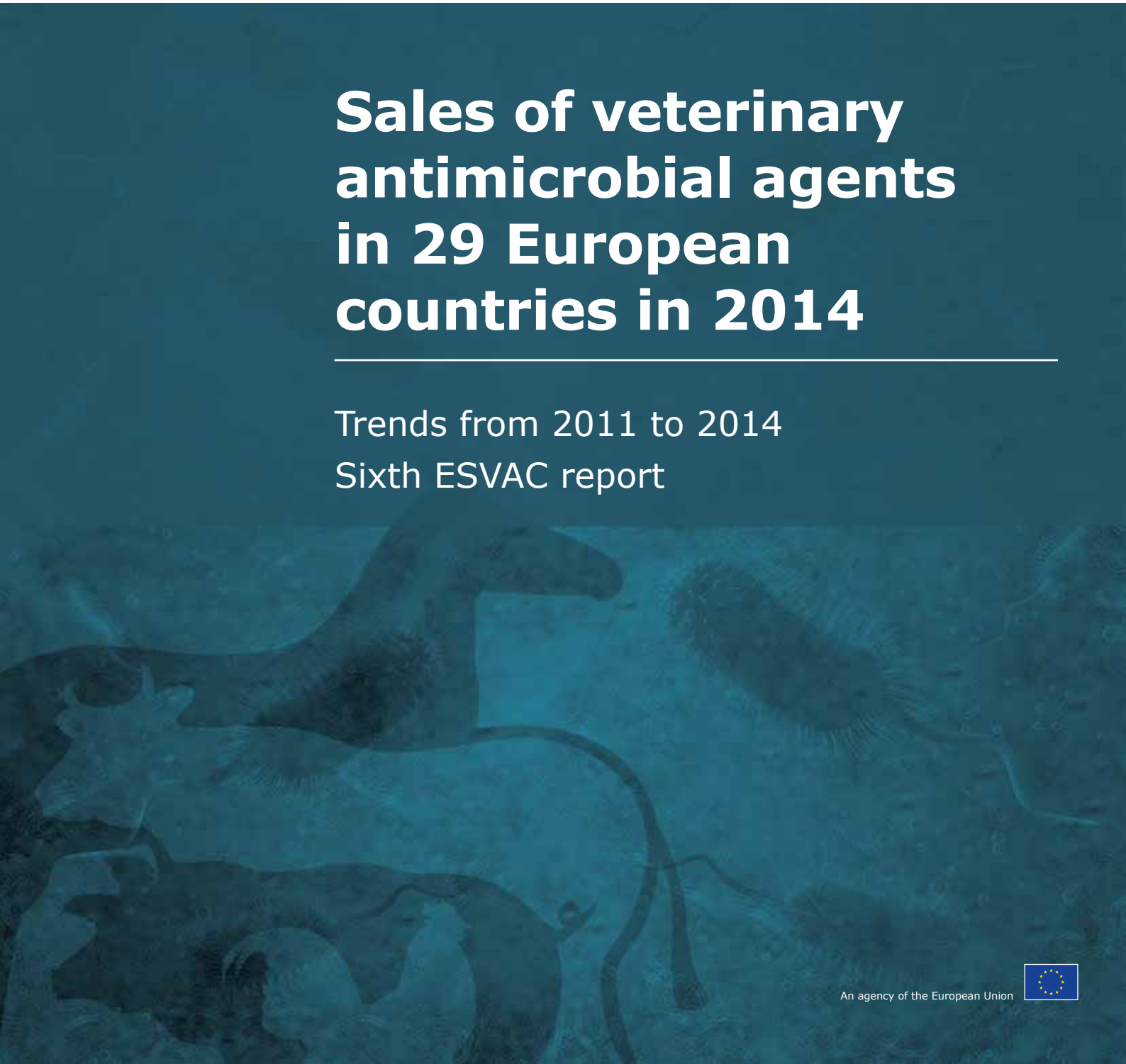
EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Sales of veterinary antimicrobial agents in 29 European countries in 2014

Trends from 2011 to 2014
Sixth ESVAC report



An agency of the European Union

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

Legal role

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

The Agency provides the Member States and the institutions of the European Union (EU) and the European Economic Area (EEA) countries with the best-possible scientific advice on any questions relating to the evaluation of the quality, safety and efficacy of medicinal products for human or veterinary use referred to it in accordance with the provisions of EU legislation relating to medicinal products.

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

Principal activities

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

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

Guiding principles

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

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

Sixth ESVAC report

14 October 2016
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About the European Medicines Agency

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

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

The Agency, with the help of its Committee for Medicinal Products for Veterinary Use (CVMP), and its Antimicrobials Working Party (AWP), has produced a strong body of scientific advice[1] in relation to the use of antimicrobials and the risk of antimicrobial resistance, with the intention of promoting the continued availability of effective antimicrobials for use in animals, while at the same time acting to minimise risks to animals or humans arising from their use.

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

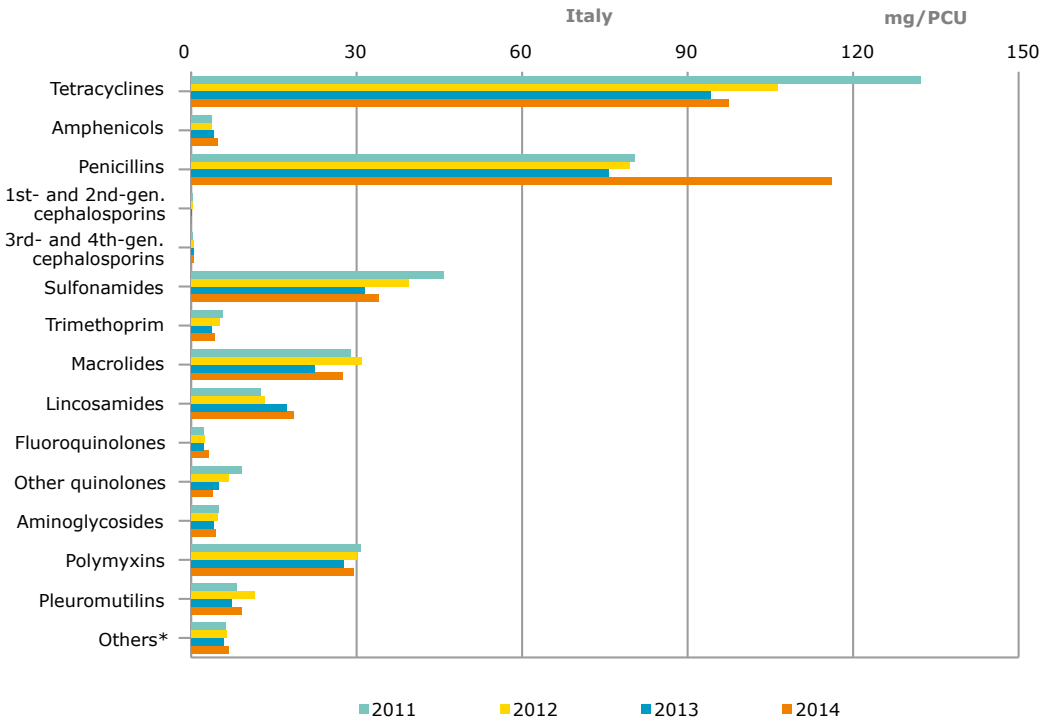
About the report

This sixth ESVAC report presents data on the sales of veterinary antimicrobial agents from 29 European countries in 2014, provided at package level according to a standardised protocol and template[1]. In addition, it includes a chapter describing changes in consumption of veterinary antimicrobials for the years 2011–2014 (Chapter 2.8). Chapter 2.4.1. also includes supplementary information on polymyxins.

Chapter 2.8.2. focuses on the changes across time in each country. Explanations for the possible reasons for the changes across time in the various ESVAC participating countries have been provided by the ESVAC national contact points from each country. This chapter emphasises in particular on changes for certain classes of antimicrobials according to the categorisation recommended by the EMA Antimicrobial Advice ad hoc Expert Group (AMEG). The AMEG takes into account the WHO catego-

Italy

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



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

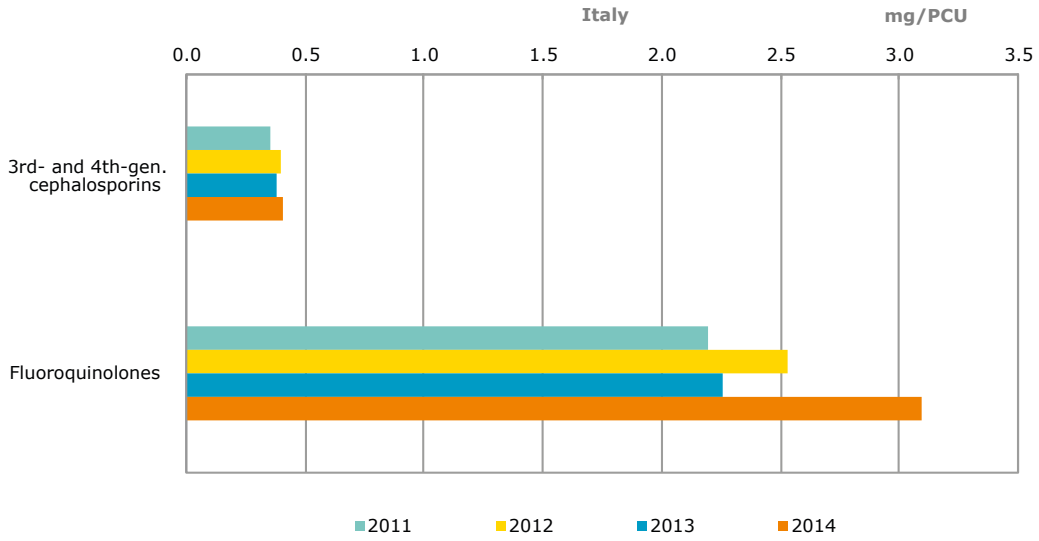
Overall, there was a 3 % drop in sales, expressed as mg/PCU, during the period 2011 to 2014; however, sales in 2014 were 16 % lower compared to 2010. This fall appears to be correlated mainly with a progressive decline in sales of tetracyclines and sulfonamides. The lower sales were probably caused by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

- In 2009, the Ministry of Health launched awareness campaigns[18] against the prophylactic use of antimicrobial agents in breeding farms and for their prudent use in pet animals[19]. Furthermore, an online training course was published on veterinary medicines surveillance and pharmacovigilance[20].
- In 2010, an information system was implemented in order to estimate the number of prescriptions of veterinary antimicrobials issued throughout each Italian region. These data allow the local competent authorities to identify the most problematic sectors where antimicrobial resistance has to be tackled in the following year. Furthermore, in 2010 and 2011, training courses were held in collaboration with the National Reference Laboratory for Antimicrobial Resistance in Rome. At the same time, in accordance with Regulation (EC) No 852/2004, the Ministry of Health validated and published species-specific good husbandry practices manuals in which basic principles for medicines management in farms are addressed.

