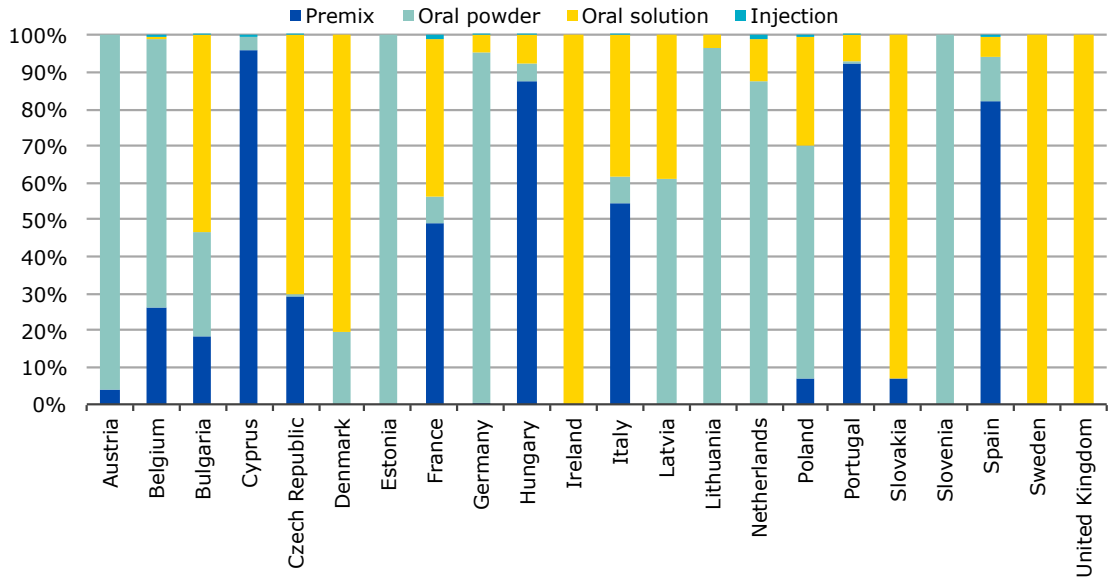
Figure 44. Distribution of sales by pharmaceutical form for aminoglycosides, in mg/PCU, by country, for 2011



2.5.13. Polymyxins

Figure 45. Spatial distribution of sales of polymyxins, in mg/PCU, in 25 EU/EEA countries, for 2011

Figure 46. Distribution of sales by pharmaceutical form for polymyxins, in mg/PCU, by country, for 2011[1,2]



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

2.5.14. Pleuromutilins

Figure 47. Spatial distribution of sales of pleuromutilins, in mg/PCU, in 25 EU/EEA countries, for 2011

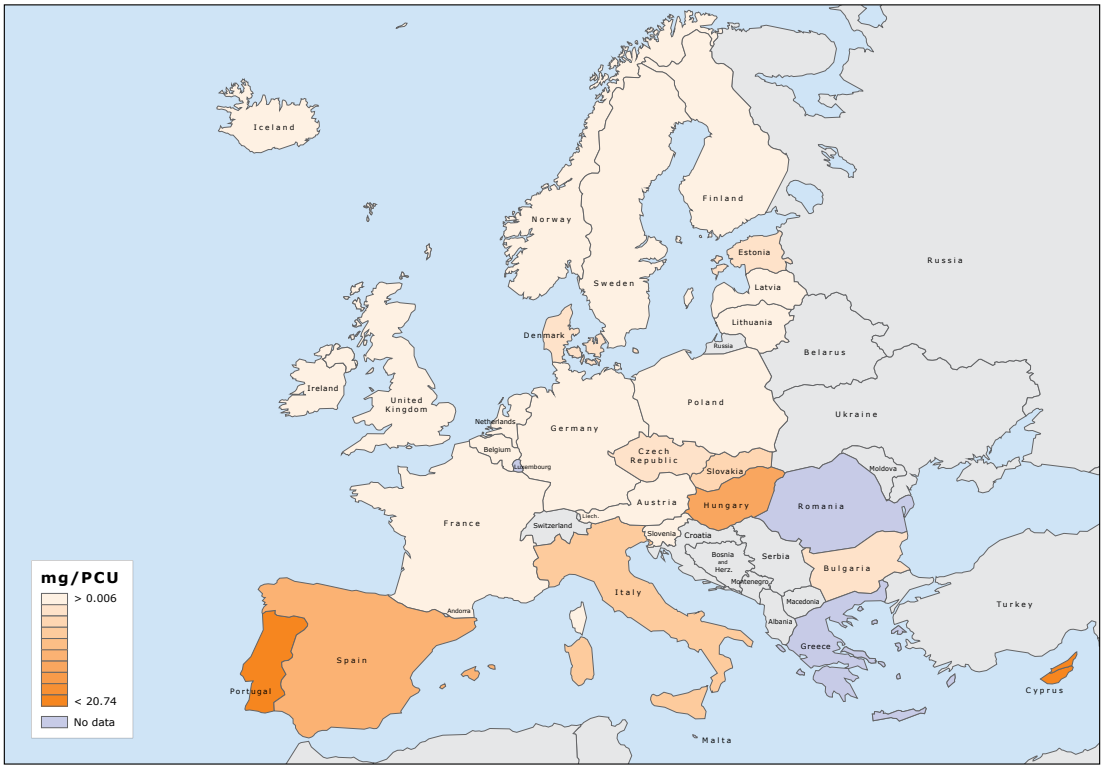
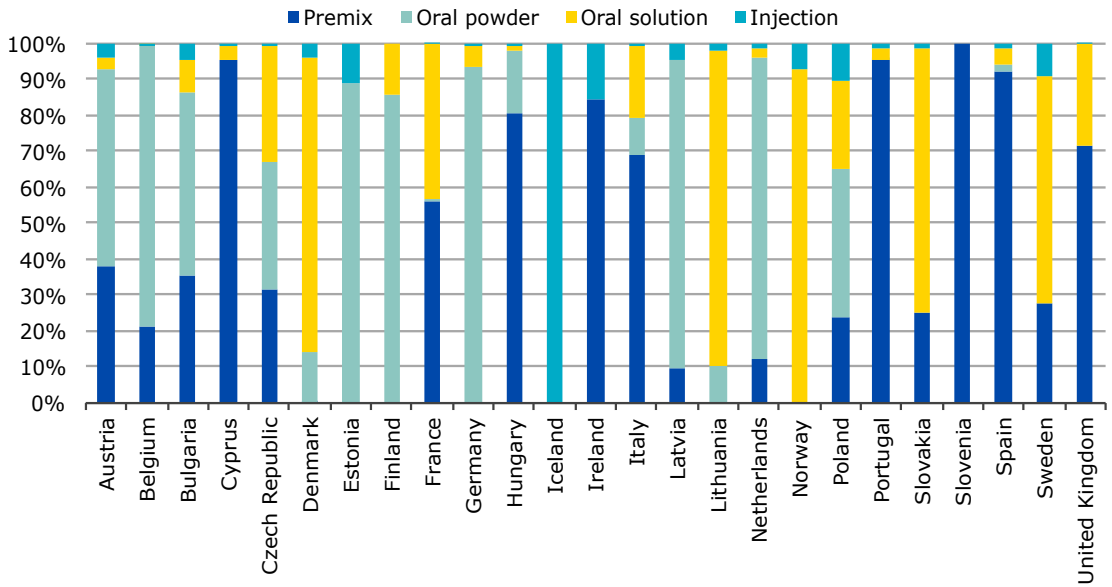


Figure 48. Distribution of sales by pharmaceutical form for pleuromutilins, in mg/PCU, by country, for 2011



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

Of the 10,057 product presentations included in the data sets — i.e. product name, form, strength and pack size (tablets excluded) — 81% contained only one active ingredient, 17% contained two active ingredients and 2% contained three active ingredients (Table 7). In addition, 0.2% (n=22) of the product presentations contained four active ingredients. Sales of products with three active ingredients were almost solely accounted for by products for individual treatment (intramammary and intrauterine preparations), and sales of products containing four ingredients were only accounted for by intramammary preparations.

