EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Sales of veterinary antimicrobial agents in 19 EU/EEA countries in 2010

Second 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 European Union (EU) and EEA-EFTA states (Iceland, Liechtenstein and Norway).

The Agency, with the help of the Committee for Medicinal Products for Veterinary Use (CVMP) and its Scientific Advisory Group on Antimicrobials (SAGAM), has produced a strong body of scientific advice[1] in relation to 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 European Medicines Agency in September 2009, following a request from the European Commission to develop a harmonised approach for the collection and reporting of data on the use of antimicrobial agents in animals from the Member States. For the first ESVAC report[2], existing data on the sales of veterinary antimicrobial agents were collected from 9 European countries that had already established surveillance programmes, and were reported in a harmonised manner.

About the report

This second ESVAC report presents data on the sales of veterinary antimicrobial agents from 19 EU/EEA countries, provided at package level according to a standardised protocol and template[2]. Data from Switzerland are included in Annex 6, 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.

Countries that have been collecting data on the sales of veterinary antimicrobial agents for several years had to change their data collection protocol and calculations in order to meet the ESVAC requirement of harmonisation of the data across the EU. Apparent changes in the sales data expressed in weight of active ingredient reported for some of these countries may therefore not reflect real changes but may have arisen due to changes in the data collection protocol and calculations.

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 time should be interpreted with due caution.

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

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[1] Available from the 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

The use of antimicrobial agents is the key risk factor for the development and spread of antimicrobial resistance. It is therefore generally recognised that data on the consumption of antimicrobial agents in food-producing animals are an essential element in identifying and quantifying the risk of developing and spreading antibiotic resistance in the food-chain.

A total of 19 European Union (EU)/European Economic Area (EEA) countries submitted to the European Medicines Agency their 2010 data on sales, at package level, of antimicrobial veterinary medicinal products (VMPs), according to a standardised protocol and using a common template. The data provided were subjected to a quality check and examined for outliers when applicable by the ESVAC project team and by the country in question. Following approval by the countries to save the data in the ESVAC database, the data were analysed and are summarised in this report.

In 15 of the 19 countries, a legal basis existed for the national competent authority to request data on sales of veterinary antimicrobial agents from the distributors of such products, while in four countries data were provided to the national competent authority voluntarily. Ten of the countries obtained the data from wholesalers, 5 from marketing-authorisation holders, 2 from pharmacies and 2 from both wholesalers and marketing-authorisation holders; in some countries, feed mills provided the data on sales of premixes used in medicated feed.

The assumed data coverage, in terms of obtaining the data from all distributors that sold antimicrobial VMPs and medicated feed to the end users for the whole year, was reported to be 100% for 16 of the countries, 99% for 1 country and 98% for 2 countries. For 8 countries, 2010 was the first year for which they had collected data on antimicrobial VMPs; 2 countries had collected data for 2009 and 2010, 1 country for four years and 8 countries for more than five years. It is generally agreed that it takes at least three to four years to establish a valid baseline of the data on sales of veterinary antimicrobial agents. Consequently, even though the data coverage is reported to be very high for all the countries, the data from countries that had collected such data for the first time should be interpreted with caution.

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

Overall in the 19 countries, approximately 90% of the sales of veterinary antimicrobial agents, in tonnes of active ingredient, were for products almost solely used for herd treatment, i.e. premixes (49%), oral powders (34%) and oral solutions (8%), and 9% were sold as injectable preparations. However, the amount accounted for by the pharmaceutical forms applied for herd treatment varied considerably between the countries. The proportion of the sales, in tonnes of active ingredient, of antimicrobial VMPs for local use (intramammaries and intrauterine preparations) was 1.2%.

An apparent 30-fold difference in the sales, expressed as mg active ingredient sold per population correction unit (PCU), is observed between the most- and least-selling countries. This is in part likely to be due to differences in the

composition of the animal population (e.g. more pigs than cattle; a high proportion of veal calves within the cattle population) in the various countries. There may also be considerable variation in terms of dosage used for the various antimicrobial agents, length of treatment period or formulation of the various antimicrobial agents 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 19 countries; other factors also need to be considered.

Of the total sales in the 19 countries, the major proportion, expressed as mg/PCU, was accounted for by tetracyclines (39%), penicillins (23%) and sulfonamides (11%). Overall in the 19 countries, the sales of the antimicrobial classes defined as the most critically important (CIA) in human medicine by the World Health Organization — namely 3rd- and 4th-generation cephalosporins, fluoroquinolones and macrolides — accounted for 0.2%, 2.2% and 5.7%, respectively, of the total sales (mg/PCU) of antimicrobial VMPs.

The prescribing patterns of the various antimicrobial classes, expressed as mg/PCU, varied substantially between the countries. Notable variations between the different countries in the proportion accounted for by 3rd- and 4th-generation cephalosporins, fluoroquinolones and macrolides were observed, ranging from 0.02% to 0.54%, 0.01% to 10.3%, and 0% to 11.7%, respectively. These variations may, for example, be due to differences between the countries in the veterinarians' prescribing behaviour, the relative proportion of the various animal species, animal production systems (e.g. veal as opposed to beef cattle on pasture), the availability of veterinary antimicrobial products on the market, prices, or the general situation with regard to infectious diseases. These factors only partly explain the differences in the sales of the CIAs between the countries.

The distribution of sales of the various antimicrobial classes by pharmaceutical form varies considerably between the 19 countries. Overall for the 19 countries, 61% of tetracyclines were sold as premixes, 32% as oral powders, 4% as oral solutions and 2% as injections, while 0.3% were for intramammary or intrauterine use. For penicillins, oral powders accounted for 51%, premixes for 22%, injections for 21%, oral solutions for 3% and intramammary preparations for 3% of the total sales in the 19 countries. For sulfonamides, premixes accounted for 44%, oral powders for 39%, oral solutions for 12%, injections for 4% and oral pastes for 1% of the total sales in the 19 countries.

Of the sales of 3rd- and 4th-generation cephalosporin preparations, none were for herd treatment; 51% were injectable preparations and 49% were intramammary preparations. For both fluoroquinolones and macrolides, the most-selling pharmaceutical forms were for herd treatment. The proportion of fluoroquinolones sold as oral solution was 78.5% and injections accounted for 20.8%. Premixes accounted for 45% of the total sales of macrolides in the 19 countries, oral powders for 36%, oral solutions for 11% and injectable preparations for 9%, respectively.

Overall in the 19 countries, the proportion of the sales in 2010 of antimicrobial VMPs applicable for herd treatment containing more than one active ingredient was relatively low. Of the total sales of premixes in the 19 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%, respectively, and for oral solutions these were 84.6%, 15.3% and 0.09%. 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 herd treatment through feed or drinking water with two or more active ingredients.

In 2010, the sales according to pharmaceutical form expressed as mg/PCU for the 19 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; injections: 47% penicillins, 21% aminoglycosides, 11% tetracyclines, 5% sulfonamides and 4% macrolides.

Of the total numbers of product presentations — i.e. product name, pharmaceutical form, strength and pack size (tablets not included) — 79.2% contained only one active ingredient, 19.4% contained two active ingredients, 1.2% contained three active ingredients and 0.2% contained four active ingredients (only intramammaries).

Important variations between the sales patterns, expressed in tonnes, of veterinary antimicrobial agents used in companion animals (tablets) are observed. However, it has to be noted that, in companion animals, human antimicrobial agents and injectable veterinary antimicrobial agents may also be used, and thus the data on sales of tablets should be interpreted with great care.

Introduction

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

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

With regard to the data collection:

- comparability with the sale/use of antimicrobials in humans should be ensured;
- a multi-annual approach should be anticipated, to allow for the evaluation of trends. The execution may be limited in time, including at least one year of monitoring, but integration of the data in a follow-up request should be foreseen.

In response to the call from the Commission, a network of ESVAC national representatives, nominated by the national competent authorities, was set up. The role of the ESVAC national representatives has been to provide the requested data to the ESVAC project and to endorse the data in the current report.

1. Material and methods

1.1. Veterinary antimicrobial agents included in the material

To harmonise the veterinary antimicrobial agents to be included in the material, the Anatomical Therapeutic Chemical classification system for veterinary medicinal products (ATCvet[3]) was applied.

To harmonise with the presentation of data on use of antimicrobial agents in human medicine, the data are presented according to the ATCvet 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 codes3 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[4]. In order to standardise the information, one of the following categories of pharmaceutical form had to be applied: 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 stratification of data into use in companion animals (tablets) and food-producing animals, including horses, and also to estimate the sales of antimicrobial agents for herd treatment.

While 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, respectively, differed between the countries. In order to present harmonised data, these categories have therefore been aggregated to express oral solutions and oral powders, respectively. Since the proportions of sales of oral powders and oral solutions for individual treatment are relatively low compared to those for herd treatment, the reported sales of oral powders and oral solutions are considered to be mainly used for herd treatment of food-producing animals.

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. 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 to the Agency's report 'Trends in the sales of veterinary antimicrobial agents in nine European countries: 2005-2009' (EMA/238630/2011)[4].

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

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

1.4. 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 data source for data on this animal category. In cases where data were not available in Eurostat (e.g. for rabbits), or when significant errors in the Eurostat statistics were identified, 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 material prior to the normalisation of the sales by the PCU.

For Norway and Sweden, data on sales of antimicrobial agents for farmed fish are not included, due to negligible sales. Consequently, farmed fish are not included in the PCU for Norway and Sweden (see further explanations in Annex 3).

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 number 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), and as these are based on health certificates, which are obligatory for all animals passing any border, they are considered reliable.

1.5. 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, rabbits 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).

1.6. Reporting of the data[5]

The main indicator applied in this report to express the consumption of veterinary antimicrobial agents is mg active ingredient normalised by the population correction unit (mg/PCU). 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 1.7.4[6].

1.7. Summary: distribution of antimicrobial veterinary medicinal products by country

Information on the systems for distribution of antimicrobial VMPs, the sources from which the data were obtained, the legal basis for the collection of the data and the assumed data coverage by country is shown in Table 2.

[5] Note that the numbers in the tables have been rounded.

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

Table 2. Summary of information on years collecting data, legal basis for collecting data, national providers of ESVAC data, sources for ESVAC data and assumed data coverage, by country

Country	Years collecting data	Legal basis	National data provider to ESVAC	Data source for ESVAC data (approx. no)	Assumed data coverage
Austria	1 year (2010)	Mandatory to report	Austrian Agency for Health and Food Safety	MAHs[1] (n=12); wholesalers (n=6)	100%
Belgium	4 years	Mandatory to report	Federal Agency for Medicines and Health Products	Wholesalers (n=24); feed mills (n=63)	99%
Czech Republic	>5 years	Mandatory to report	Institute for State Control of Veterinary Biologicals and Medicines	Wholesalers (n=76); feed mills (n=79), wholesalers other country (n=1)	98%
Denmark	>5 years	Mandatory to report	Danish Veterinary and Food Administration	VetStat (n=1) obtaining data from pharmacies; wholesalers; veterinarians; feed mills	100%
Estonia	>5 years	Mandatory to report	State Agency of Medicines	Wholesalers (n=14)	100%
Finland	>5 years	Mandatory to report	Finnish Medicines Agency	Wholesalers (n=5); feed mills (n=1) and importers of medicated feed (n=1)	100%
France	>5 years	Not mandatory	National Agency for Veterinary Medicinal Products (Anses-ANMV)	MAHs (n=31)	100%
Hungary	1 year (2010)	Mandatory to report	Directorate of Veterinary Medicinal Products	MAHs (n=22); wholesalers (n=54); wholesalers other countries (n=2)	100%
Iceland	1 year (2010)	Mandatory to report	Icelandic Medicines Agency	Wholesalers (n=2)	100%
Ireland	2 years	Not mandatory	Irish Medicines Board	MAHs (n=49)	100%
Latvia	1 year (2010)	Mandatory to report	Assessment and Registration Agency of Food and Veterinary Service	Wholesalers (n=27)	100%
Lithuania	1 year (2010)	Mandatory to report	State Food and Veterinary Service	Wholesalers (n=21)	100%
Netherlands	>5 years	Not mandatory	Federation of the Dutch Veterinary Pharmaceutical Industry (FIDIN)	MAHs (n=69)	98%
Norway	>5 years	Mandatory to report	Norwegian Veterinary Institute	Wholesalers (n=5)	100%
Portugal	1 year	Mandatory to report	National Authority for Animal Health	Wholesalers (n=75)	100%
Slovenia	1 year (2010)	Mandatory to report	Veterinary Administration of the Republic of Slovenia (VARS)	Wholesalers (n=11)	100%
Spain	2 years	Not mandatory	Spanish Agency for Medicines and Health Products	MAHs (n=41)	100%
Sweden	>5 years	Mandatory to report	National Veterinary Institute and Swedish Board of Agriculture	Apotekens Service AB (n=1) obtaining data from pharmacies	100%
United Kingdom	>5 years	Mandatory to report	Veterinary Medicines Directorate	MAHs (n=48)	100%

[1] MAHs = marketing-authorisation holders.

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. More than 60-fold differences between the highest (France) and the lowest (Iceland) PCU values were observed.

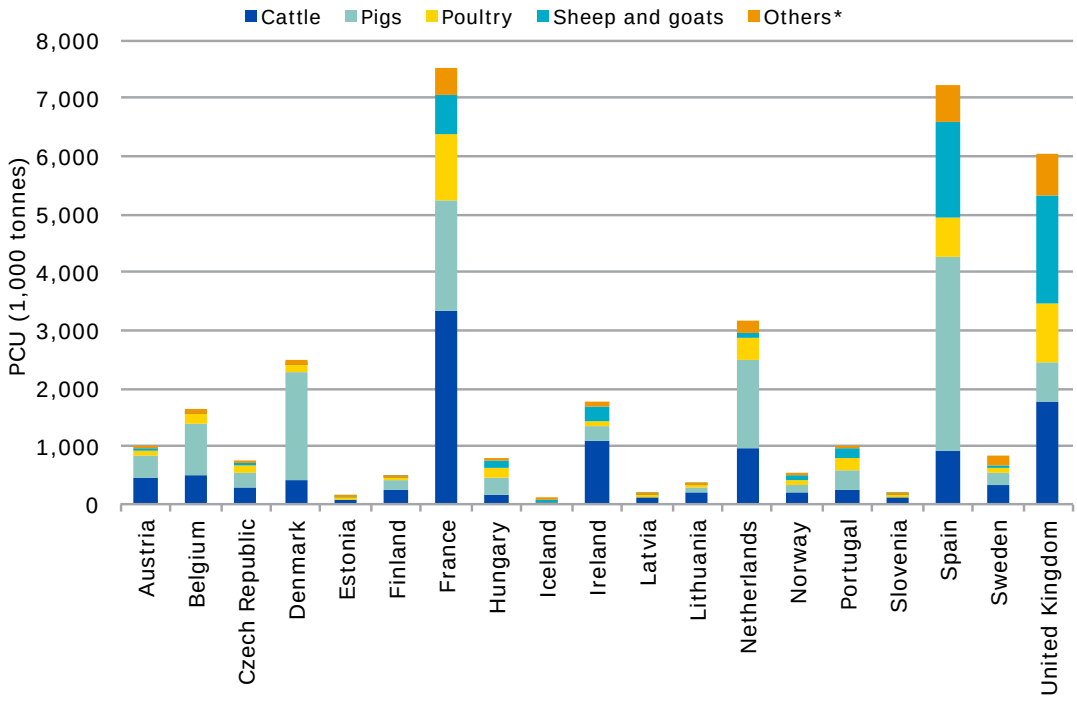
For 15 of the countries, the major food-producing species, as expressed by PCU, were cattle, pigs and poultry, while for 4 of the countries (Iceland, Ireland, Norway and Spain) these were cattle, pigs and sheep/goats (Figure 2).