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

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

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



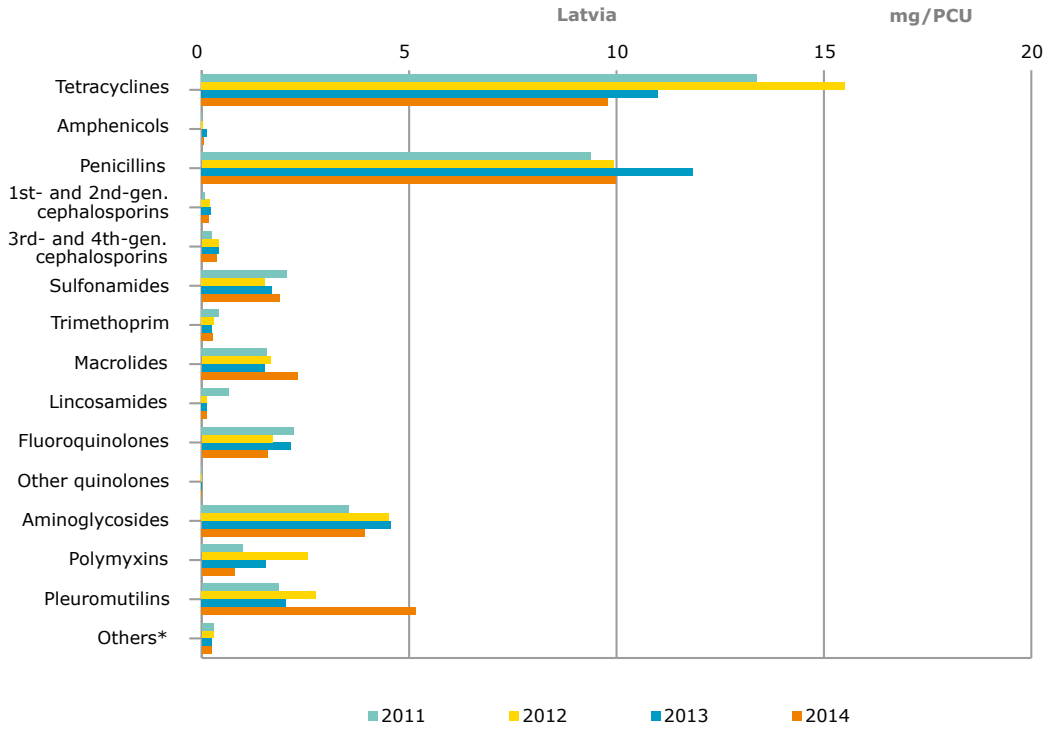
Sales (mg/PCU) of 3rd- and 4th-generation cephalosporins were relatively stable during the period 2011 to 2014, accounting for approximately 0.1% of total sales each year. In 2014, the sales of 3rd- and 4th-generation cephalosporins were 0.41 mg/PCU, while the average figure for 25 countries was 0.26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

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

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

Latvia

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



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

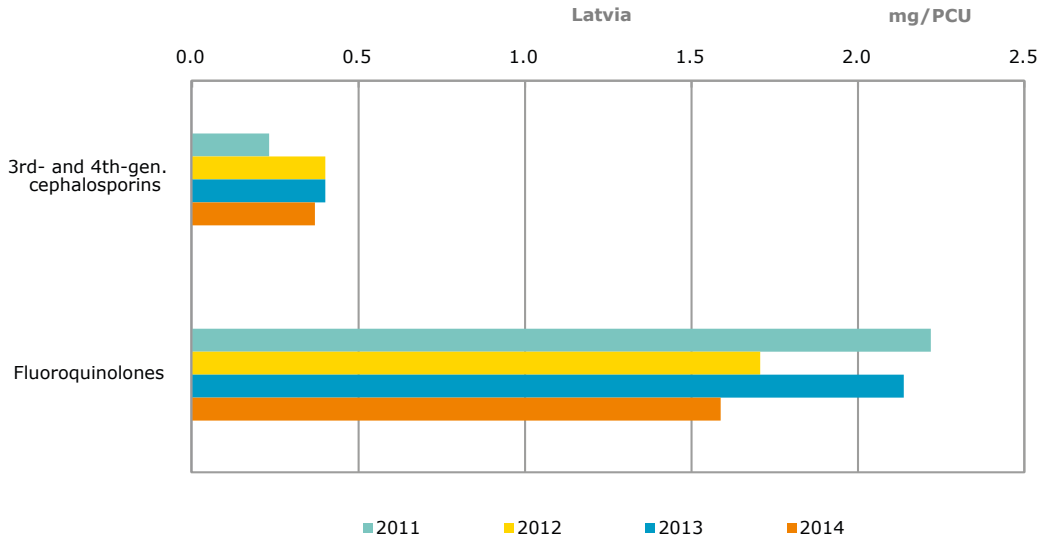
The annual sales (mg/PCU) of antimicrobial VMPs were stable during the period 2011 to 2014; sales in both 2011 and 2014 were 37 mg/PCU. Overall sales declined by 7% from 2010 to 2014, while the proportion accounted for by most of the various antimicrobial classes fluctuated.

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

Sales of pleuromutilins increased from 1.9 mg/PCU to 5.2 mg/PCU from 2011 to 2014, which is almost double the sales of this class during the period. At the moment, no precise data are available to explain the change in sales patterns.

In order to improve the situation regarding the consumption of veterinary antimicrobial agents in Latvia, a number of activities have been carried out to inform farmers and animal owners, and to give additional information to veterinarians about the prudent use of antimicrobial agents in animals. For example, in 2014, representatives from the Food and Veterinary Service, Institute of Food Safety, Animal Health and Environment BIOR and Veterinary Medicine Faculty in Latvia participated in the seminar 'Prevalence of zoonotic agents in food-producing animals in the population and foodstuffs of animal origin'. A list of first- and second-choice antimicrobial agents is currently being drawn up. During 2014, several training courses were organised for inspectors carrying out inspections of the distribution and use of veterinary medicines, and for veterinary practitioners.

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

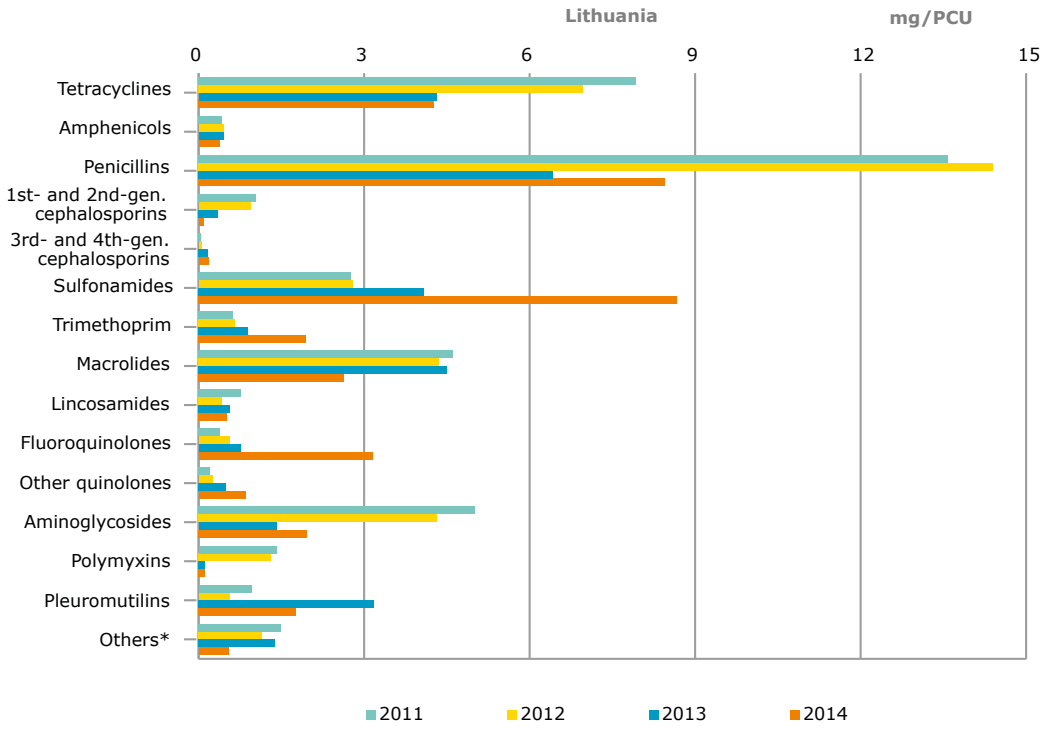


The sales of 3rd- and 4th-generation cephalosporins rose from 0.23 mg/PCU in 2011 to 0.37 mg/PCU in 2014; the average figure for 25 countries was 0.26 mg/PCU in 2014 (Figure 56). In 2011, 3rd- and 4th-generation cephalosporins accounted for 0.6% of total sales, while this figure was 1.0% for 2014.

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

Lithuania

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

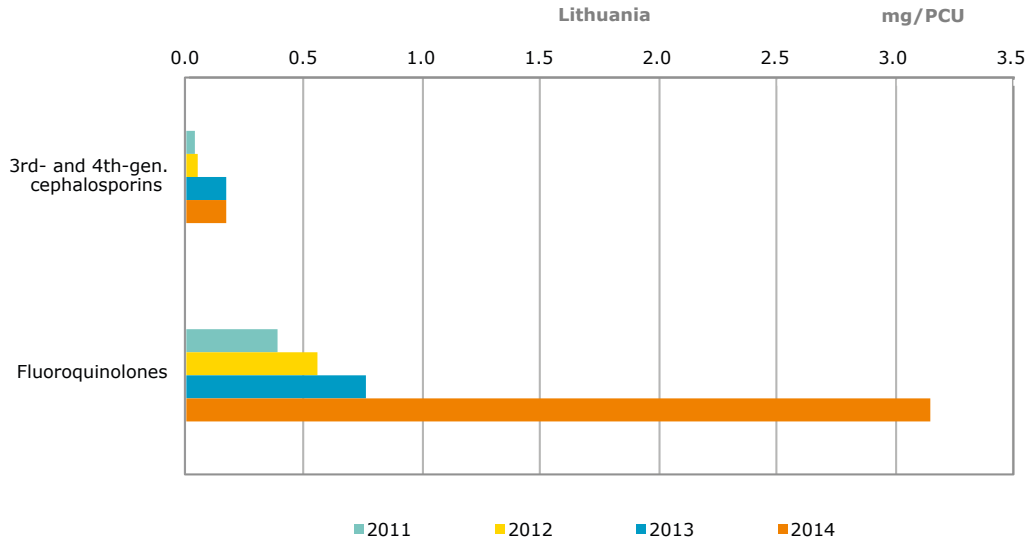


* Other antimicrobials (classified as such in the ATCvet system).
[1] No sales of pleuromutilins in 2010.

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

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

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

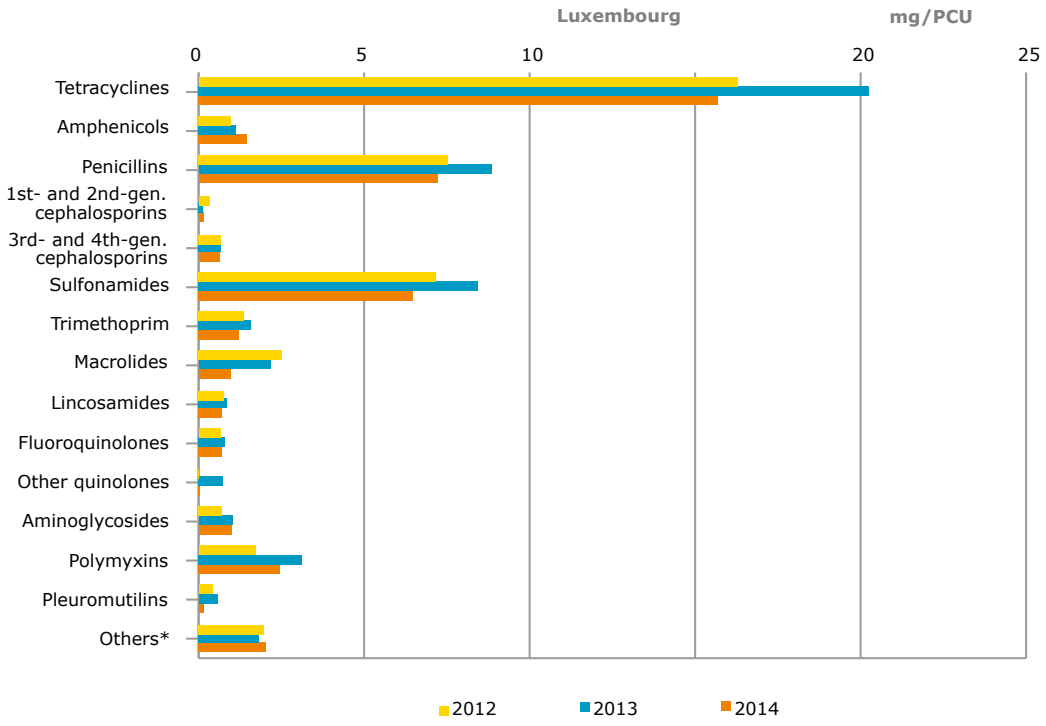


The sales (mg/PCU) of 3rd- and 4th-generation cephalosporins increased from 0.04 mg/PCU to 0.13 mg/PCU from 2011 to 2014. In 2014, the average sales of 3rd- and 4th-generation cephalosporins VMPs were 0.26 mg/PCU across 25 countries (Figure 56). In 2011, sales of this subclass accounted for 0.10 % of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

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

Luxembourg

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

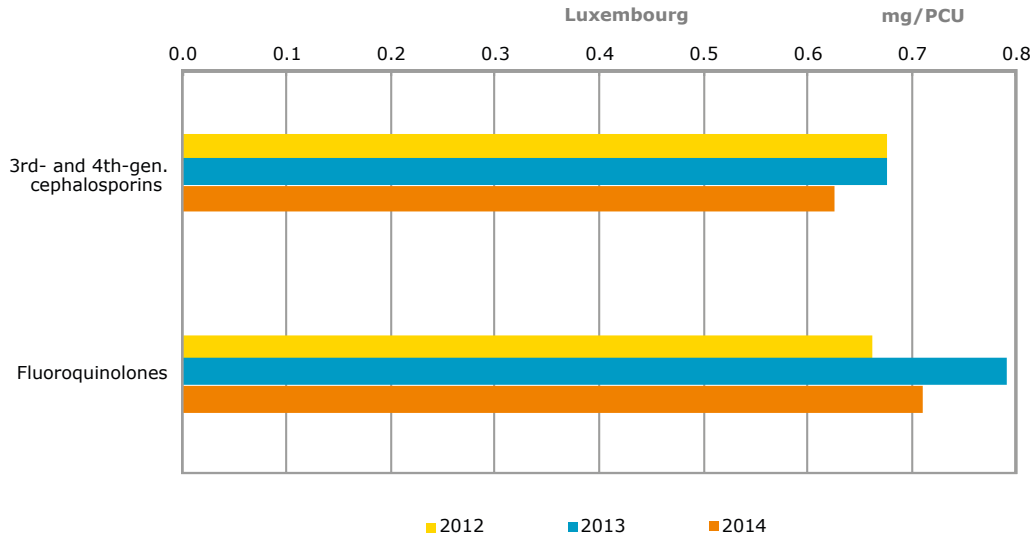


* Other antimicrobials (classified as such in the ATCvet system).