Table 7. Number of product presentations (product name, form, strength and pack size) containing 1, 2 and 3 antimicrobial agents[1], by country, for 2011 (tablets excluded from the data)

Country	1 ingredient	2 ingredients	3 ingredients	Total number
Austria	217	59	9	285
Belgium	294	49	2	345
Bulgaria	160	45	2	207
Cyprus	116	42	3	161
Czech Republic	414	86	8	508
Denmark	232	63	6	301
Estonia	122	32	7	161
Finland	99	27	2	128
France	618	204	4	826
Germany	515	93	7	615
Hungary	307	59	7	373
Iceland	28	9	2	39
Ireland	437	63	9	509
Italy	969	199	20	1,188
Latvia	200	59	17	276
Lithuania	131	37	6	174
Netherlands	249	67	5	321
Norway	59	16	2	77
Poland	480	90	11	581
Portugal	415	81	12	508
Slovakia	784	108	11	903
Slovenia	122	40	3	165
Spain	696	108	6	810
Sweden	93	26	1	120
United Kingdom	406	63	7	476
Total 25 countries	**8,163**	**1,725**	**169**	**10,057**

[1] In addition, 22 intramammary preparations contained 4 active ingredients, accounting for 0.2% of the product presentations in the 25 countries.

Table 8. Number of product presentations (product name, form, strength and pack size) for premixes, oral powders and oral solutions containing 1, 2 and 3 antimicrobial agents, by country, for 2011

Country	1 ingredient	2 ingredients	3 ingredients	Total number
Austria	90	29	6	125
Belgium	114	21	0	135
Bulgaria	90	14	0	104
Cyprus	58	22	0	80
Czech Republic	253	50	2	305
Denmark	96	15	1	112
Estonia	31	6	0	37
Finland	32	4	0	36
France	361	103	0	464
Germany	255	44	0	299
Hungary	182	27	0	209
Iceland	10	2	0	12
Ireland	173	17	0	190
Italy	609	110	8	727
Latvia	72	11	0	83
Lithuania	52	7	0	59
Netherlands	101	29	0	130
Norway	21	1	0	22
Poland	270	46	0	316
Portugal	172	25	1	198
Slovakia	427	63	5	495
Slovenia	37	17	1	55
Spain	388	24	0	412
Sweden	28	2	0	30
United Kingdom	163	20	0	183
Total 25 countries	**4,085**	**709**	**24**	**4,818**

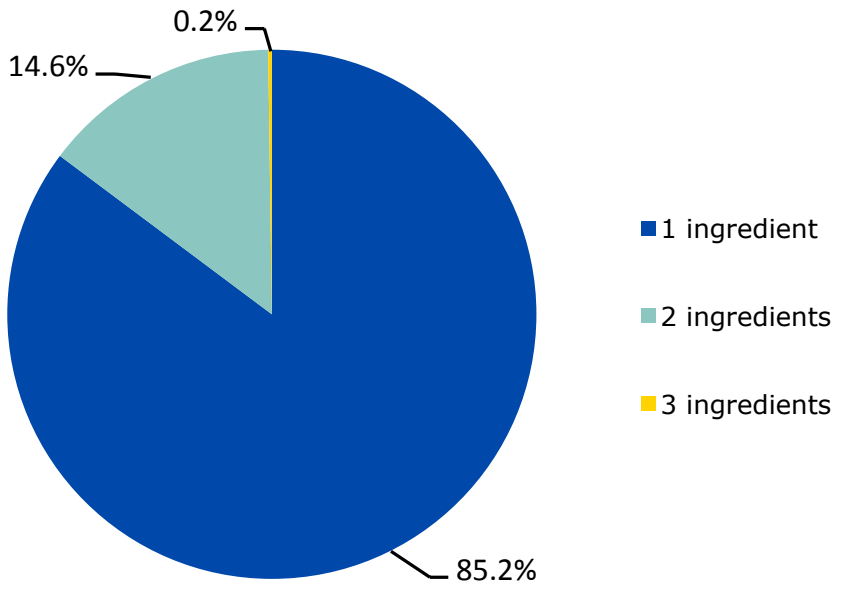
For all 25 countries, the major proportion of the sales of pharmaceutical forms of antimicrobial VMPs applicable for group treatment — premixes, oral powders and oral solutions — was for products with one active ingredient (range 50%–96%). Overall in the 25 countries, 85% of the sales (in tonnes) were for products with one active ingredient, 15% with two active ingredients and only 0.2% with three active ingredients.

Table 9. Sales, in tonnes of active ingredient, of antimicrobial agents as premixes, oral powders and oral solutions containing 1, 2 and 3 active ingredients, by country, for 2011

Country	1 ingredient		2 ingredients		3 ingredients		Tonnes (premixes, oral powders and oral solutions)
	Tonnes	%	Tonnes	%	Tonnes	%	
Austria	38	82%	6	13%	2.4	5%	46
Belgium	177	66%	89	34%			266
Bulgaria	28	92%	2	8%			30
Cyprus	33	67%	16	33%			49
Czech Republic	39	76%	12	23%	0.3	1%	52
Denmark	53	87%	8	13%	0.0003	0.001%	61
Estonia	4	85%	1	15%			5
Finland	2	50%	2	50%			4
France	614	79%	165	21%			780
Germany	1,564	90%	183	10%			1,748
Hungary	129	91%	13	9%			142
Iceland	0.14	85%	0.02	15%			0
Ireland	45	79%	12	21%			57
Italy	1,185	75%	377	24%	14	1%	1,575
Latvia	4	92%	0.3	8%			4
Lithuania	6	84%	1.1	16%			7
Netherlands	271	83%	55	17%			327
Norway	1	77%	0.3	23%			1
Poland	376	93%	30	7%			406
Portugal	146	94%	9	6%			155
Slovakia	6	85%	1	15%			7
Slovenia	4	70%	1	20%	0.6	9%	6
Spain	1,637	96%	61	4%			1,698
Sweden	1	94%	0.1	6%			1
United Kingdom	215	73%	78	27%			293

Of the total sales of premixes, oral powders and oral solutions in the 25 countries, in tonnes of active ingredient, 85.2%, 14.6% and 0.2% were accounted for by products containing one, two and three active ingredients, respectively (Figure 49).

