

Sales of veterinary antibiotics in Ireland during 2022

INTRODUCTION

This report presents the data collected by the Health Products Regulatory Authority (HPRA) for the year 2022, on the sales of veterinary antibiotics that are marketed in Ireland. This work is conducted in conjunction with the European Surveillance of Veterinary Antimicrobial Consumption (ESVAC) project, a European Commission initiative coordinated by the European Medicines Agency (EMA) and with the assistance of the companies involved. The data are based on the voluntary declarations by marketing authorisation holders on the supply of their products. The HPRA has been collecting these data since 2009. The ESVAC program has now concluded; in accordance with Regulation 2019/6, the collection of sales and use data on antimicrobials became a mandatory activity of Member States. In the case of Ireland, the Department of Agriculture, Food and the Marine is responsible for collecting and reporting usage data to the European Medicines Agency. The first report is expected in 2025, with data from 2023 and 2024.

The sales data provided in this report should be interpreted with caution; annual sales figures have been observed to fluctuate and such variation is regarded as normal. It should be noted that changes in animal demographics from one year to the next will also influence the demand for antibiotics.

1.1 Methodology

Companies marketing veterinary antibiotics in Ireland were requested to submit annual returns for quantities of individual presentations of product supplied in the State during 2022. Sales data for veterinary antibiotic medicines authorised in Ireland (including both medicines authorised nationally by the HPRA as well as those authorised centrally by the EU Commission) were collected. These covered 52 individual antibiotic substances. The data are based on self-declarations by applicant companies and have not been subject to independent verification or audit. It should be noted that certain other veterinary antibiotics (such as those authorised under special licence by the Department of Agriculture, Food and the Marine) and human antibiotics (which might be prescribed or used by veterinary practitioners where there is not a suitable veterinary alternative authorised) were not included in this analysis. However, the contribution from these sources to the overall figure is likely to be very small.

The data were collated by the HPRA and reviewed for discrepancies before being entered into the ESVAC database for additional validation. The methodology for collection is a harmonised approach that is followed in each of the European Member States. The analysis of the data in respect of individual substances of the same antibiotic classes have been grouped together and classified under the appropriate class headings. In this report the headings are as follows: penicillins, amphenicols, tetracyclines, fluoroquinolones, aminoglycosides, macrolides, lincosamides, sulfonamides & trimethoprim, cephalosporins and other classes. The EMA also publishes an annual report on the sales of veterinary antibiotics throughout Europe. Please note,

as historical sales data are periodically updated to take into account errors or new information, discrepancies in values published between reports may be observed.

1.2 Results

The quantity of veterinary antibiotics (as active substance) sold in Ireland in 2022 was 76.5 tonnes. For comparison purposes the sales over the period 2013 to 2022 are presented in Table 1 below.

Table 1. Sales (tonnes sold) of veterinary antibiotics for the years 2013 - 2022

	2013	2014	2015	2016	2017	2018	2019	2020	2021	2022
Tonnes sold	99.1	89.4	96.9	103.4	99.7	99.4	88.3	103.9	94.2	76.5

The proportion of sales supplied into the market for 2022 by antibiotic classes and by pharmaceutical form can be found in Figure 1 and 2, respectively:

Figure 1. Distribution of sales (based on tonnes sold) of veterinary antibiotics supplied in 2022 in Ireland.

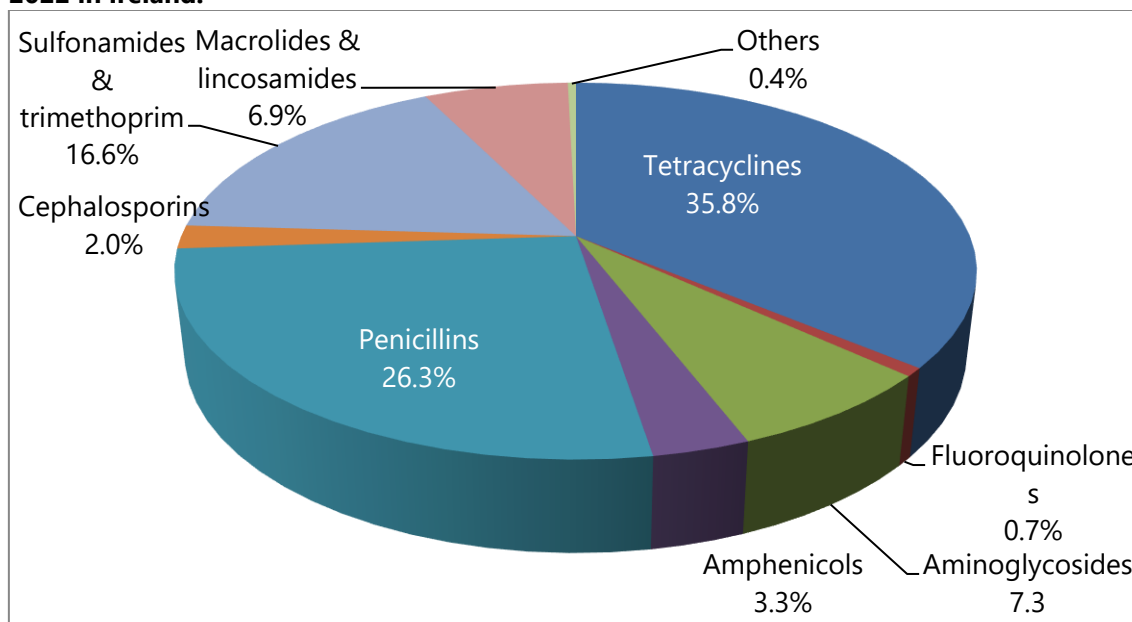
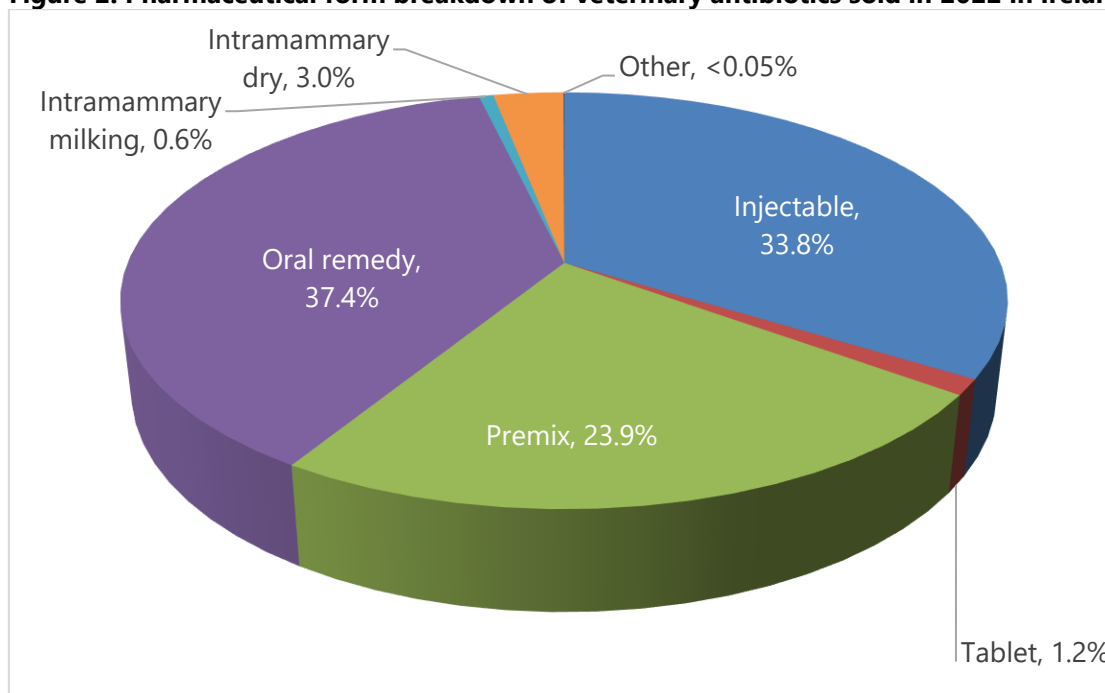


Figure 2. Pharmaceutical form breakdown of veterinary antibiotics sold in 2022 in Ireland.



*Oral remedy: includes oral powders, pastes, boluses and solutions.

The European Medicines Agency's Antimicrobial Advice Ad Hoc Expert Group (AMEG) review in 2019 of the categorisation of antibiotics¹ included the WHO's highest priority critically important antibiotics [the 3rd and 4th generation cephalosporins, quinolones (fluoroquinolones, other quinolones) and polymyxins] in Category B ("Restrict"). That is, these restricted antibiotics should only be used for the treatment of clinical conditions in animals when there are no alternative antibiotics in a lower category that could be clinically effective. The other highest priority critically important class of antibiotics, macrolides, were included in Category C ("Caution") of the AMEG categorisation. Given the importance of these classes they are reported separately in Table 2 below:

Table 2. Sales (tonnes sold) of 3rd & 4th generation cephalosporins, fluoroquinolones and macrolides for the years 2014 - 2022

	2014	2015	2016	2017	2018	2019	2020	2021	2022
3 rd & 4 th gen. cephalosporins	0.24	0.22	0.25	0.30	0.33	0.28	0.36	0.35	0.16
Fluoroquinolones	0.69	0.79	0.94	0.85	0.84	0.74	0.80	0.85	0.54
Macrolides	6.26	5.58	6.58	7.17	7.07	5.60	5.15	5.37	4.28

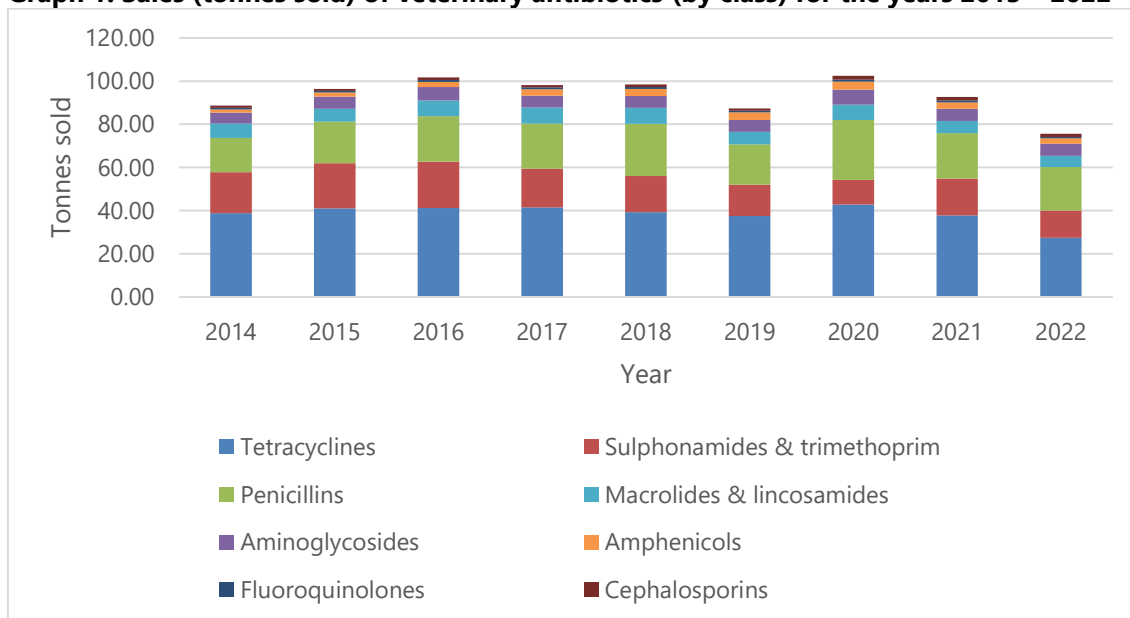
No sales of polymyxins (colistin) were recorded in 2022.

¹ Categorisation of antibiotics in the European Union. Answer to the request from the European Commission for updating the scientific advice on the impact on public health and animal health of the use of antibiotics in animals (https://www.ema.europa.eu/en/documents/report/categorisation-antibiotics-european-union-answer-request-european-commission-updating-scientific_en.pdf)

1.3 Discussion

Overall sales of veterinary antibiotics in 2022 decreased by 18.8% to 76.5 tonnes when compared to sales in 2021.

Graph 1. Sales (tonnes sold) of veterinary antibiotics (by class) for the years 2013 – 2022



The significant decline in sales of veterinary antibiotics is welcome, given the target in the European Green Deal and the Farm to Fork strategy for a 50% reduction in sales of antimicrobials for farmed animals and in aquaculture in the European Union by 2030 in comparison to the reference year 2018. The decline in 2022, which has continued from the previous year, is evident in respect of all antimicrobial classes save the aminoglycosides (which remained at the same level), but importantly in the highest priority critically important antibiotics.