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

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

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

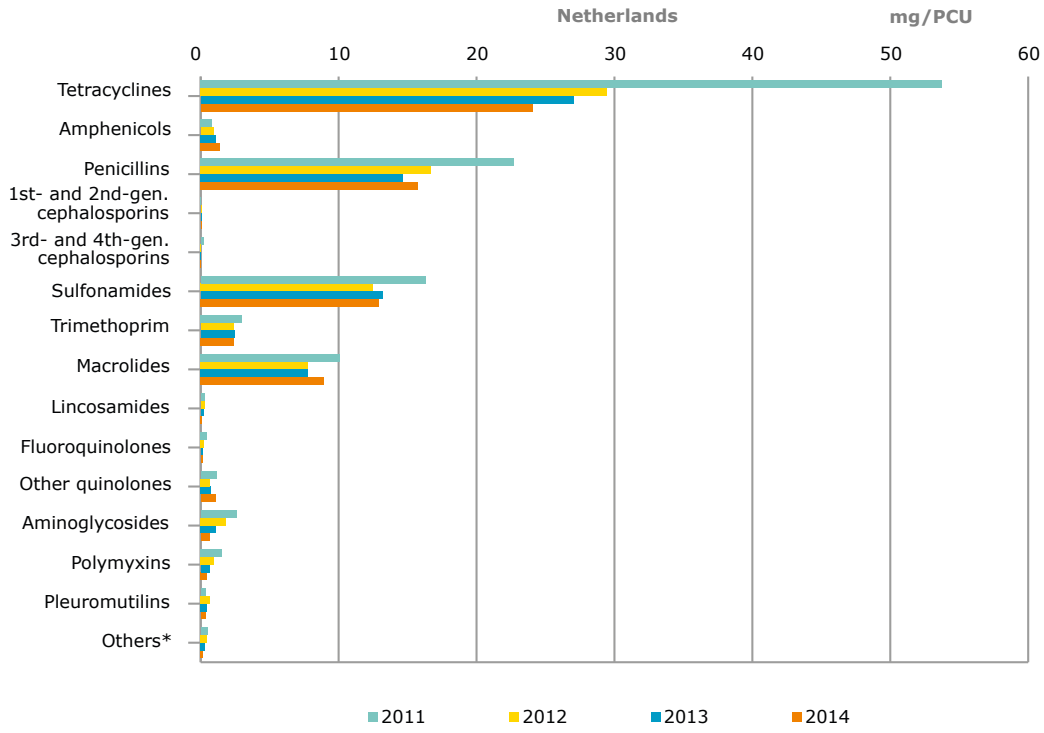


Sales (mg/PCU) of 3rd- and 4th-generation cephalosporins were relatively stable; a slight drop was observed for 2014. In 2012, this subclass accounted for 1.6% of total sales, while in 2014, this figure was 1.5%. In 2014, the sales of 3rd- and 4th-generation cephalosporins VMPs were 0.63 mg/PCU, while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

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

Netherlands

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



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

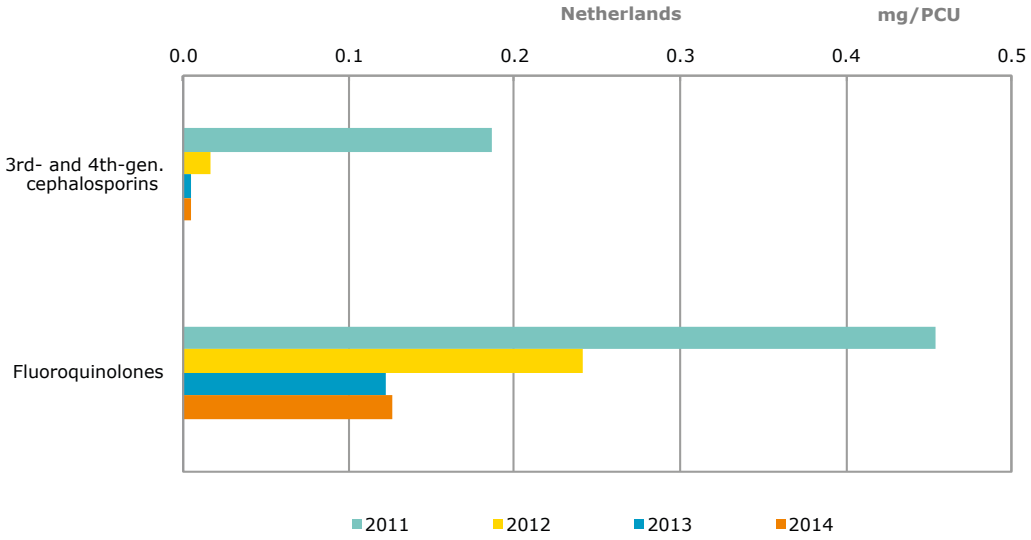
A 35 % drop in sales (in mg/PCU) of veterinary antimicrobial agents was observed from 2011 to 2014; compared to 2010, sales declined by 53 % in 2014. This is the result of efforts by the major production sectors and veterinarians which agreed with the government to set reduction targets in 2010 for the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

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

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

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

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



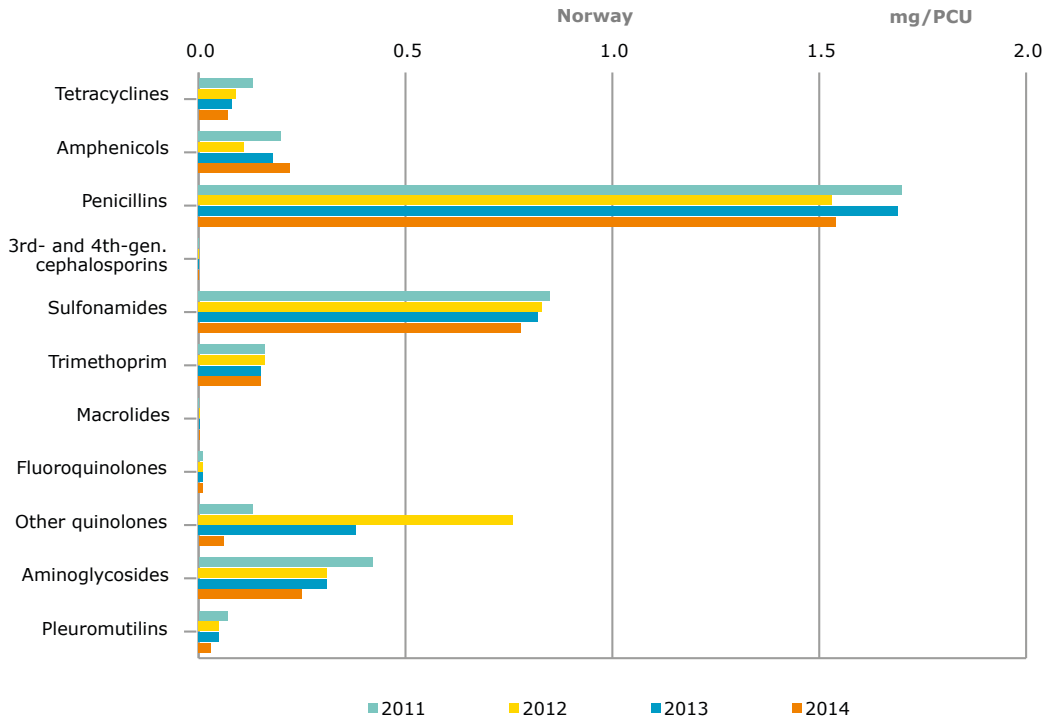
The sales (mg/PCU) of 3rd- and 4th-generation cephalosporins fell by 98 % from 2011 to 2014; in 2011, this subclass accounted for 0.17 % of total sales while for 2014, the figure was 0.01 %. This result was achieved thanks to efforts within private quality-production systems. Private quality systems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

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

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

Norway

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



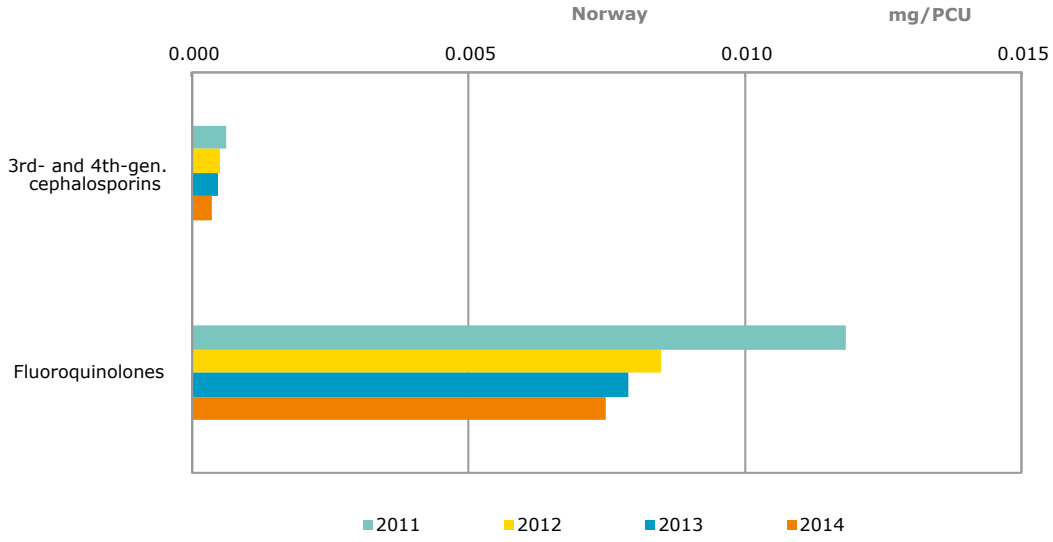
[1] No sales of 1st- and 2nd-generation cephalosporins or polymyxins in any of the years; minor amounts of macrolides sold in 2011, 2012 and 2013 (< 0.002 mg/PCU).

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

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

From 1995 to 1999, a 40% reduction was achieved in the sale of antimicrobials for terrestrial animals. Since then, sales of antimicrobial agents for use in terrestrial food-producing animals have been relatively stable, showing only minor fluctuations (http://www.vetinst.no/eng/Publications/NORM-NORM-VET-Report). It should be noted that, since 1981, the sales of antimicrobials for use in farmed fish has declined by 97%, while during the same period the production of farmed fish increased more than 100-fold.