Table 3. Estimated PCU (in 1,000 tonnes) of the population of food-producing species (including horses), by country, for 2010

Country	Cattle	Pigs	Poultry	Sheep/ goats	Fish	Rabbits	Horses	Total
Austria	444	403	79	34	na	na	33	994
Belgium	479	901	174	16	1	4	86	1,660
Czech Republic	292	240	146	15	20	12	30	755
Denmark	409	1,856	120	14	34	na	70	2,503
Estonia	61	35	10	5	1	na	4	115
Finland	224	181	60	10	12	na	30	517
France	3,340	1,887	1,151	696	234	49	181	7,538
Hungary	151	316	170	102	na	1	27	768
Iceland	19	6	5	47	5	na	31	113
Ireland	1,091	250	80	275	47	na	36	1,778
Latvia	104	33	16	6	1	0.02	5	165
Lithuania	224	67	40	4	3	0.04	3	342
Netherlands	983	1,493	391	109	7	3	169	3,155
Norway1	222	125	62	94	na	na	15	517
Portugal	238	349	205	190	8	8	22	1,020
Slovenia	100	26	34	11	1	0.04	9	181
Spain	926	3,333	703	1,651	269	89	277	7,247
Sweden[1]	320	230	82	47	na	na	145	824
United Kingdom	1,750	705	1,009	1,881	196	na	520	6,061
Total 19 countries	**11,377**	**12,437**	**4,537**	**5,208**	**839**	**165**	**1,692**	**36,256**

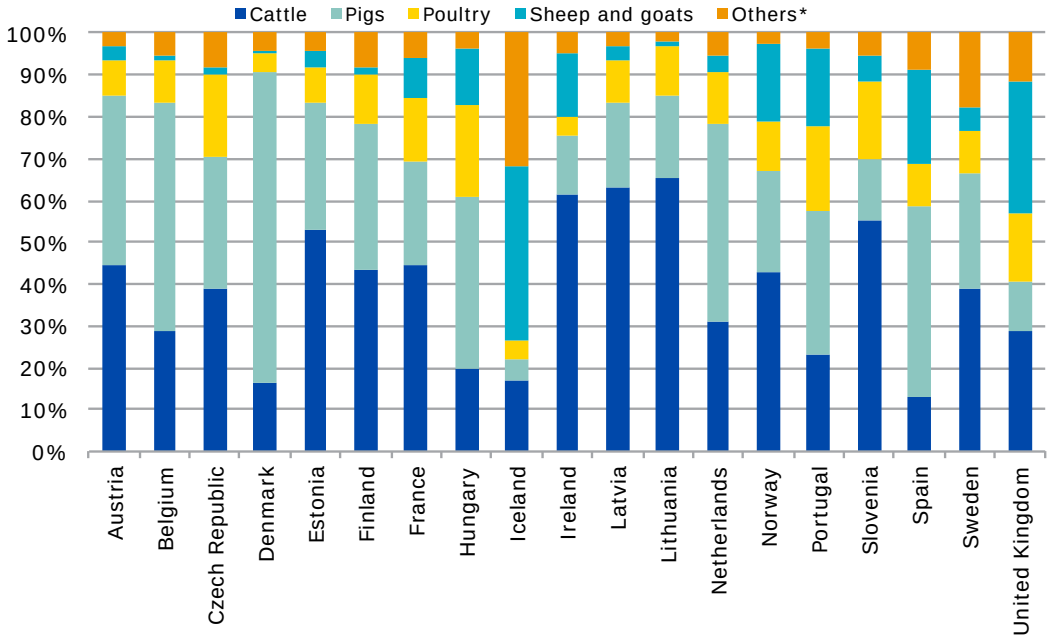
[1] Farmed fish not included as sales of antimicrobial VMPs not included in the sales data; na = not applicable.

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



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

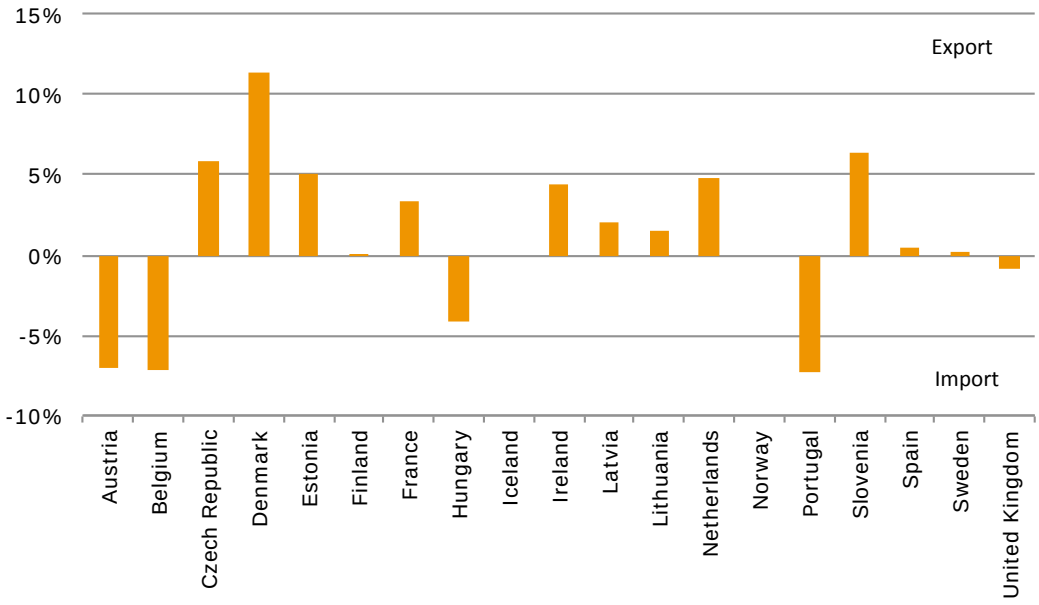
Figure 2. Distribution of PCU (1,000 tonnes) by food-producing animal species, including horses, by country, for 2010



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

The percentage of the total PCU accounted for by the net export or import of animals for slaughter and/or fattening in another country is shown in Figure 3. Of the 19 countries, Denmark, Slovenia and the Czech Republic are the major net exporters of animals for slaughter and/or fattening to another country; such exports account for (added to the total PCU of livestock and slaughter animals) 11.4%, 6.4% and 5.8% of the total PCU, respectively, in these three countries. Of the 19 countries, Belgium, Portugal and Austria are the major net importers of animals for slaughter and/or fattening from another country; these imports account for (subtracted from the total PCU of livestock and slaughter animals) 7.2%, 7.2% and 7.0% of the total PCU, respectively.

Figure 3. Net export and net import[1], as percentage of the total PCU, of animals for fattening or slaughter in another Member State, for 2010



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

2.2. Overall sales

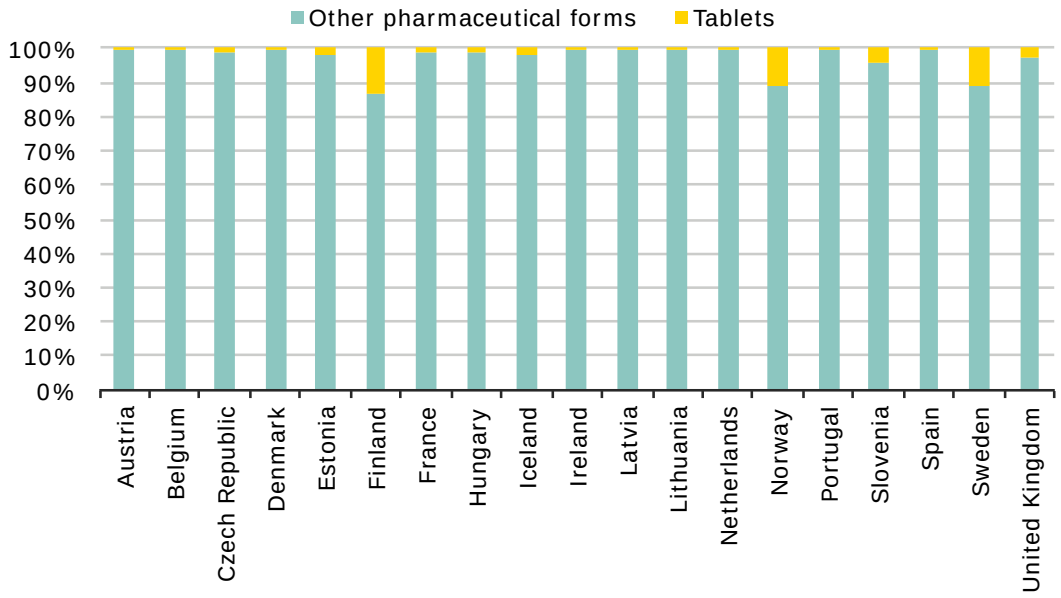
The overall national sales data provided covered sales for use in companion animals (mainly tablets) and food-producing animals, including horses (all other pharmaceutical forms). Injectable veterinary antimicrobial agents are also used in companion animals, but due to minor use, in terms of weight of active ingredient, such sales are included in the statistics for food-producing animals. Except for Finland, Norway and Sweden, where tablets accounted for 13.3%, 10.9% and 10.8%, respectively, sales of tablets, and therefore use in companion animals, accounted for a minor proportion of the overall sales in 2010.

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 2010

	Tablets		All other pharmaceutical forms		Total
Country	**Tonnes**	**% of overall sales**	**Tonnes**	**% of overall sales**	**Tonnes**
Austria	0.3	0.4%	63	99.6%	63
Belgium	1.5	0.5%	299	99.5%	300
Czech Republic	0.8	1.1%	71	98.9%	72
Denmark	0.9	0.8%	119	99.2%	120
Estonia	0.1	1.8%	8	98.2%	8
Finland	2.0	13.3%	13	86.7%	15
France	14.5	1.4%	997	98.6%	1,011
Hungary	3.2	1.6%	206	98.7%	209
Iceland	0.02	2.0%	0.9	98.0%	0.9
Ireland	0.6	0.6%	93	99.4%	93
Latvia	0.05	0.7%	6.6	99.3%	6.6
Lithuania	0.05	0.3%	16	99.7%	16
Netherlands	2.8	0.6%	461	99.4%	464
Norway[1]	0.7	10.9%	5.7	89.1%	5.7
Portugal	0.3	0.2%	176	99.8%	177
Slovenia	0.4	4.5%	8.4	95.5%	9
Spain	2.1	0.1%	1,746	99.9%	1,748
Sweden[1]	1.5	10.8%	13	89.2%	14
United Kingdom	13.1	2.8%	456	97.2%	469
Total 19 countries	**45**		**4,757**		**4,802**

[1] Sales of antimicrobial VMPs for farmed fish not included in the data.

Figure 4. Distribution of 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 2010



2.3. Sales for food-producing animals, including horses

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

Country	Sales (tonnes) for food-producing animals	PCU (1,000 tonnes)	mg/PCU
Austria	63	994	63
Belgium	299	1,660	180
Czech Republic	71	755	94
Denmark	119	2,503	47
Estonia	8	115	68
Finland	13	517	25
France	997	7,538	132
Hungary	206	768	268
Iceland	0.9	113	8
Ireland	93	1,778	52
Latvia	6.6	165	40
Lithuania	16	342	46
Netherlands	461	3,155	146
Norway[2]	5.7	517	11
Portugal	176	1,020	166
Slovenia	8.4	181	46
Spain	1,746	7,247	241
Sweden[2]	13	824	15
United Kingdom	456	6,061	75

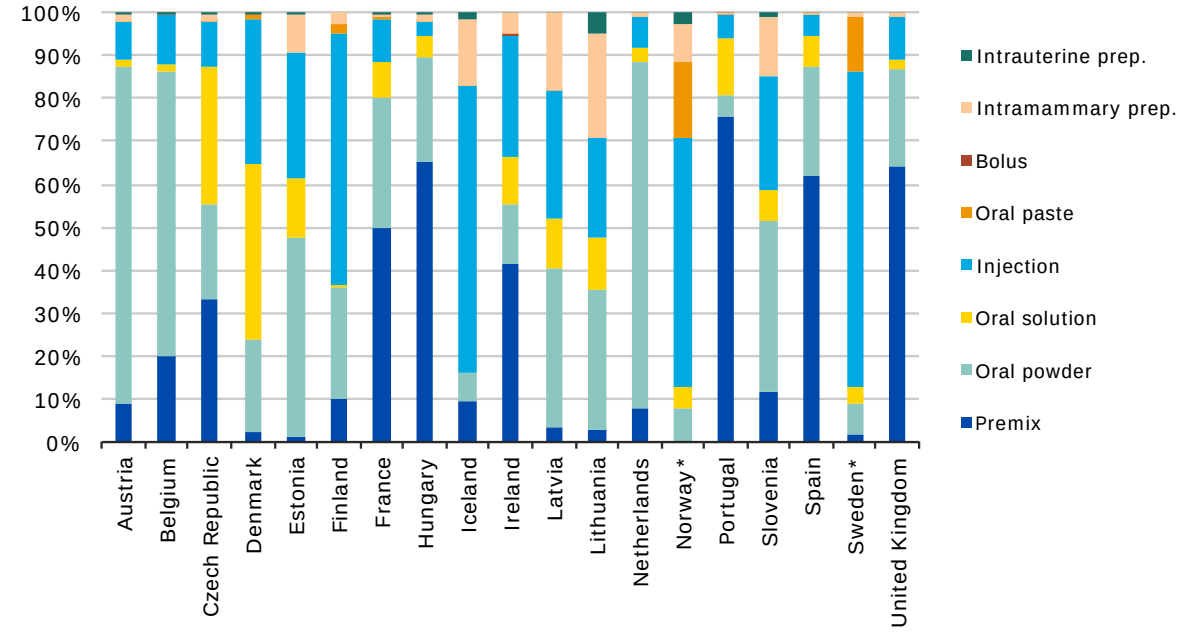
[1] Tablets excluded as major part used in companion animals; injectable antimicrobial VMPs can also be used in companion animals, but as the proportional use is minor, these are included in the sales for food-producing animals. [2] Sales of antimicrobial VMPs for farmed fish not included in the sales data; fish not included in PCU.

2.4. Sales for food-producing animals, including horses, by pharmaceutical form

The sales of veterinary antimicrobial agents, stratified into pharmaceutical forms, are shown in Figure 5. For the 19 countries overall, premixes, oral powders and oral solutions accounted for the major part (90%) of the total sales of antimicrobial VMPs in 2010 (Figure 6); however, the proportion sold of these three forms varies noticeably between the countries. 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 herd treatment is performed by application of oral powder as top-dressing on the feed at the farm.

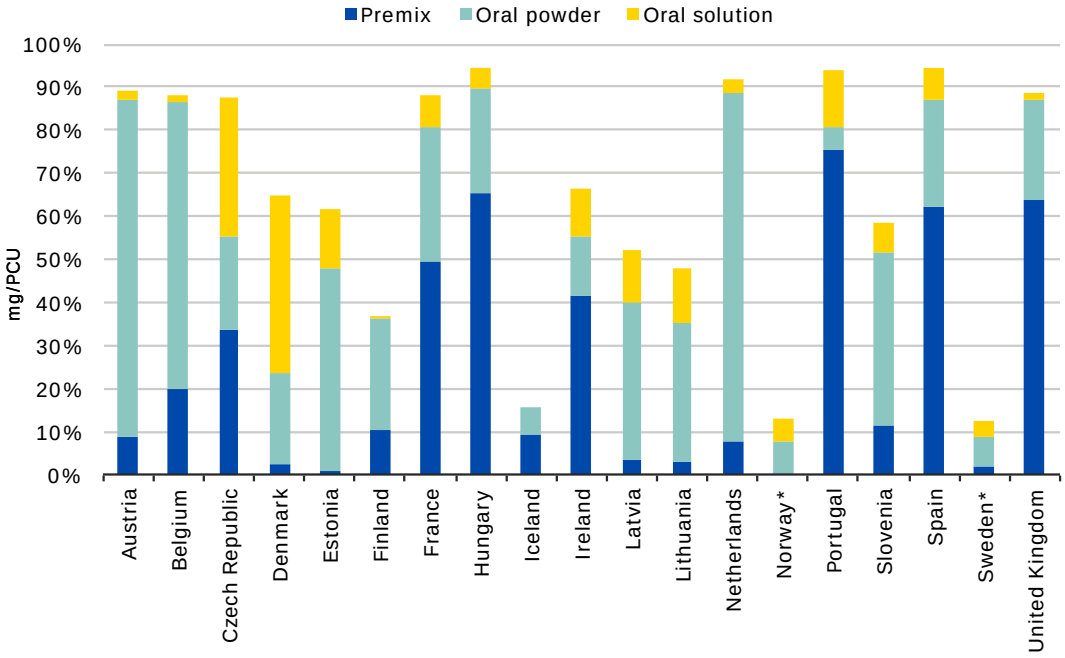
Although some of the oral powders and oral solutions are used for treatment of individual animals, the data show that herd treatment is the most frequently used method for administration of antimicrobial VMPs to food-producing animals, except in Iceland, Finland, Norway and Sweden.

Figure 5. 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 2010



* Sales of antimicrobial VMPs for farmed fish not included in the sales data; fish not included in PCU.

Figure 6. Oral solutions, oral powders and premixes as percentages of total sales, in mg per population correction unit (mg/PCU), of veterinary antimicrobial agents for food-producing animals (including horses), by country, for 2010



* Sales of antimicrobial VMPs for farmed fish not included in the sales data; fish not included in PCU.