The supply of oral antibiotic premixes declined by 43.6% in 2022, with intramammary dry cow antibiotics reduced by 24.4% and injectable antibiotics reduced by 7.6%. Changes in respect of tablets and other intramammary antibiotics were less than 7%. Within the oral remedies category, sales of oral solutions increased by 7.9%, while sales of oral powders decreased by 18.4%.

Whilst many actors play a part in bringing about this result, it is fair to point out that the publicity surrounding the introduction of new restrictions on veterinary antibiotics under Regulation 2019/6, including the launch of the Veterinary Council's Code of Professional Conduct and political debate in the Oireachtas has helped focus attention on reducing the use of veterinary antibiotics. The ongoing work by the National Interdepartmental AMR Consultative Committee and the iNAP Animal Health Implementation Committee in supporting responsible use of antibiotics in Ireland as well as development of codes of good practice on use of antibiotics on farms by Animal Health Ireland are also important in helping raising awareness and in promoting behavioural changes to antibiotic use on farms. The new EU rules governing the validity of an antibiotic prescription (now restricted to 5 days, previously one year) has also been a major milestone. There has been a significant reduction in the use of medicated feeds prepared from antibiotic premixes. However, it is not known if this is solely due to improved prescribing practices, or a switch to other forms of oral antibiotic medicines or related to some extraneous factor such as consolidation and increased specialisation of pig production.

During the course of 2023 and 2024, further restrictions on veterinary antibiotics will be manifest, including:

- Updating of labelling and package leaflets of veterinary antibiotics to remove any indication for preventative use (antibiotics are not to be used for prophylaxis other than in exceptional cases, for the administration to an individual animal or a restricted number of animals when the risk of an infection or of an infectious disease is very high and the consequences are likely to be severe),
- New EU legislation on off-label use of veterinary antibiotics by veterinary practitioners,
- Initiation of collection of use data on antibiotics used in cattle, pigs, chickens and turkeys in 2023, with reporting to the EMA from 2024 onwards.

It is expected that these efforts will drive further changes in the years ahead.

2 CONCLUSION

The 2022 sales data for veterinary antibiotics in Ireland reveal a significant decline of 18.8% compared to the previous year, which itself had seen a decrease of 9.3% on 2020. This trend is particularly encouraging, as it aligns with the European Green Deal and the Farm to Fork strategy, aiming for a 50% reduction in antimicrobial use in farmed animals and aquaculture by 2030, based on the 2018 reference year.

Notably, this decline extends across all antimicrobial classes, including the highest priority critically important antibiotics. The reduction is even more pronounced in specific medicine categories, such as the supply of oral antibiotic premixes, which decreased by 43.6% in 2022, intramammary dry cow antibiotics, down by 24.4%, and injectable antibiotics, which decreased by 7.6%.

The collective efforts of various stakeholders, including the Veterinary Council's Code of Professional Conduct, political discourse in the Oireachtas, and initiatives like the National Interdepartmental AMR Consultative Committee have played a pivotal role in raising awareness amongst stakeholders and encouraging behavioural shifts in antibiotic use on farms. The introduction of new EU legislation, which shortened the validity of antibiotic prescriptions to just five days, is another significant milestone in achieving this result.

Looking ahead, Ireland in common with other EU Member States is set to implement further restrictions on veterinary antibiotic use, such as updating labelling and package leaflets to curtail preventative use, limitations on off-label use by veterinary practitioners, and the initiation of data collection on antibiotic usage in specific livestock categories. This latter measure will help provide insights into areas of excess usage for further attention and future focus. It will be important to maintain commitment to responsible antibiotic use in animals to solidify Ireland's position in global animal food production as well as in promoting sustainable agricultural practices.

ENDS

Report on sales of veterinary antibiotics in Ireland during 2021

INTRODUCTION

This report presents the data collected by the Health Products Regulatory Authority (HPRA) for the year 2021, on the sales of veterinary antibiotics that are marketed in Ireland. This work is conducted in conjunction with the European Surveillance of Veterinary Antimicrobial Consumption (ESVAC) project, a European Commission initiative coordinated by the European Medicines Agency (EMA) and with the assistance of the companies involved. The data are based on the voluntary declarations by marketing authorisation holders on the supply of their products. The HPRA has been collecting these data since 2009.

The sales data provided in this report should be interpreted with caution; annual sales figures have been observed to fluctuate and such variation is regarded as normal. It should be noted that changes in animal demographics from one year to the next will also influence the demand for antibiotics.

1.1 Methodology

Companies marketing veterinary antibiotics in Ireland were requested to submit annual returns for quantities of individual presentations of product supplied in the State during 2021. Sales data for veterinary antibiotic medicines authorised in Ireland (including both medicines authorised nationally by the HPRA as well as those authorised centrally by the EU Commission) were collected. These covered 52 individual antibiotic substances. The data are based on self-declarations by applicant companies and have not been subject to independent verification or audit. It should be noted that certain other veterinary antibiotics (such as those authorised under special licence by the Department of Agriculture, Food and the Marine) and human antibiotics (which might be prescribed or used by veterinary practitioners where there is not a suitable veterinary alternative authorised) were not included in this analysis. However, the contribution from these sources to the overall figure is likely to be very small.

The data were collated by the HPRA and reviewed for discrepancies before being entered into the ESVAC database for additional validation. The methodology for collection is a harmonised approach that is followed in each of the European Member States. The analysis of the data in respect of individual substances of the same antibiotic classes have been grouped together and classified under the appropriate class headings. In this report the headings are as follows: penicillins, amphenicols, tetracyclines, fluoroquinolones, aminoglycosides, macrolides, lincosamides, sulfonamides & trimethoprim, cephalosporins and other classes. The EMA also publishes an annual report on the sales of veterinary antibiotics throughout Europe. Please note, as historical sales data are periodically updated to take into account errors or new information, discrepancies in values published between reports may be observed.

1.2 Results

The quantity of veterinary antibiotics (as active substance) sold in Ireland in 2021 was 94.2 tonnes. For comparison purposes the sales over the period 2013 to 2021 are presented in Table 1 below.

Table 1. Sales (tonnes sold) of veterinary antibiotics for the years 2013 - 2021

	2013	2014	2015	2016	2017	2018	2019	2020	2021
Tonnes sold	99.1	89.4	96.9	103.4	99.7	99.4	88.3	103.9	94.2

The proportion of sales supplied into the market for 2021 by antibiotic classes and by pharmaceutical form can be found in Figure 1 and 2, respectively:

Figure 1. Distribution of sales (based on tonnes sold) of veterinary antibiotics supplied in 2021 in Ireland.

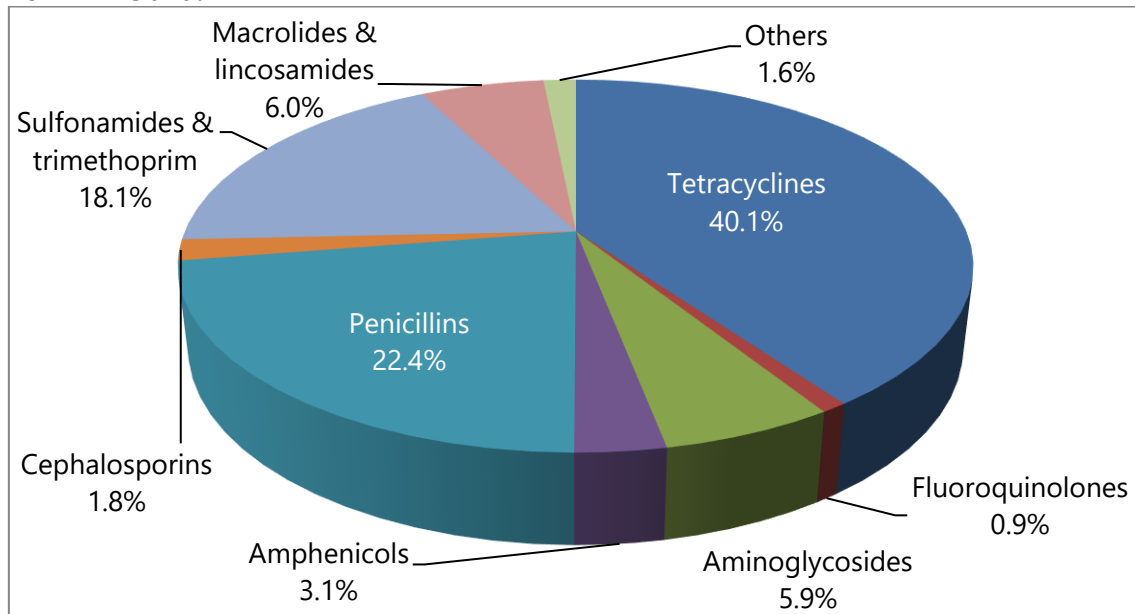
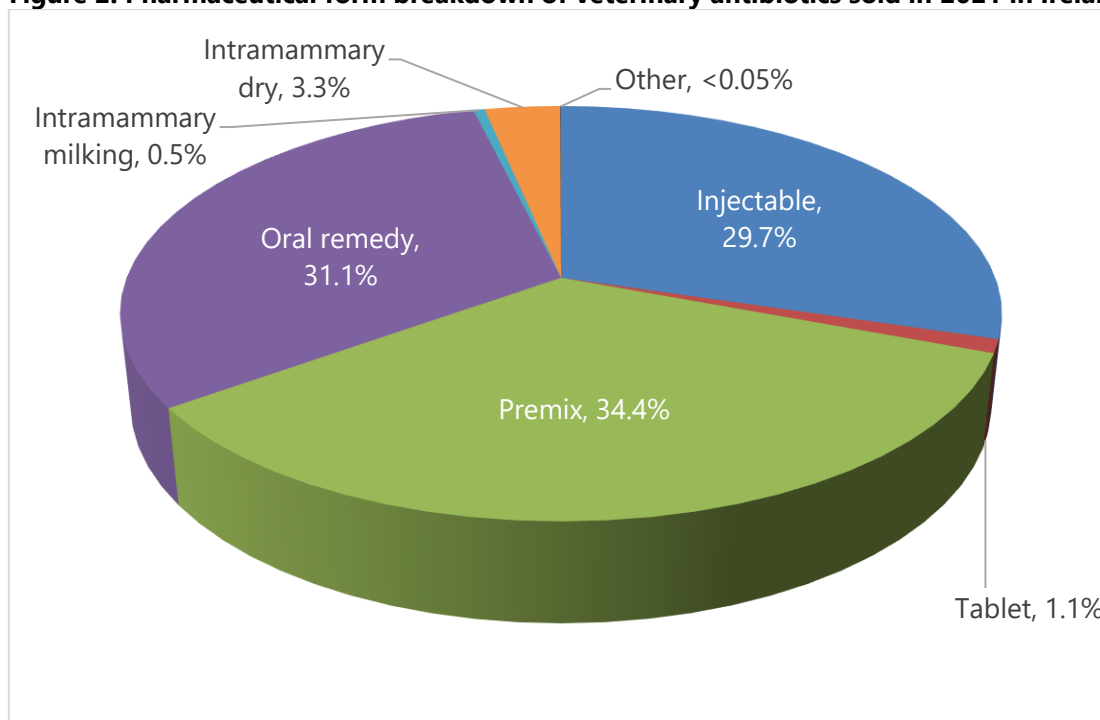


Figure 2. Pharmaceutical form breakdown of veterinary antibiotics sold in 2021 in Ireland.



The European Medicines Agency’s Antimicrobial Advice Ad Hoc Expert Group (AMEG) review in 2019 of the categorisation of antibiotics¹ included the WHO’s highest priority critically important antibiotics; the 3rd and 4th generation cephalosporins, quinolones (fluoroquinolones, other quinolones) and polymyxins in Category B (“Restrict”). That is, these restricted antibiotics should only be used for the treatment of clinical conditions in animals when there are no alternative antibiotics in a lower category that could be clinically effective. The other highest priority critically important class of antibiotics, macrolides, were included in Category C (“Caution”) of the AMEG categorisation. Given the importance of these classes they are reported separately in Table 2 below:

Table 2. Sales (tonnes sold) of 3rd & 4th generation cephalosporins, fluoroquinolones and macrolides for the years 2013 - 2021

	2013	2014	2015	2016	2017	2018	2019	2020	2021
3 rd & 4 th gen. cephalosporins	0.17	0.24	0.22	0.25	0.30	0.33	0.28	0.36	0.35
Fluoroquinolones	0.89	0.69	0.79	0.94	0.85	0.84	0.74	0.80	0.85
Macrolides	6.25	6.26	5.58	6.58	7.17	7.07	5.60	5.15	5.37

No sales of polymyxins (colistin) were recorded in 2021 for the first time. There are no veterinary medicinal products authorised in Ireland containing ‘other quinolones’.