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



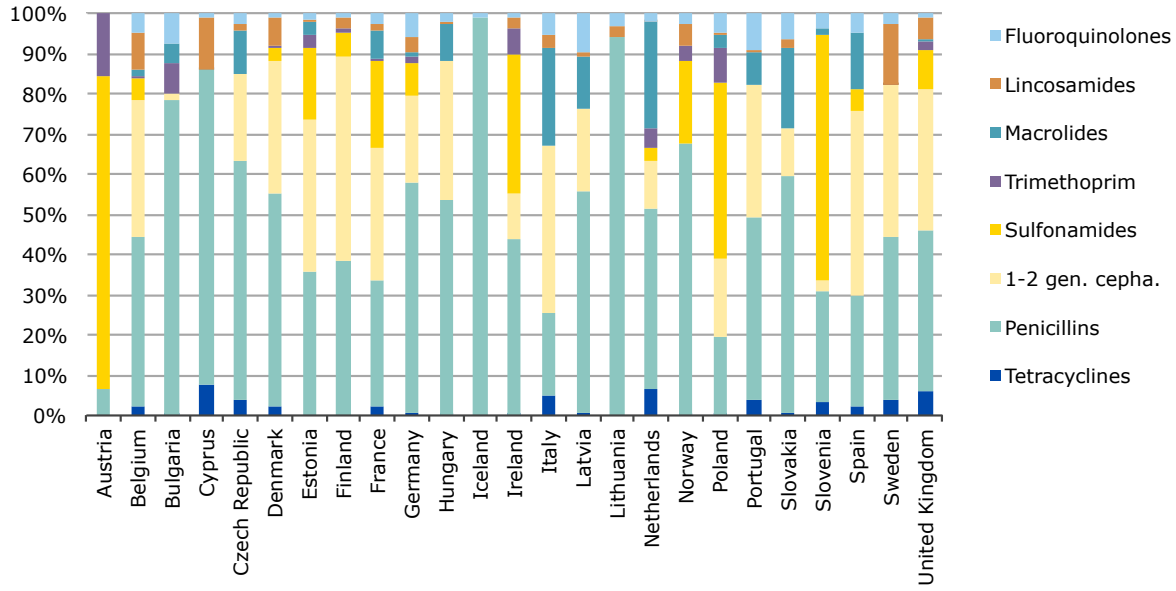
2.7. Sales of tablets by veterinary antimicrobial class for companion animals

Figure 50 shows the distribution of sales of tablets, in tonnes of active ingredient, by antimicrobial class and country for 2011. For the majority of countries, penicillins were the most-sold veterinary antimicrobial agent in tablet form; the sales patterns varied substantially between the countries.

Overall in the 25 countries, 36% of the sales of tablets (in tonnes) were penicillins, 31% were 1st- and 2nd-generation cephalosporins, 12% were sulfonamides, 6% were macrolides, 3% were lincosamides, fluoroquinolones and tetracyclines, and 1% was trimethoprim.

Since the tablets included in the data sets are almost solely used for companion animals, the sales figures presented are thought to be a good estimate for sales of tablets of veterinary antimicrobial agents for companion animals. Antimicrobial products marketed for human use are also used in companion animals, in application of the 'cascade' (Articles 10 and 11 of Directive 2001/82/EC of the European Parliament and of the Council). Such sales are included in the sales data for human antimicrobial agents (ESAC-net data) if they are based, for instance, on the sales of pharmacies, and not on the reimbursement of physicians' prescriptions as provided by insurance companies. In the current report, all injectable veterinary antimicrobial products are included in the sales for food-producing animals, but some of these products are used in companion animals as well. Consequently, the data presented in Figure 50 do not give a complete picture of the sales patterns of antimicrobial agents in companion animals for 2011.

Figure 50. Distribution of sales of tablets, in tonnes of active ingredient, by antimicrobial class (reported according to the ATCvet hierarchical system), by country, for 2011[1]

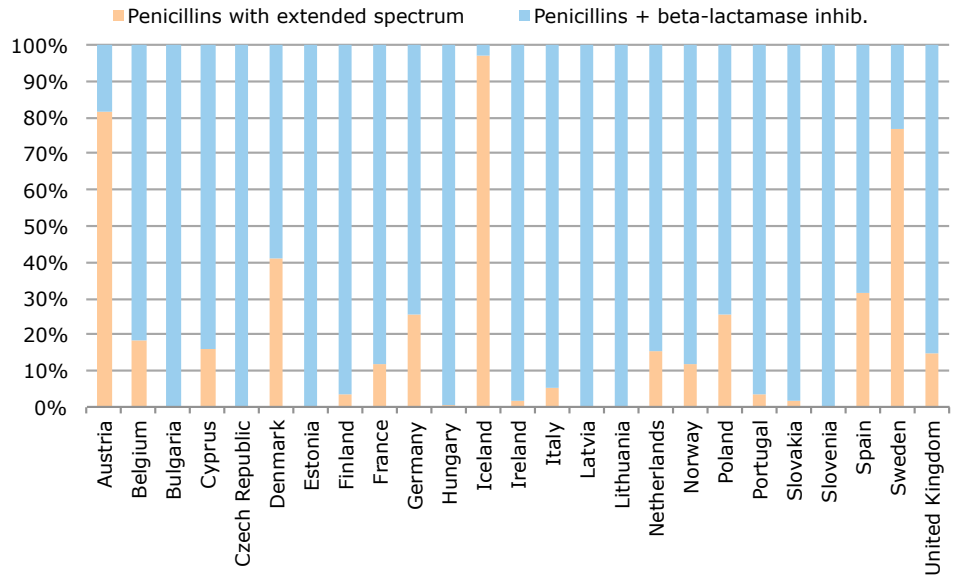


[1] Minor amounts of aminoglycosides, amphenicols, other quinolones, imidazole derivatives and other antibacterials (classified as such in the ATCvet system) were sold, which are not included in this figure.

Aggregated by the 25 countries, penicillins (35.5%), 1st- and 2nd-generation cephalosporins (30.7%), sulfonamides (12.2%) and macrolides (6.6%) were the most-sold antimicrobial classes of tablets.

The distribution of penicillins by subclass for tablets varied significantly between the 25 countries for the veterinary penicillins available as tablets (Figure 51). The sales of tablets with the combination of penicillins + beta-lactamase inhibitors (tonnes of clavulanic-acid inhibitors not included in the data) accounted for between 3% and 100% (5 countries) of the total sales of penicillin tablets.

Figure 51. Distribution of sales of tablets containing penicillins, by subclass (in weight of active ingredient), by country, for 2011



3. Discussion

3.1. Materials and methods

It is important to note that the results presented in this report may differ slightly from those presented in national reports, because, for example, of differences in inclusion criteria for veterinary antimicrobial agents and in the reporting of data in the national surveillance systems, e.g. reporting of the data as base instead of salt (see references to national reports in Annexes 5 and 6).