2.5. 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 8 to 268 mg/PCU between the 19 countries. Also, the sales patterns of the antimicrobial classes varied substantially between the 19 countries (Table 6).

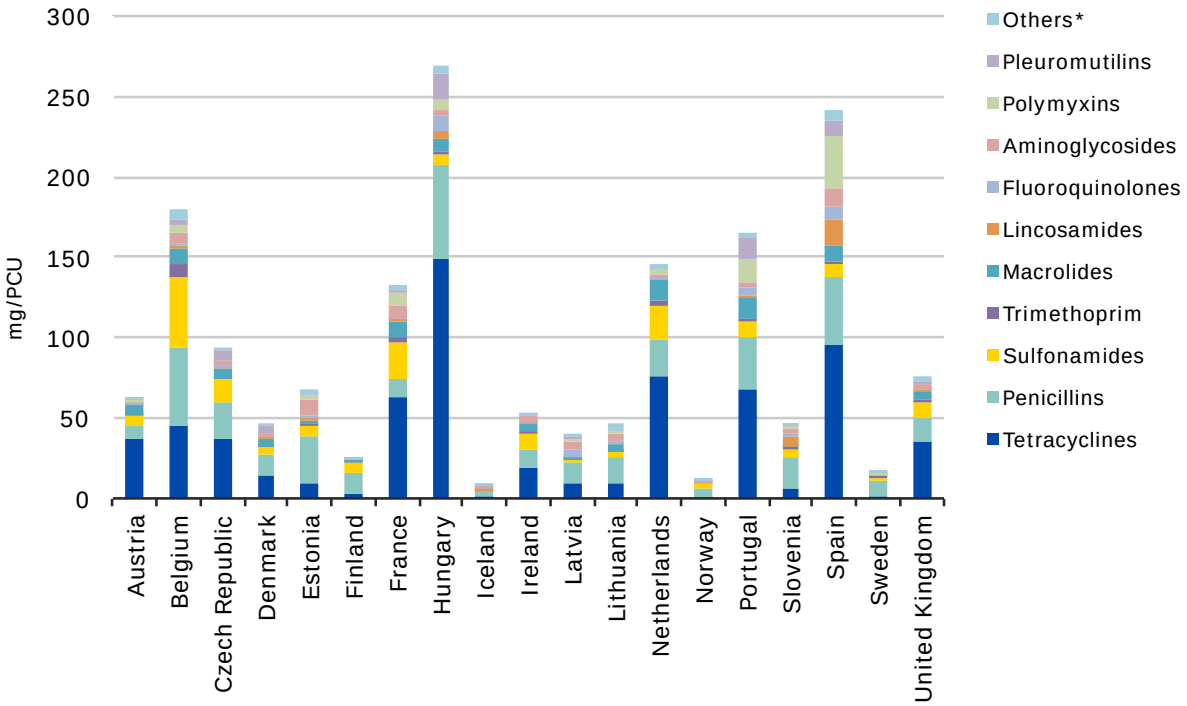
Overall in the 19 countries, tetracyclines, penicillins and sulfonamides were the most-sold antimicrobial classes, accounting for 39%, 23% and 11% of the total sales in mg/PCU, respectively (Table 6, Figure 9).

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 (presented according to ATCvet hierarchical system), by country, for 2010

Country	Tetracyclines	Amphenicols	Penicillins	1-2 gen. cepha.	3-4 gen. cepha.	Sulfonamides	Trimethoprim	Macrolides	Lincosamides	Fluoroquinolones	Other quinolones	Aminoglycosides	Polymyxins	Pleuromutilins	Others	Total mg/PCU
Austria	59%	0.6%	12%	0.07%	0.5%	10%	1.4%	10%	0.5%	1.0%		2.4%	1.5%	0.7%	0.6%	63
Belgium	25%	0.5%	27%	0.05%	0.3%	25%	5.0%	5%	1.6%	0.4%	0.9%	3.4%	3.3%	1.2%	2.5%	180
Czech Republic	40%	1.2%	24%	0.2%	0.4%	15%	1.0%	6%	0.4%	1.4%	0.2%	3.4%	1.0%	6%	0.5%	94
Denmark	31%	0.6%	27%	0.05%	0.1%	8%	1.4%	12%	2.3%	0.01%	0.7%	3.3%	0.4%	11%	1.9%	47
Estonia	13%	0.2%	44%	1.2%	0.5%	9%	2.2%	3.3%	1.6%	3.5%	0.2%	13%	4.8%	0.4%	2.1%	68
Finland	14%	0.5%	54%	0.3%	0.04%	21%	4.1%	4.5%	1.1%	0.6%		0.6%		0.4%	0.0%	25
France	47%	0.5%	9%	0.1%	0.2%	17%	2.6%	8%	0.6%	0.5%	0.8%	6%	6.4%	0.8%	0.4%	132
Hungary	56%	0.2%	22%	0.2%	0.1%	2.7%	0.6%	2.8%	1.9%	3.3%	0.1%	1.3%	2.6%	6%	0.9%	268
Iceland	10%		54%		0.1%	3.9%	0.5%		1.3%	0.1%	3.0%	24%		0.3%	2.6%	8
Ireland	36%	1.4%	21%	0.6%	0.1%	20%	2.5%	9%	0.3%	0.7%		8%		0.05%	0.3%	52
Latvia	24%	0.05%	31%	1.6%	0.5%	5%	0.9%	2%	3.1%	10.3%	0.002%	14%	2.4%	3.6%	2.1%	40
Lithuania	19%	3.8%	35%	2.3%	0.05%	8%	1.8%	8%	1.5%	1.5%	0.8%	12%	3.8%		3.0%	46
Netherlands	51%	0.5%	16%	0.02%	0.2%	15%	2.7%	9%	0.2%	0.4%	1.0%	2.1%	1.6%	0.5%	0.4%	146
Norway[1]	4.1%	0.5%	50%		0.02%	25%	4.6%			0.3%		13%		1.8%		11
Portugal	41%	0.8%	19%	0.2%	0.2%	6%	1.2%	8%	0.6%	3.2%	0.4%	1.7%	9%	8%	0.5%	166
Slovenia	13%	1.7%	41%	0.3%	0.2%	13%	1.8%	0.5%	13%	5.5%	0.3%	8%	0.1%	0.1%	2.0%	46
Spain	40%	0.4%	17%	0.05%	0.3%	4%	0.6%	4.2%	7%	3.5%	0.3%	4.5%	13%	4.4%	1.4%	241
Sweden[1]	8%		63%		0.1%	16%	2.8%	4.2%		0.9%		3.0%	0.8%	1.4%		15
United Kingdom	46%	0.8%	19%	0.2%	0.3%	13%	2.6%	8%	1.4%	0.4%		2.8%	0.2%	2.6%	2.5%	75
Average 19 countries	**39%**	**0.6%**	**23%**	**0.3%**	**0.2%**	**11%**	**1.9%**	**6%**	**2.2%**	**2.2%**	**0.4%**	**4.3%**	**4.5%**	**3.5%**	**1.2%**	

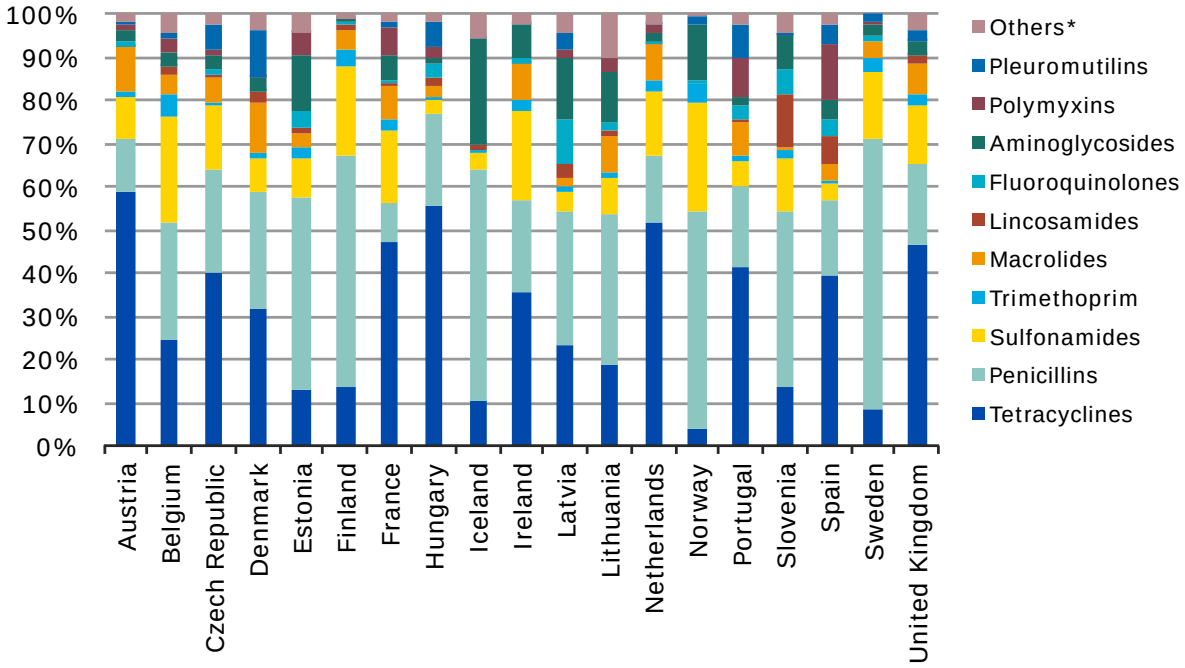
[1] Sales of antimicrobial VMPs for farmed fish not included in the sales data; fish not included in PCU.

Figure 7. Sales for food-producing species, including horses, in mg/PCU, of the various veterinary antimicrobial classes, by country[1], for 2010



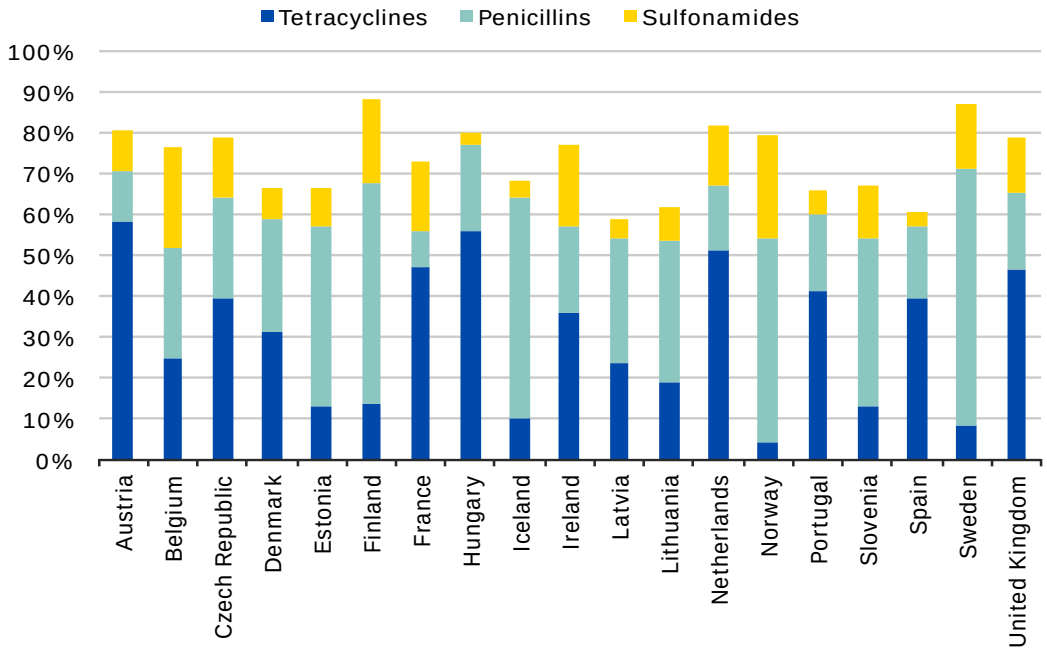
[1] Differences between countries can partly be explained by differences in animal demographics, in the selection of antimicrobial agents and in dosage regimes, among other factors. * Amphenicols, cephalosporins, other quinolones and other antibacterials (classified as such in the ATCvet system).

Figure 8. Proportion of the total sales of the different veterinary antimicrobial classes, in mg/PCU, by country, for 2010



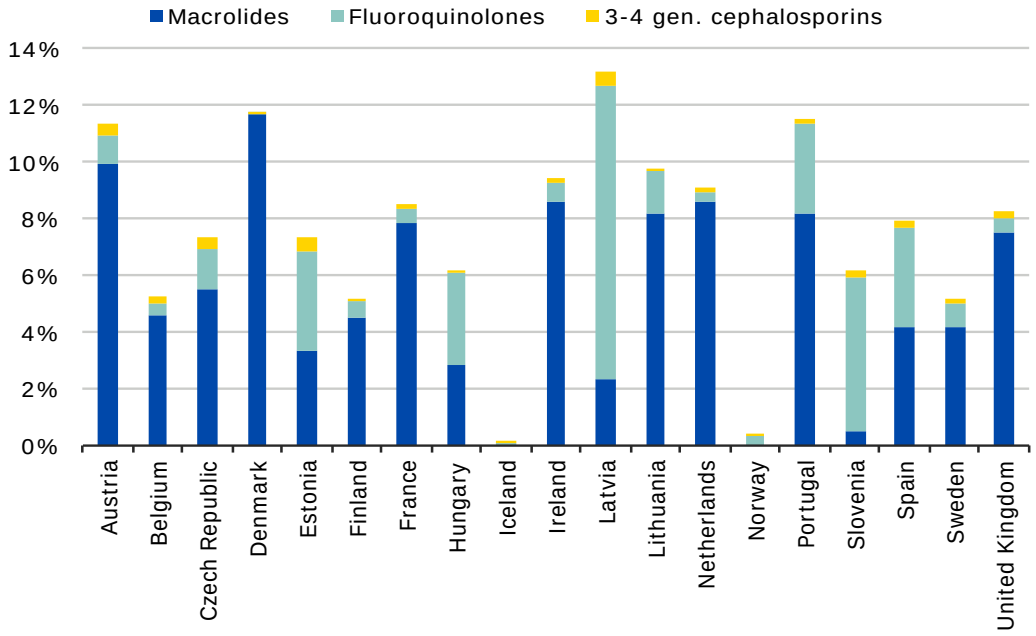
* Amphenicols, cephalosporins, other quinolones and other antibacterials (classified as such in the ATCvet system).

Figure 9. 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



Overall in the 19 countries, the sales of the antimicrobial classes defined as the most critically important in human medicine — i.e. 3rd- and 4th-generation cephalosporins, fluoroquinolones and macrolides — accounted for 0.2%, 2.2% and 5.7%, respectively, of the total sales of antimicrobial VMPs. The proportion accounted for by these antimicrobial classes in the different countries ranged from 0.02% to 0.54%, 0.01% to 10.3% and 0% to 11.7%, respectively (Figure 10).

Figure 10. Percentages of the sales of macrolides, fluoroquinolones and 3rd- and 4th-generation cephalosporins for food-producing species, including horses, in mg/PCU, by country, for 2010



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

The distribution of sales, in mg/PCU, of the various antimicrobial classes by pharmaceutical form varied considerably between the 19 countries and the classes of antimicrobial agents.

Overall for the 19 countries, 61% of the tetracyclines were sold (tonnes) as premixes, 32% as oral powders, 4% as oral solutions and 2% as injections, while 0.3% were for local treatment (intrauterine preparations).

For penicillins, oral powders accounted for 51%, premixes for 22%, injections for 21%, oral solutions for 3% and intramammary preparations for 3% of the total sales (tonnes) by the 19 countries; 0.4% (others) were bolus and uterine preparations.

Premixes accounted for 44%, oral powders for 39%, oral solutions for 12%, injections for 4% and oral pastes for 1% of the total sales (tonnes) of sulfonamides in the 19 countries.

Overall, injectable preparations accounted for 59% of the sales (tonnes) of 3rd- and 4th-generation cephalosporins, and intramammary preparations accounted for 41%.