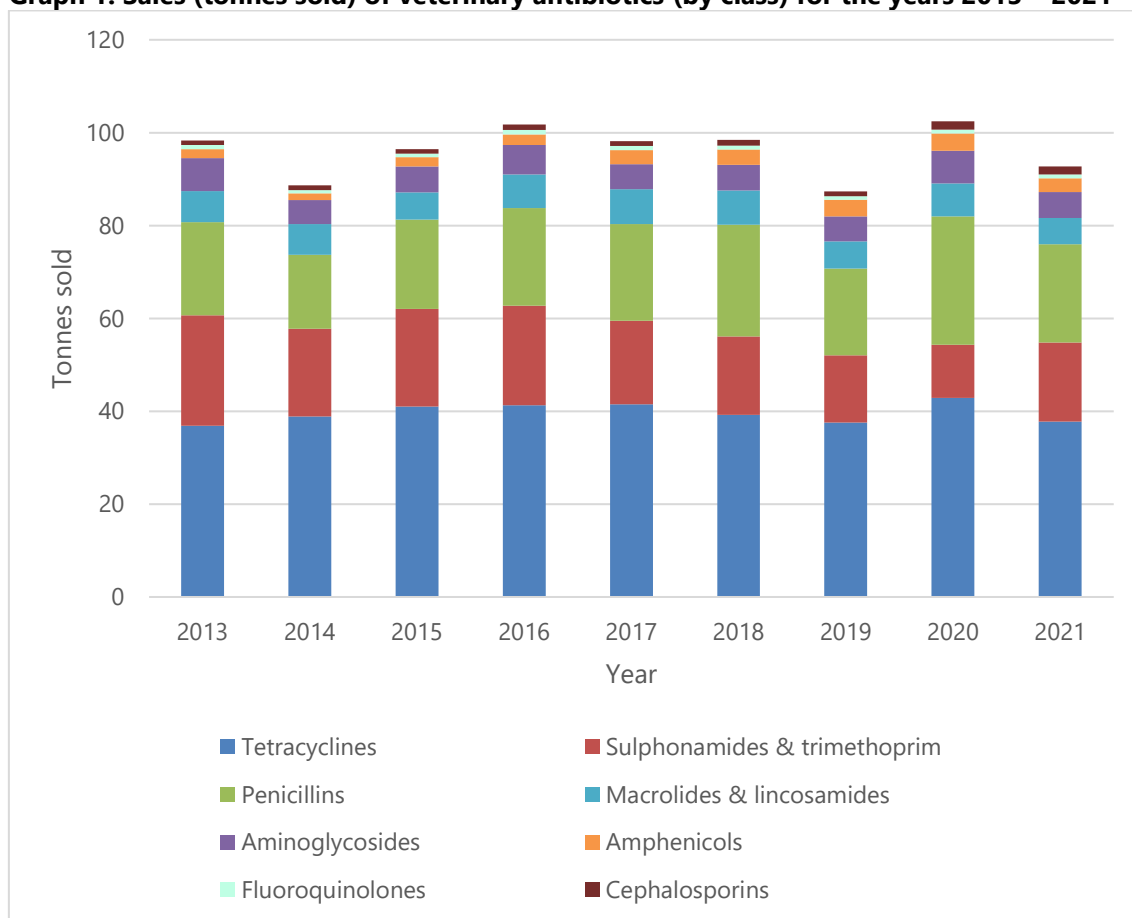
¹ Categorisation of antibiotics in the European Union. Answer to the request from the European Commission for updating the scientific advice on the impact on public health and animal health of the use of antibiotics in animals (https://www.ema.europa.eu/en/documents/report/categorisation-antibiotics-european-union-answer-request-european-commission-updating-scientific_en.pdf)

1.3 Discussion

Overall sales of veterinary antibiotics in 2021 decreased by 9.3% to 94.2 tonnes when compared to sales in 2020. As in previous years, the three highest selling antibiotic classes were tetracyclines, penicillins and sulfonamides (in combination with trimethoprim), which accounted for 40.1%, 22.4% and 18.1% of total sales, respectively (Figure 1).

Reductions in the sales of tetracyclines, penicillins, aminoglycosides and amphenicols were observed (Graph 1). The decrease in the sales of macrolides & lincosamides was attributed to a decrease in sales of lincosamides, with sales of macrolides relatively unchanged. In contrast, an increase in sales of sulfonamides was observed, reversing the decreases observed in 2019 and 2020.

Graph 1. Sales (tonnes sold) of veterinary antibiotics (by class) for the years 2013 – 2021



In relation to sales of 3rd & 4th generation cephalosporins, the quantity sold in 2021 was comparable to that of 2020. Sales of fluoroquinolones remained comparable to previous years.

In 2021, under Ireland's national action plan to address antimicrobial resistance, a statement of intent supporting the voluntary cessation of use of colistin to treat disease in the animal sector was published. This coincided with zero sales of colistin in 2021.

The type and proportion of pharmaceutical forms (i.e. presentations of product) supplied to the market remained similar to previous years (Figure 2). Orally administered veterinary medicines

accounted for almost two-thirds (65.5%) of all antibiotic sales, with the majority intended for use in feed and water.

2 CONCLUSION

The sales of veterinary antibiotics decreased by 9.3% compared to 2020. Of the highest priority critically important antibiotics, sales of 3rd & 4th generation cephalosporins, fluoroquinolones and macrolides remained essentially unchanged, with no sales of polymyxins (colistin) recorded.

Ireland's second one health national action plan on antimicrobial resistance for the period 2021-2025 (iNAP2), builds on the work accomplished under the previous national action plan (2017-2020), further strengthening multidisciplinary collaborative efforts across the health, agricultural and environmental sectors. Together with the new regulation on veterinary medicinal products (Regulation (EU) 2019/6) which introduces new controls on the authorisation, supply and use of veterinary antimicrobials, further reductions in the sales of veterinary antibiotics are expected in the coming years.

ENDS

Report on sales of veterinary antibiotics in Ireland during 2020

INTRODUCTION

This report presents the data collected by the Health Products Regulatory Authority (HPRA) during 2020, on the sales of veterinary antibiotics that are marketed in Ireland. This work is conducted in conjunction with the European Surveillance of Veterinary Antimicrobial Consumption (ESVAC) project, a European Commission initiative coordinated by the European Medicines Agency (EMA) and with the assistance of the companies involved. The data are based on the voluntary declarations by marketing authorisation holders on the supply of their products. The HPRA has been collecting these data since 2009.

The sales data provided in this report should be interpreted with caution; annual sales figures have been observed to fluctuate and such variation is regarded as normal. It should be noted that changes in animal demographics from one year to the next will also influence the demand for antibiotics.

1.1 Methodology

Companies marketing veterinary antibiotics in Ireland were requested to submit annual returns for quantities of individual presentations of product supplied in the State during 2020. Sales data from 539 veterinary antibiotic medicines authorised in Ireland (including both medicines authorised nationally by the HPRA as well as those authorised centrally by the EU Commission) were collected. These covered 49 individual antibiotic substances. The data are based on self-declarations by applicant companies and have not been subject to independent verification or audit. It should be noted that certain other veterinary antibiotics (such as those authorised under special licence by the Department of Agriculture, Food and the Marine) and human antibiotics (which might be prescribed or used by veterinary practitioners where there is not a suitable veterinary alternative authorised) were not included in this analysis. However, the contribution from these sources to the overall figure is likely to be very small.

The data were collated by the HPRA and reviewed for discrepancies before being entered into the ESVAC database for additional validation. The methodology for collection is a harmonised approach that is followed in each of the European Member States. The analysis of the data in respect of individual substances of the same antibiotic classes have been grouped together and classified under the appropriate class headings. In this report the headings are as follows: penicillins, amphenicols, tetracyclines, fluoroquinolones, aminoglycosides, macrolides, lincosamides, sulphonamides & trimethoprim (TMP), cephalosporins and other classes. The EMA also publishes an annual report on the sales of veterinary antibiotics throughout Europe. Please note, as historical sales data are periodically updated to take into account errors or new information, discrepancies in values published between reports may be observed.

1.2 Results

The total reported tonnage of veterinary antibiotics sold in Ireland in 2020 was 103.9 tonnes. These results are broken down by antibiotic classes supplied into the market in Figure 1 and by pharmaceutical form in Figure 2 below:

Figure 1. Distribution of sales (based on tonnes sold) of veterinary antibiotics supplied in 2020 in Ireland.

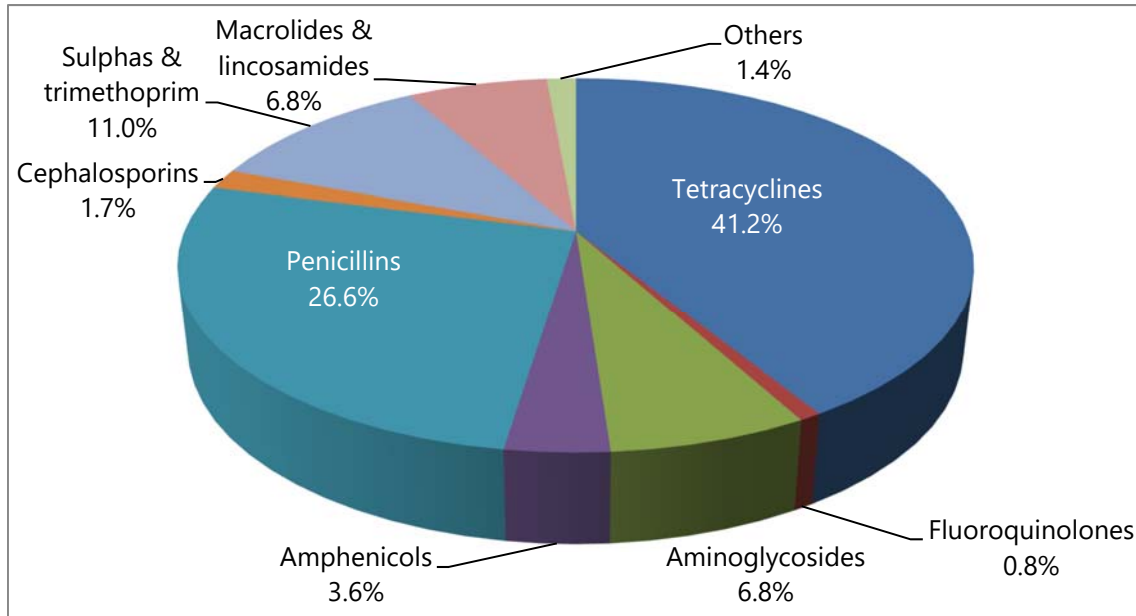
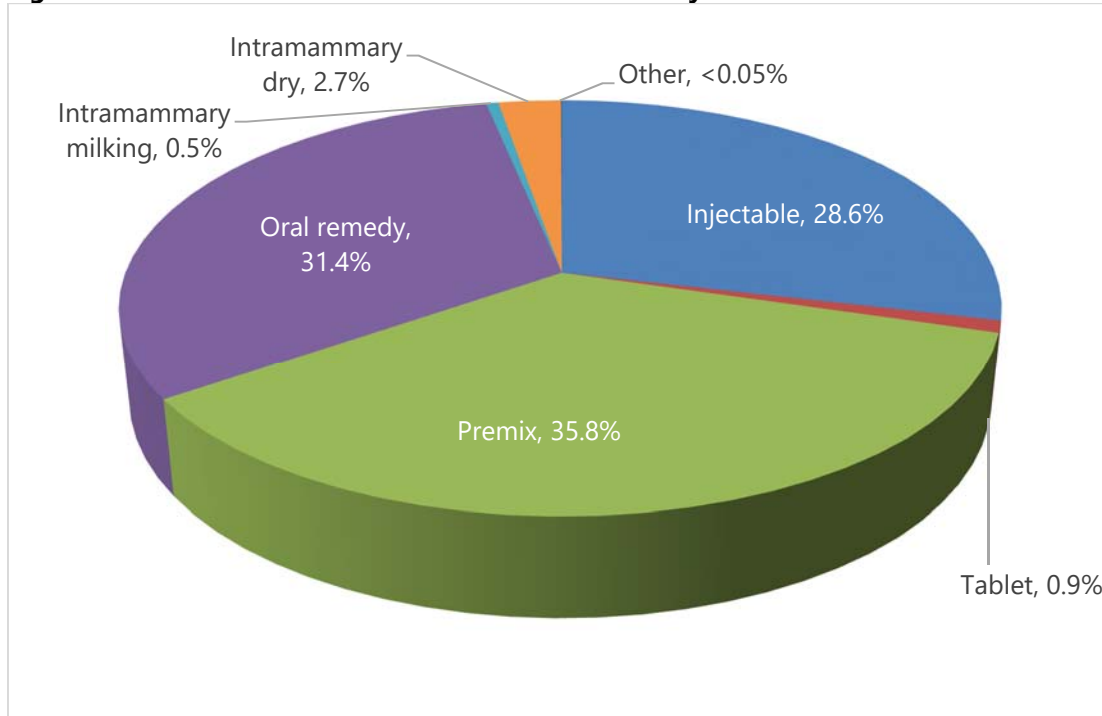


Figure 2. Pharmaceutical form breakdown of veterinary antibiotics sold in 2020 in Ireland.