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

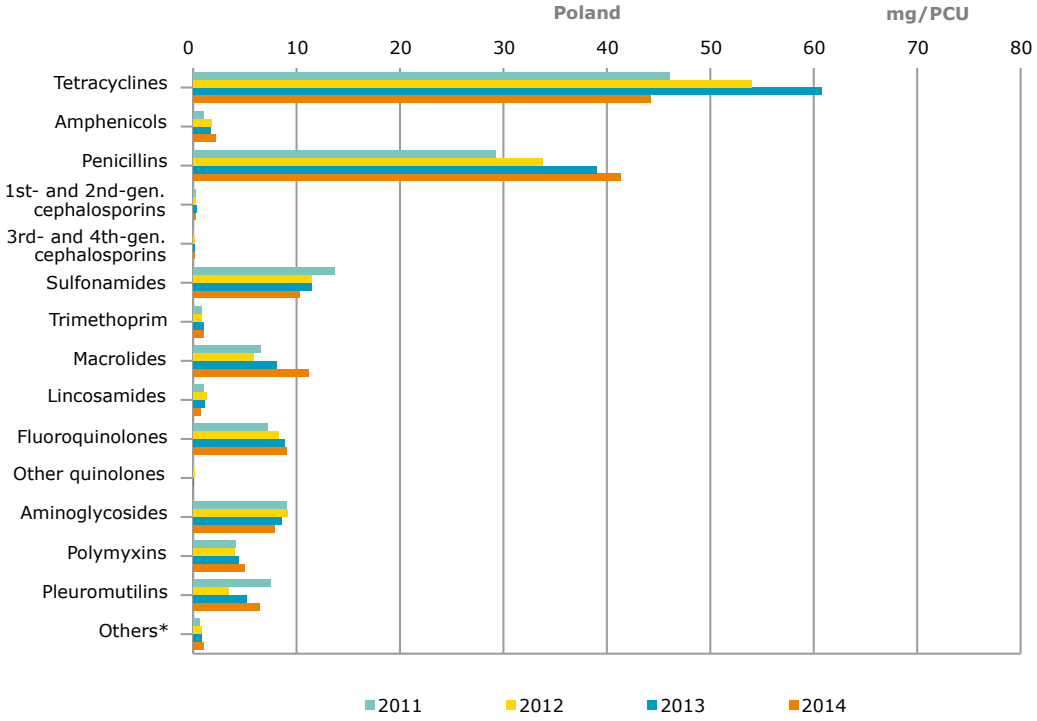


The sales (mg/PCU) of 3rd- and 4th-generation cephalosporins decreased from 2011 to 2014; in 2011, this subclass accounted for 0.02 % of the total sales, while for 2014, this figure was 0.01 %. In 2014, sales of 3rd- and 4th-generation cephalosporins VMPs were 0.004 mg/PCU, while the average sales for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

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

Poland

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



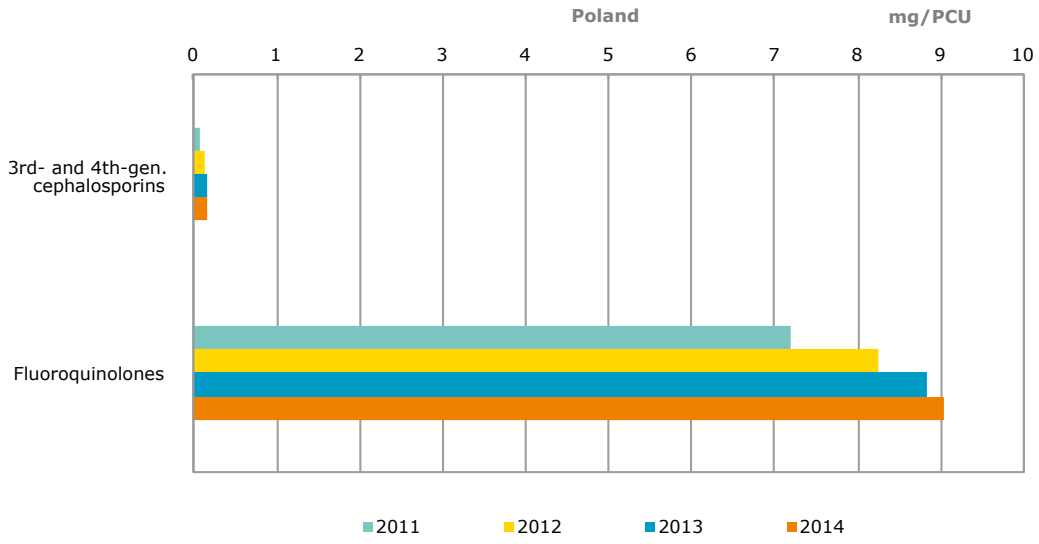
* Other antimicrobials (classified as such in the ATCvet system).

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

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

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

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

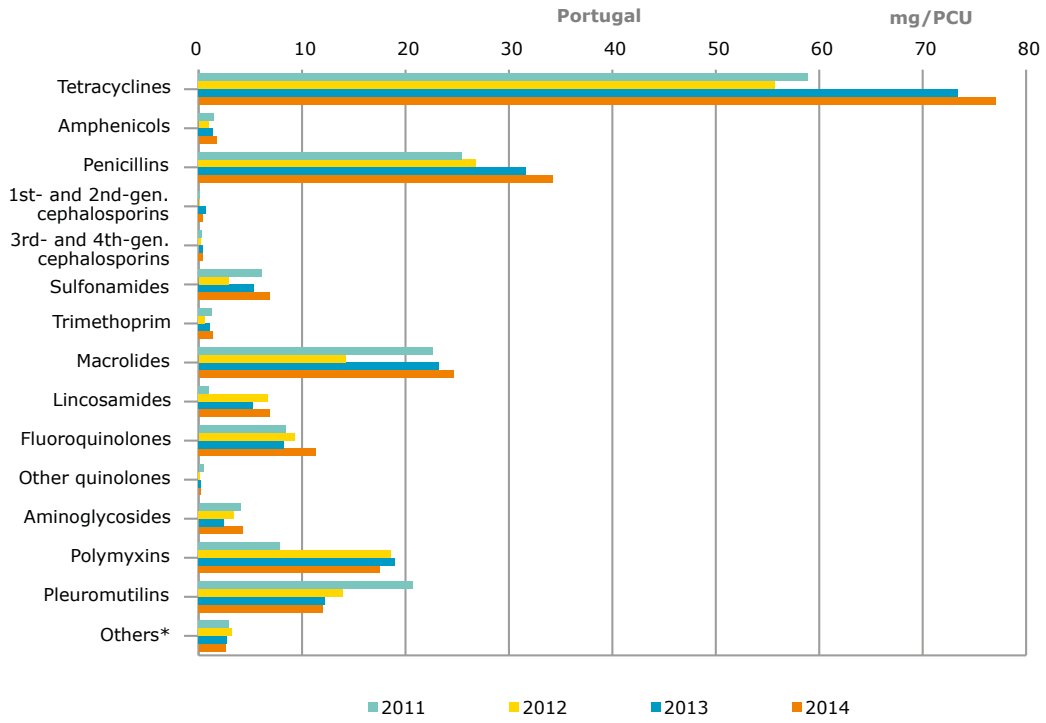


The sales (mg/PCU) of 3rd- and 4th-generation cephalosporins increased slightly from 2011 to 2014; in 2011, this subclass accounted for 0.07% of total sales, while for 2014, this figure was 0.12%. In 2014, the sales of 3rd- and 4th- generation cephalosporins VMPs were 0.17 mg/PCU, while the average sales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

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

Portugal

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

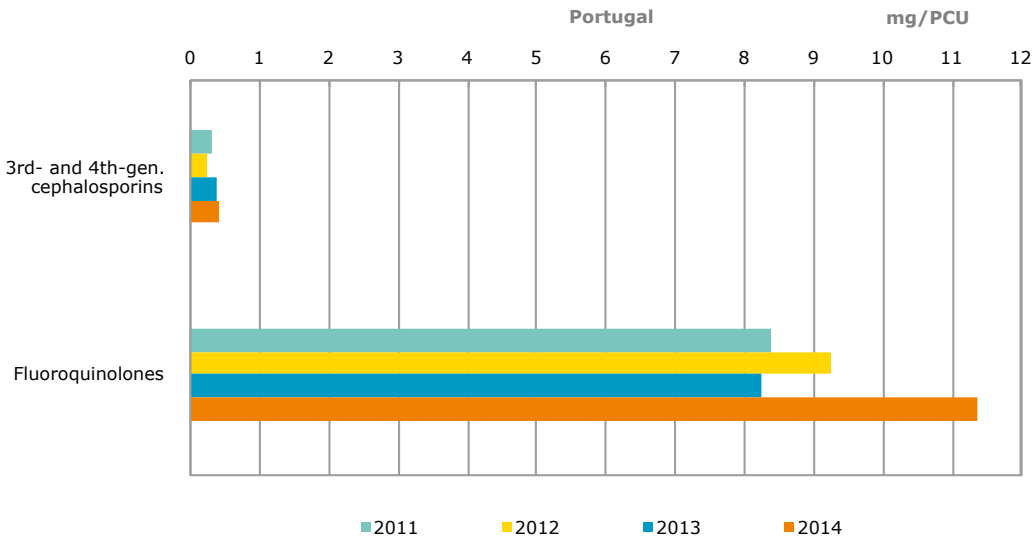


* Other antimicrobials (classified as such in the ATCvet system).

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

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

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



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

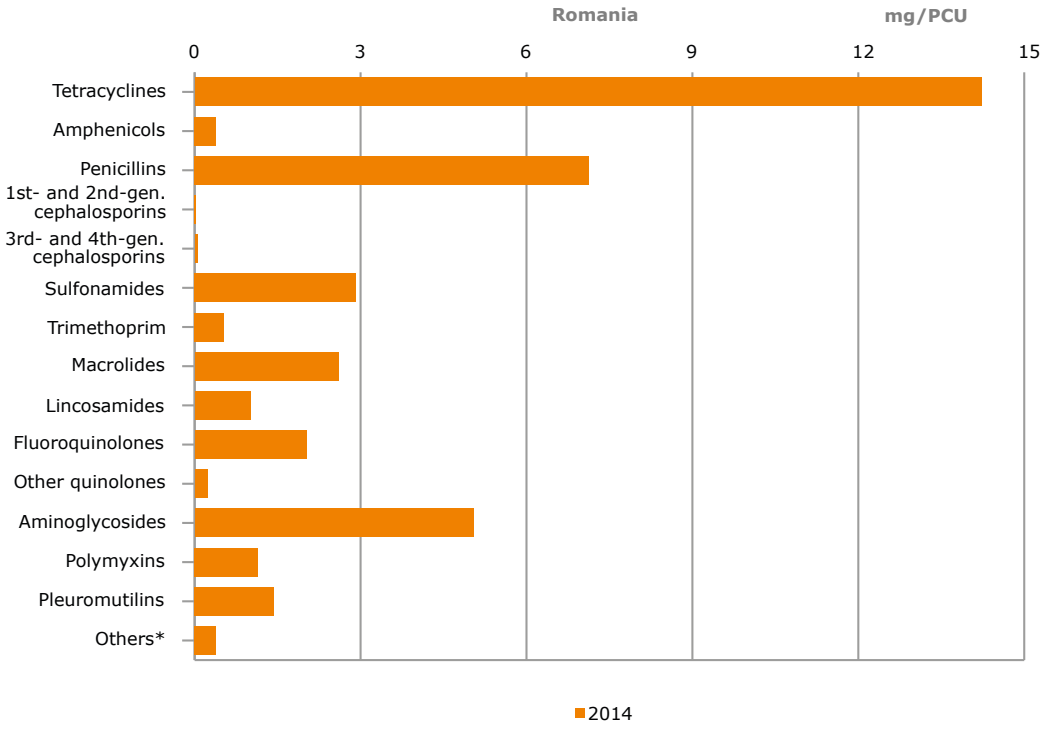
From 2011 to 2014, an increase was observed in the sales (mg/PCU) of fluoroquinolones, which peaked in 2014. In 2011, the proportion of total sales of fluoroquinolones was 5.2%, rising to 5.6% in 2014. This increase is mainly attributed to the availability of several wide spectrum generic VMPs, particularly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