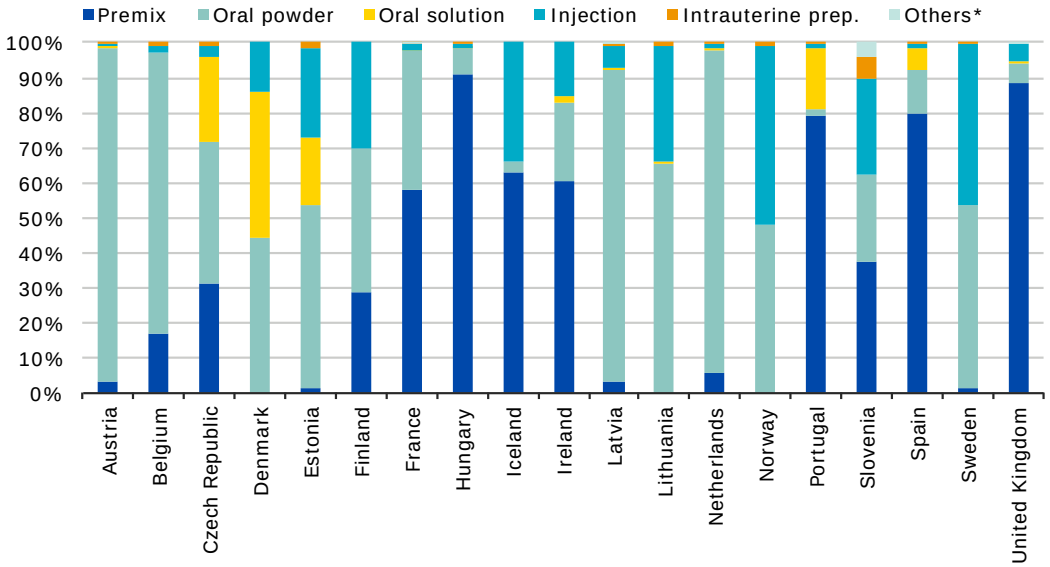
For fluoroquinolones, the most-selling pharmaceutical form in the 19 countries was oral solution (78.5%); the proportion accounted for by injections was 20.8%, while 0.6% were sold (tonnes) as oral pastes.

Premixes accounted for 45% of the total sales (tonnes) of macrolides in the 19 countries, oral powders for 36%, oral solutions for 11% and injectable preparations for 9%, respectively.

2.6.1. Tetracyclines

Figure 11. Spatial distribution of sales of tetracyclines for food-producing animals, in mg/PCU, in 19 countries, for 2010

Figure 12. Distribution of sales by pharmaceutical form for tetracyclines, in tonnes of active ingredient, by country, for 2010



* Bolus, intramammary preparations and oral pastes.

2.6.2. Amphenicols

Figure 13. Spatial distribution of sales of amphenicols, in mg/PCU, in 19 EU/EEA countries, for 2010

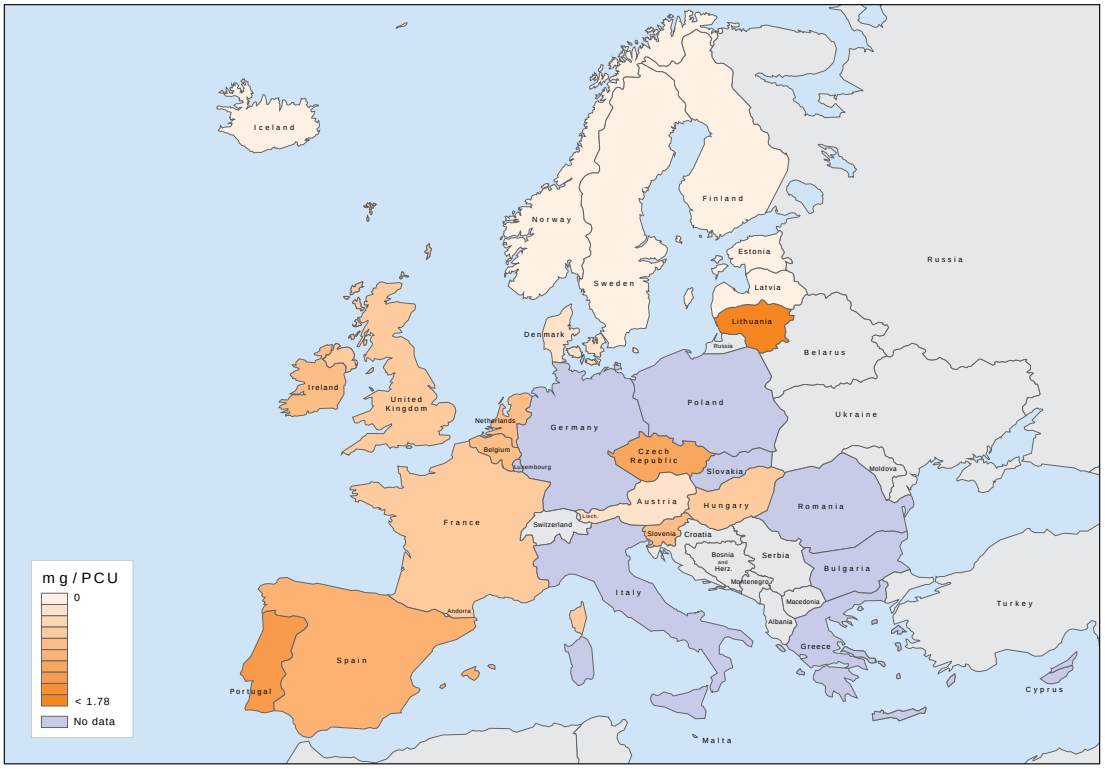
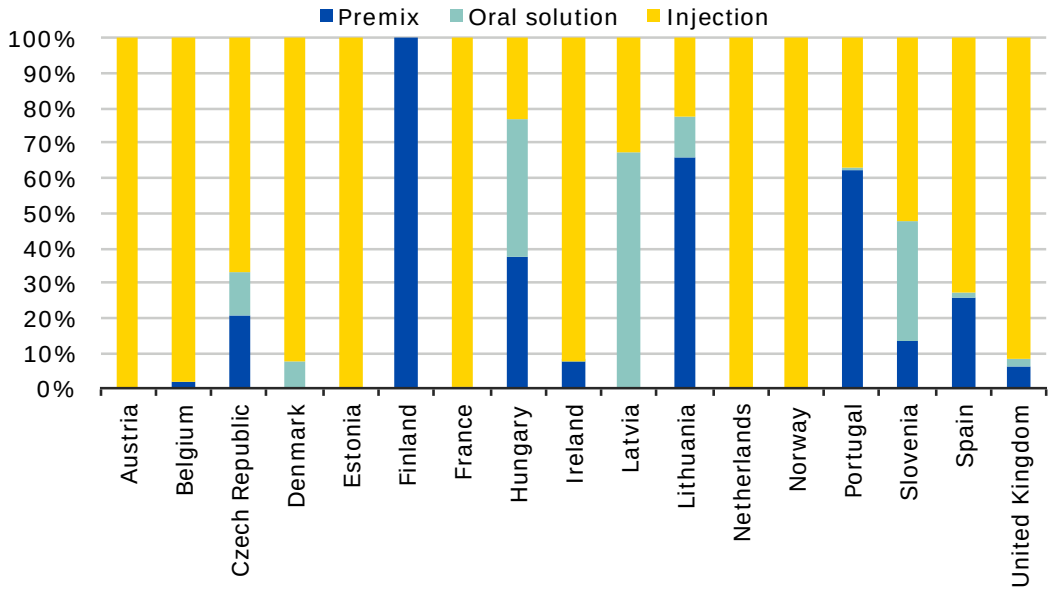


Figure 14. Distribution of sales by pharmaceutical form for amphenicols, in tonnes of active ingredient, by country, for 2010[1]

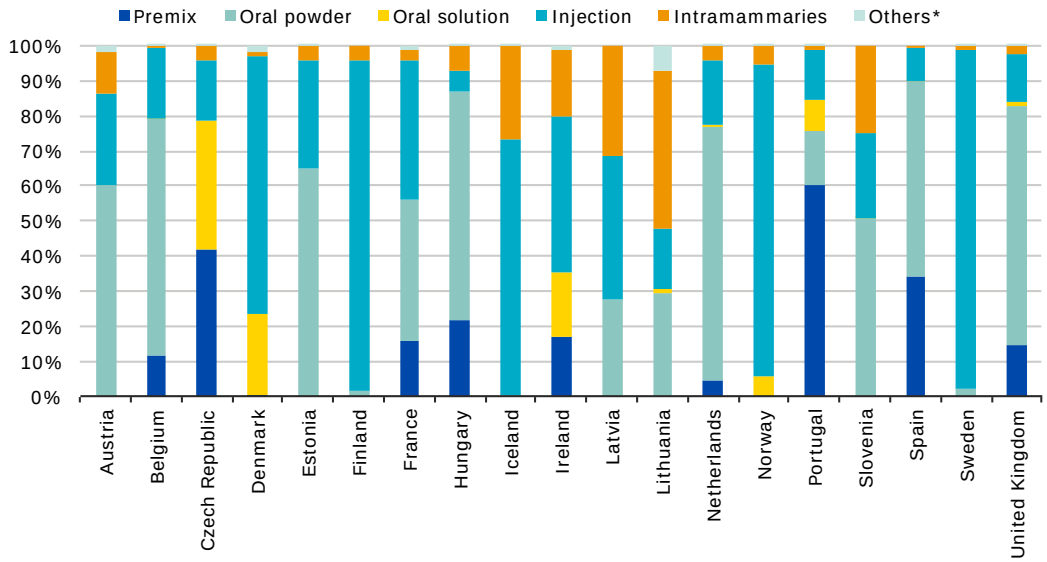


[1] No sales in Iceland or Sweden.

2.6.3. Penicillins

Figure 15. Spatial distribution of sales of penicillins for food-producing animals, in mg/PCU, in 19 EU/EEA countries, for 2010

Figure 16. Distribution of sales by pharmaceutical form for penicillins, in tonnes of active ingredient, by country, for 2010

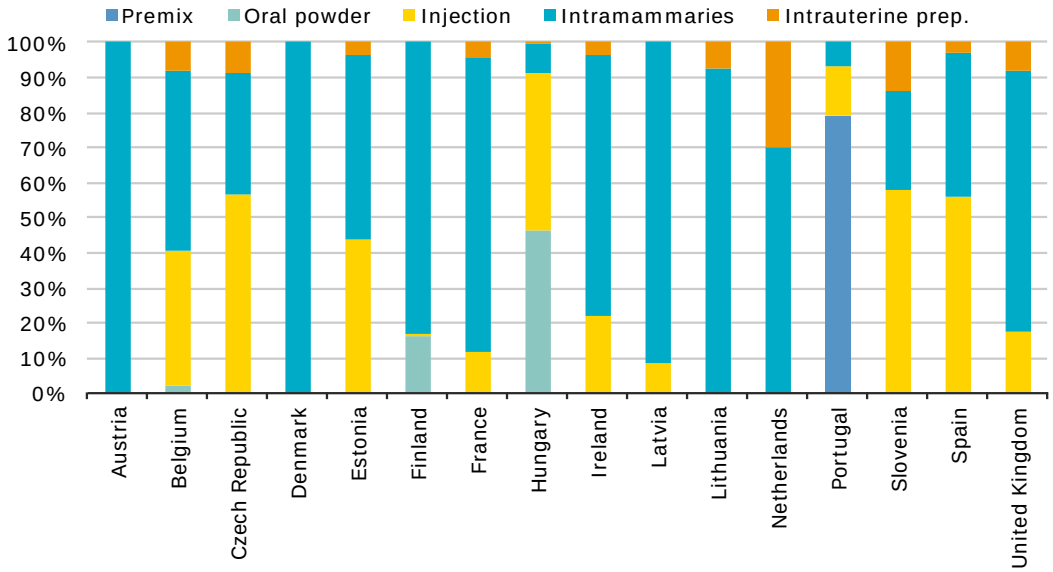


* Bolus, intrauterine preparations and oral pastes.

2.6.4. 1st- and 2nd-generation cephalosporins

Figure 17. Spatial distribution of sales of 1st- and 2nd-generation cephalosporins, in mg/PCU, in 19 EU/EEA countries, for 2010

Figure 18. Distribution of sales by pharmaceutical form for 1st- and 2nd-generation cephalosporins, in tonnes of active ingredient, by country, for 2010[1,2]

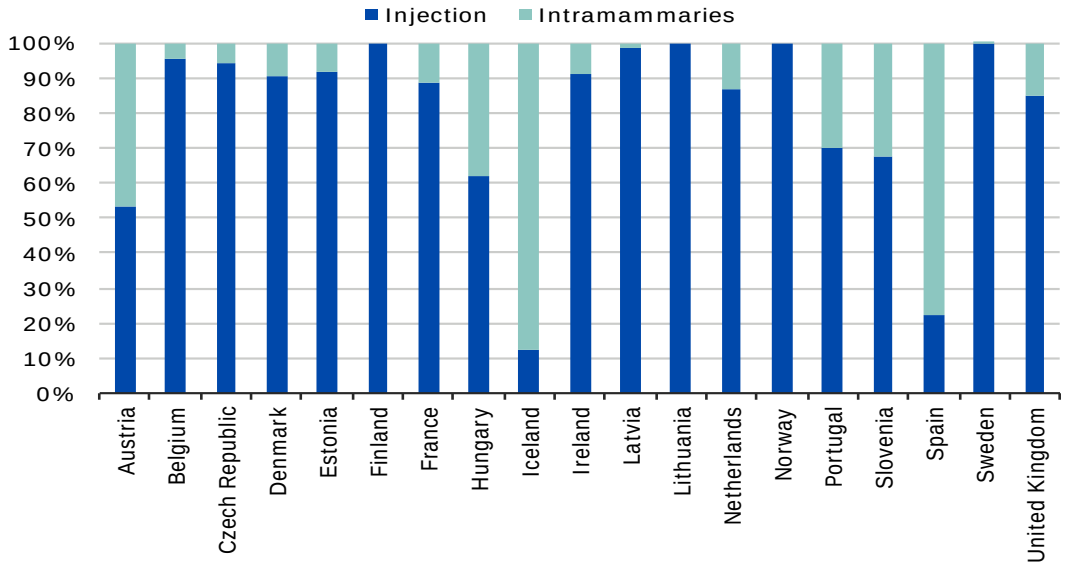


[1] No sales in Iceland, Norway or Sweden. [2] Negligible amounts of oral pastes and oral solutions sold.

2.6.5. 3rd- and 4th-generation cephalosporins

Figure 19. Spatial distribution of sales of 3rd- and 4th-generation cephalosporins, in mg/PCU, in 19 EU/EEA countries, for 2010

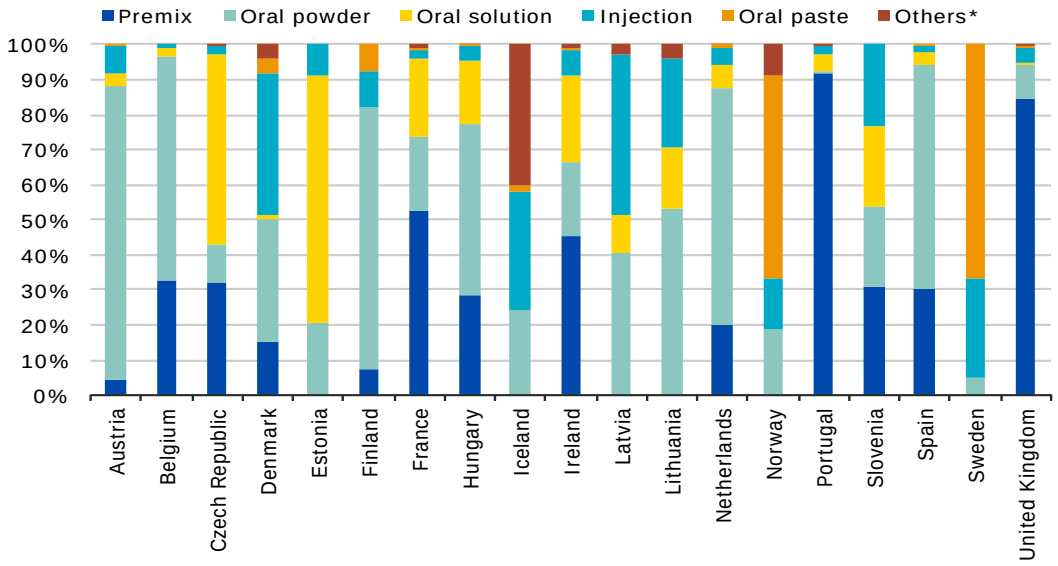
Figure 20. Distribution of sales by pharmaceutical form for 3rd- and 4th-generation cephalosporins, in tonnes of active ingredient, by country, for 2010



2.6.6. Sulfonamides

Figure 21. Spatial distribution of sales of sulfonamides, in mg/PCU, in 19 EU/EEA countries, for 2010

Figure 22. Distribution of sales by pharmaceutical form for sulfonamides, in tonnes of active ingredient, by country, for 2010

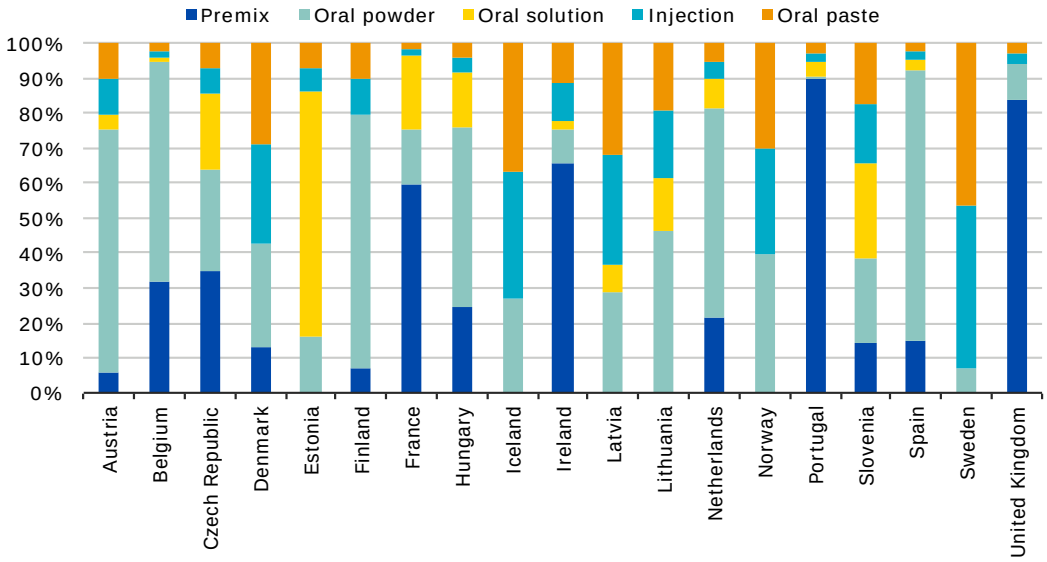


* Bolus, intramammaries and intrauterine preparations.