The sales of the highest priority critically important antibiotics, 3rd and 4th generation cephalosporins, fluoroquinolones and macrolides are provided in detail below. Due to the low

number of products authorised on the market in Ireland, sales of polymyxins (colistin) cannot be reported here for reasons of commercial confidentiality.

Table 1. Sales (tonnes sold) of 3rd & 4th generation cephalosporins, fluoroquinolones and macrolides for the years 2013 - 2020

	2013	2014	2015	2016	2017	2018	2019	2020
3 rd & 4 th gen. cephalosporins	0.17	0.24	0.22	0.25	0.30	0.33	0.28	0.36
Fluoroquinolones	0.89	0.69	0.79	0.94	0.85	0.84	0.74	0.80
Macrolides	6.25	6.26	5.58	6.58	7.17	7.07	5.60	5.15

1.3 Discussion

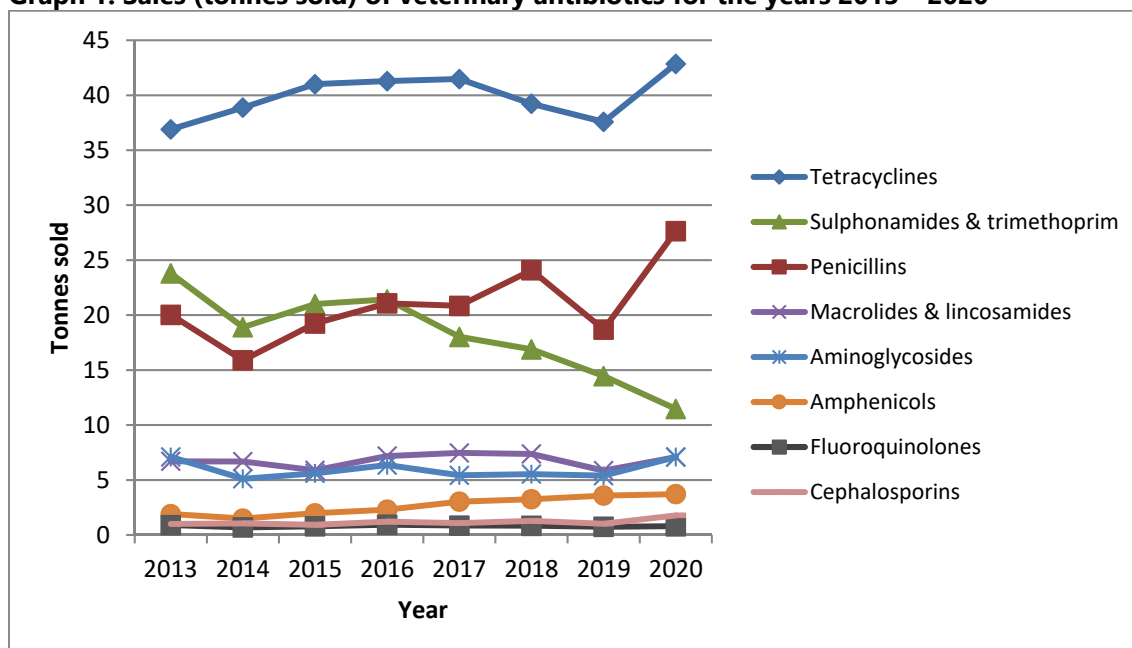
The antibiotic sales data reported for 2020 indicates that sales of veterinary antibiotics increased by approximately 15.6 tonnes when compared to the previous year (Table 2).

Table 2. Sales (tonnes sold) of veterinary antibiotics for the years 2013 - 2020

	2013	2014	2015	2016	2017	2018	2019	2020
Tonnes sold	99.1	89.4	96.9	103.4	99.7	99.4	88.3	103.9

As illustrated in Graph 1 below, the majority of this increase can be attributed to an increase in the reported sales of penicillins and tetracyclines. Sales of tetracyclines and penicillins continued to account for the majority of veterinary antibiotics sold, representing 41.2% and 26.6% of total sales (Figure 1). Notable increases in the sales of aminoglycosides and lincosamides were also observed. As for previous years, the increasing trend in sales of amphenicols continued.

Graph 1. Sales (tonnes sold) of veterinary antibiotics for the years 2013 – 2020



Sales of sulphonamides in combination with trimethoprim decreased further.

In relation to sales of 3rd & 4th generation cephalosporins, while noting the decrease in sales in 2019, the overall trend in sales is increasing. While the sales of fluoroquinolones vary from year to year, sales for 2020 remain relatively unchanged when compared to previous years. The data on macrolides is beginning to show a decreasing trend in sales.

The proportion of pharmaceutical forms (i.e. presentations of product) supplied to the market remained similar to previous years (Figure 2). Orally administered animal remedies accounted for just over two-thirds (68.1%) of all antibiotic sales, with the majority intended for use in feed and water.

While fluctuations in sales of antibiotic products occur from year to year, exact reasons for the magnitude of the changes are unknown. In addition to seasonal disease prevalence, changes in animal demographics, prescribing preferences, and drug pricing are expected to play a part. Of note is that there was a significant increase in the overall sales of antibiotics during 2020. A contributory factor might be uncertainty around Brexit and the potential implications for availability of veterinary medicines, which is expected to have led to increased stocks being traded before 31 December 2020. Consequently, the effect of national initiatives encouraging prudent use of antibiotics are likely to have been masked by these other variables.

The new veterinary regulation (Regulation (EU) 2019/6), which came into effect in 2019 and which applies throughout the EU on 28 January 2022, will bring about a number of important new controls on the authorisation, supply and use of veterinary antimicrobials, including the following:

- Strengthening their prudent use, including avoiding routine prophylactic or metaphylactic use, restricting antimicrobials that are critically important for preventing or treating life-threatening infections in humans,
- Improving knowledge on the potential risks of new veterinary antimicrobials on the development of antimicrobial resistance in humans or animals,
- Defining restrictive conditions for the use of veterinary antimicrobials to ensure that those prescribed and used are sufficiently effective and appropriate to treat the diagnosed disease,
- Ensuring that the amounts of veterinary antimicrobials prescribed by veterinarians are restricted to the amount required for treatment of the animals concerned,
- The limitation on the duration of validity of a veterinary prescription for an antimicrobial medicine, for a period of five days from the date of issue,
- The phased collection of data on the volume of sales and use of antimicrobial medicines used in animals over the period to 2030, to enable evaluation at farm level.
- The addition of instructions for cleaning of equipment used for administration of medicines given orally in feed or drinking water to animals to avoid cross-contamination.

These measures are expected to lead to a reduction in the sales of veterinary antimicrobials in the coming years. They are also expected to lead to more granular data on antimicrobial use that will inform future policy on antimicrobial stewardship.

2 CONCLUSION

A 17.6% increase in the sales of veterinary antibiotics was recorded for 2020, countering a decrease observed since 2016. During 2020, an increase in sales of 3rd & 4th generation cephalosporins, categorised as highest priority critically important antibiotics, was also noted.

Of the many factors that could have played a role in the increases observed, over-purchasing of antimicrobial medicines in advance of the UK departure from the EU customs area on 31 December 2020 in order to ensure adequate stock in quarter 1, 2021 might have influenced sales

patterns. Furthermore, the number of animals in the national herd has increased in recent years, and other extraneous factors might also have played a role.

The new veterinary regulation, which will apply on 28 January 2022, will bring a number of changes to the regulatory landscape for veterinary medicinal products generally, and for veterinary antimicrobials in particular. The HPRA expects that with the availability of additional usage data on veterinary antimicrobials over the next five to ten years, additional insights into effective control measures will come into play, which might lead to yet further restrictions.

ENDS

Report on sales of veterinary antibiotics in Ireland during 2019

INTRODUCTION

This report presents the data collected by the Health Products Regulatory Authority (HPRA) during 2019, on the sales of veterinary antibiotics that are marketed in Ireland. This work is conducted in conjunction with the European Surveillance of Veterinary Antimicrobial Consumption (ESVAC) project, a European Commission initiative coordinated by the European Medicines Agency (EMA) and with the assistance of the companies involved. The data are based on the voluntary declarations by marketing authorisation holders on the supply of their products. The HPRA, as competent authority for the authorisation and monitoring of veterinary medicinal products in Ireland, has been collecting these data since 2009.

The sales data provided in this report should be interpreted with caution; annual sales figures have been observed to fluctuate and slight annual variations are regarded as normal due to changing disease incidence. It should be noted that changes in animal demographics from one year to the next, will also influence the demand for antibiotics.

1.1 Methodology

Companies marketing veterinary antibiotics in Ireland were requested to submit annual returns for quantities of individual presentations of product supplied in the State during 2019. Sales data from 520 veterinary antibiotic medicines authorised in Ireland (including both medicines authorised nationally by the HPRA as well as those authorised centrally by the EU Commission) were collected. These covered 51 individual antibiotic substances. The data are based on self-declarations by applicant companies and have not been subject to independent verification or audit. It should be noted that certain other veterinary antibiotics (such as those authorised under special licence by the Department of Agriculture, Food and the Marine) and human antibiotics (which might be prescribed or used by veterinary practitioners where there is not a suitable veterinary alternative authorised) were not included in this analysis. However, the contribution from these sources to the overall figure is likely to be very small.

The data were collated by the HPRA and reviewed for discrepancies before being entered into the ESVAC database for additional validation. The methodology for collection is a harmonised approach that is followed in each of the European Member States. The analysis of the data in respect of individual substances of the same antibiotic classes have been grouped together and classified under the appropriate class headings. In this report the headings are as follows: penicillins, amphenicols, tetracyclines, fluoroquinolones, aminoglycosides, macrolides, lincosamides, sulphonamides & trimethoprim (TMP), cephalosporins and other classes. The EMA also publishes an annual report on the sales of veterinary antibiotics throughout Europe.

1.2 Results

Analysis of the sales data for 2019 indicated that the total tonnage of veterinary antibiotics sold in Ireland was 88.8 tonnes. These results are broken down by antibiotic classes supplied into the market in Figure 1 and by pharmaceutical form in Figure 2 below:

Figure 1. Distribution of sales (based on tonnes sold) of veterinary antibiotics supplied in 2019 in Ireland.

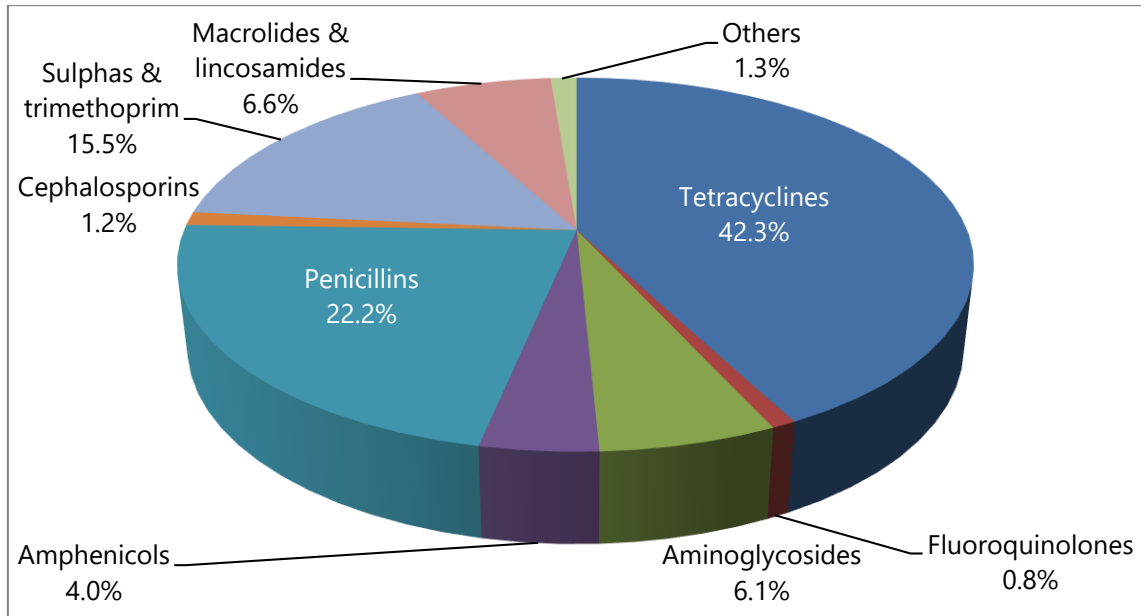
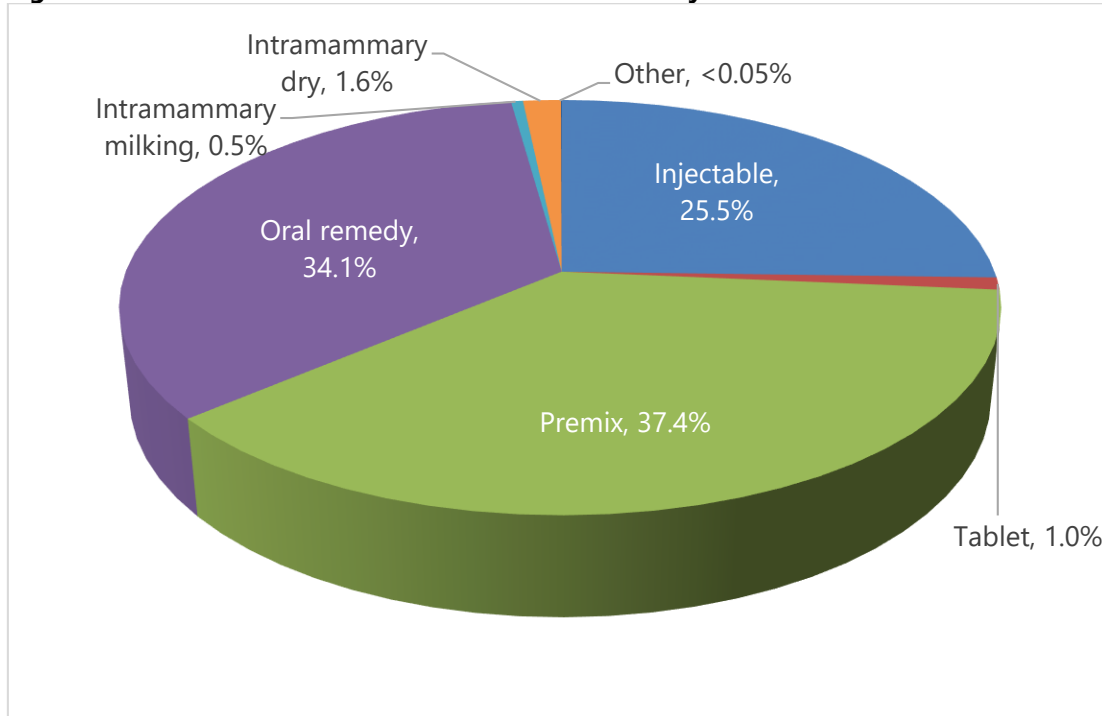