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

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

Romania

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

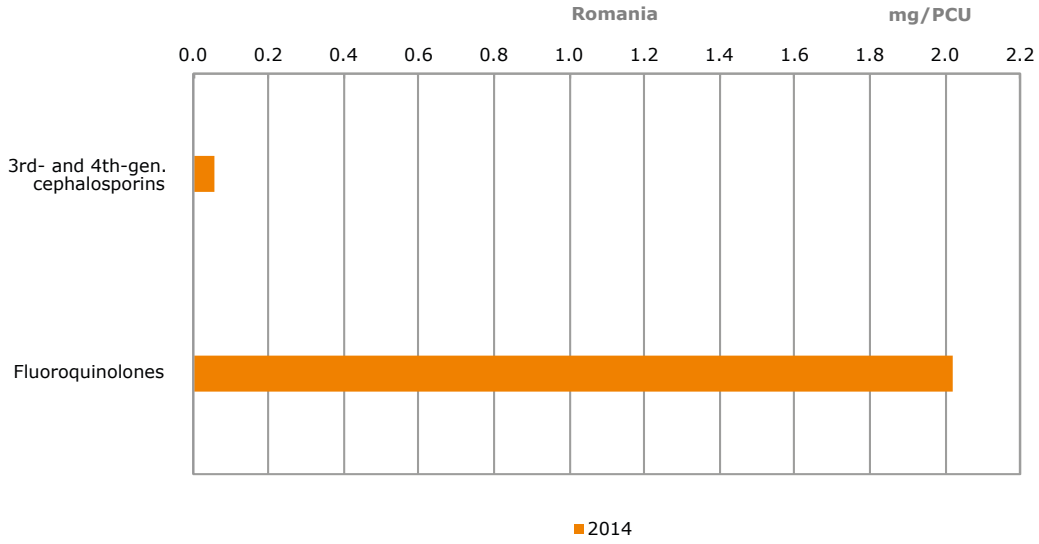


* Other antimicrobials (classified as such in the ATCvet system)

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

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

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

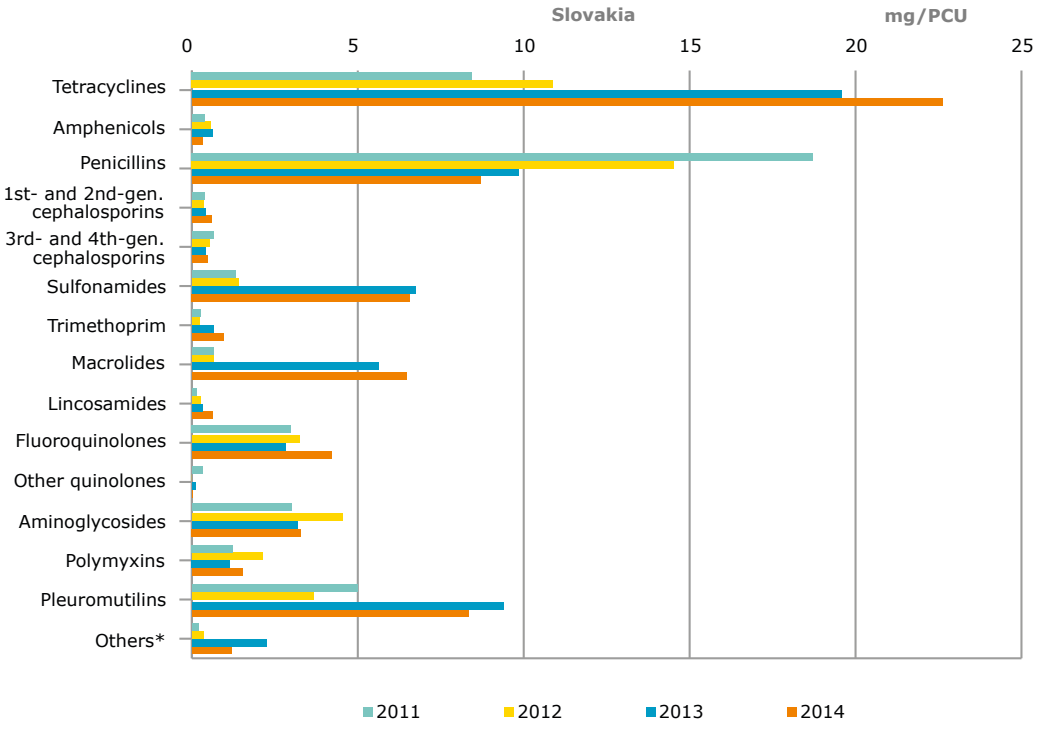


Sales of 3rd- and 4th-generation cephalosporins and fluoroquinolones accounted for 0.1% and 5.2%, respectively, of total sales. In 2014, the sales of 3rd- and 4th-generation cephalosporins VMPs were 0.05 mg/PCU; average sales for 25 countries in that year were 0.26 mg/PCU (Figure 56). Sales for fluoroquinolones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

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

Slovakia

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

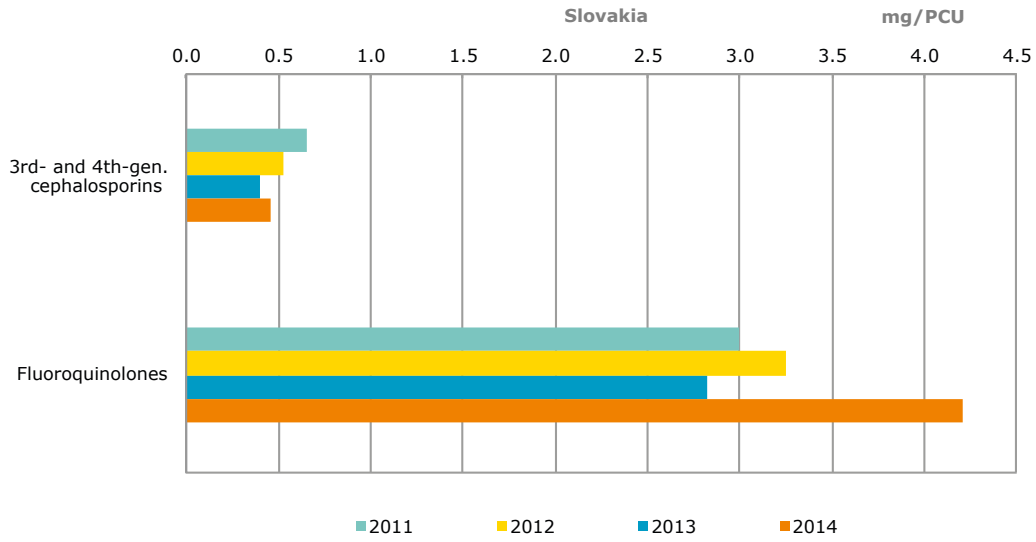


* Other antimicrobials (classified as such in the ATCvet system).

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

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

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

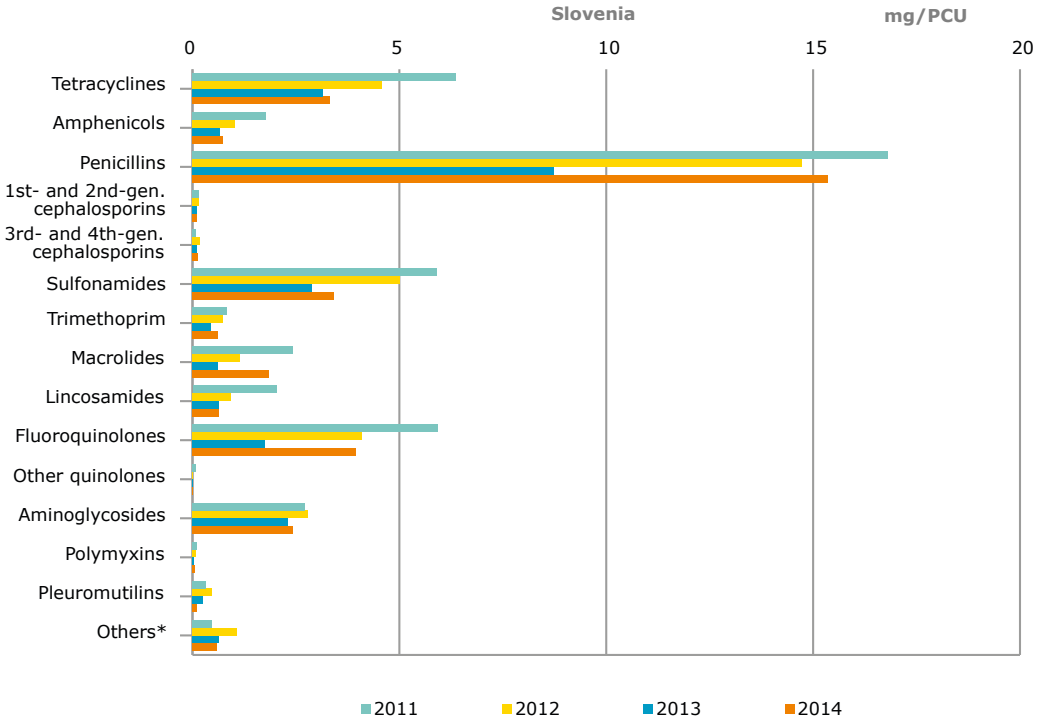


Sales (imports in 2011 and 2012), in mg/PCU, of 3rd- and 4th-generation cephalosporins declined from 2011 to 2014; in 2011, this subclass accounted for 1.5% of total sales; in 2014, this figure was 0.7%. In 2014, the sales of 3rd- and 4th-generation cephalosporins VMPs were 0.46 mg/PCU, while the average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

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

Slovenia

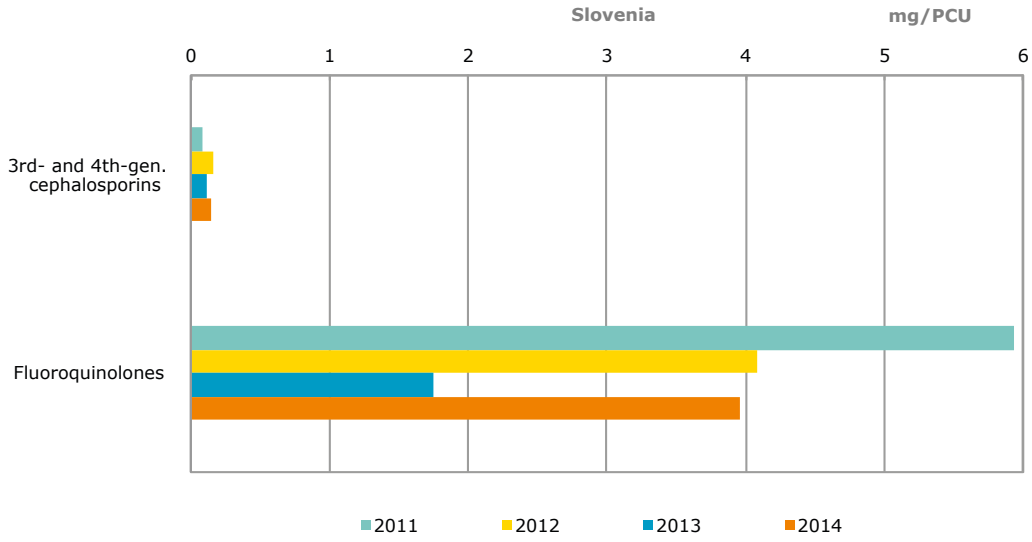
Figure 112. Sales (mg/PCU) by antimicrobial class for food-producing species, in Slovenia, from 2011 to 2014



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

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

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

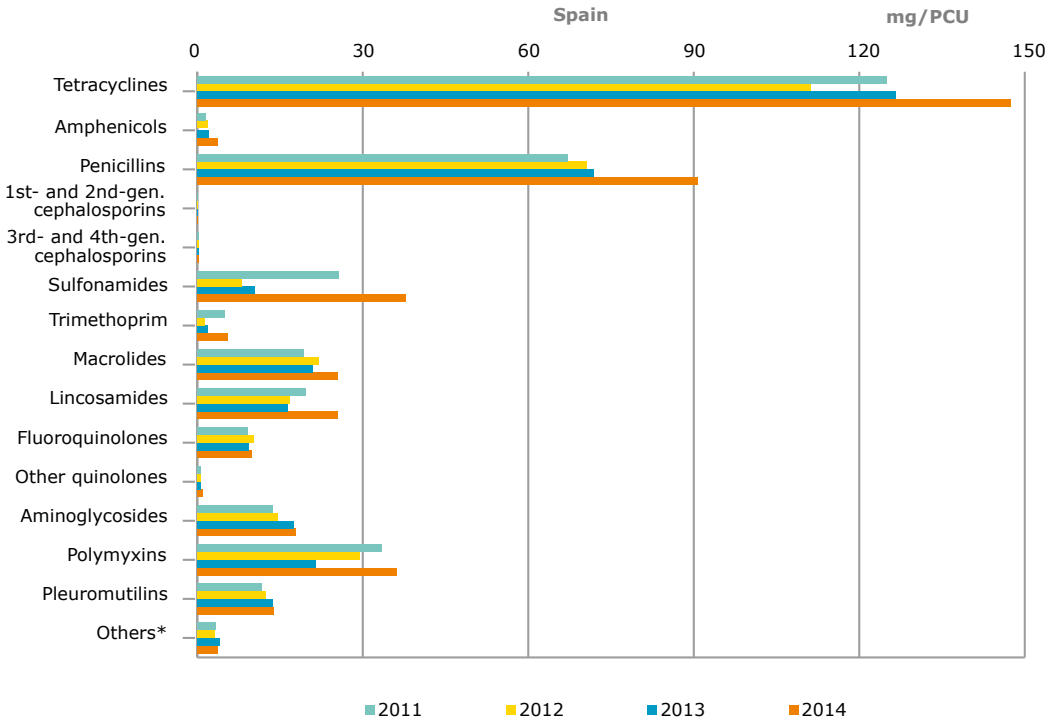


Sales (mg/PCU) of 3rd- and 4th-generation cephalosporins were relatively stable from 2011 to 2014. In 2011, this subclass accounted for 0.2 % of total sales, while for 2014, this figure was 0.4 %. In 2014, sales of 3rd- and 4th-generation cephalosporins VMPs were 0.14 mg/PCU, while the average sales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