Dermatological preparations (ATCvet group QD) and preparations for sensory organs (ATCvet group QS) (Table 1) were not included in the data sets. The contribution from these groups of antimicrobial agents, in tonnes of active ingredients, to the total amounts is minimal, and therefore the effect of the deviation is negligible. Injectable antimicrobial agents are also used in companion animals; however, the proportion of such use is minor, as outpatient companion animals are typically treated with tablets (including capsules), and therefore the impact on the data reported as sold for food-producing animals, including horses, is considered minimal.

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

All countries for which it was applicable had requested data on sales to end-users, or had asked the national data providers to exclude sales between data sources, e.g. between wholesalers, and consequently, double reporting is assumed to have been avoided.

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

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

The dosing of the various antimicrobial agents within a class and between animals species varies substantially. For example, the dose for a whole treatment with a fluoroquinolone may be 2–5 mg/kg (for terrestrial animals), while with a tetracycline this may be 140 mg/kg, i.e. up to 70 times higher. This implies that a given weight of active ingredient of fluoroquinolone sold can be used to treat 70 times as many animals as the same weight of active ingredient of tetracycline. Furthermore, within an antimicrobial class there may be different dosages for different substances; for example, the dosage of doxycycline is about one quarter of the dosage of oxytetracycline. Another consideration is that the treatment dosage may differ significantly according to species; for fish, the typical tetracycline dosage for

the whole treatment is 800 mg/kg, or some six times higher than that for terrestrial animals. The data in this report cover all food-producing animals together, and therefore it was not possible to take into account differences in dosing when reporting the data. Since the sales patterns and the animal demographics vary substantially between countries, comparison of the sales data between the countries should be done with great care.

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

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

3.2. Results

Nineteen of the 20 countries that reported sales to ESVAC in both 2010 and 2011 reported a decrease in sales (range 0.4%–28%) expressed as mg/PCU. For one country, an increase of 3.5% was reported from 2010 to 2011. However, one marketing-authorisation holder in this country failed to report the sales data in 2010; for this company, the reported sales were 21% of the total sales in 2011. Provided that the sales for this company were at the same level as in 2010, the sales have actually declined substantially.

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

A large difference in the sales, expressed as the indicator mg/PCU, is observed between the most- and least-selling countries. This is likely to be partly due to differences in the composition of the animal population (e.g. more pigs than cattle, or a high proportion of veal calves within the cattle population) in the various countries. There is also considerable variation in terms of daily dosage and length of treatment between the various antimicrobial agents and formulations used, and other factors also need to be considered. Furthermore, differences in the selection of data source — i.e. sales data or purchase data (one country for 2010 and one for 2011) — may have an impact, but this is considered to be low.

The prescribing patterns of the various veterinary antimicrobial classes, expressed as mg/PCU, varied substantially between the countries. Notable variations between the different countries in the proportion accounted for by the CIAs with highest priority in human medicine — 3rd- and 4th-generation cephalosporins, fluoroquinolones and macrolides — were observed; proportions ranged from 0.05% to 0.78%, 0.01% to 13.8% and 0% to 14%, respectively. Since the major proportion of the sales of these classes/subclasses was accounted for by macrolides, the observed variations between the countries are likely, in part, to reflect differences between the countries in the relative proportion of the various animal species, and in particular, differences in pig production (use of macrolides).

Generally, some of the variations in the sales patterns and in the magnitudes of sales may be due to differences between the countries in the relative proportion of the various animal species, the availability of veterinary antimicrobial products on the market, prices, animal-production systems (e.g. veal as opposed to beef cattle on pasture) and the general situation with regard to infectious diseases. These factors can, however, only partly explain the differences; other factors, such as implementation of responsible-use campaigns in some countries that have affected the veterinarians' prescribing patterns, could also have impacted on the sales patterns.

Also, important variations between the sales, expressed in tonnes, of veterinary antimicrobial agents used almost solely in food-producing animals and of those used in companion animals (tablets) were observed. However, it has to be noted that human medicinal products containing antimicrobial agents and injectable veterinary medicinal products

containing antimicrobial agents may also be used in companion animals, and thus the data on sales of tablets should be interpreted with great care.

Another important finding was that the total sales, both in tonnes and in mg/PCU, of veterinary antimicrobial agents in the 25 EU/EEA countries were mainly accounted for by pharmaceutical forms applicable for mass treatment (premixes) or group treatment (oral powder and oral solution); however, this varies noticeably between the countries.

Of the total numbers of product presentations (tablets excluded), 81% contained only one active ingredient, 17% contained two active ingredients, 2% contained three active ingredients and 0.2% contained four active ingredients (only intramammaries). Overall, the proportions of the sales of premixes, oral powders and oral solutions containing more than one active ingredient are relatively low. Of the total sales of premixes in the 25 countries, in tonnes of active ingredient, 88.5%, 11.5% and 0.01% were accounted for by products containing one, two and three active ingredients, respectively. For oral powders, the corresponding figures were 83.5%, 16.3% and 0.15%, and for oral solutions these were 84.6%, 15.3% and 0.09%. However, as it is possible (legal) to mix more than one premix/oral powder and oral solution into feed or drinking water, respectively, these data do not provide a reliable estimate of treatment through feed or drinking water with two or more active ingredients.

4. Concluding remarks

In the current report, the sales of veterinary antimicrobial classes and some subclasses, as well as pharmaceutical forms, are documented for 25 of the 29 EU/EEA countries. This covers approximately 95% of the food-producing animal population in the EU/EEA area. Identification of the determining factors and reasons behind the changes observed in the consumption of different classes or subclasses of antimicrobial agents remains difficult without data by species, and without taking into account differences in daily dose and length of treatment. In order to increase the understanding of the development and occurrence of resistance and the impact of interventions, it is important to obtain data by animal species, production type and weight class, and to take into account differences in dosing between the various antimicrobial agents and the pharmaceutical forms when reporting the data.

Annex 1. Tables

Table A1. Sales, in tonnes of active ingredient, of veterinary antimicrobial agents applicable mainly for food-producing animals, including horses, by antimicrobial class (presented according to ATCvet hierarchical system), by country, for 2011 (Tablets not included)