Figure 2. Pharmaceutical form breakdown of veterinary antibiotics sold in 2019 in Ireland.



The sales of the highest priority critically important antibiotics, 3rd and 4th generation cephalosporins, fluoroquinolones and macrolides are provided in detail below. Due to the low

number of products authorised on the market in Ireland, sales of polymyxins (colistin) cannot be reported here for reasons of commercial confidentiality.

Table 1. Sales (tonnes sold) of 3rd & 4th generation cephalosporins, fluoroquinolones and macrolides for the years 2013 - 2019

	2013	2014	2015	2016	2017	2018	2019
3 rd & 4 th gen. cephalosporins	0.17	0.24	0.22	0.25	0.30	0.33	0.21
Fluoroquinolones	0.89	0.69	0.79	0.94	0.85	0.84	0.74
Macrolides	6.25	6.26	5.58	6.58	7.17	7.07	5.60

1.3 Discussion

A significant reduction in the sales of veterinary antibiotics was observed in 2019 (Table 2). This is considerably lower than in recent years and is comparable with a figure of 88.3 tonnes in 2009 (as re-stated in the 2014 HPRA report).

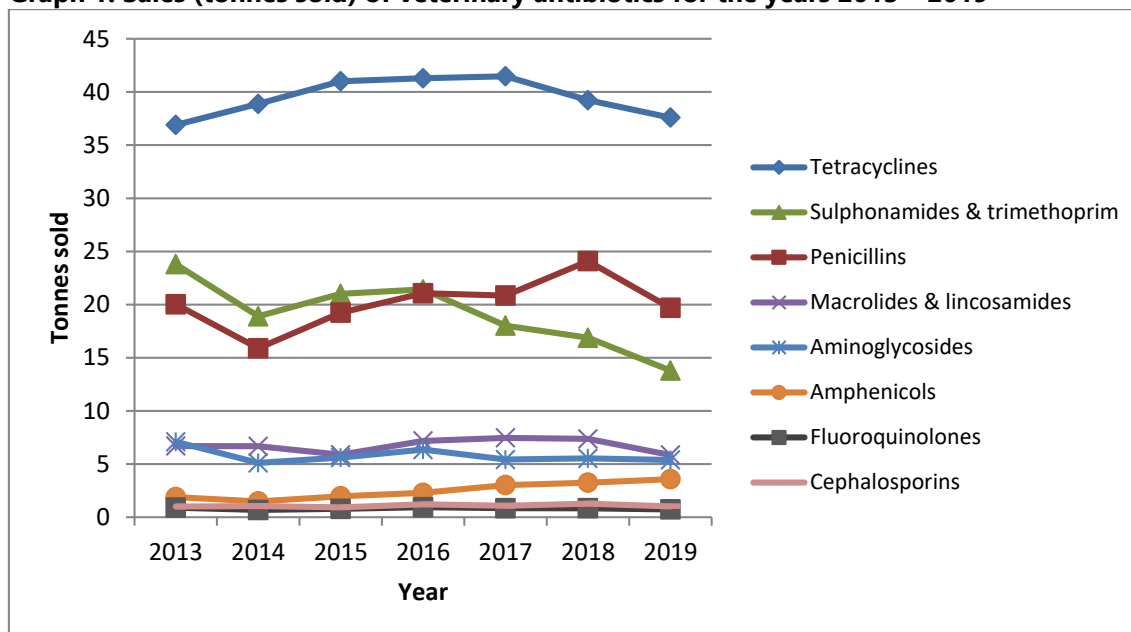
Table 2. Sales (tonnes sold) of veterinary antibiotics for the years 2013 - 2019

	2013	2014	2015	2016	2017	2018	2019
Tonnes sold	99.1	89.4	96.9	103.4	99.7	99.4	88.8

As for previous years, the proportion of pharmaceutical forms (i.e. presentations of product) supplied to the market remained similar. In 2019, a minor shift from oral remedies (oral pastes, powders and solutions) and injectables back to premixes was observed (Figure 2).

Further investigation into the sales of individual veterinary antibiotic classes showed fluctuations from year to year. This variation can be due to a number of factors, such as seasonal disease prevalence, prescribing preferences, drug pricing as well as logistical factors (e.g. the precise timing of end of year transactions for individual antibiotics, quantities of product stored in veterinary practices, at feed mills or on farms etc.).

Graph 1. Sales (tonnes sold) of veterinary antibiotics for the years 2013 – 2019



A decrease in sales of tetracyclines, penicillins and sulphonamides in combination with trimethoprim was observed. In contrast, the increasing trend in sales of amphenicols continued. As in previous years, tetracyclines accounted for the greatest proportion of sales (42.3%), followed by penicillins (22.1%) (Figure 1).

From Table 1 above, it can be seen that the increasing trend in sales of 3rd & 4th generation cephalosporins observed in previous years changed in 2019, with a reduction in sales reported. Although the sales of macrolides and fluoroquinolones fluctuate over the years, a decrease in sales was reported for 2019.

While the reduction in sales of antibiotics in Ireland during 2019 is encouraging and very welcome, it should be noted that the sales of antibiotics used in animals throughout the EU fell by more than 34% between 2011 and 2018. Out of 25 countries that provided data to ESVAC covering the period 2011-2018, 18 countries observed a decline in antibiotic sales by more than 5% [https://www.ema.europa.eu/documents/report/sales-veterinary-antimicrobial-agents-31-european-countries-2018-trends-2010-2018-tenth-esvac-report_en.pdf].

The new veterinary regulation (Regulation (EU) 2019/6), which comes into force in January 2022, requires that data on antibiotic sales be complemented by data on actual usage in animals. The requirement to collect use data, additional to sales data, is expected to commence in 2023 and to proceed on a phased basis to encompass all species by 2029, in accordance with the legislation. This new information will allow a better understanding of how veterinary antibiotics are used in practice and will help pinpoint whether further regulatory measures are needed to ensure responsible use.

Further regulatory restrictions on the use of antibiotics for prevention of infections as well as for medicating groups of animals, as well as off-label use (use of a medicine outside the terms of the marketing authorisation) are also being elaborated at EU level, and will be implemented nationally in the coming years.

2 CONCLUSION

A significant reduction in the overall sales of veterinary antibiotics was reported for 2019, with reductions in several classes of antibiotics noted. Most importantly, sales of the highest priority critically important antibiotics were also reduced. This is both welcome and encouraging, and may be the result of national initiatives by a number of stakeholders to encourage prudent use of antimicrobials as part of Ireland's National Action Plan on Antimicrobial Resistance 2017-2020. However, reference to international comparisons show that we must not become complacent.

Indeed, the European regulatory climate is changing in an effort to address antimicrobial resistance and further measures to ensure responsible use of veterinary antibiotics are being elaborated.

ENDS

Report on consumption of veterinary antibiotics in Ireland during 2018

INTRODUCTION

This report presents the data collected by the Health Products Regulatory Authority (HPRA) during 2018, on the consumption of veterinary antibiotics that are marketed in Ireland. This survey was conducted in conjunction with the European Surveillance of Veterinary Antimicrobial Consumption (ESVAC) project, a European Commission initiative coordinated by the European Medicines Agency (EMA) and with the assistance of the companies involved. The data are based on the voluntary declarations by marketing authorisation holders on the supply of their products. The HPRA has been collecting these data since 2009.

The consumption data provided in this report should be interpreted with caution; annual consumption figures have been observed to fluctuate and such variation is regarded as normal. It should be noted that changes in animal demographics from one year to the next, will also influence the demand for antibiotics.

1.1 Methodology

As for previous years, companies marketing veterinary antibiotics in Ireland were requested to submit annual returns for quantities of individual presentations of product supplied in the State during 2018. The data to be provided were described in a format prescribed by the ESVAC protocol (www.ema.europa.eu). Sales data from over 530 veterinary antibiotic medicines authorised in Ireland (including both medicines authorised nationally by the HPRA as well as those authorised centrally by the EU Commission) were collected. These covered 50 individual antibiotic substances. The data are based on self-declarations by applicant companies and have not been subject to independent verification or audit. It should be noted that certain other veterinary antibiotics (such as those authorised under special licence by the Department of Agriculture, Food and the Marine) and human antibiotics (which might be prescribed or used by veterinary practitioners where there is not a suitable veterinary alternative authorised) were not included in this analysis. However, the contribution from these sources to the overall figure is likely to be very small.

The data were collated by the HPRA and reviewed for discrepancies before being entered into the ESVAC database for additional validation. Any anomalies identified were investigated further. The methodology for collection is a harmonised approach that is followed in each of the European Member States. The analysis of the data in respect of individual substances of the same antibiotic classes have been grouped together and classified under the appropriate class headings. In this report the headings are as follows: penicillins, amphenicols, tetracyclines, fluoroquinolones, aminoglycosides, macrolides, lincosamides, sulphonamides & trimethoprim (TMP), cephalosporins and other classes. The EMA also publishes an annual report on the sales of veterinary antibiotics throughout Europe.

1.2 Results

The total tonnage of veterinary antibiotics sold in Ireland was 99.4 tonnes in 2018. These results are broken down by antibiotic classes supplied into the market in Figure 1 and by pharmaceutical form in Figure 2 below:

Figure 1. Distribution of sales (based on tonnes sold) of veterinary antibiotics supplied in 2018 in Ireland.