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

Spain

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

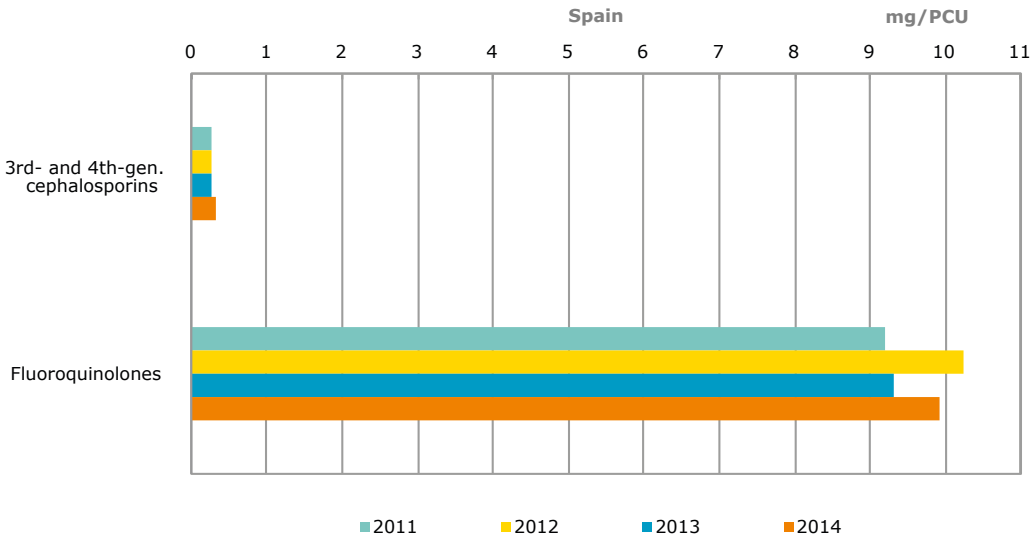


* Other antimicrobials (classified as such in the ATCvet system).
[1] Sales of 1st- and 2nd-generation cephalosporins were low each year (< 0.05% of total sales).

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

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

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

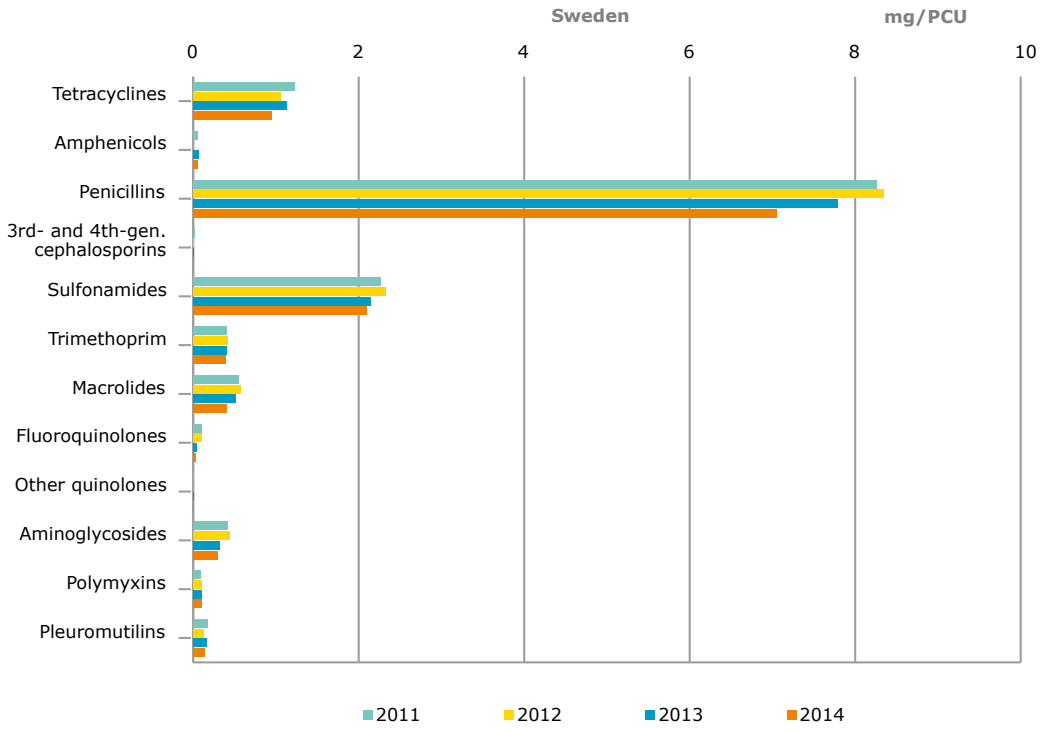


Sales (mg/PCU) of 3rd- and 4th-generation cephalosporins were stable from 2011 to 2014, accounting for 0.8% of the total sales in both years. In 2014, the sales of 3rd- and 4th-generation cephalosporins VMPs were 0.33 mg/PCU, while the average sales for 25 countries in that year were 0.26 mg/PCU (Figure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

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

Sweden

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



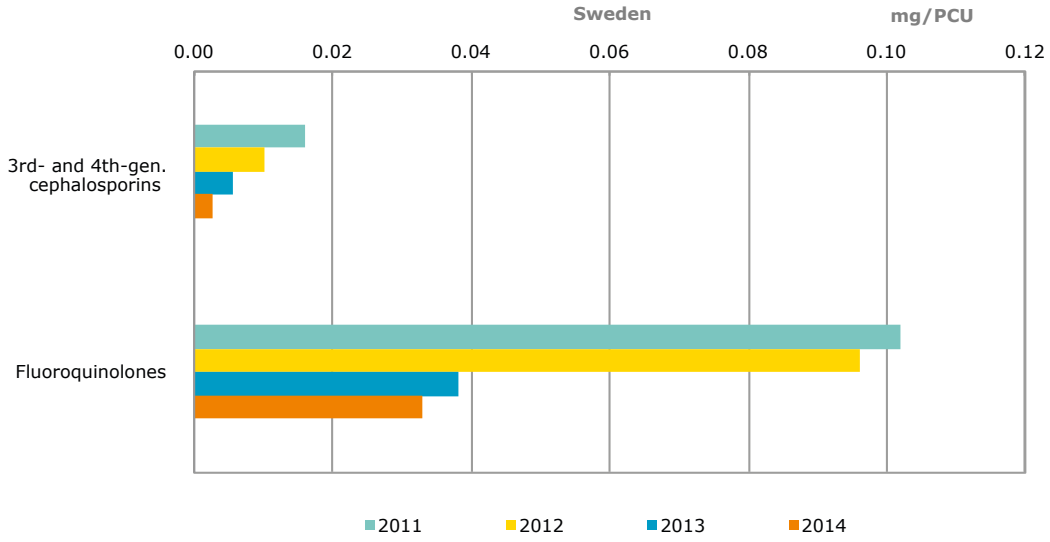
[1] No sales of 1st- and 2nd-generation cephalosporins in any of the years; minor amounts of lincosamides sold in 2012 (not shown in the graph); no sales of other quinolones in 2012 because sales for fish were not available.

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

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

The fall in overall sales (mg/PCU) from 2011 to 2014 was 15 % and thus larger than the estimated lack of completeness. This means that there is an actual reduction, although its magnitude is uncertain. During the same period, sales of products for the medication of individual animals fell by 13 % and products for group medication by 27 %. The latter is part of a long-term trend since the early 1990s, explained by a change towards medication of individual animals and by the reduced occurrence of relevant diseases. In 2014, sales of products for group medication were 10 % of the total sales. These long-term overall changes are the result of a working model built on continuous collaboration between academia, governmental organisations, advisers in preventive medicine (animal health organisations), veterinarians and farmers. The core element of the strategy is to reduce the need for antimicrobials through, for example, biosecurity, disease-control programmes, and optimised management and husbandry. When antimicrobials are needed, guidance on their prudent use is available.

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



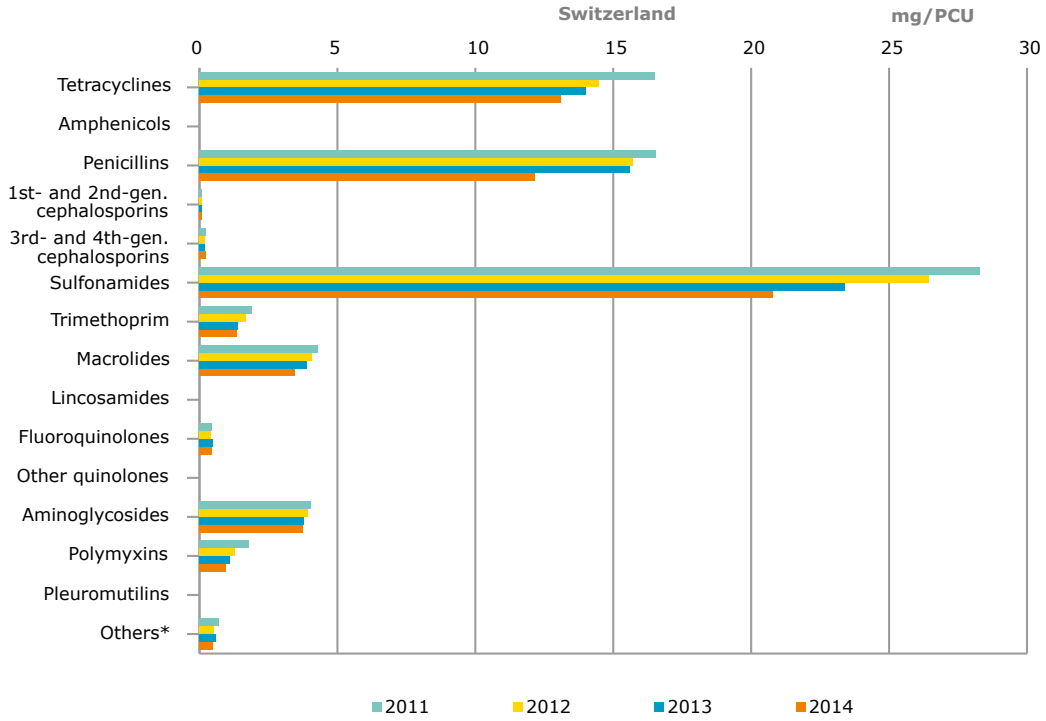
From 2011 to 2014, the sales of 3rd- and 4th-generation cephalosporins and fluoroquinolones, expressed as mg/PCU, decreased substantially by 83 % and 68 %, respectively. In 2011, 3rd- and 4th generation cephalosporins accounted for 0.1 % of the total sales; for 2014, this figure was 0.02 %. The corresponding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

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

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

Switzerland

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



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

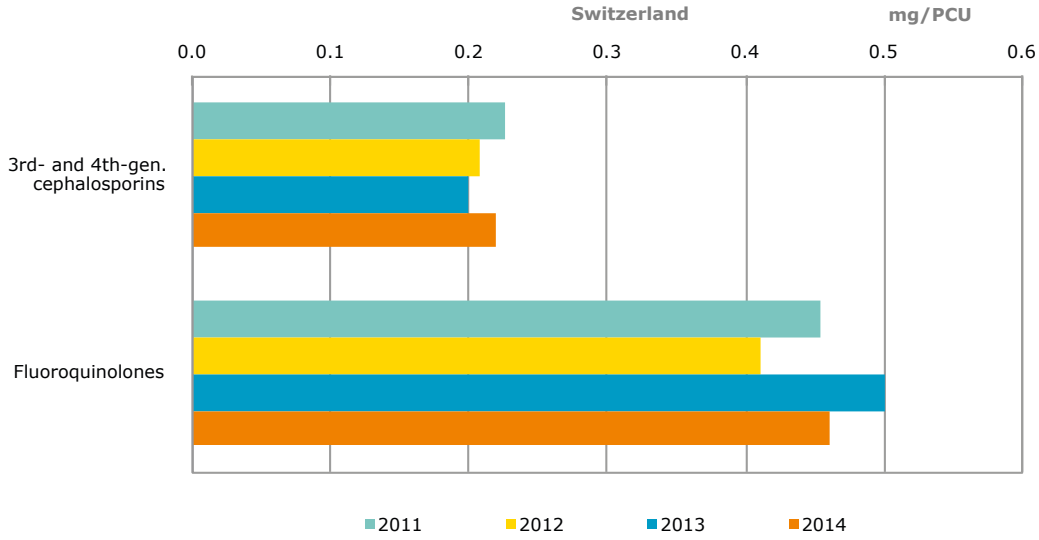
[1] For confidentiality reasons, amphenicols, other quinolones and pleuromutilins are grouped with others and lincosamides are grouped with macrolides. 2Data for 2011–2013 has not been submitted to the ESVAC database but have been retrieved from Annex 9 in previous ESVAC reports.