Country	Tetracyclines	Amphenicols	Penicillins	1-2 gen. cephalosporins	3-4 gen. cephalosporins	Sulfonamides	Trimethoprim	Macrolides	Lincosamides	Fluoroquinolones	Other quinolones	Aminoglycosides	Polymyxins	Pleuromutilins	Others[1]	Total tonnes
Austria	31.7	0.3	5.5	0.04	0.3	5.6	0.8	4.9	0.3	0.6		0.3	1.0	0.4	1.5	53
Belgium	72.1	1.4	87.0	0.1	0.9	70.6	14.2	16.0	5.7	1.3	2.7	1.5	9.1	2.7	11.7	297
Bulgaria	24.1	0.5	3.5	0.01	0.02	1.0	0.1	4.4	0.5	2.0	0.2	0.2	1.3	1.6	2.3	42
Cyprus	16.6	0.1	7.2	0.001	0.02	11.6	2.3	3.4	5.5	0.1	0.2	0.1	1.0	2.5	1.3	52
Czech Republic	28.0	0.3	11.7	0.2	0.2	9.7	0.7	2.4	0.2	1.1	0.2	0.2	0.4	2.8	2.6	61
Denmark	30.7	0.9	35.4	0.1	0.1	8.1	1.4	10.9	2.5	0.01	0.4	0.7	0.4	9.1	4.9	106
Estonia	1.1	0.02	3.3	0.1	0.1	0.6	0.1	0.3	0.1	0.2		0.1	0.5	0.4	0.6	7.5
Finland	1.8	0.1	6.6	0.04	0.01	2.4	0.5	0.5	0.1	0.1		0.03		0.1	0.02	12.4
France	394.1	4.6	85.1	1.6	2.3	167.0	24.9	69.1	5.1	4.8	6.2	27.9	59.7	6.8	36.4	896
Germany	606.8	6.0	596.9	0.4	3.4	184.6	29.9	173.3	17.2	7.8		34.7	127.6	17.2	12.9	1,819
Hungary	73.1	1.8	31.8	0.5	0.1	4.7	1.0	4.9	3.0	5.2	0.2	0.4	6.8	11.1	2.9	147
Iceland	0.0		0.3		0.001	0.02	0.004		0.005	0.001	0.04	0.1		0.001	0.2	0.7
Ireland	30.4	1.4	20.9	0.7	0.1	18.6	1.7	4.6	0.3	0.7		1.5	0.2	0.03	6.4	87
Italy	594.4	15.6	361.2	1.2	1.6	202.2	25.6	130.2	56.4	9.8	41.0	10.8	136.2	36.7	39.9	1,663
Latvia	2.3	0.002	1.6	0.0	0.04	0.3	0.1	0.3	0.1	0.2	0.001	0.1	0.2	0.3	0.6	6
Lithuania	2.7	0.1	4.7	0.4	0.01	0.9	0.2	1.6	0.3	0.1	0.1	0.5	0.5	0.3	1.7	14
Netherlands	171.3	2.6	72.7	0.1	0.6	51.9	9.5	32.2	0.9	1.4	3.7	5.4	5.0	1.2	4.5	363
Norway	0.2	0.3	2.8		0.001	1.4	0.3	0.0		0.0	0.2	0.0		0.1	0.7	6.2
Poland	179.6	3.9	113.0	0.9	0.4	53.7	3.2	25.6	4.1	28.3	0.3	8.8	16.3	5.9	27.3	471
Portugal	59.9	1.5	25.3	0.1	0.3	6.2	1.3	23.0	1.0	8.5	0.5	2.7	8.0	21.1	4.4	164
Slovakia	2.1	0.1	4.6	0.1	0.2	0.3	0.1	0.2	0.03	0.7	0.1	0.04	0.3	1.3	0.8	11
Slovenia	1.2	0.3	3.1	0.03	0.02	0.5	0.2	0.4	0.4	1.1	0.01	0.1	0.02	0.1	0.5	7.8
Spain	639.1	9.2	377.6	0.5	1.8	44.9	7.4	135.6	133.6	60.4	0.3	66.9	186.0	78.0	38.1	1,779
Sweden	1.0	0.04	6.9		0.01	1.9	0.3	0.5		0.1	0.001	0.1	0.1	0.1	0.3	11
United Kingdom[2]	114.1		77.3	0.6	1.2	58.6	11.5	36.8	5.5	1.9		2.9		12.2	21.4	344
Total 25 countries	**3,078.6**	**51.0**	**1,947.0**	**7.58**	**13.6**	**907.9**	**137.2**	**681.0**	**242.7**	**136.5**	**56.0**	**166.0**	**560.5**	**212.0**	**223.7**	**8,421.4**

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

Table A2. Distribution of sales, in mg/PCU, of veterinary antimicrobial agents applicable mainly for food-producing animals, including horses[1], by administration route/form and country for 2011

Country	Premix	Oral powder	Oral solution	Injection	Oral paste	Bolus	Intramammary prep.	Intrauterine prep.	Total mg/PCU
Austria	4.2	41.9	1.3	5.5	0.03		1.3	0.2	54.5
Belgium	33.9	119.3	3.8	17.3	0.02	0.1	0.5	0.3	175.2
Bulgaria	49.2	18.2	7.9	23.5			0.7	4.9	104.3
Cyprus	322.6	52.4	13.1	19.0	0.1	0.2	0.2	0.01	407.6
Czech Republic	16.3	32.4	21.7	10.7	0.03		1.3	0.4	82.8
Denmark	1.0	6.0	17.5	17.4	0.5	0.01	0.1	0.1	42.6
Estonia	0.4	33.4	9.8	20.0	0.0001		2.1	0.3	66.0
Finland	2.2	6.2	0.02	13.9	0.8		0.7		23.8
France	53.9	37.3	10.9	13.8	0.1		1.1	0.2	117.2
Germany	0.7	199.4	3.1	6.7	0.1		1.0	0.5	211.5
Hungary	130.3	43.6	10.8	6.9	0.005		0.4	0.3	192.4
Iceland	0.3	0.4	0.6	4.6	0.03		0.2	0.02	6.3
Ireland	16.3	7.1	8.6	14.8	0.02		2.6	0.01	49.4
Italy	165.2	129.3	55.4	18.7	0.3		0.6	0.2	369.7
Latvia	1.0	19.7	1.7	9.9	0.0		2.3	0.4	35.0
Lithuania	0.4	13.0	7.0	9.1			9.9	2.2	41.5
Netherlands	4.2	93.4	5.0	10.0	0.1	0.01	1.1	0.2	113.9
Norway	0.3	0.2	0.2	2.0	0.6		0.3	0.1	3.7
Poland	14.4	77.9	11.0	14.9			1.7	0.1	119.9
Portugal	113.8	11.3	27.7	8.1	0.01		0.3	0.03	161.2
Slovakia	8.5	2.6	19.0	12.3	0.03		1.3	0.2	43.9
Slovenia	6.0	19.5	5.3	10.6			1.3	0.5	43.2
Spain	165.1	54.7	18.0	10.8	0.0		0.6	0.04	249.4
Sweden	0.3	0.8	0.4	10.0	1.8		0.2	0.002	13.6
United Kingdom	29.0	11.5	3.1	6.3	0.3	0.4	0.5	0.002	51.2

[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 2011[1]