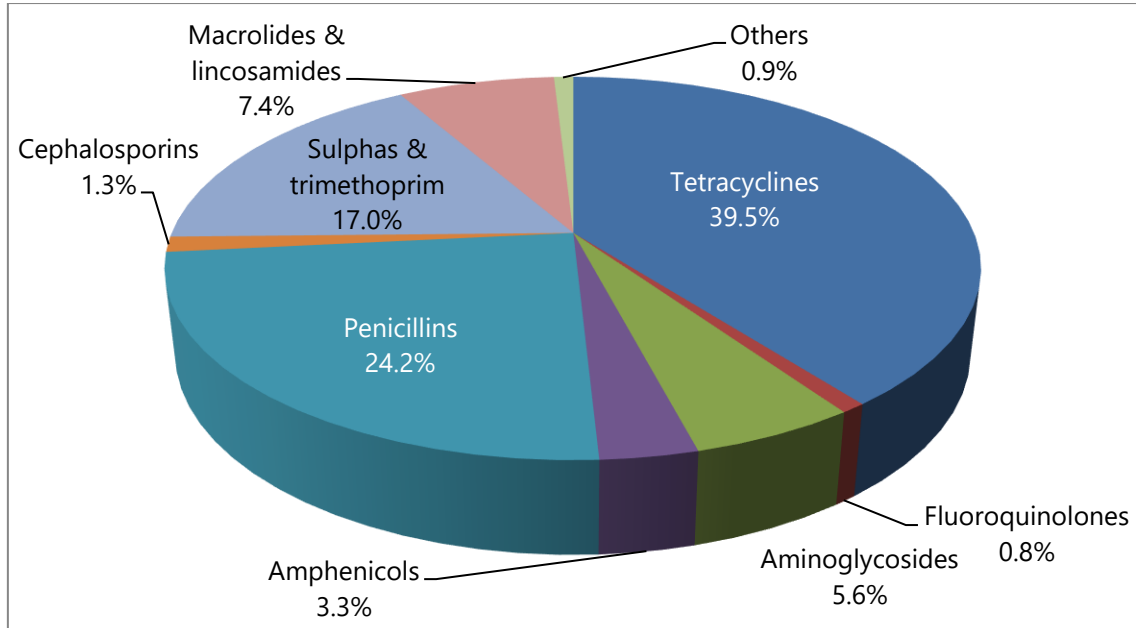
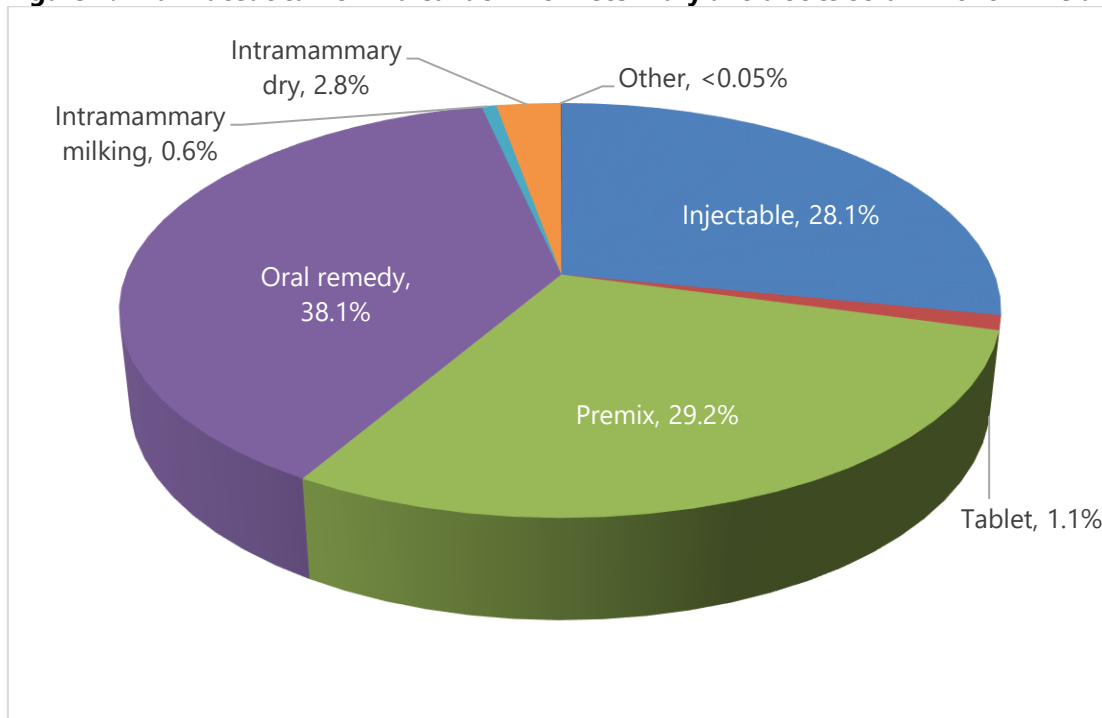


Figure 2. Pharmaceutical form breakdown of veterinary antibiotics sold in 2018 in Ireland.



1.3 Discussion

The sales of veterinary antibiotics in 2018 remained consistent with previous years (Table 1).

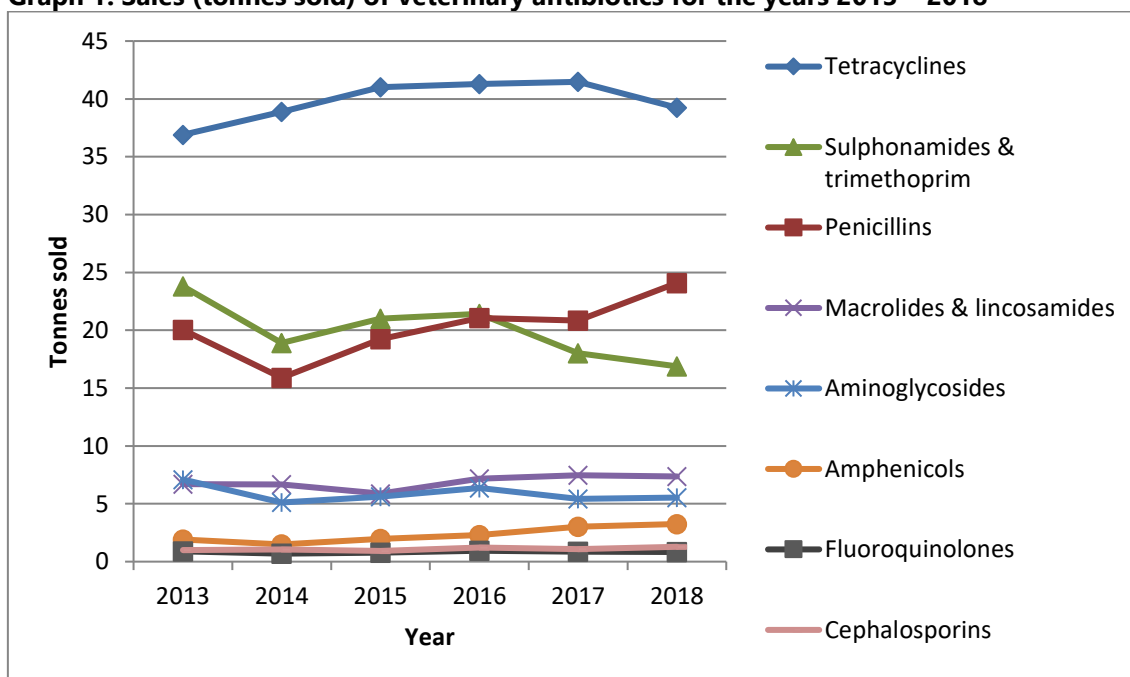
Table 1. Sales (tonnes sold) of veterinary antibiotics for the years 2013 - 2018

	2013	2014	2015	2016	2017	2018
Tonnes sold	99.1	89.4	96.9	103.4	99.7	99.4

The proportion of pharmaceutical forms (i.e. presentations of product) supplied to the market remained similar to previous years. A small shift from premixes to other oral remedies (oral pastes, powders and solutions) was observed (Figure 2).

Further investigation into the sales of individual veterinary antibiotic classes showed fluctuations from year to year. This variation can be due to a number of factors, such as seasonal disease prevalence, prescribing preferences, drug pricing as well as logistical factors (e.g. the precise timing of end of year transactions for individual antibiotics, quantities of product stored in veterinary practices, at feed mills or on farms etc.).

Graph 1. Sales (tonnes sold) of veterinary antibiotics for the years 2013 – 2018



In relation to the general sales trends for the different classes of antibiotics, a decrease in sales of tetracyclines and sulphonamides in combination with trimethoprim was observed. In contrast, sales of penicillins increased. This was primarily attributed to an increase in sales of penicillins with extended spectrum. Tetracyclines accounted for the greatest proportion of sales (39.5%), followed by penicillins (24.2%) (Figure 1). Much smaller quantities of the critically important antibiotics, 3rd and 4th generation cephalosporins, fluoroquinolones, polymixins and macrolides were sold compared to these other classes. However, it should be noted that smaller quantities of these antibiotics are required to treat animals as the drugs are more potent and are used therefore in lower dosages.

The sales of the critically important antibiotics, 3rd and 4th generation cephalosporins, fluoroquinolones and macrolides are provided in more detail below. Due to the low number of products authorised on the market in Ireland, sales of polymyxins (colistin) cannot be reported here for reasons of commercial confidentiality.

From Table 2 below it can be seen that an increasing trend in sales of 3rd & 4th generation cephalosporins continues. The sales of macrolides and fluoroquinolones are effectively unchanged from 2017.

Table 2. Sales (tonnes sold) of 3rd & 4th generation cephalosporins, fluoroquinolones and macrolides for the years 2013 - 2018

	2013	2014	2015	2016	2017	2018
3 rd & 4 th gen. cephalosporins	0.17	0.24	0.22	0.25	0.30	0.33
Fluoroquinolones	0.89	0.69	0.79	0.94	0.85	0.84
Macrolides	6.25	6.26	5.58	6.58	7.17	7.07

1.4 Future developments

The European legislation (Regulation (EU) 2019/6, which has already been adopted but which has an application date of January 2022) will place further restrictions on the use of veterinary antibiotics. The aim of the legislation is to control antimicrobial resistance (AMR). In the future, veterinary antibiotics will not be allowed for routine use in animals to compensate for poor disease control practices or lapses in good farm management. In particular, they will not be allowed for use for preventative purposes to control disease. Furthermore, under the new regulation, the European Commission has been mandated to elaborate further legislative restrictions governing the use of veterinary antibiotics, including designating certain classes of antibiotics for exclusive use for treatment of infections in humans. Additional measures to gather national data on the use of antibiotics at farm level are also foreseen. These new developments are, in due course, expected to have a significant impact on the prescribing and use of veterinary antibiotics in this country.

2 CONCLUSION

The overall sales of veterinary antibiotics remained largely unchanged for 2018 from the position in 2017. Increases in use of extended spectrum penicillins and the critically important 3rd and 4th generation cephalosporins were reported. The HPRA notes that initiatives to encourage prudent use of antimicrobials as part of Ireland's National Action Plan on Antimicrobial Resistance 2017-2020 have been undertaken and expects that they will result in a reduction in sales of veterinary antibiotics over the coming years.

As part of the new veterinary regulation (Regulation (EU) 2019/6), which comes into force in January 2022, the collection of veterinary antibiotic sales will be complemented by data on the use of veterinary antibiotics in animal species, collected by the Department of Agriculture, Food and the Marine. This will provide a better understanding of how veterinary antibiotics are used in Ireland, and will facilitate the introduction of more effective measures to regulate their use. Moreover, additional restrictions on the use of veterinary antibiotics are expected as new complementary EU legislation on AMR control is introduced over the coming years.

ENDS

Report on consumption of veterinary antibiotics in Ireland during 2017

INTRODUCTION

This report presents the data collected by the Health Products Regulatory Authority (HPRA) during 2017, on the consumption of veterinary antibiotics that are marketed in Ireland. This survey was conducted in conjunction with the European Surveillance of Veterinary Antimicrobial Consumption (ESVAC) project, a European Commission initiative coordinated by the European Medicines Agency (EMA) and with the assistance of the companies involved. The data are based on the voluntary declarations by marketing authorisation holders on the supply of their products.

The consumption data provided in this report should be interpreted with caution; annual consumption figures have been observed to fluctuate and a certain amount of variation is regarded as normal. It should be noted that changes in animal demographics are not taken into account, and that would also influence the uptake of antibiotics in a given year.

The availability of the annual data serves to benchmark progress in the delivery of the National Action Plan on Antimicrobial Resistance 2017-2020¹.

1.1 Methodology

Companies marketing veterinary antibiotics in Ireland were requested to submit annual returns for quantities of individual presentations of product supplied in the State during 2017. The data to be provided were described in a format prescribed by the ESVAC protocol (www.ema.europa.eu). Over 500 veterinary antibiotic medicines are currently authorised in Ireland (including both medicines authorised nationally by the HPRA as well as those authorised centrally by the EU Commission). These cover 50 individual antibiotic substances contained in over 900 product presentations. The data are based on self-declarations by applicant companies and have not been subject to independent verification or audit. It should be noted that certain other veterinary antibiotics (such as those authorised under special licence by the Department of Agriculture, Food and the Marine) and human antibiotics (which might be prescribed or used by veterinary practitioners where there is not a suitable veterinary alternative authorised) were not included in this analysis. However, the contribution from these sources to the overall figure is likely to be very small.

The data were collated by the HPRA and reviewed for discrepancies before being entered into the ESVAC database for validation. The methodology for collection is harmonised in each of the European Member States. The analysis of the data in respect of individual substances of the same antibiotic classes have been grouped together and classified under the appropriate class headings. In this report the headings are as follows: penicillins, amphenicols, tetracyclines,

¹ National Action Plan on Antimicrobial Resistance 2017-2020, Available on https://health.gov.ie/wp-content/uploads/2017/10/iNAP_web-1.pdf

fluoroquinolones, aminoglycosides, macrolides, lincosamides, sulphonamides & trimethoprim (TMP), cephalosporins and other classes.

1.2 Results

The total tonnage of veterinary antibiotics sold in Ireland in 2017 was 99.7 tonnes. These results are broken down by antibiotic classes supplied into the market in Figure 1 and by pharmaceutical form in Figure 2 below:

Figure 1. Distribution of sales (based on tonnes sold) of veterinary antibiotics supplied in 2017 in Ireland.