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

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

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

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



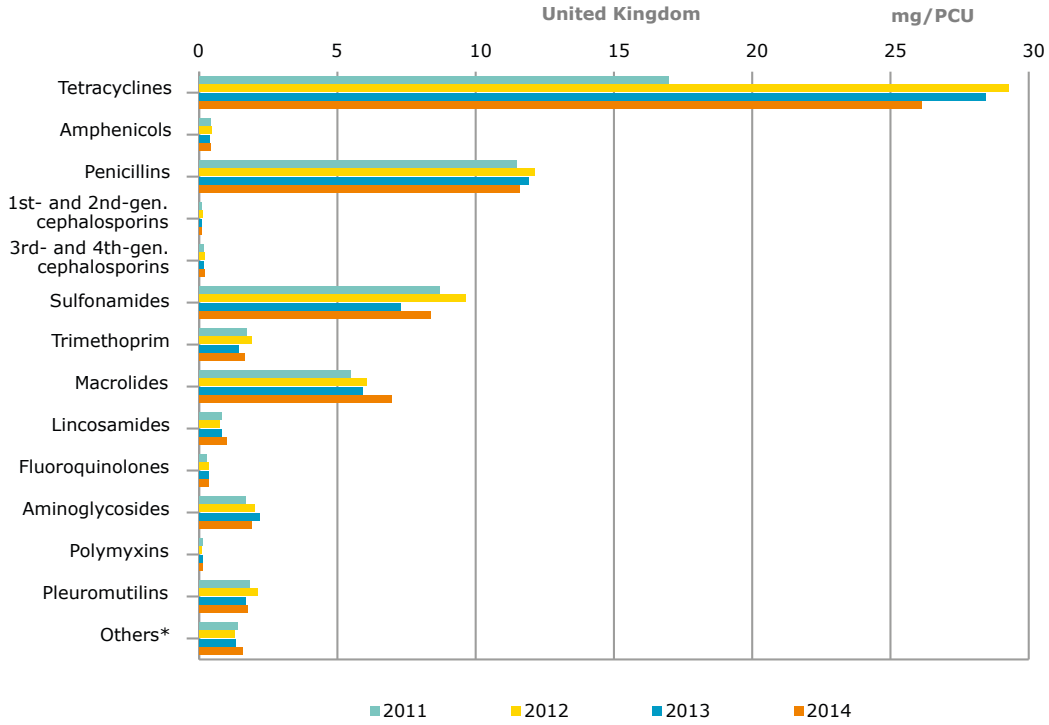
[1] Data for 2011–2013 were not submitted at package level.

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

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

United Kingdom

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



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

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

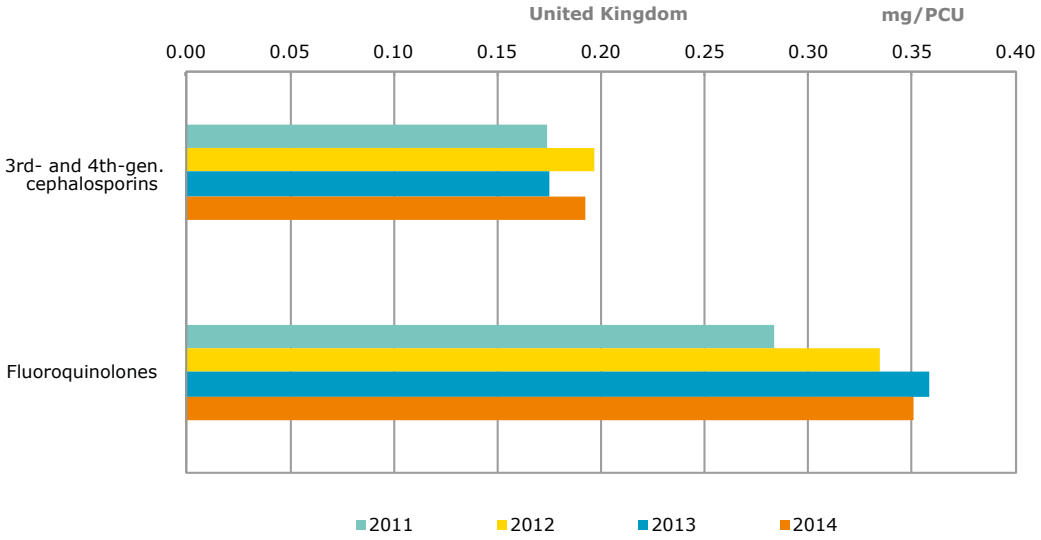
The increase in sales is accounted for by most of the antimicrobial classes although, in particular, there was an increase in sales of tetracyclines as well as macrolides.

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

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

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

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



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

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

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

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

3. Discussion

3.1. Materials and methods

It is important to note that the results presented in this report may differ slightly from those presented in national reports because, for example, of differences in inclusion criteria for veterinary antimicrobial agents and in the reporting of data in the national surveillance systems, e.g. reporting of the data as the base, while for the ESVAC the strength is reported as given on the label summary of product characteristics/label of the VMP, which typically is the salt (see references to national reports in Annex 6).

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

Dermatological preparations (ATCvet group QD) and preparations for sensory organs (ATCvet group QS) were not included in the data sets. Since, in 2011, these pharmaceutical forms represented, for example, only 0.13% in Denmark, (E. Jacobsen, unpublished data), 0.2% in the Czech Republic (Lucie Pokludová, unpublished data), 0.35% in France (G. Moulin, unpublished data), 0.002% in Norway (www.vetinst.no/eng/Publications/Norm-Norm-Vet-Report) and 0.49% in the United Kingdom (Hannah Reeves, unpublished data) of the total tonnes sold, the annual contribution from these groups of antimicrobial agents, in tonnes of active ingredients, to the total amounts is thought to be minimal, and therefore the effect of the deviation is negligible.

Injectable antimicrobial agents are used both in food-producing and in companion animals. With the exception of some long-acting products, injection of antimicrobial agents in companion animals is generally limited to hospitalised animals or perioperative treatments. Data from Denmark and France for 2011 showed that approximately 0.1% and 1.2%, respectively, of the injectable antimicrobial VMPs sold were used for dogs and cats (E. Jacobsen and G. Moulin, unpublished data). Therefore, the assumption that all injectable antimicrobials are used in food-producing species has minimal impact on the accuracy of the data for injectable preparations.

Twelve countries (Table 2) included veterinary antimicrobial agents obtained on special licence (use on exemption from marketing authorisation, i.e. obtained from another Member State) in the data sets. For five of these countries — Denmark, Norway, Finland, Estonia and Sweden — the proportion of sales of antimicrobial veterinary medicinal products (VMPs) on special licence is reported by the ESVAC NCs/alternates in 2011 to be approximately 0.01%, 1%, 3%, 9% and 10% of the total sales, respectively[23]. These are all countries with a comparatively low number of antimicrobial VMPs on the market (Table 7). As the proportion of antimicrobial products used on special licence (obtained from another Member State) is likely to be negligible in countries with a relatively high number of antimicrobial VMPs on the market, the impact caused by deviations in the included data sets is considered relatively low and does not significantly influence the general results.

Depending on the source of the data, countries had requested data on sales to end-users, or had asked the national data providers to exclude sales among data sources, for example, between wholesalers, and consequently it is assumed that double reporting has been avoided.

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

Regarding the material and methods, it should be noted that in all the participating countries antimicrobial agents have a 'prescription only' status. According to Directive 2001/82/EC, as amended, of the European Parliament, all veterinary medicinal products, including veterinary antimicrobial agents, have to be sold through distributors authorised by the competent authority in each country. This made it possible for all the participating countries to identify all distributors of antimicrobial VMPs in their country, and consequently 100% data-source coverage could be obtained. It is therefore reasonable to assume that the data presented in this report provide a good picture of the total sales of antimicrobial agents in the 29 countries.

In the current report, data presented on sales of veterinary antimicrobial agents for companion animals are based solely on the sales of tablets. For countries with a relatively low number of dogs and cats, the market for antimicrobial VMPs as tablets is typically low, and thus the proportion of human antimicrobial agents that are used according to the cascade could account for a higher proportion than in those countries with a high number of dogs and cats. Furthermore, injectable antimicrobial

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

VMPs are used in both food-producing animals, including horses, and companion animals. Therefore, the data on sales of veterinary antimicrobial agents for companion animals presented in this report are likely to be underestimated, while the data on sales for food-producing animals are slightly overestimated. The national sales data (nominator) cover all food-producing species, including horses, which are considered as food-producing species according to EU legislation. Thus, the animal population 'at risk' of being treated with antimicrobial agents (denominator) includes all food species. However, the use of antimicrobial agents in the various animal species varies considerably; for example, the use in sheep is relatively low, due to the generally extensive production system. Therefore, interpretation of the data should take into account the distribution of the PCU value between the species in the various countries. It should also be emphasised that the PCU only represents a technical unit of measurement and not a real value for the animal population that could potentially be treated with antimicrobial agents.

Dosing of the various antimicrobial agents between and within classes, as well as between animal species, varies substantially, sometimes by several orders, as reflected by the DDDvet and DCDvet values published by EMA in 2016[24]. For example, the dose for a whole treatment (DCDvet) with an oral fluoroquinolone VMP may be 10–40 mg/kg between cattle, pigs and poultry, while with an oral tetracycline VMP this may vary between 110 and 280 mg/kg. This implies that a given weight of active ingredient of fluoroquinolone sold can be used to treat several times as many animals as the same weight of active ingredient of a tetracycline. Furthermore, within an antimicrobial class there may be different dosages for different substances; for example, the dosage of doxycycline is about one-quarter of the dosage of oxytetracycline. Another consideration is that the treatment dosage may differ significantly according to species; for fish, a typical tetracycline dosage for the whole treatment is 800 mg/kg, or some six times higher than that for terrestrial animals. The data in this report cover all food-producing animals together, and therefore it was not possible to take into account differences in dosing when reporting the data. Since the sales patterns and the animal demographics vary substantially between countries, comparison of the sales data across the countries should be done with great care.

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

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

3.2. Results

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

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

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

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

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

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

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

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

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

In 2014, the prescribing patterns for the various veterinary antimicrobial classes, expressed as mg/PCU, varied substantially between the countries. Notable variations were observed between the different countries in the proportion of the sales accounted for by the CIAs with the highest priority in human medicine — 3rd- and 4th-generation cephalosporins, fluoroquinolones and macrolides, with proportions ranging from 0.01% to 1.5%, 0.01% to 11.9%, and 0% to 16.9%, respectively. Since the major proportion of the sales of these classes/subclasses was accounted for by macrolides, the variations observed between the countries are likely, in part, to reflect difference in the relative proportion of the various animal species and, in particular, differences in pig production (use of macrolides).

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

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

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

Of the total number of product presentations (i.e. product name, form, strength and pack size) of antimicrobial VMPs applicable for food-producing animals (tablets excluded) sold in 2014, 81.2% contained only one active ingredient, 16.8% contained two active ingredients and 1.9% contained three active ingredients; in addition, 0.2% (n=15) of the product presentations contained four active ingredients. Sales of products with three active ingredients were almost solely accounted for by products for individual treatment (intramammary and intrauterine preparations), and sales of products containing four ingredients were only accounted for by intramammary preparations.