2.6.7. Trimethoprim

Figure 23. Spatial distribution of sales of trimethoprim, in mg/PCU, in 19 EU/EEA countries, for 2010

Figure 24. Distribution of sales by pharmaceutical form for trimethoprim, in tonnes of active ingredient, by country, for 2010[1]

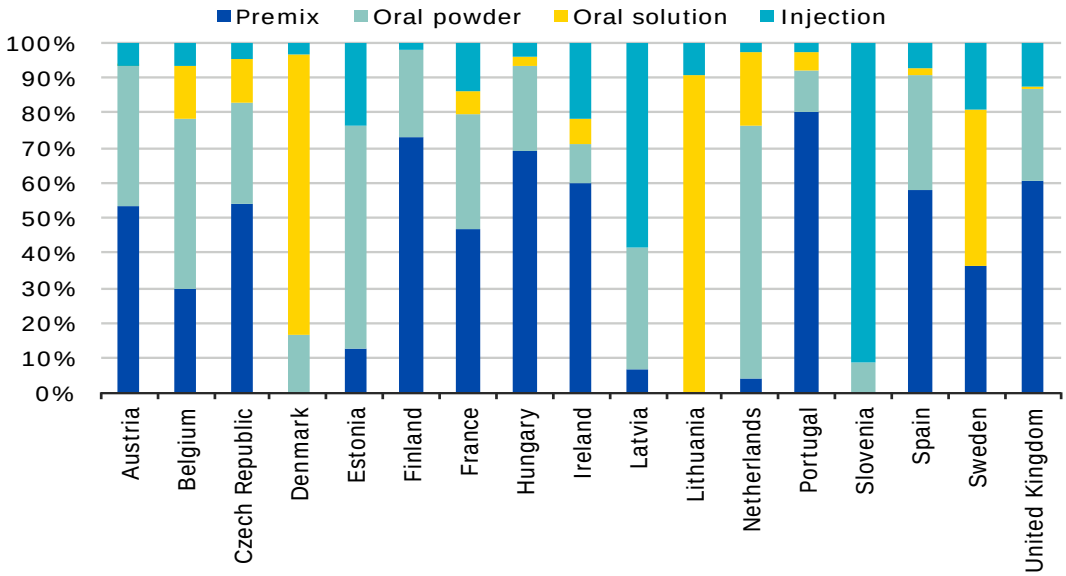


[1] Negligible amounts sold as intramammaries and bolus not included in figure.

2.6.8. Macrolides

Figure 25. Spatial distribution of sales of macrolides, in mg/PCU, in 19 EU/EEA countries, for 2010

Figure 26. Distribution of sales by pharmaceutical form for macrolides, in tonnes of active ingredient, by country, for 2010[1,2]

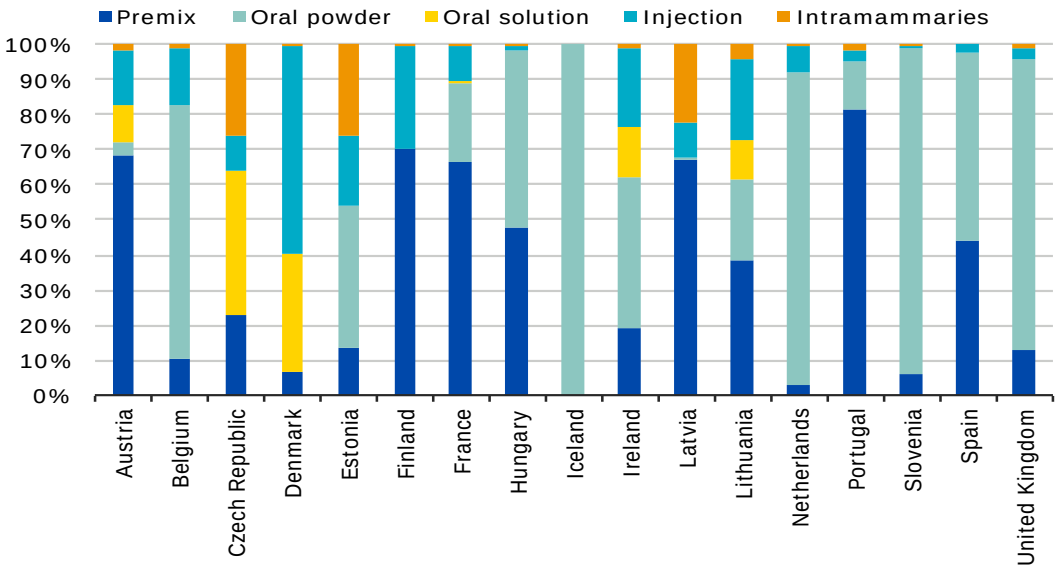


[1] No sales in Iceland or Norway. [2] Negligible amounts sold as intramammaries not included in figure.

2.6.9. Lincosamides

Figure 27. Spatial distribution of sales of lincosamides, in mg/PCU, in 19 EU/EEA countries, for 2010

Figure 28. Distribution of sales by pharmaceutical form for lincosamides, in tonnes of active ingredient, by country, for 2010[1]

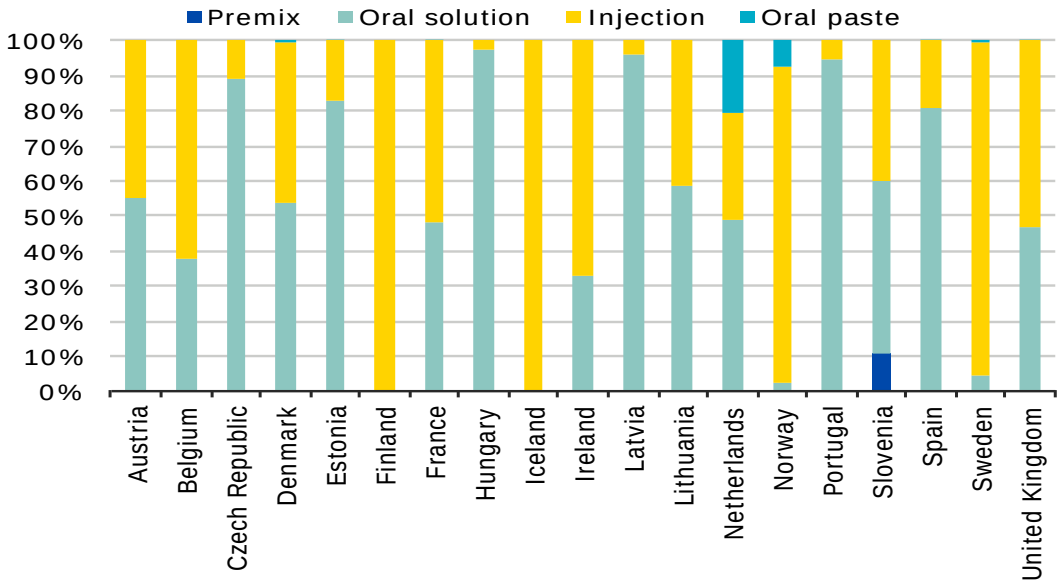


[1] No sales in Norway or Sweden.

2.6.10. Fluoroquinolones

Figure 29. Spatial distribution of sales of fluoroquinolones, in mg/PCU, in 19 EU/EEA countries, for 2010

Figure 30. Distribution of sales by pharmaceutical form for fluoroquinolones, in tonnes of active ingredient, by country, for 2010[1]

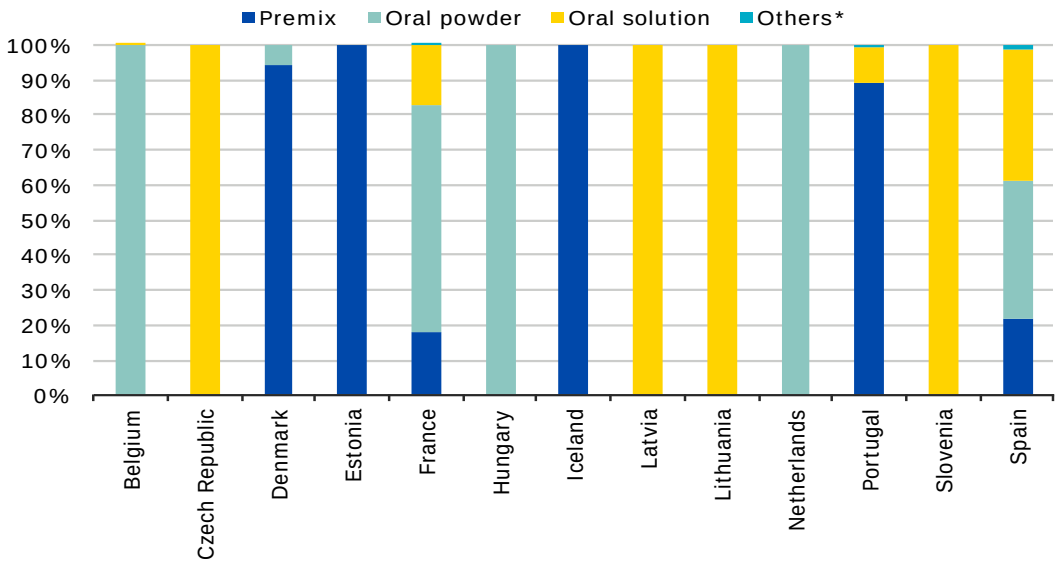


[1] Negligible amounts sold as oral powders not included in figure.

2.6.11. Other quinolones

Figure 31. Spatial distribution of sales of other quinolones, in mg/PCU, in 19 EU/EEA countries, for 2010

Figure 32. Distribution of sales by pharmaceutical form for other quinolones, in tonnes of active ingredient, by country, for 2010[1]



[1] No sales in Austria, Finland, Ireland, Norway, Sweden or the United Kingdom. * Bolus, injections and oral pastes.

2.6.12. Aminoglycosides

Figure 33. Spatial distribution of sales of aminoglycosides, in mg/PCU, in 19 EU/EEA countries, for 2010

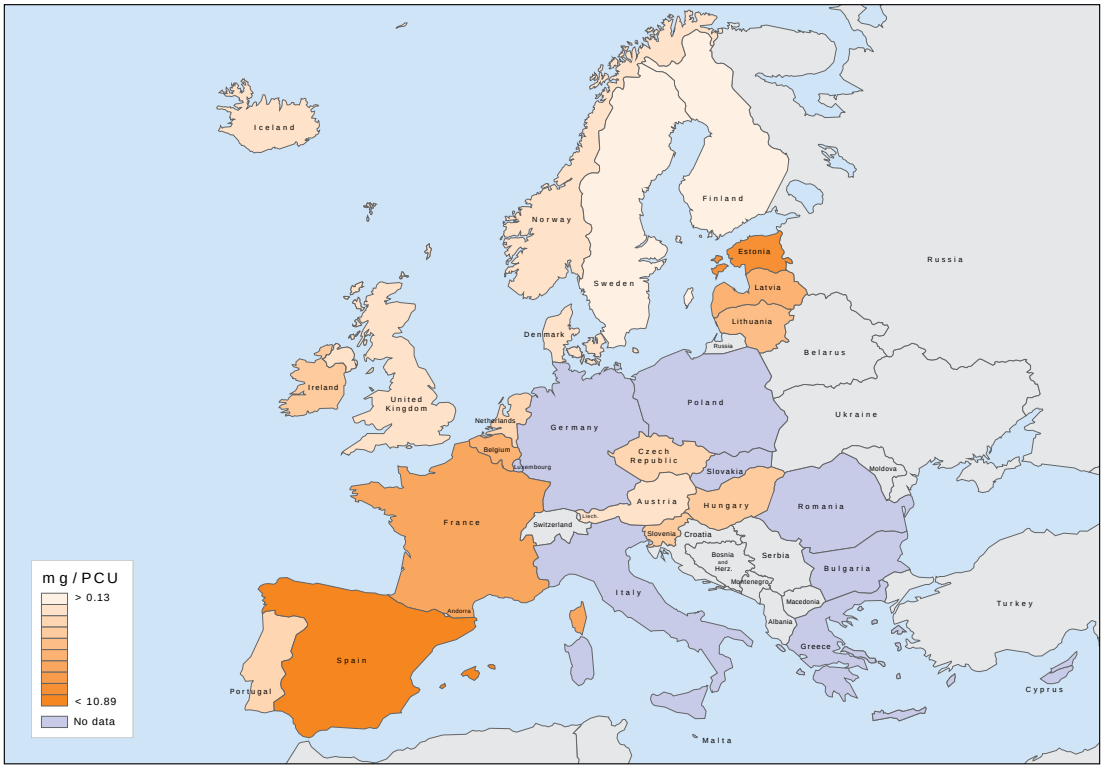
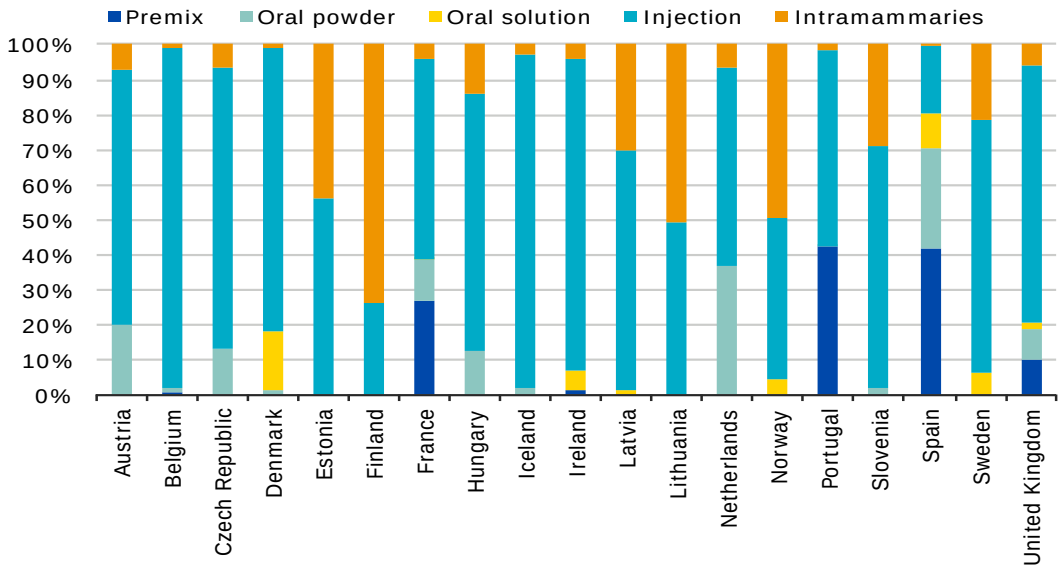


Figure 34. Distribution of sales by pharmaceutical form for aminoglycosides, in tonnes of active ingredient, by country, for 2010[1]

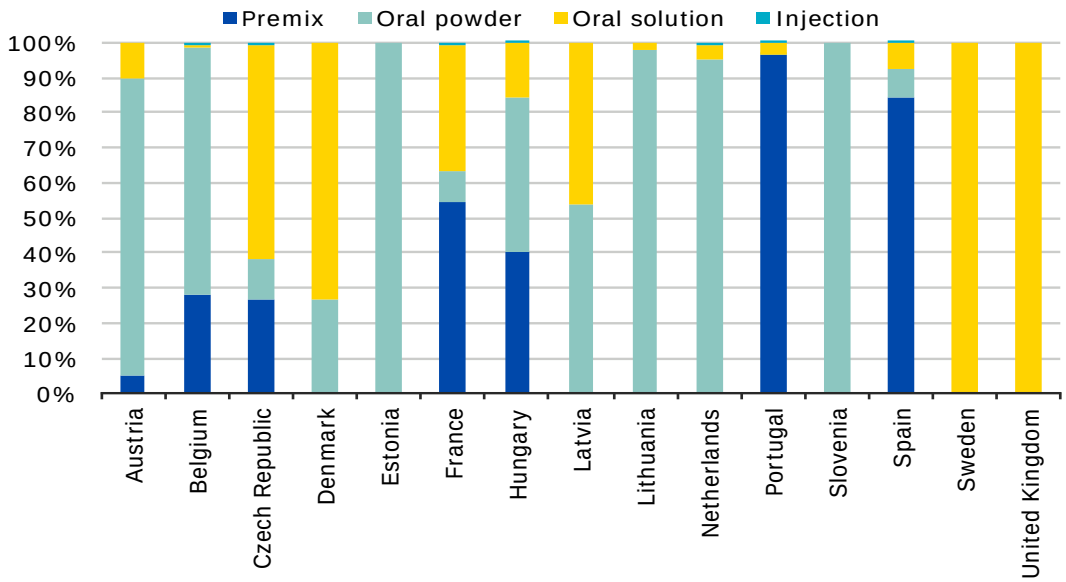


[1] Negligible amounts were sold as intrauterine preparations in some countries.