Country	Tetracyclines	Amphenicols	Penicillins	Sulfonamides	Trimethoprim	Macrolides	Lincosamides	Other quinolones	Aminoglycosides	Polymyxins	Pleuromutilins	Others[2]	Total mg/PCU premixes
Austria	39.9	0.05		7.3	1.5	35.2	5.7			1.0	3.8	5.7	4.2
Belgium	23.3	0.03	16.2	39.5	7.9	6.1	1.0		0.2	4.1	1.0	0.6	33.9
Bulgaria	81.5	1.0		2.7		10.2	0.6			1.2	2.9		49.2
Cyprus	29.7		12.7	25.9	5.2	4.9	13.0			2.4	5.7	0.5	322.6
Czech Republic	35.1	0.2	20.6	17.1	2.3	13.2	0.7			1.0	7.4	2.4	16.3
Denmark			4.2	60.1	12.1		5.7	13.2			0.8	3.9	1.0
Estonia	23.2					47.5	21.3					8.0	0.4
Finland	45.7	9.7		4.6	0.9	32.8	6.4						2.2
France	53.1		3.1	20.4	3.4	7.2	0.8	0.3	3.5	7.1	0.9	0.2	53.9
Germany	72.8		13.6	7.4	1.5	0.3				4.4			0.7
Hungary	64.7	0.5	11.6	1.4	0.3	3.4	1.7			6.0	9.0	1.5	130.3
Iceland								100.0					0.3
Ireland	58.8	0.6	7.4	21.2	4.2	6.2	0.2		1.1		0.1	0.2	16.3
Italy	43.0	0.6	16.8	13.4	1.2	4.2	3.8	2.1	0.7	10.0	3.4	0.9	165.2
Latvia	8.1					24.3	49.3				17.6	0.6	1.0
Lithuania		3.8					96.2						0.4
Netherlands	40.4		6.6	39.3	7.9	4.7	0.0				1.1	0.04	4.2
Norway	0.1	60.1						39.8					0.3
Poland	14.9	0.1	8.5	64.1	0.1	6.9	0.8			2.0	2.5	0.001	14.4
Portugal	39.4	0.5	10.4	4.0	0.9	16.3	0.4	0.3	2.3	6.4	17.3	1.8	113.8
Slovakia	51.7	0.1	25.3	4.4	0.9	0.9	0.03			1.1	15.5	0.03	8.5
Slovenia	38.9	17.8		28.7	5.7		1.5				5.4	1.5	6.0
Spain	42.5	0.2	18.6	1.5	0.2	8.6	4.0		4.1	13.0	6.1	1.1	165.1
Sweden	2.4	15.4				67.9		0.3			14.1		0.3
United Kingdom	44.1	0.2	8.5	24.8	5.0	11.7	0.4		0.7		4.5	0.3	29.0

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

Table A4. Percentage of sales, in mg/PCU, of oral powders by antimicrobial class (according to ATCvet system) by country for 2011[1]

Country	Tetracyclines	Penicillins	Sulfonamides	Trimethoprim	Macrolides	Lincosamides	Other quinolones	Aminoglycosides	Polymyxins	Pleuromutilins	Others[2]	Total mg/PCU oral powder
Austria	70.9	6.0	11.2	1.4	7.3	0.03		0.3	2.3	0.5	0.03	41.9
Belgium	28.3	30.1	21.7	4.4	5.0	2.1	1.3	0.0	3.3	1.0	2.8	119.3
Bulgaria	30.0	31.5	1.0	0.2	14.4	4.0	2.3	0.3	4.9	11.1	0.2	18.2
Cyprus	60.5	7.1	2.5	0.1	19.4	2.5	1.8	0.8	0.5		4.9	52.4
Czech Republic	72.6	5.6	14.2	0.7	1.5			0.0	0.0	4.2	1.2	32.4
Denmark	55.7		18.4	3.7	11.5		0.3	0.3	0.5	8.4		6.0
Estonia	11.4	55.3	2.3	0.5	5.8	1.2			12.1	9.0	2.3	33.4
Finland	24.5	3.3	54.8	11.0	4.3					1.9		6.2
France	57.9	11.9	13.3	1.4	8.6	0.5	1.4	2.8	1.5	0.0	0.8	37.3
Germany	34.8	33.0	9.7	1.5	9.8	0.9		1.7	7.1	0.9	0.5	199.4
Hungary	23.0	53.9	5.7	1.4	3.1	3.5	0.5	0.9	1.0	5.7	0.6	43.6
Iceland	18.7	8.7	17.3	3.5		9.7		22.8			19.4	0.4
Ireland	66.5		30.7	1.1	0.4	1.2						7.1
Italy	41.0	36.4	2.0		11.6	3.6	1.4	0.3	1.7	0.7	1.2	129.3
Latvia	62.6	18.2	3.0	0.6	4.3	0.1			3.1	8.1	0.0001	19.7
Lithuania	42.8	27.8	14.4	3.1		0.6			10.5	0.7	0.03	13.0
Netherlands	54.1	18.7	13.0	2.3	7.4	0.3	1.2	0.9	1.5	0.3	0.5	93.4
Norway	25.1		62.4	12.5								0.2
Poland	53.6	28.5	2.6	0.3	6.6	0.9	0.04	2.3	3.4	0.8	1.0	77.9
Portugal	8.4	60.5	1.3	0.2	18.7	4.5		0.04	0.1	0.1	6.3	11.3
Slovakia	33.0		26.5	5.3				0.2			35.1	2.6
Slovenia	9.4	66.5		1.0	11.3	9.7		0.2	0.6		1.2	19.5
Spain	21.1	32.1	6.0	1.2	6.7	21.8	0.01	2.3	5.5	0.3	2.9	54.7
Sweden	79.9	5.9	12.3	1.9								0.8
United Kingdom	18.6	59.8	6.9	1.4	11.8	0.5		1.0				11.5

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

Table A5. Percentage of sales, in mg/PCU, of oral solutions by antimicrobial class (according to ATCvet system) by country for 2011[1]

Country	Tetracyclines	Amphenicols	Penicillins	Sulfonamides	Trimethoprim	Macrolides	Lincosamides	Fluoroquinolones	Other quinolones	Aminoglycosides	Polymyxins	Pleuromutilins	Others[2]	Total mg/PCU oral solution
Austria	46.2		14.9	3.0	0.7	2.9	25.6				1.0	5.8	14.9	1.3
Belgium			54.0	9.5	26.7		8.7	0.1		0.7	0.0	0.2	54.0	3.8
Bulgaria		4.8	6.6	1.4	0.6		60.3			21.3	4.8	0.2	6.6	7.9
Cyprus	4.2		36.9	6.2	0.7		2.6	3.6	1.0		5.3		36.9	13.1
Czech Republic	28.1	0.3	25.4	1.2	1.7	0.3	5.9	1.0		1.9	5.6	0.5	25.4	21.7
Denmark	40.1	0.1	0.2		20.1	2.0	0.01		1.4	0.7	17.2	3.8	0.2	17.5
Estonia	37.6	0.04	36.7	9.2			16.5						36.7	9.8
Finland											100			0.02
France	0.6	0.02	47.1	7.5	6.4	0.05	2.9	1.6	0.0	30.4	3.5		47.1	10.9
Germany		0.5	40.7	8.3	5.6		12.2		6.3	22.6	3.7	0.1	40.7	3.1
Hungary	0.1	12.0	14.6	3.0	3.9		58.3			6.0	1.8	0.3	14.6	10.8
Iceland							0.01		100					0.6
Ireland	0.6	0.01	47.2	0.1	5.8	0.2	1.1		4.0	1.0		0.7	47.2	8.6
Italy	10.8	2.2	32.7	6.4	9.7	1.9	2.7	6.7	0.01	20.8	2.9	3.0	32.7	55.4
Latvia	3.7	0.2		5.4			65.0	0.3	2.8	22.6				1.7
Lithuania	1.2	1.4	4.8	1.7	63.4	2.8	1.8	3.0		0.7	12.0	7.2	4.8	7.0
Netherlands	0.5		30.2	6.9	54.5		4.2	0.01		3.5	0.2		30.2	5.0
Norway							0.1		10.0		30.9			0.2
Poland	5.9	2.2	19.0	4.6	1.3		49.6	0.4	2.5	11.1	3.3		19.0	11.0
Portugal	41.7	0.1	3.8	0.8	5.4		29.1	0.6		2.1	2.3		3.8	27.7
Slovakia	4.9	0.1			2.0	0.2	14.5	1.7		6.1	20.5	0.5		19.0
Slovenia		5.5	0.0	2.5			90.4	1.5					0.0	5.3
Spain	35.0		1.1	0.2	0.4		38.4	0.2	6.0	8.5	2.9	0.03	1.1	18.0
Sweden					47.4		0.7		7.3	20.7	23.9			0.4
United Kingdom	5.0	0.2	1.0		0.6	19.5	4.4		0.5	4.2	16.6	41.3	1.0	3.1