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

Annex 1. Tables

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

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

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

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

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

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

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

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

Table A3. Percentage of sales, in mg/PCU, of premixes by veterinary antimicrobial class (according to ATCvet system) by country, for 2014[1]

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

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

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

Table A4. Percentages of sales, in mg/PCU, of oral powders by antimicrobial class (according to ATCvet system) by country, for 2014[1,2]

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

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

[2] France has no sales of oral powder.

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

Table A5. Percentage of sales, in mg/PCU, of oral solutions by antimicrobial class (according to ATCvet system) by country, for 2014

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

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

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

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

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

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

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

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

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

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

Table A8. Number of product presentations (product name, form, strength and pack size) of premixes, oral powders and oral solutions sold containing 1, 2 and 3 antimicrobial agents sold, by country, for 2014[1]

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

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

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

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

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

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

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

	Variable	Description of variable	Justification
	COUNTRY	**ISO code** (http://www.iso.org/iso/country_codes)	To identify place of collected sales data.
	YEAR		To identify time period for collected sales data.
	MA	**Marketing authorisation number**	To allow a unique identification of the veterinary medicinal product (VMP) and enable link with other databases. To allow for market analysis if all the products are available.
PRODUCT INFORMATION	**ID**	**Medicinal product package code value** Digit code is a unique identifier for each package size, strength and formulation of the VMP. Because it is a key variable in many databases it has to be stable over time, i.e. so that VMPs no longer available on the market or that are no longer registered can still be identified to allow for analysis of historical data.	To allow for analysis of historical data. To allow for identification of duplicate reporting of sales.
	NAME	**Medicinal product name (in national language)** e.g. Harmony vet tablets 2 × 30; Harmony vet long-acting injection 10 ml.	For validation purposes. To allow, for example, for analysis of use of, for example, long-acting preparations and antimicrobial resistance.
	FORM	**Pharmaceutical form** Bolus (BOLUS), Injection (INJ), Intramammary preparation (INTRAMAM), Intramammary preparation dry cow (INTRAMAM-DC), Oral solution (ORAL SOLU), Oral paste (ORAL PASTE), Oral powder (ORAL POWD), Premix (PREMIX), Capsules and Tablets, etc. (TABL), Intrauterine preparation (INTRAUT).	Important to avoid misinterpretation of pharmaceutical form if given in a language other than English. Allows for reporting of data as individual or group treatment.
	LONG ACTING	**Long-acting injectable preparations** It refers to injectable preparations that maintain their antimicrobial activity over a long period of time once injected.	Optional.
	PACKSIZE	**Content quantity in package: pack size (numerical only)** e.g. 100 for 100 tablets or 100 intramammary prep.; 10 for 10 ml injection; Package of 2 kg premix: 2; Box of 10 blisters of 30 tablets: 300; Box of 12 injectors: 12.	To allow for calculation of the amount of active ingredient in each package/product.
	PACKSIZEU	**Content unit of measurement** e.g. ML, L, G, KG, PIECE (for example, for tablets, capsules, boluses and intramammary prep.).	To allow for calculation of amount of active ingredient in each package/product.
	ATCvet - 5th LEVEL	**ATCvet: Anatomical Therapeutic Chemical (Classification) Veterinary** WHO ATCvet code last version to be used.	Generally, a classification system needs to have a common language when reporting use and analysing data with data on AMR, e.g. for 3rd- and 4th-generation cephalosporins. To have a common language for defining confidentiality of the data (can be converted into ATCvet 3rd level).

	SPECIES	**Animal species** All the animal species for which the VMP is approved, e.g. cattle (CA), poultry (POU).	Optional.
	NO SOLD	**Number of packages sold/year/country**	To calculate weight of active ingredient sold.
INGREDIENT	**INGR**	**Active ingredient name (ATCvet name)** In case of multi-ingredient VMP, the ATCvet names of all the ingredients have to be given.	Important to avoid misinterpretation of ingredient name if given in a language other than English. Use of ATCvet names facilitates the identification of active ingredients as well as standardised reporting.
	SALT	**Salt of active ingredient** e.g. colistin sulfate and colistin methanesulfonate.	Only in cases when the strength is given in IU, IU/ML or IU/UNIT and when different salts exist, to allow for conversion to weight of active ingredient.
	PRODRUG	**Prodrug name (ATCvet name)** e.g. procaine penicillin that is prodrug for benzylpenicillin.	Only in cases when a product contains a prodrug.
	STRENGTH	**Quantity of the active ingredient in each unit as declared in SPC/label: strength (numerical only)** e.g. 10 for 10 MG/TABLET, 10 IU/TABLET, 10 MG/ML, 10 IU/ML, 10 MG/PIECE or 10 IU/PIECE. In case of a multi-ingredient VMP, strength has to be given for each ingredient separately.	To allow for calculation of amount active ingredient in each package/product and to validate INGR CONTENT.
	STRENGTHU	**Unit of measurement for strength** E.g. IU, IU/G, IU/ML, IU/PIECE, G, G/KG, G/L, MG, MG/ML, MG/PIECE. In case of a multi-ingredient VMP, unit of measurement strength has to be given for each ingredient on a separate line.	To allow for calculation of the amount of active ingredient in each package/product and to validate INGR CONTENT.
	CONV FACT IU	**Conversion factor IU** When strength is given as IU, IU/ML or IU/PIECE.	When strength is only given as IU, IU/ML or IU/PIECE. To allow for calculation of weight of the active ingredient in the package.
	CONV FACT PRODR	**Conversion factor prodrug** Only when strength is given for the prodrug and not for the active ingredient (e.g. procaine penicillin that is prodrug for benzylpenicillin).	To allow for calculation of weight of the active ingredient in the package.
	INGR CONTENT	**Content of active ingredient in package** In case of a multi-ingredient VMP, the content in the package has to be given separately for each ingredient on a separate line.	Optional: to allow for validation of the ESVAC calculations.
	CONT UNIT (G)	**Unit of active ingredient in package** To be given in grams (g) for all substances. In case of a multi-ingredient VMP, the content unit has to be given separately for each ingredient on a separate line.	Optional: to allow for validation of the ESVAC calculations.
	TONNES SOLD	**Tonnes sold of active ingredient**	

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

Table A11. Conversion factors used to convert from international units (IU) to weight (mg) of active ingredient, based on WHO standards[1]

Active ingredient	IU/mg	Conversion factor (mg/IU)
Bacitracin	74	0.01351
Benzylpenicillin (and prodrugs to benzylpenicillin)[4]	1,667	0.00060
Chlortetracycline[2]	900	0.00111
Colistin sulphate	20,500	0.00005
Colistin methane sulphonate[3]	12,700	0.00008
Dihydrostreptomycin	820	0.00122
Erythromycin	920	0.00109
Gentamicin	620	0.00161
Kanamycin	796	0.00126
Neomycin	755	0.00133
Framycetin	670	0.00149
Oxytetracycline	870	0.00115
Paromomycin[2]	675	0.00148
Polymyxin B	8,403	0.00012
Spiramycin	3,200	0.00031
Streptomycin	785	0.00127
Tetracycline	982	0.00102
Tobramycin	875	0.00114
Tylosin	1,000	0.00100

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

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

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

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

Annex 3. Population correction unit (PCU)

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

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

Table A14. Weights used to calculate the population correction unit

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

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

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

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

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

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

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

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

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

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

[3] MRLs not established for poultry (not allowed to be used).

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

Austria

Distribution of veterinary medicines

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

Legal basis for the monitoring of sales

The collection of sales data by pharmaceutical companies and wholesalers is based on the national law on animal drug control: BGBl. II Nr. 83/2014 Veterinär-Antibiotika-MengenströmeVO.

Data sources

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

Belgium

Distribution of veterinary medicines

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

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

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

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

Legal basis for the monitoring of sales

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

Data sources

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

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

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

Bulgaria

Distribution of veterinary medicines

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

Legal basis for the monitoring of sales

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

Data sources

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

Croatia

Distribution of veterinary medicines

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

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

Legal basis for the monitoring of sales

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

Data sources

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

Cyprus

Distribution of veterinary medicines

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

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

Legal basis for the monitoring of sales

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

Data sources

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

Czech Republic

Distribution of veterinary medicines

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

Legal basis for the monitoring of sales

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

Data sources

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

Brief description of data collection

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

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

Denmark

Distribution of veterinary medicines

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

Legal basis for the monitoring of sales

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

Data sources

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

Estonia

Distribution of veterinary medicines

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

Legal basis for the monitoring of sales

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

Data source

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

Finland

Distribution of veterinary medicines

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

Legal basis for the monitoring of sales

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

Data source

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

France

Distribution of veterinary medicines

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

Legal basis for the monitoring of sales

There is no specific national legal framework for monitoring the sales of antimicrobial VMPs in France; the data are provided by the marketing authorisation holders on a voluntary basis. A new law published at the end of 2014 makes the provision of data on antimicrobial sales to the competent authority mandatory.

Data sources

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

Germany

Distribution of veterinary medicines

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

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

Legal basis for the monitoring of sales

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

Data sources

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

Hungary

Distribution of veterinary medicines

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

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

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

Legal basis for the monitoring of sales

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

Data sources

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

Iceland

Distribution of veterinary medicines

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

Legal basis for the monitoring of sales

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

Data sources

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

Ireland

Distribution of veterinary medicines

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

Legal basis for the monitoring of sales

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

Data sources

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

Italy

Distribution of veterinary medicines

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

Wholesale of veterinary medicines

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

Wholesale of veterinary medicinal products includes transactions between:

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

Direct sale of veterinary medicinal products

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

Retail veterinary medicinal products

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

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

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

Legal basis for the monitoring of sales

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

Data sources

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

Latvia

Distribution of veterinary medicines

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

Legal basis for the monitoring of sales

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

Data sources

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

Lithuania

Distribution of veterinary medicines

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

Legal basis for the monitoring of sales

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

Data sources

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

Luxembourg

Distribution of veterinary medicines

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

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

Legal basis for the monitoring

Wholesalers, pharmacies, veterinarians and farmers are legally obliged to keep records of all sales. They are legally bound to provide any data or information they are asked for.

Data sources

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

Netherlands

Distribution of veterinary medicines

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

Legal basis for the monitoring of sales

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

Data sources

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

Norway

Distribution of veterinary medicines

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

Legal basis for the monitoring of sales

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

Data sources

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

Poland

Distribution of veterinary medicines

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

Legal basis for the monitoring of sales

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

Data sources

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

Portugal

Distribution of veterinary medicines

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

Wholesaler-distributors obtain the VMPs from a wholesaler or from the marketing authorisation holder/manufacturer. Antimicrobial VMPs are only available to animal owners/farmers by means of an official veterinary prescription. Veterinarians do not sell VMPs, and they may only charge for those they use for treatment of animals under their care. Premixes are distributed through wholesalers or wholesaler-distributors directly to feed mills. Only farmers are receivers from feed mills. Medicated feeds containing antimicrobial premixes also have to be prescribed by a veterinarian and can only be manufactured by officially authorised feed mills.

Legal basis for the monitoring of sales

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

Data sources

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

Romania

Distribution of veterinary medicines

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

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

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

Legal basis for the monitoring of sales

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

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

Data sources

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

Slovakia

Distribution of veterinary medicines

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

Legal basis for the monitoring of sales

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

Data sources

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

Brief description of data collection

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

Slovenia

Distribution of veterinary medicines

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

Legal basis for the monitoring of sales

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

Data sources

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

Spain

Distribution of veterinary medicines

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

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

Legal basis for the monitoring of sales

There is a legal basis for mandatory reporting of sales data from the distributors of such products, while monitoring of sales from the MAHs takes place voluntarily.

Data sources

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

Sweden

Distribution of veterinary medicines

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

Legal basis for the monitoring of sales

All pharmacies in Sweden are required to provide sales statistics on a daily basis to a central database. Until and including 2013, this was an infrastructure company owned by the state, Apotekens Service AB. From 1 January 2014, all activities of that company have been transferred to the Swedish eHealth Agency. All feed mills and farms authorised to mix medicated feed are requested to report their purchases and sales on a yearly basis to the Board of Agriculture.

Data sources

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

Switzerland

Distribution of veterinary medicines

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

Legal basis for the monitoring of sales

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

Data sources

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

Data coverage

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

United Kingdom

Distribution of veterinary medicines

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

Legal basis for the monitoring of sales

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

Data sources

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

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

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Table A17. List of ESVAC sales Advisory Expert Group members

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