2.6.13. Polymyxins

Figure 35. Spatial distribution of sales of polymyxins, in mg/PCU, in 19 EU/EEA countries, for 2010

Figure 36. Distribution of sales by pharmaceutical form for polymyxins, in tonnes of active ingredient, by country, for 2010[1,2]

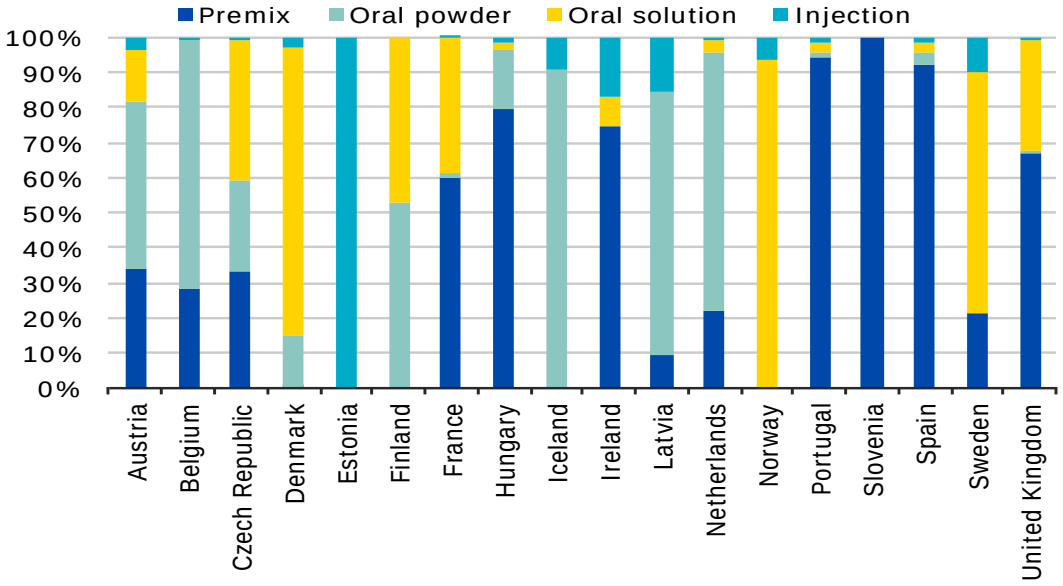


[1] No sales in Finland, Iceland, Ireland or Norway. [2] Negligible amounts sold as bolus, oral pastes, intramammary and intrauterine preparations.

2.6.14. Pleuromutilins

Figure 37. Spatial distribution of sales of pleuromutilins, in mg/PCU, in 19 EU/EEA countries, for 2010

Figure 38. Distribution of sales by pharmaceutical form for pleuromutilins, in tonnes of active ingredient, by country, for 2010[1]



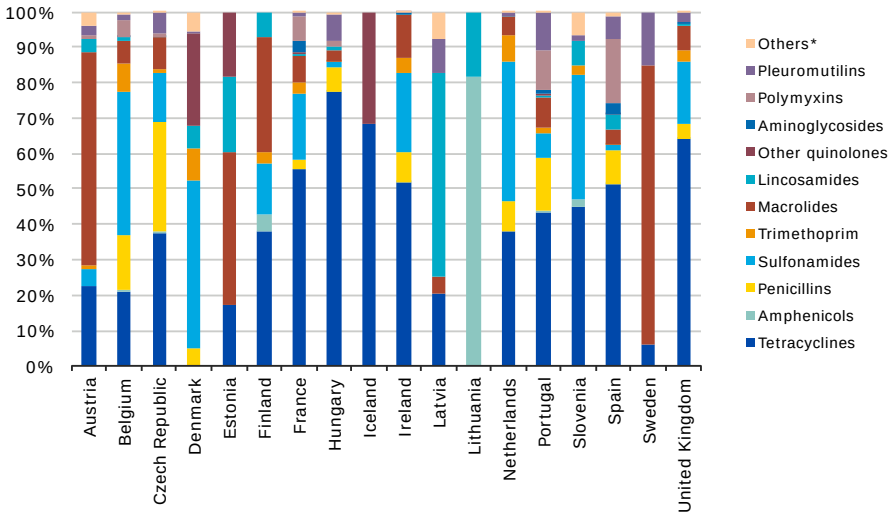
[1] No sales in Lithuania.

2.7. Sales for food-producing animals, including horses, of the major pharmaceutical forms by antimicrobial class

The major antimicrobial classes sold, in tonnes, were for premixes (49%), oral powders (34%), oral solutions (8%) and injectable preparations (9%).

In total for the 19 countries, 55% of the sales of premixes in 2010 were for tetracyclines, 10% for penicillins, 10% for sulfonamides, 7% for polymyxins, 6% for macrolides and 6% for pleuromutilins (Figure 39).

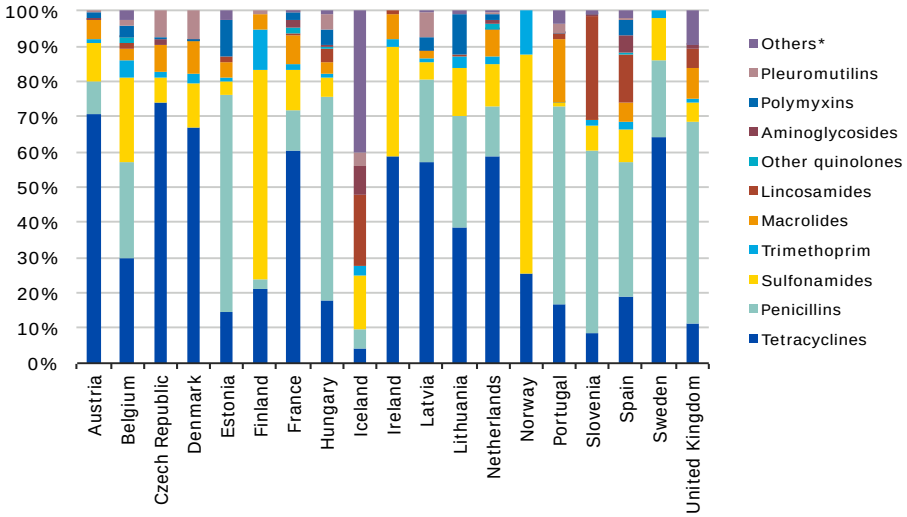
Figure 39. Distribution of sales of premixes, in mg/PCU, by the various veterinary antimicrobial classes (according to ATCvet system), by country[1], for 2010



[1] No sales in Norway. * Bacitracin and spectinomycin (classified as 'Other antibacterials' in the ATCvet system).

The major antimicrobial classes sold as oral powders in total by the 19 countries (Figure 40) in 2010 were tetracyclines (40%), penicillins (28%), sulfonamides (13%) and macrolides (5%).

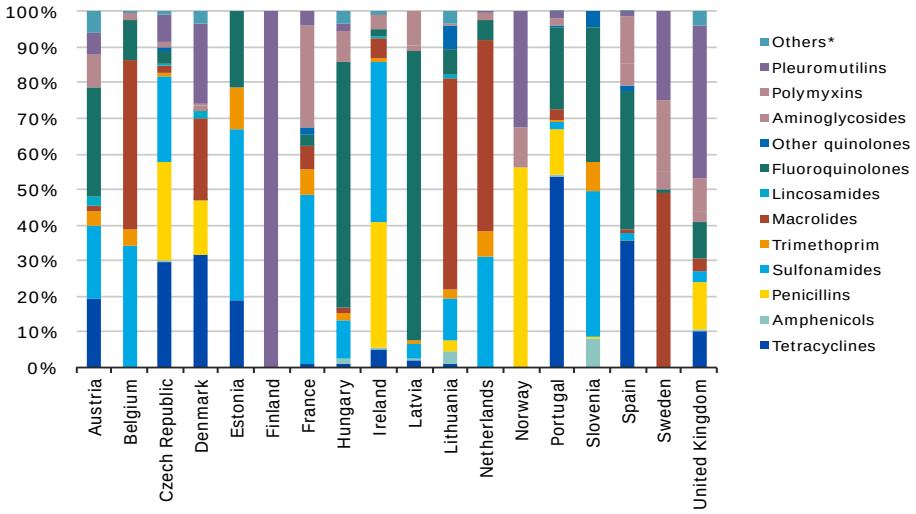
Figure 40. Distribution of sales of oral powders, in mg/PCU, by the various veterinary antimicrobial classes (according to ATCvet system), by country[1], for 2010



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

The major antimicrobial classes sold, expressed in mg/PCU, as oral solutions (Figure 41) by the 19 countries were tetracyclines (24%), fluoroquinolones (20%), sulfonamides (17%), penicillins (11%), macrolides (10%), polymyxins (6%) and pleuromutilins (6%).

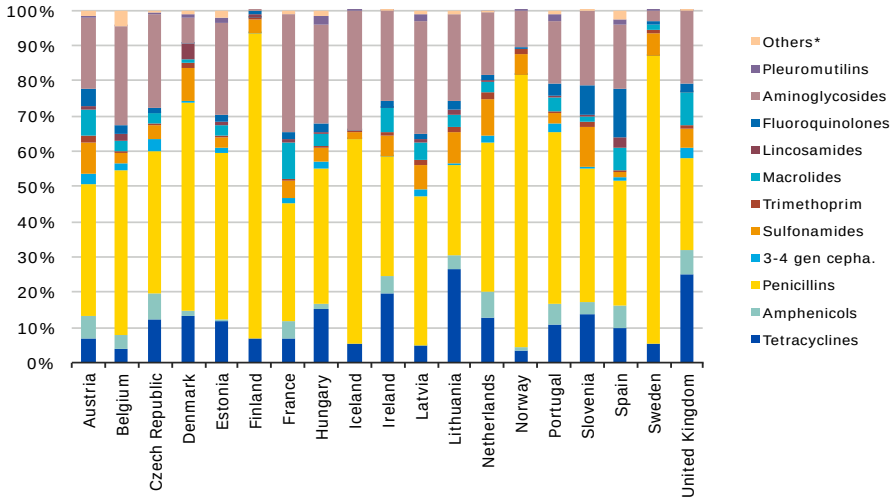
Figure 41. Distribution of sales of oral solutions, in mg/PCU, by the various veterinary antimicrobial classes (according to ATCvet system), by country[1], for 2010



[1] No sales in Iceland. * Spectinomycin (classified as 'Other antibacterials' in the ATCvet system).

Overall, the major antimicrobial classes sold, expressed as mg/PCU, as injectable preparations (Figure 42) by the 19 countries in 2010 were penicillins (47%), aminoglycosides (21%), tetracyclines (11%), sulfonamides (5%) and macrolides (4%).

Figure 42. Distribution of sales of injectable preparations, mg/PCU, by the various veterinary antimicrobial classes (according to ATCvet system), by country[1], for 2010



[1] Negligible amounts of 1st- and 2nd-generation cephalosporins, other quinolones and polymyxins not in figure. * Paromycin and spectinomycin (classified as 'Other antibacterials' in the ATCvet system).

2.8. Combination-product presentations of veterinary antimicrobial agents

Of the total number of product presentations (n=5,915) — i.e. product name, form, strength and pack size (tablets excluded) — 79.2% (n=4,693) contained only one active ingredient, 19.4% (n=1,149) contained two active ingredients, 1.2% contained three active ingredients (n=73) and 0.2% (n=12) contained four active ingredients (Table 7).

Of the total sales of premixes in the 19 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 (Figure 43). For oral powders, the corresponding figures were 83.5%, 16.3% and 0.15%, respectively, and for oral solutions these were 84.6%, 15.3% and 0.09%.

Sales of products with three active ingredients were almost solely accounted for by 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], respectively, by country, for 2010 (tablets are excluded from the data)

Country	1 ingredient	2 ingredients	3 ingredients	Total number
Austria	250	58	7	315
Belgium	269	48	2	319
Czech Republic	524	103	8	635
Denmark	211	59	6	276
Estonia	103	31	3	137
Finland	92	26	0	118
France	603	207	4	814
Hungary	281	60	4	345
Iceland	25	9	1	35
Ireland	357	69	3	429
Latvia	160	54	10	224
Lithuania	109	34	5	148
Netherlands	246	65	3	314
Norway	42	17	1	60
Portugal	321	84	6	411
Slovenia	104	36	3	143
Spain	588	99	3	690
Sweden	80	27	0	107
United Kingdom	328	63	4	395
Total 19 countries	**4,693**	**1,149**	**73**	**5,915**

[1] Twelve products contained 4 active ingredients, accounting for total sales of 0.007 tonnes in the 19 countries.