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

Table A6. Percentage of sales, in mg/PCU, of injection preparations by antimicrobial class (according to ATCvet system) by country, for 2011[1]

Country	Tetracyclines	Amphenicols	Penicillins	1-2 gen. cephalosporins	3-4 gen. cephalosporins	Sulfonamides	Trimethoprim	Macrolides	Lincosamides	Fluoroquinolones	Aminoglycosides	Pleuromutilins	Others[2]	Total mg/PCU injection prep.
Austria	7.6	5.8	37.2		3.3	8.2	1.6	7.7	0.8	4.6	1.3	0.3	21.5	5.5
Belgium	3.8	4.6	55.2	0.1	2.6	1.8	0.8	2.6	2.4	2.6	4.2	0.1	19.0	17.3
Bulgaria	62.0	1.1	11.9	0.0	0.2	2.2	0.4	4.4	0.6	0.9	1.2	0.7	14.3	23.5
Cyprus	12.6	3.5	36.5		0.8	8.9	0.5	2.9	1.2	0.9	1.1	1.0	29.3	19.0
Czech Republic	23.3	2.6	37.0	1.6	2.5	3.4	0.7	2.5	0.3	1.6	0.5	0.4	23.7	10.7
Denmark	11.7	1.6	65.3		0.1	7.3	1.2	1.2	3.4	0.0		0.9	7.3	17.4
Estonia	10.1	0.7	47.3	1.3	2.3	3.2	0.6	2.5	1.3	2.7	2.5	1.9	23.6	20.0
Finland	7.1	0.2	86.4	0.002	0.1	3.4	0.7	0.2	0.4	1.2	0.1		0.1	13.9
France	7.2	4.3	33.8	0.1	1.9	5.0	0.6	9.1	0.4	2.3	3.3	0.02	31.5	13.8
Germany	4.2	8.2	39.2		5.0	10.5	1.9	7.7	2.2	7.9	4.1	0.2	8.8	6.7
Hungary	9.9	6.1	37.6	2.8	1.9	3.8	0.8	3.4	1.6	6.1	0.9	2.1	22.9	6.9
Iceland	6.0		56.1		0.1	2.0	0.4			0.1		0.1	35.2	4.6
Ireland	18.9	4.8	34.7	0.9	0.4	5.4	1.1	7.1	0.3	2.1	1.2	0.0	23.3	14.8
Italy	10.5	6.0	27.7	0.1	1.5	10.6	1.1	9.1	3.0	3.6	4.8	0.4	21.5	18.7
Latvia	6.4	0.1	39.6	0.5	2.3	9.5	1.9	4.8	1.0	2.1	1.2	0.8	29.9	9.9
Lithuania	24.4	3.4	29.8		0.4	6.1	1.2	1.9	1.3	2.9	2.9	0.3	25.5	9.1
Netherlands	14.1	8.2	43.0		1.6	10.0	2.0	2.5	0.3	1.4	7.0	0.0	9.6	10.0
Norway	3.6	0.7	76.4		0.03	6.7	1.3	0.0		0.6	0.3	0.2	10.0	2.0
Poland	7.7	4.9	30.8	0.4	0.5	2.3	0.2	1.6	0.9	11.7	0.3	1.0	37.6	14.9
Portugal	19.2	10.6	26.0	0.7	3.4	4.4	0.9	6.0	0.8	4.1	0.4	4.4	18.8	8.1
Slovakia	17.9	2.9	49.8	2.4	4.5	1.8	0.4	1.7	0.3	1.8	0.2	0.5	15.8	12.3
Slovenia	15.8	4.0	30.9	1.0	0.6	12.3	1.6	2.2	0.2	10.7	2.2		18.4	10.6
Spain	13.0	8.8	26.2	0.2	1.7	2.3	0.5	9.6	2.0	14.3	2.4	1.2	17.6	10.8
Sweden	5.6		81.0		0.2	6.6	1.3	1.1		1.0	0.4	0.2	2.5	10.0
United Kingdom	24.9	5.6	26.5	0.2	2.2	5.7	0.8	11.0	0.6	2.3	0.7	0.1	19.3	6.3

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

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

Table A7. Variables reported to ESVAC for each antimicrobial veterinary medicinal product for 2011

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

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

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

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

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

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

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

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

Prodrug	Conversion factor	Active ingredient
Benethamine benzylpenicillin	0.65	Benzyl penicillin
Benzathine benzylpenicillin	0.39	Benzyl penicillin
Benzathine phenoxymethylpenicillin	0.38	Phenoxymethylpenicillin
Cloxacillin benzathine	0.43	Cloxacillin
Oxacilline benzathine	0.69	Oxacilline
Penethamate hydriodide	0.63	Benzyl penicillin
Procaine benzylpenicillin	0.61	Benzyl penicillin

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

Annex 3. Population correction unit (PCU)

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

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

Table A11. Weights used to calculate the population correction unit

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

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

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

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

Table A12. List of substances reported sold in ESVAC

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

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

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

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

Austria

Distribution of veterinary medicines

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

Legal basis for the monitoring of sales

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

Data sources

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

Belgium

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 by delivery from a pharmacy, on veterinary prescription, or directly from the veterinarian.

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

Legal basis for the monitoring of sales

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

Data sources

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

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

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

Bulgaria

Distribution of veterinary medicines

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

Legal basis for the monitoring of sales

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

Data sources

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

Cyprus

Distribution of veterinary medicines

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

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

Legal basis for the monitoring of sales

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

Data sources

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

Czech Republic

Distribution of veterinary medicines

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

Legal basis for the monitoring of sales

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

Data sources

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

Brief description of data collection

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

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

Denmark

Distribution of veterinary medicines

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

Legal basis for the monitoring of sales

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

Data sources

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

Estonia

Distribution of veterinary medicines

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

Legal basis for the monitoring of sales

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

Data source

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

Finland

Distribution of veterinary medicines

In Finland, all VMPs that contain antimicrobials are prescription-only medicines. They are available either from pharmacies on veterinarian's prescription or directly from veterinarians. Veterinarians are allowed to dispense medicines for the treatment of animals under their care, but are not allowed to profit from the sales. Pharmacies and veterinarians are supplied by wholesalers. Medicated feeds may either be produced by feed mills or imported to Finland, but always require a prescription by a veterinarian.