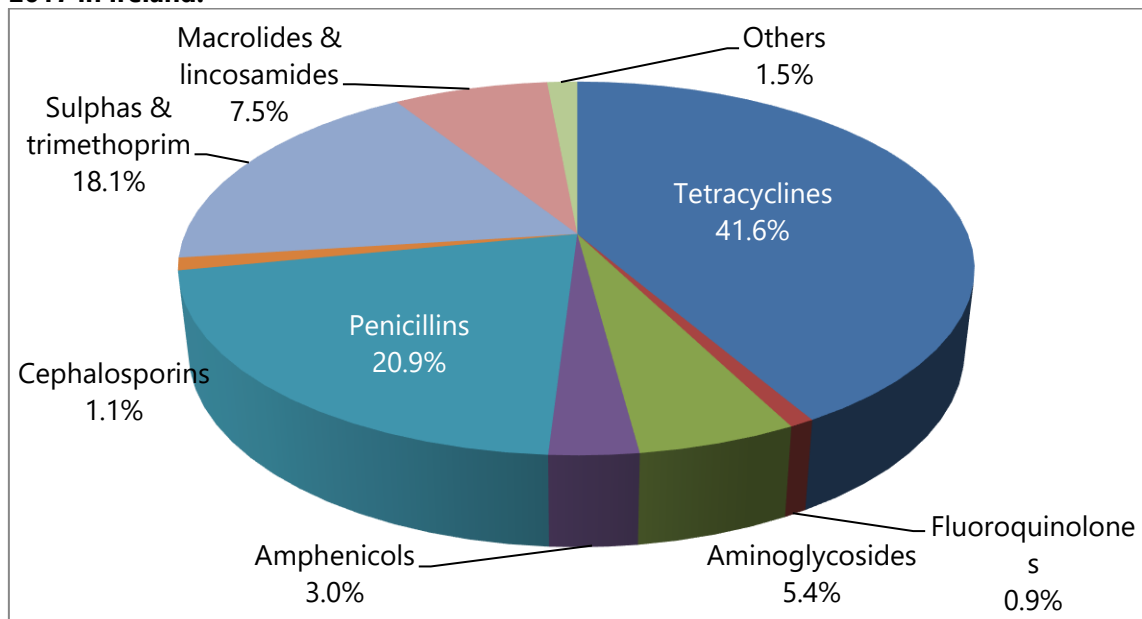
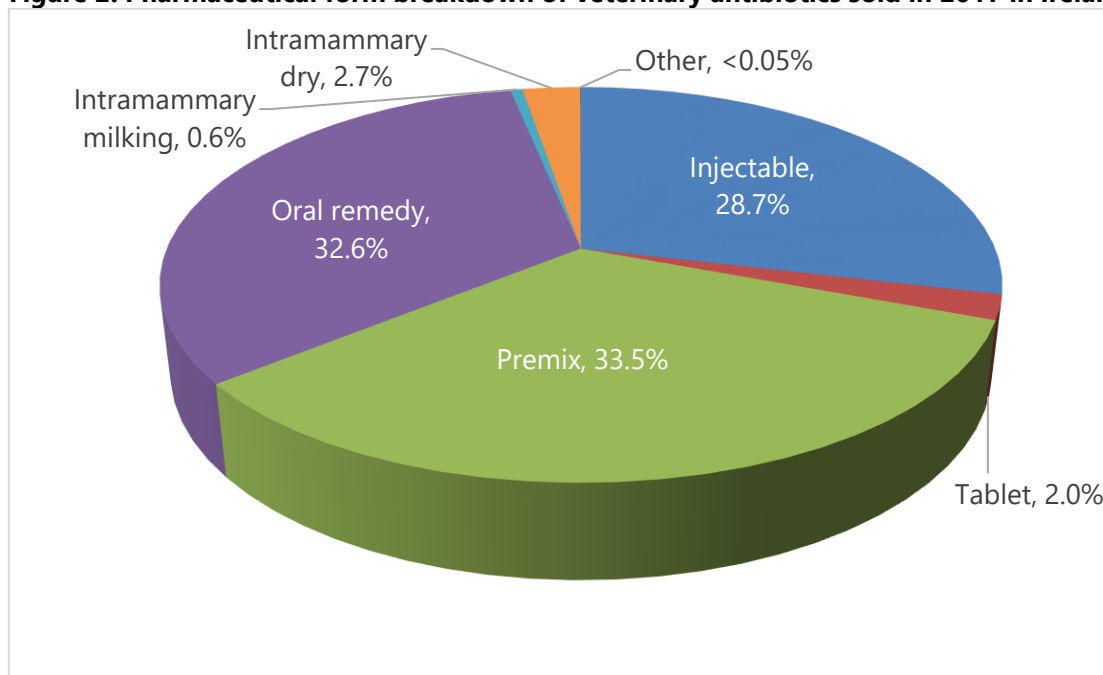


Figure 2. Pharmaceutical form breakdown of veterinary antibiotics sold in 2017 in Ireland.



1.3 Discussion

The sales of veterinary antibiotics in 2017 was consistent with previous years (Table 1). Fluctuations in the sales are observed each year and can be due to a number of factors, such as:

- Seasonal disease prevalence;
- The precise timing of end of year transactions for individual antibiotics;
- Quantities of product held in the supply chain (e.g. stored in veterinary practices, at feed mills or on farms);
- Changes in the size of the national herd;
- Export of veterinary medicines for use outside the State; or
- Changes in the class of antibiotic being prescribed. Some [newer] antibiotic classes are more potent [on a unit weight basis] than others and the dosage for these may be much lower than for other [older] antibiotic classes.

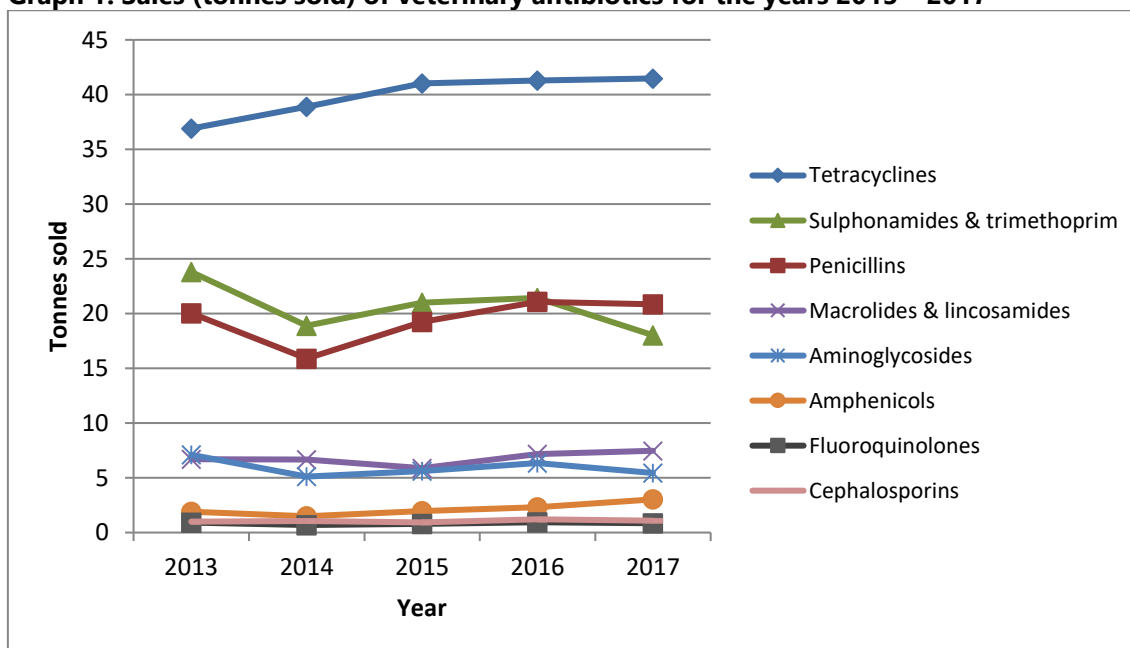
Table 1. Sales (tonnes sold) of veterinary antibiotics for the years 2013 - 2017

	2013	2014	2015	2016	2017
Tonnes sold	99.1	89.4	96.9	103.4	99.7

Of the over 500 veterinary antibiotic medicines authorised in Ireland, almost 200 reported no sales for the year 2017. This may be due to individual company marketing plans, logistical reasons or for strategic reasons (such as supporting the marketing authorisation of the products concerned in international markets). The proportion of pharmaceutical forms (i.e. presentations of product) supplied to the market remained consistent with previous years with only minor changes observed (Figure 2).

The overall antibiotic sales for the different classes remains similar to previous years, with a decrease in the sales of sulphonamides and trimethoprim the only noteworthy change (Graph 1). As in previous years, tetracyclines account for the greatest proportion of sales (41.6%), followed by penicillins (20.9%) (Figure 1).

Graph 1. Sales (tonnes sold) of veterinary antibiotics for the years 2013 – 2017



Sales of the critically important antibiotics, 3rd and 4th generation cephalosporins, fluoroquinolones, macrolides and polymixins (colistin) are collected. Due to the low number of products authorised on the market in Ireland, sales of polymixins cannot be separately identified in this report for reasons of commercial confidentiality. For the same reason, sales of macrolides are combined with those of lincosamides in this report. As much smaller quantities of these antibiotics are required to treat animals, they make up a much smaller percentage of the overall tonnage used. While sales of fluoroquinolones have remained relatively unchanged over the years, an increasing trend in the sales of 3rd & 4th generation cephalosporins and macrolides has been observed (Table 2).

Table 2. Sales (tonnes sold) of 3rd & 4th generation cephalosporins, fluoroquinolones and macrolides & lincosamides for the years 2013 - 2017

	2013	2014	2015	2016	2017
3 rd & 4 th gen. cephalosporins	0.17	0.24	0.22	0.25	0.30
Fluoroquinolones	0.89	0.69	0.79	0.94	0.85
Macrolides & lincosamides	6.7	6.7	5.9	7.2	7.5

In conjunction with the ESVAC project, the possibility to stratify the sales data of veterinary antibiotics by animal species in the future is being investigated. This is made more complex by the fact that many products are indicated for use in two or more species, rather than in a single species. In the absence of prescription data, the allocation of consumption to individual species will have to be estimated.

2 CONCLUSION

The overall sales of veterinary antibiotics in Ireland appear relatively unchanged in 2017. However, an increasing trend in the sales of the critically important antimicrobials, 3rd & 4th generation cephalosporins and macrolides has been noted.

As stated in the National Action Plan on Antimicrobial Resistance 2017-2020 improvements in the availability of antibiotic consumption data are needed so that progress in reducing the overall quantities of antibiotics can be demonstrated. The HPRA understands that the Department of Agriculture, Food and the Marine are investigating how best to capture consumption data at an individual species level for the future. In the interim, the HPRA hopes that this report will help raise awareness of antimicrobial resistance, which continues to be a significant threat to animal and human health.

ENDS

Report on consumption of veterinary antibiotics in Ireland during 2016

INTRODUCTION

This report presents the data collected by the Health Products Regulatory Authority (HPRA) during 2016, on the consumption of veterinary antibiotics that are marketed in Ireland. This survey was conducted in conjunction with the European Surveillance of Veterinary Antimicrobial Consumption (ESVAC) project, a European Commission initiative coordinated by the European Medicines Agency (EMA) and with the assistance of the companies involved.

As advised in previous reports on this subject, the consumption data provided in this report should be interpreted with caution; annual consumption figures vary within certain limits and such variation is regarded as normal. It should also be noted that the data are based on the voluntary declarations by marketing authorisation holders of the supply of their products.

1.1 Methodology

Companies marketing veterinary antibiotics in Ireland were requested to submit annual returns for quantities of individual presentations of product supplied in the State during 2016. The data to be provided were described in a format prescribed by the ESVAC protocol (www.ema.europa.eu). Data were collected from a total of 51 individual antibiotic substances contained in over 900 product presentations which have been authorised for use in Ireland (including both medicines authorised nationally by the HPRA as well as those authorised centrally by the EU Commission). The data are based on self-declarations by applicant companies and have not been subject to independent verification or audit. It should be noted that certain other veterinary antibiotics (such as those authorised under special licence by the Department of Agriculture, Food and the Marine) and human antibiotics (which might be prescribed or used by veterinary practitioners where there is not a suitable veterinary alternative authorised) were not included in this analysis. However, the contribution from these sources to the overall figure is likely to be very small.

The data were collated by the HPRA and reviewed for discrepancies before being entered into the ESVAC database for validation. The database includes data from other countries within the European Union, as well as some neighbouring countries. The methodology for collection is a harmonised approach that is followed in each of the European Member States. The analysis of the data in respect of individual substances of the same antibiotic classes have been grouped together and classified under the appropriate class headings. In this report the headings are as follows: penicillins, amphenicols, tetracyclines, fluoroquinolones, aminoglycosides, macrolides, lincosamides, sulphonamides & trimethoprim (TMP), cephalosporins and other classes.