Figure 43. Percentage of sales, in tonnes of active ingredient, of the various pharmaceutical forms of veterinary antimicrobial agents containing 1, 2, 3 and 4 active ingredients, respectively (tablets are excluded from the data)

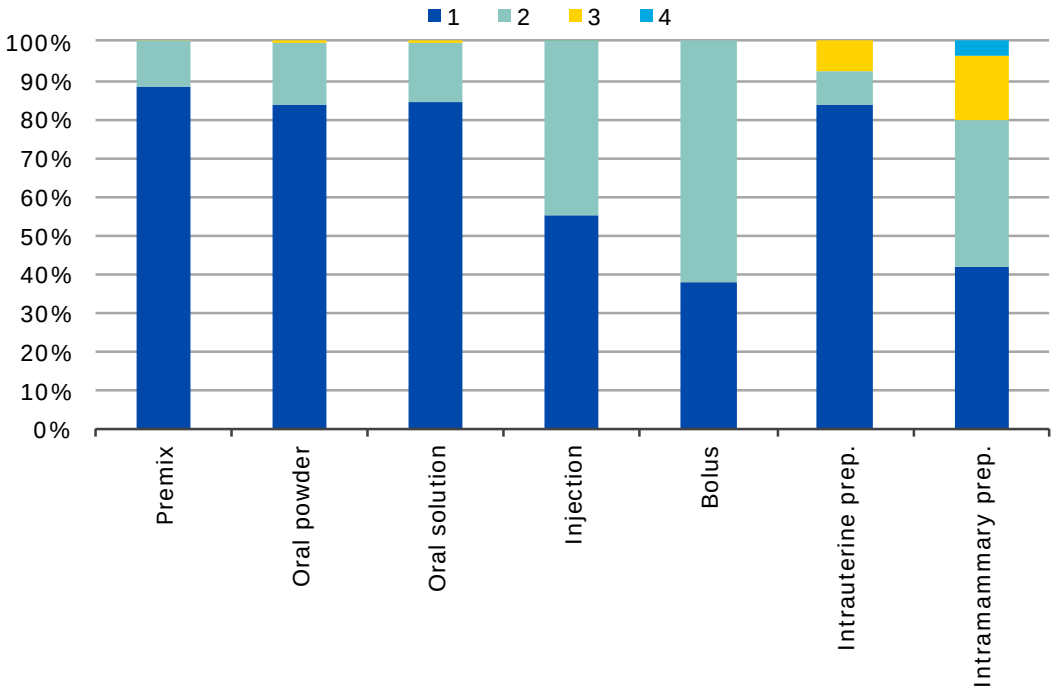


Table 8. Number of product presentations (product name, form, strength and pack size) of premixes, oral powders and oral solutions containing 1, 2 and 3 active ingredients, by country, for 2010

Country	1 ingredient	2 ingredients	3 ingredients	Total number
Austria	123	28	6	157
Belgium	105	20	0	125
Czech Republic	294	52	3	349
Denmark	85	13	1	99
Estonia	26	4	0	30
Finland	27	4	0	31
France	359	105	0	464
Hungary	174	25	0	199
Iceland	7	2	0	9
Ireland	155	17	0	172
Latvia	57	9	0	66
Lithuania	46	6	0	52
Netherlands	102	26	0	128
Norway	7	1	0	8
Portugal	133	26	1	160
Slovenia	31	17	1	49
Spain	330	23	0	353
Sweden	20	2	0	22
United Kingdom	130	21	0	151
Total 19 countries	**2,211**	**401**	**12**	**2,624**

Table 9. Sales, in tonnes of active ingredient, of antimicrobial VMPs as premixes, oral powders and oral solutions containing 1, 2 and 3 active ingredients, by country, for 2010

Country	1 ingredient	2 ingredients	3 ingredients	Tonnes (premixes, oral powders and oral solutions)
Austria	47	7	2.34	56
Belgium	171	92		263
Czech Republic	50	11	0.34	62
Denmark	68	9	0.0002	77
Estonia	4	1		5
Finland	2	3		5
France	710	170		881
Hungary	172	22		195
Iceland	0.1	0.04		0.9
Ireland	48	14		62
Latvia	3	1		3
Lithuania	6	1		8
Netherlands	351	73		424
Norway1	0.4	0.3		1
Portugal	153	13	0.001	166
Slovenia	3	2	0.23	5
Spain	1,575	78		1,653
Sweden[1]	2			2
United Kingdom	320	85		405
Total 19 countries	**3,685**	**581**	**3**	**4,270**

[1] Sales for farmed fish not included.

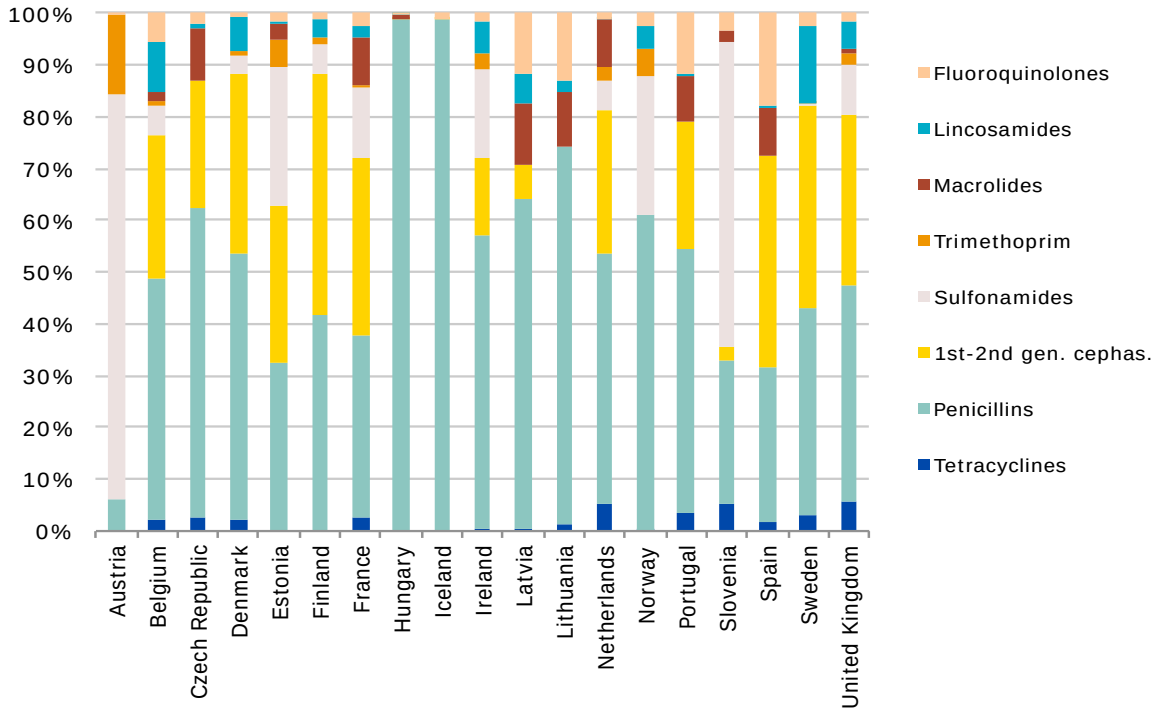
2.9. Sales of tablets by veterinary antimicrobial class for companion animals

Figure 44 shows the distribution of sales of tablets, in tonnes of active ingredient, by veterinary antimicrobial class and country for 2010. 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 19 countries, 44% of the sales of tablets (in tonnes) were for penicillins, 30% for 1st- and 2nd-generation cephalosporins, 10% for sulfonamides, 5% for macrolides, 4% for lincosamides, 3% for fluoroquinolones and tetracyclines, and 1% for trimethoprim.

Antimicrobial products marketed for human use are also used in companion animals (in application of the 'cascade' (Arts. 10 & 11 of Directive 2001/82/EC of the European Parliament and of the Council). Such sales are then included in the sales data for human antimicrobial agents (ESAC-net data), if based on the sales of e.g. the wholesalers and not based on the prescriptions of the physicians. In the current report, 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 in Figure 44 do not give a complete picture of the sales/usage patterns of antimicrobial agents in companion animals for 2010.

Figure 44. Distribution of sales of tablets, in tonnes of active ingredient, by antimicrobial class (reported according to the ATCvet hierarchical system), by country, for 2010[1,2]



[1] Minor amounts of aminoglycosides, amphenicols, other quinolones, imidazole derivatives and other antibacterials (classified as such in the ATCvet system) sold not included in figures. [2] For the United Kingdom, minor sales of macrolides have not been included in figure for confidentiality reasons.

2.10. Sales in 8 countries for the period 2005-2010

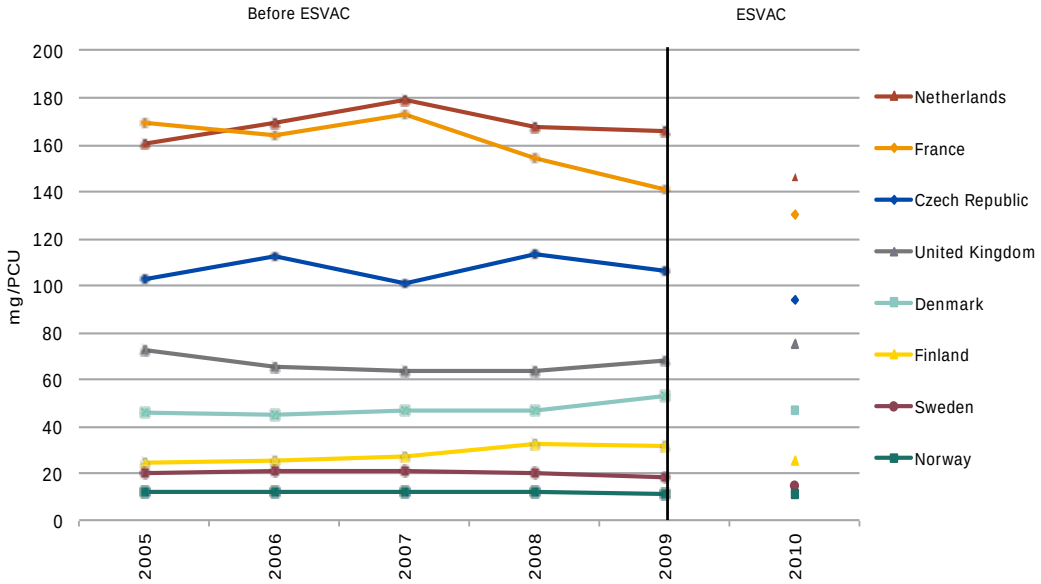
The sales, expressed in mg per population correction unit (mg/PCU), of veterinary antimicrobial agents by country before and after the 2010 ESVAC protocol and data collection form were implemented are shown in Figure 45.

Several of the countries had to change their reporting methods for the 2010 data to meet the ESVAC requirement for harmonisation of the data across the EU. Most importantly, for Denmark and Finland, penicillin prodrugs (e.g. benzylpenicillin procaine) were reported as such for the period 2005-2009, while for 2010 such drugs were reported as active ingredient (benzylpenicillin), resulting in a lower value, in weight of substance, compared to if the data had been reported as prodrugs. Furthermore, for Denmark, some active ingredients were reported as base for 2005-2009 while as salt for the 2010 data, and since the weight of the salt is higher than that of the base, this resulted in a higher value compared to when using the previous method of reporting. The Czech Republic system of reporting also differs (salts vs. bases, drugs vs. prodrugs, conversion factors for colistin, inclusion of sensory organ VMPs), and the dataset for 2010 was processed both by use of the national reporting system and of the ESVAC system. Also (especially in some groups, such as tetracyclines, penicillins, pleuromutilins and polymyxins), differences were identified that led to difficulties in expressing the long-term trends. Finally, sales of tablets (companion animals) are excluded from the 2010 data, while this administration form was included for the years 2005-2009. For countries like Finland, Norway and Sweden (Table 4), where the sales of tablets are 10-15% of the total, this difference in presentation of data will result in a noticeably lower value of the mg/PCU.

Therefore, some of the observed changes in the sales data from 2009 to 2010 for some of these countries may not be due to changes in sales of antimicrobial agents, but to changes in the coverage and reporting system. In conclusion, the sales data for the period 2005-2009 obtained before the ESVAC protocol and reporting were implemented and those obtained afterwards (2010) cannot be used directly to evaluate development in the trends in the sales from 2009 to 2010. However, the patterns observed in terms of monitoring countries according to mg/PCU remained largely consistent with those seen over the period 2005-2009.

Detailed information on the sales in the 8 countries is available from the national reports in Annex 4.

Figure 45. Sales, expressed in mg per population correction unit (mg/PCU), of veterinary antimicrobial agents[1]



[1] Data for number of slaughter pigs were updated for the PCU for Norway for 2005-2009, due to errors in the original data. Sales data for 2005-2009 were obtained before the ESVAC protocol and harmonised collection of data were implemented. Data for 2010 should not be used to evaluate development in the sales from 2009 to 2010.

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 (see references to national reports in Annex 4).

Dermatological preparations (ATCvet group QD) and preparations for sensory organs (ATCvet group QS) (Table 3) were not included in the material. 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. 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 minimal. Also, in some countries veterinary antimicrobials obtained on special licence (exemption from marketing authorisation) are included in the material, while not in others. Overall, the impact of these deviations is considered of low importance and does not influence the general results. Furthermore, sales for fish are not included in the data for Norway and Sweden (see Annex 3), leading to an overestimate of the sales expressed as mg/PCU for these countries.

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 antimicrobials that are used according to the cascade could account for a higher proportion than for 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 have to be interpreted with care as they only represent sales of tablets.

The national sales data (nominator) cover all food-producing species, including horses, which are considered as food-producing species according to the 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 and goats 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 by 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. 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. 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. The data in this report cover all food-producing animals, and since the dosing varies between the species, 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 individual and herd treatment for oral solutions and powder forms. However, during the analysis of the 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. The data have therefore been aggregated to express oral solutions and oral powders, respectively. Since the proportion of sales of oral powders and oral solutions for individual treatment is relatively low, compared to the sales for herd treatment, the reported sales of oral powders and oral solutions are thought to be used mainly for herd treatment of food-producing animals.

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

3.2. Results

An apparent 30-fold difference in sales, in 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; a high proportion of veal calves within the cattle population) in the various countries; there may also be considerable variation in terms of dosage between the various antimicrobial agents, length of treatment periods and formulation of the various antimicrobial agents used. Although these factors can to some extent explain the observed differences in the sales between the 19 countries, other factors also need to be considered.

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 3rd- and 4th-generation cephalosporins, fluoroquinolones and macrolides were observed; such sales ranged from 0.02% to 0.54%, 0.01% to 10.3% and 0% to 11.7%, respectively. Some of these variations 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 prudent-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 mainly in food-producing animals and of those used in companion animals (tablets) were observed. However, it has to be noted that human antimicrobial agents and injectable veterinary 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 19 EU/EEA countries were mainly accounted for by pharmaceutical forms for herd treatment (premixes, oral powder and oral solution); however, this varies noticeably between the countries.

Of the total numbers of product presentations (tablets excluded), 79.2% contained only one active ingredient, 19.4% contained two active ingredients, 1.2% contained three active ingredients and 0.2% contained four active ingredients (only intramammaries). Overall, the proportion of the sales of antimicrobial VMPs applicable for herd treatment containing more than one active ingredient is relatively low. Of the total sales of premixes in the 19 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%, respectively, 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 herd treatment through feed or drinking water with two or more active ingredients.

4. Concluding remarks

In the current report, the overall sales of veterinary antimicrobial classes and pharmaceutical forms for 19 EU/EEA countries are documented. The next step is to collect overall sales data from all the EU/EEA countries. It is recognised that the PCU (denominator) used may not be optimal, and may therefore need to be refined in the future. Furthermore, data should be collected by animal species, production category and age class, and these should be reported by taking into account the differences in dosing between the various antimicrobial veterinary medicinal products.

Annex 1. Tables

Table A1. Distribution of sales, in tonnes of active ingredient, of veterinary antimicrobial agents used mainly for food-producing animals, including horses[1], by administration route/form and country, for 2010

Country	Premix	Oral powder	Oral solution	Injection	Oral paste	Bolus	Intramammary prep.	Intrauterine prep.	Total tonnes
Austria	9%	78%	1.7%	9%	0.1%		1.9%	0.3%	63
Belgium	20%	66%	1.4%	12%	0.01%	0.1%	0.3%	0.2%	299
Czech Republic	33%	22%	32%	11%	0.03%	0.1%	1.5%	0.5%	71
Denmark	2.5%	21%	41%	34%	0.9%	0.01%	0.3%	0.3%	119
Estonia	1.0%	47%	14%	29%			9%	0.4%	8
Finland	10%	26%	0.2%	59%	1.81%		2.8%		13
France	50%	31%	8%	10%	0.1%	0.3%	0.8%	0.2%	997
Hungary	65%	24%	4.6%	3.4%	0.01%		2.0%	0.2%	206
Iceland	10%	6%		67%	0.1%		15%	1.8%	0.9
Ireland	42%	14%	11%	28%	0.03%	0.6%	4.8%	0.02%	93
Latvia	3.6%	37%	12%	30%	0.005%		18%	0.2%	7
Lithuania	3.1%	32%	13%	23%			24%	5.0%	16
Netherlands	8%	81%	3.3%	7%	0.2%	0.01%	0.8%	0.1%	461
Norway[2]		8%	5.2%	58%	18%		9%	2.6%	6
Portugal	76%	5.4%	13%	5.4%	0.004%	0.0002%	0.4%	0.2%	176
Slovenia	12%	40%	7%	26%			14%	0.9%	8
Spain	62%	25%	7%	4.9%	0.01%		0.3%	0.1%	1,746
Sweden[2]	1.9%	7%	4%	74%	13%		1.1%	0.02%	13
United Kingdom	64%	23%	2%	10%	0.04%	0.2%	0.8%	0.01%	456
Total 19 countries	**49%**	**34%**	**8%**	**9%**	**0.1%**	**0.1%**	**0.9%**	**0.2%**	

[1] Injectable antimicrobial VMPs included are also used in companion animals. [2] Sales of antimicrobial VMPs for farmed fish not included in the sales data.