Legal basis for the monitoring of sales

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

Data source

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

France

Distribution of veterinary medicines

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

Legal basis for the monitoring of sales

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

Data sources

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

Germany

Distribution of veterinary medicines

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

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

Legal basis for the monitoring of sales

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

Data sources

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

Hungary

Distribution of veterinary medicines

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

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

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

Legal basis for the monitoring of sales

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

Data sources

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

Iceland

Distribution of veterinary medicines

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

Legal basis for the monitoring of sales

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

Data sources

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

Ireland

Distribution of veterinary medicines

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

Legal basis for the monitoring of sales

There is currently no legal basis requiring manufacturers or wholesalers to supply data relating to the volume of sales of authorised veterinary medicinal products.

Data sources

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

Italy

Distribution of veterinary medicines

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

Wholesale of veterinary medicines

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

Wholesale of veterinary medicinal products includes transactions between:

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

Direct sale of veterinary medicinal products

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

Retail veterinary medicinal products

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

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

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

Legal basis for the monitoring of sales

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

Data sources

Sales data are collected from pharmaceutical companies (n=48) producing or importing VMPs.

Latvia

Distribution of veterinary medicines

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

Legal basis for the monitoring of sales

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

Data sources

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

Lithuania

Distribution of veterinary medicines

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

Legal basis for the monitoring of sales

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

Data sources

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

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 is 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% is 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 (n=69) that are (represented by) members of FIDIN. Since sales data are obtained from marketing-authorisation holders only, including both their sales to wholesalers and their direct sales to veterinarians, there is no double reporting of wholesalers' sales.

Norway

Distribution of veterinary medicines

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

Legal basis for the monitoring of sales

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

Data sources

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

Poland

Distribution of veterinary medicines

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

Legal basis for the monitoring of sales

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

Data sources

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

Portugal

Distribution of veterinary medicines

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

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

Legal basis for the monitoring of sales

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

Data sources

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

Slovakia

Distribution of veterinary medicines

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

Legal basis for the monitoring of sales

The collection of import data is based on a national law on pharmaceuticals, Act No. 140/1998 Coll.

Data sources

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

Brief description of data collection

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

Slovenia

Distribution of veterinary medicines

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

Legal basis for the monitoring of sales

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

Data sources

Data on sales of the included 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' cooperatives) are authorised according to national law and have a mandatory pharmacist control service. Dispensing is most frequently done by retailers. Veterinarians in Spain are allowed to use VMPs in their daily practice, but they cannot sell VMPs to animal owners.

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

Legal basis for the monitoring of sales

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

Data sources

The sales data were collected from marketing-authorisation holders at package level by the Spanish Agency for Veterinary Medicinal Products (AEMPS), in collaboration with the Spanish veterinary medicine industry association (Veterindustria).

Sweden

Distribution of veterinary medicines

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

Legal basis for the monitoring of sales

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

Data sources

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

United Kingdom

Distribution of veterinary medicines

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

Legal basis for the monitoring of sales

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

Data sources

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

Annex 6. References to national reports

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

Table A13. List of ESVAC national representatives/alternates

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Annex 8. ESVAC ad hoc Expert Group members and observers

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

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

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Annex 9. Data from Switzerland[8]

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

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

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

Table A17. Estimated population correction unit (PCU) (in 1,000 tonnes) of the animal population, for 2011

Country	Cattle	Pigs	Poultry	Sheep/ goats	Fish	Rabbits	Horses	Total
Switzerland	484	219	53	38	0	1	22	818

Table A18. Sales, in tonnes of active ingredient, split into sales of veterinary antimicrobial agents marketed for food-producing animals (terrestrial animals), marketed for companion animals only (i.e. tablets) and total sales, for 2011

	Tablets		All other pharmaceutical forms		Total
	Tonnes	% of total	Tonnes	% of total	Tonnes
Switzerland	0.9	1	64.5	99	65.4

Table A19. Sales, in tonnes of active ingredient, of veterinary antimicrobial agents marketed for food-producing animals, including horses, population correction unit (PCU), and mg active ingredients of veterinary antimicrobial agents sold per PCU, for 2011

Country	Sales (tonnes) for food-producing animals	PCU (1,000 tonnes)	mg/PCU
Switzerland	64.5	818	79

[8] In the previous report (ESVAC 2010 report), data were mistakenly provided to ESVAC for the year 2011 instead of 2010; therefore, the 2011 data for Switzerland are republished here in identical form.

Table A20. Sales, in tonnes of active ingredient, of veterinary antimicrobial agents for food-producing animals, including horses, split into administration route/form, for 2011

Country	Premix	Oral powder	Oral solution	Injection	Intramammary prep.	Intrauterine prep.	Oral paste	Bolus	Total
Switzerland	44.6[1]	4.5	–[1]	9.5	4.8	0.9	–[1]	0.2[2]	64.5

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

Table A21. Sales for food-producing animals, in tonnes of active ingredient, of the various veterinary antimicrobial classes, for 2011

Country	Tetracyclines	Amphenicols	Penicillins	1-2 gen. cepha.	3-4 gen. cepha.	Sulfonamides	Trimethoprim	Macrolides	Lincosamides	Fluoroquinolones	Other quinolones	Aminoglycosides	Polymyxins	Pleuromutilins	Others	Total
Switzerland	14.5	–[1]	13.2	0.1	0.2	25.7	1.7	3.9	–[2]	0.4	–[1]	3.2	1.5	–[1]	0.2	64.5

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

Table A22. Sales for food-producing animals, in mg per population correction unit (mg/PCU), of the various veterinary antimicrobial classes, for 2011

Country	Tetracyclines	Amphenicols	Penicillins	1-2 gen. cepha.	3-4 gen. cepha.	Sulfonamides	Trimethoprim	Macrolides	Lincosamides	Fluoroquinolones	Other quinolones	Aminoglycosides	Polymyxins	Pleuromutilins	Others	Total
Switzerland	17.7	–[1]	16.2	0.1	0.2	31.4	2.1	4.7	–[2]	0.5	–[1]	3.9	1.8	–[1]	0.3	78.9

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

Table A23. Number of product presentations of premixes, oral powders and oral solutions containing 1, 2 and 3 active ingredients, respectively, for 2011

Country	1	2	3	Total number
Switzerland	47	19	27	93

Table A24. Sales, in tonnes of active ingredient, of veterinary antimicrobial agents as premixes, oral powders and oral solutions containing 1, 2 and 3 active ingredients, respectively, for 2011

Country	1	2	3	Tonnes (premixes, oral powders and oral solutions)
Switzerland	11	8.1	30	49.1

Distribution of veterinary medicines

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

Legal basis for the monitoring of sales

The legal basis for data collection is Art. 36 of the Federal Ordinance on Veterinary Medicines, enacted in September 2004. It requests Swissmedic to "specifically establish a statistic about usage of veterinary antimicrobials for the purpose of monitoring resistances". The data are therefore requested, processed and analysed by Swissmedic. Sales of veterinary antimicrobials are published yearly in the ARCH-VET report[9] covering sales and resistances to veterinary antimicrobials.

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

Data sources

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

Data coverage

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

Data provider

Country	Name and affiliation
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[9] ARCH-VET report (extensive version in German only): www.swissmedic.ch/archvet-e.asp

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EMA/236501/2013