Table A2. Percentage of sales, in mg/PCU, of premixes, by veterinary antimicrobial class (according to ATCvet system), by country, for 2010[1,2]

Country	Tetracyclines	Amphenicols	Penicillins	Sulfonamides	Trimethoprim	Macrolides	Lincosamides	Other quinolones	Aminoglycosides	Polymyxins	Pleuromutilins	Others[3]	Total mg/PCU premixes
Austria	23%			5%	1%	60%	4%			1%	3%	4%	6
Belgium	21%	0.04%	16%	40%	8%	7%	1%		0.2%	5%	2%	1%	36
Czech Republic	37%	1%	31%	14%	1%	9%	0.2%			1%	6%	0.2%	31
Denmark			5%	47%	10%		6%	26%			1%	5%	1
Estonia	17%					43%	22%	18%					1
Finland	38%	5%		15%	3%	32%	7%						3
France	56%		3%	18%	3%	7%	1%	0.3%	3%	7%	1%	0.2%	66
Hungary	77%	0.1%	7%	1%	0.2%	3%	1%			2%	7%	1%	175
Iceland	68%							32%					1
Ireland	52%	0.2%	8%	22%	4%	12%	0.2%		0.3%		0.1%	0.2%	22
Latvia	21%					5%	58%				9%	8%	1
Lithuania		82%					18%						1
Netherlands	38%		9%	39%	8%	5%	0.1%				1%	0.1%	11
Portugal	43%	1%	15%	7%	1%	9%	1%	0.5%	1%	11%	10%	0.4%	125
Slovenia	45%	2%		35%	3%		7%				1%	7%	5
Spain	51%	0.2%	10%	2%	0.2%	4%	5%	0.1%	3%	18%	7%	1%	150
Sweden	6%					78%					15%		0.3
United Kingdom	64%	0.1%	4%	17%	3%	7%	0.3%		0.4%		3%	0.2%	48
Total 18 countries	**55%**	**0.4%**	**10%**	**10%**	**2%**	**6%**	**2%**	**0.02%**	**1%**	**7%**	**6%**	**1%**	

[1] No sales in Norway. [2] Negligible amounts of fluoroquinolones sold not included in the table. [3] Bacitracin and spectinomycin (classified as 'Other antibacterials' in the ATCvet system).

Table A3. Percentage of sales, in mg/PCU, of oral powders, by antimicrobial class (according to ATCvet system), by country, for 2010[1]

Country	Tetracyclines	Penicillins	Sulfonamides	Trimethoprim	Macrolides	Lincosamides	Other quinolones	Aminoglycosides	Polymyxins	Pleuromutilins	Others[2]	Total mg/PCU powders
Austria	71%	9%	11%	1%	5%	0.03%		1%	2%	0.4%	0.03%	49
Belgium	30%	28%	24%	5%	3%	2%	1%	0.1%	4%	1%	3%	120
Czech Republic	74%		8%	2%	7%			2%	0.5%	7%		20
Denmark	67%		13%	3%	9%		0.2%	0.2%	1%	8%		10
Estonia	15%	62%	4%	1%	4%	1%			10%		3%	32
Finland	21%	3%	59%	12%	4%					1%		6
France	61%	11%	12%	1%	8%	0.5%	2%	2%	2%	0.03%	1%	41
Hungary	18%	58%	5%	1%	3%	4%	0.5%	1%	5%	4%	1%	65
Iceland	4%	5%	15%	3%		20%		8%		4%	40%	0.5
Ireland	59%		31%	2%	7%	1%						7
Latvia	57%	23%	5%	1%	2%	0.04%			4%	7%	0.1%	15
Lithuania	38%	32%	13%	3%		1%			11%		1%	15
Netherlands	59%	14%	12%	2%	8%	0.3%	1%	1%	2%	0.4%	0.5%	118
Norway	26%		62%	12%								1
Portugal	17%	56%	1%	0.1%	18%	1%		0.03%	0.1%	3%	4%	9
Slovenia	8%	52%	7%	1%	0.1%	29%		0.4%	0.3%		1%	19
Spain	19%	38%	9%	2%	5%	14%	0.4%	5%	4%	1%	2%	61
Sweden	64%	22%	12%	2%								1
United Kingdom	12%	57%	6%	1%	9%	5%		1%		0.003%	10%	17
Total 19 countries	**40%**	**28%**	**13%**	**2%**	**5%**	**3%**	**1%**	**1%**	**3%**	**2%**	**1%**	

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

Table A4. Percentage of sales, in mg/PCU, of oral solutions, by antimicrobial class (according to ATCvet system), by country, for 2010[1]

Country	Tetracyclines	Amphenicols	Penicillins	Sulfonamides	Trimethoprim	Macrolides	Lincosamides	Fluoroquinolones	Other quinolones	Aminoglycosides	Polymyxins	Pleuromutilins	Others[2]	Total mg/PCU oral solutions
Austria	19%			20%	4%	1%	3%	31%			9%	6%	6%	1
Belgium			0.1%	34%	5%	48%		11%	0.1%		2%	0.03%	0.3%	3
Czech Republic	30%	0.4%	28%	24%	1%	2%	0.4%	4%	1%		2%	7%	1%	30
Denmark	32%	0.1%	15%	0.2%		23%	2%	0.01%		1%	1%	22%	4%	19
Estonia	19%			48%	12%			21%						9
Finland												100%		0.04
France	1%	0.02%		48%	7%	7%	0.1%	3%	2%	0.03%	29%	4%		10
Hungary	1%	2%		11%	2%	2%		69%			9%	2%	3%	12
Ireland	5%	0.03%	36%	45%	1%	6%	0.4%	2%		4%		0.03%	1%	6
Latvia	2%	0.3%		4%	1%			81%	0.02%	2%	9%			5
Lithuania	1%	4%	3%	12%	3%	59%	1%	7%	7%		1%		3%	6
Netherlands	0.05%		0.04%	31%	7%	54%		5%			2%	0.5%		5
Norway			56%							12%		33%		1
Portugal	54%	0.1%	13%	2%	0.4%	3%		23%	0.3%		2%	2%	0.1%	22
Slovenia		8%	0.2%	41%	8%			38%	4%					3
Spain	36%	0.1%	0.01%	2%	0.3%	1%		39%	1%	6%	13%	1%	0.01%	18
Sweden						49%		1%		5%	20%	25%		1
United Kingdom	10%	1%	13%	3%		4%		10%		3%	9%	43%	4%	1
Total 18 countries	**24%**	**1%**	**11%**	**17%**	**2%**	**10%**	**0.4%**	**20%**	**1%**	**1%**	**6%**	**6%**	**1%**	

[1] No sales in Iceland. [2] Spectinomycin (classified as 'Other antibacterials' in the ATCvet system).

Table A5. Percentage of sales, in mg/PCU, of injection preparations, by antimicrobial class (according to ATCvet system), by country, for 2010[1]

Country	Tetracyclines	Amphenicols	Penicillins	3-4 gen. cepha.	Sulfonamides	Trimethoprim	Macrolides	Lincosamides	Fluoroquinolones	Aminoglycosides	Pleuromutilins	Others[2]	Total mg/PCU
Austria	7%	7%	37%	3%	9%	2%	8%	1%	5%	20%	0.3%	2%	5
Belgium	4%	4%	47%	2%	3%	1%	3%	2%	2%	28%	0.1%	4%	21
Czech Republic	12%	7%	40%	4%	4%	1%	3%	0.3%	1%	26%	0.5%	1%	10
Denmark	13%	1%	59%	0.3%	9%	2%	1%	4%	0.01%	8%	1%	1%	16
Estonia	11%	1%	46%	2%	3%	1%	3%	1%	2%	26%	1%	2%	20
Finland	7%		87%	0.1%	4%	1%	0.2%	1%	1%	0.3%			15
France	7%	5%	33%	2%	5%	0.5%	10%	1%	2%	33%	0.02%	1%	14
Hungary	15%	1%	38%	2%	4%	1%	3%	1%	2%	27%	3%	1%	9
Iceland	5%		58%	0.02%	2%	0.4%			0.1%	34%	0.03%		5
Ireland	20%	5%	34%	0.3%	6%	1%	7%	0.3%	2%	26%	0.03%	0.1%	15
Latvia	5%	0.1%	42%	2%	7%	1%	5%	1%	1%	32%	2%	1%	12
Lithuania	27%	4%	26%	0.2%	9%	2%	3%	1%	3%	24%		1%	11
Netherlands	13%	7%	42%	2%	10%	2%	3%	0.3%	2%	18%	0.1%	1%	10
Norway	4%	1%	77%	0.03%	6%	1%			1%	10%	0.2%		6
Portugal	11%	6%	49%	2%	3%	1%	4%	0.4%	3%	18%	2%	1%	9
Slovenia	14%	3%	38%	1%	11%	1%	2%	0.2%	8%	21%		0.2%	12
Spain	10%	6%	35%	1%	2%	0.3%	6%	3%	14%	18%	1%	3%	12
Sweden	5%		82%	0.2%	6%	1%	1%		1%	3%	0.2%		11
United Kingdom	25%	7%	26%	3%	6%	1%	9%	0.4%	2%	20%	0.1%	0.1%	8
Total 19 countries	**11%**	**3%**	**47%**	**1%**	**5%**	**1%**	**4%**	**1%**	**3%**	**21%**	**1%**	**1.2%**	

[1] Negligible amounts of 1st- and 2nd-generation cephalosporins, other quinolones and polymyxins not included in 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 A6. Variables reported to ESVAC for each antimicrobial veterinary medicinal product

	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 mzulti-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 have to be given for these as well.

Table A7. Conversion factors used to convert from international units (IU) to weight (mg) of active ingredient based on WHO standards[1]

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

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

Table A8. 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
Penethamate hydriodide	0.63	Benzyl penicillin
Procaine benzylpenicillin	0.61	Benzyl penicillin

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

Annex 3. Legal framework, data sources and veterinary medicines distribution 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 and 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 (n=12) producing or importing VMPs and from wholesalers (n=6) that are assigned by the industry to distribute a product.

Belgium

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

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

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

Legal basis for the monitoring of sales

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

Data sources

To avoid double counting, all wholesaler-distributors (n=24) 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 (n=63) 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.

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 (n=76) and feed mills (n=79) licensed in the Czech Republic, and from one wholesaler from another Member State, that deliver VMPs directly to final customers (veterinarians, pharmacies or farmers) 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, 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, which 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 (n=14). 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 import of medicated feeds has 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 (n=5) 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 (n=1) and other importers (n=1).

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 (n=31) 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.

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 Minister of Agriculture and Rural Development on VMPs).

Data sources

Data were collected from marketing-authorisation holders (n=22), wholesalers in Hungary (n=54), wholesalers from other Member States that deliver VMPs directly to final Hungarian customers (n=2) and retailers that import directly from other Member States (n=1). These companies only submit data for those products which 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, and have to be dispensed to animal owners by veterinarians (or used by the veterinarians in their practices) or pharmacies, i.e. veterinarians are allowed to dispense VMPs in the same way as pharmacies. Veterinarians and pharmacies can only purchase VMPs from licensed wholesalers. No medicated feeds for livestock are produced in Iceland.

Legal basis for the monitoring of sales

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

Data sources

The data on sales of the included veterinary antimicrobial agents at package level were provided by wholesalers (n=2) 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 (n=49) 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 (Ireland is an island), this is not seen as a major route of supply into the country.

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 Assessment and Registration Agency. 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 (n=27) wholesalers in Latvia at package level by the Assessment and Registration Agency of the Food and Veterinary Service. The wholesalers are asked to report in detail which 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. All VMPs have to be dispensed to veterinarians or farmers through wholesalers or pharmacies. Medicated feed is also subject to prescription by veterinarians.

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 by the State Food and Veterinary Service of the Republic of Lithuania from wholesalers (n=21).

Netherlands

Distribution of veterinary medicines

In the Netherlands, antimicrobial VMPs are available on prescription only. Veterinarians purchase approximately 40% of their VMPs directly from the manufacturers and approximately 60% through wholesalers. About 98% of the total volume of antimicrobial VMPs are dispensed by marketing-authorisation holders that are either direct members (n=16) 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 market 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, 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, herd/flock treatment of livestock with antimicrobial agents is possible, again subject to veterinary prescription, through drinking water or as a 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 feeding stuffs, 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, which collects its data from authorised wholesalers (n=5). 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. Sales of antimicrobial agents for use in farmed fish in Norway amounted to only 0.65 tonnes of active ingredient, and the PCU for fish was 1,137 thousand tonnes — i.e. 2.2 times higher than the PCU for other food-producing animals. Sales for farmed fish were therefore not included in the data for Norway in the current report, to avoid skewed data for the mg/PCU for Norway (without fish the value is 11 mg/PCU, while by including fish in the sales data and in the denominator, this figure would have been only 3.6 mg/PCU).

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 dated 29 July 2009 (Art. 120) No 148 and amended and reprinted by law No 314 on 28 October 2009.

Data sources

Data were provided by wholesalers (n=75) that are authorised to sell veterinary medicinal products containing antibiotics.

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 the antimicrobial VMPs to the retailers, i.e. veterinary organisations and chemists, and to the approved medicated feed mills (preparing premixes to be incorporated into medicated feeds).

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 (including premixes to be incorporated into medicated feeds).

Data sources

The data on sales of the included veterinary antimicrobial agents at package level were obtained from the wholesalers (n=11).

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 (retailers, pharmacies and farmers' cooperatives) are authorised according to national law and benefit from 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. Sales for farmed fish are generally not included, as medicated feed for fish is currently bought from feed mills in other countries. Consequently, the VMPs used are not sold by Swedish pharmacies nor by Swedish feed mills, and the sales are therefore not captured in the collection system. Data on use of antimicrobials in fish farming are collected through the Swedish Fish Health Control Programme. In 2010, the total use was 0.029 tonnes active substance and the PCU for fish was 9-10 thousand tonnes. Given that the total sales for all terrestrial animals in Sweden was 14 tonnes active substance and the total PCU (fish excluded) was 824 thousand tonnes, the effect of not including fish in the overall statistics is negligible.

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 (n=47).

Annex 4. References to national reports

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Link: www.aemps.gob.es/en/informa/notasInformativas/medicamentosVeterinarios/

Sweden. SVARM 2010. Swedish Veterinary Antimicrobial Resistance Monitoring. ISSN 1650-6332.
Link: www.sva.se/en/Antibiotika/SVARM-reports/

United Kingdom. VMD 2011. Sales of antimicrobial products authorised for use as veterinary medicines in the UK in 2010.
Link: www.vmd.defra.gov.uk/vet/antimicrobial_pubs.aspx

Annex 5. ESVAC national representatives

Table A9. List of ESVAC national representatives/alternates

Country	Name and affiliation
Austria	Klemens Fuchs Österreichische Agentur für Gesundheit und Ernährungssicherheit Austrian Agency for Health and Food Safety Betriebsstätte Graz Beethovenstrasse 8 8010 Graz AUSTRIA E-mail: klemens.fuchs@ages.at
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Annex 6. Data from Switzerland

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

Table A10. Information on years collecting data, legal basis for collecting data by country, 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 A11. Estimated population correction unit (PCU) (in 1,000 tonnes) of the animal population, for 2010

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

Table A12. Sales, in tonnes of active ingredient, split into sales of antimicrobial VMPs marketed for food-producing animals (terrestrial animals), marketed for companion animals only (i.e. tablets) and total sales, for 2010

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

Table A13. Sales of veterinary antimicrobial agents (tonnes active ingredient) marketed for food-producing animals, including horses, population correction unit (PCU), and mg active ingredients of veterinary antimicrobial agents sold per PCU, for 2010

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

Table A14. Sales, in tonnes of active ingredient, of veterinary antimicrobial agents for food-producing animals, including horses, split into administration route/form, for 2010

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 A15. Sales for food-producing animals, in tonnes of active ingredient, of the various veterinary antimicrobial classes, for 2010

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 A16. Sales for food-producing animals, in mg per population correction unit (mg/PCU), of the various veterinary antimicrobial classes, for 2010

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 A17. Number of product presentations of premixes, oral powders and oral solutions containing 1, 2 and 3 active ingredients, respectively, for 2010

Country	1	2	3	Total number
Switzerland	47	19	27	93

Table A18. Sales, in tonnes of active ingredient, of antimicrobial VMPs as premixes, oral powders and oral solutions containing 1, 2 and 3 active ingredients, respectively, for 2010

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[7] covering sales and resistances to veterinary antimicrobials.

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

Data sources

Data are obtained at package level from the marketing-authorisation holders. Due to confidentiality reasons and Switzerland not being an EU Member State, data were analysed and processed at national level before transmission. Aggregation was done when necessary to keep 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
Switzerland	Institut für Veterinärpharmakologie und Toxikologie Winterthurerstrasse 260 8057 Zürich SWITZERLAND E-mail: cedric.muentener@vetpharm.uzh.ch On behalf of Swissmedic, Swiss Agency for Therapeutic Products, Berne

[7] ARCH-VET report (extensive version in German only): www.swissmedic.ch/archvet-e.asp

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Sales of veterinary antimicrobial agents in 19 EU/EEA countries in 2010
Second ESVAC report
EMA/88728/2012