1.2 Results

The total tonnage of veterinary antibiotics used in Ireland was 103.4 tonnes in 2016. These results are broken down by antibiotic classes supplied into the market in Figure 1 and by pharmaceutical form in Figure 2 below:

Figure 1. Distribution of sales (based on tonnes sold) of veterinary antibiotics supplied in 2016 in Ireland.

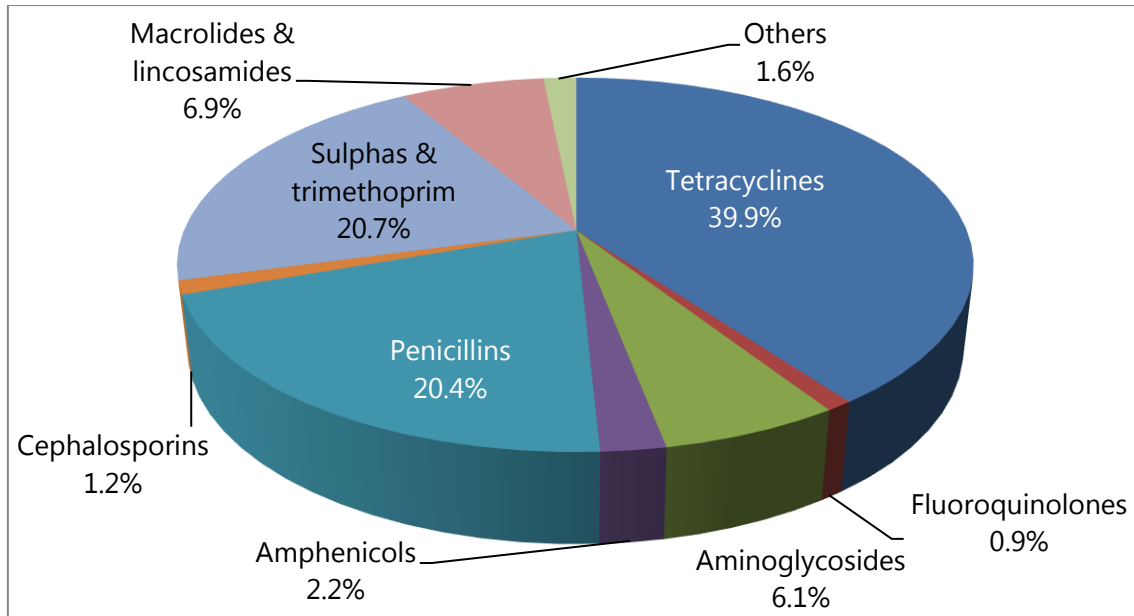
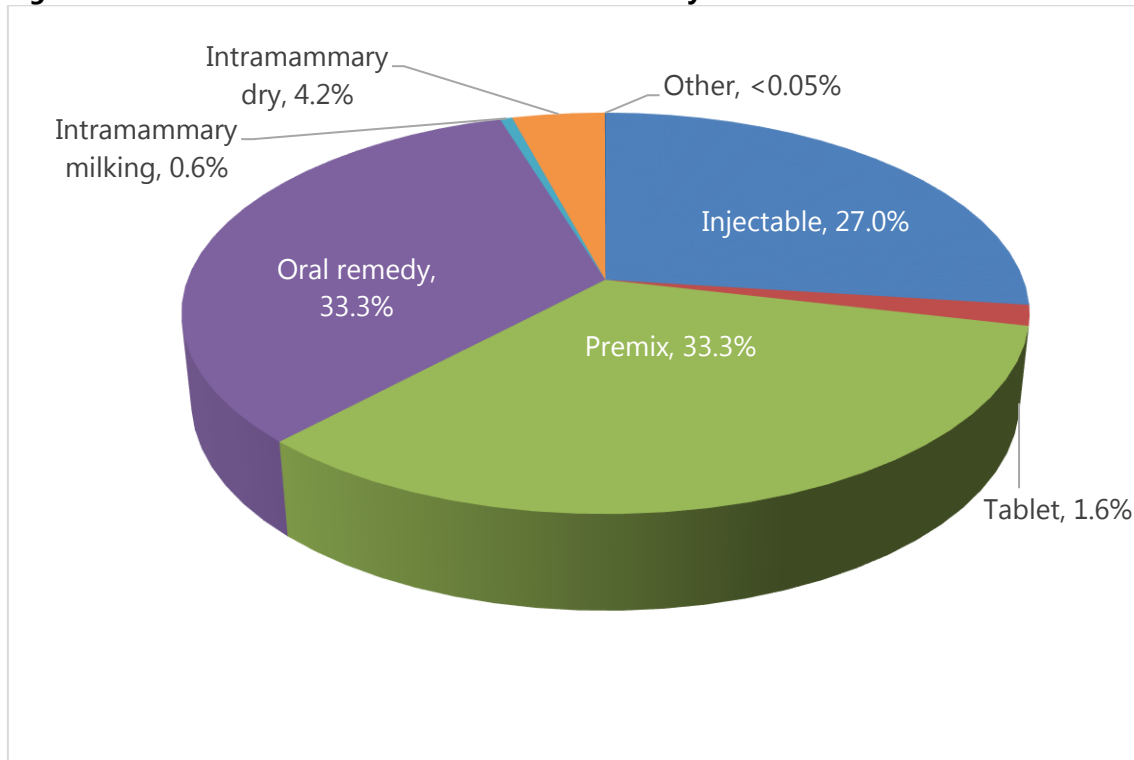


Figure 2. Pharmaceutical form breakdown of veterinary antibiotics sold in 2016 in Ireland.



1.3 Discussion

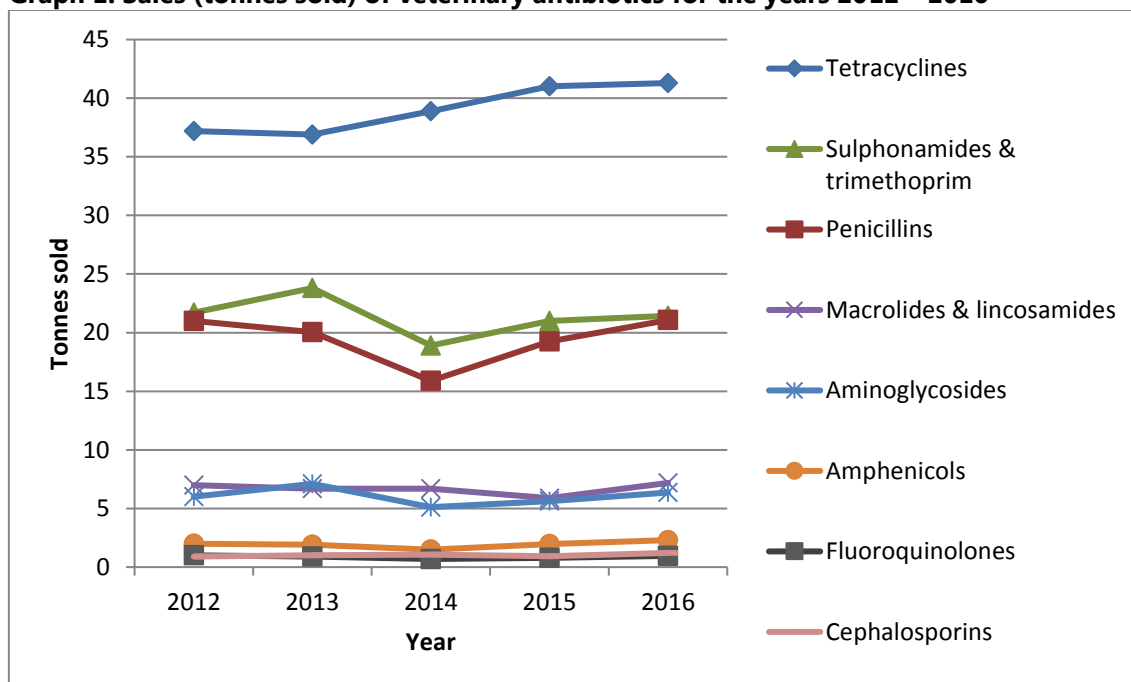
The data collected indicates that sales of veterinary antibiotics increased by approximately 6.5 tonnes in 2016 (Table 1). From the table below it can be seen that the overall tonnage fluctuates from year to year.

Table 1. Sales (tonnes sold) of veterinary antibiotics for the years 2012 - 2016

	2012	2013	2014	2015	2016
Tonnes sold	97.4	99.1	89.4	96.9	103.4

An investigation of sales on a class basis, highlights that tetracyclines comprise a substantial portion of overall tonnage, representing 39.9% of the total (Figure 1). The sales of sulphonamides & trimethoprim, penicillins and aminoglycosides remained consistent with the general trend observed in the previous years. The overall proportion of sales based on tonnes sold remained relatively unchanged (Graph 1).

Graph 1. Sales (tonnes sold) of veterinary antibiotics for the years 2012 – 2016



In particular, the sales of the critically important antibiotics, 3rd & 4th generation cephalosporins, fluoroquinolones and macrolides remained broadly in line with the ranges observed previously (Table 2).

Table 2. Sales (tonnes sold) of 3rd & 4th generation cephalosporins, fluoroquinolones and macrolides & lincosamides for the years 2012 - 2016

	2012	2013	2014	2015	2016
3 rd & 4 th gen. cephalosporins	0.21	0.17	0.24	0.22	0.25
Fluoroquinolones	1.00	0.89	0.69	0.79	0.94
Macrolides & lincosamides	7	6.7	6.7	5.9	7.2

The proportion of pharmaceutical forms (i.e. presentations of product) supplied to the market was similar compared with previous years (Figure 2). Premixes and oral remedies (oral pastes, powders, solutions and boluses) accounted for 33.3% and 33.3% of sales, respectively. The next major group consisted of injectable products accounting for 27.0% of sales.

The range of veterinary antibiotic products in Ireland continues to expand with an additional 21 products authorised. This was offset by a small number of products being withdrawn. However, it should be noted that not all authorised products are marketed. These authorisations may support the marketing of the products in international markets or may be held by the companies concerned for strategic or commercial purposes.

2 CONCLUSION

A 6.7% increase in the overall sales of veterinary antibiotics was recorded for the year 2016. It is not known if this marks a true indication of increased use, or may be explained by other factors. As noted in previous reports, fluctuations in annual sales within a range of plus or minus 5 % may occur, due to a variety of factors such as seasonal disease prevalence, changes in the size of the national herd or product held in the supply chain between years.

Report on consumption of veterinary antibiotics in Ireland during 2015

INTRODUCTION

This report presents the data collected during 2015 on the consumption of veterinary antibiotics in Ireland by the Health Products Regulatory Authority (HPRA). This survey was conducted in conjunction with the European Surveillance of Veterinary Antimicrobial Consumption (ESVAC) project, a European Commission initiative coordinated by the European Medicines Agency (EMA) and the companies marketing the veterinary antibiotics.

As noted in the previous reports, the consumption data provided in this report should be interpreted with caution; annual consumption figures fluctuate and are subject to various extraneous factors, which are discussed in the body of this report. It should also be noted that the data are based on the voluntary declarations by marketing authorisation holders of supply of their products. Even though these declarations are made in good faith they are not subject to independent audit verification. As a consequence, minor errors in the data reported are possible.

1.1 Methodology

Companies marketing veterinary antibiotics in Ireland were requested to submit annual returns for quantities of individual presentations of product supplied in the State during 2015. The data to be provided were described in a format prescribed by the ESVAC protocol (www.ema.europa.eu). Data were collected from a total of 55 individual antibiotic substances contained in over 800 product presentations which have been authorised for use in Ireland (including both medicines authorised nationally by the HPRA as well as those authorised centrally by the EU Commission). The data are based on self-declarations by applicant companies and have not been subject to independent verification or audit. It should be noted that certain other veterinary antibiotics (such as those authorised under special licence by the Department of Agriculture, Food and the Marine) and human antibiotics (which might be prescribed or used by veterinary practitioners where there is no suitable veterinary alternative authorised) were not included in this analysis. However, the contribution from these sources is likely to be very small.

The data were collated by the HPRA and reviewed for discrepancies before being entered into the ESVAC database for validation. This harmonised approach is followed in each of the European Member States. The analysis of the data in respect of individual substances of the same antibiotic classes have been grouped together and classified under the appropriate class headings. In this report the headings are as follows: penicillins, amphenicols, tetracyclines, fluoroquinolones, aminoglycosides, macrolides, lincosamides, sulphonamides & trimethoprim (TMP), cephalosporins and other classes.

1.2 Results

The total tonnage of veterinary antibiotics used in Ireland was 96.7 tonnes in 2015. These results are broken down by antibiotic classes supplied into the market in Figure 1 and by pharmaceutical form in Figure 2 below:

Figure 1. Distribution of sales (based on tonnes sold) of veterinary antibiotics supplied in 2015 in Ireland.

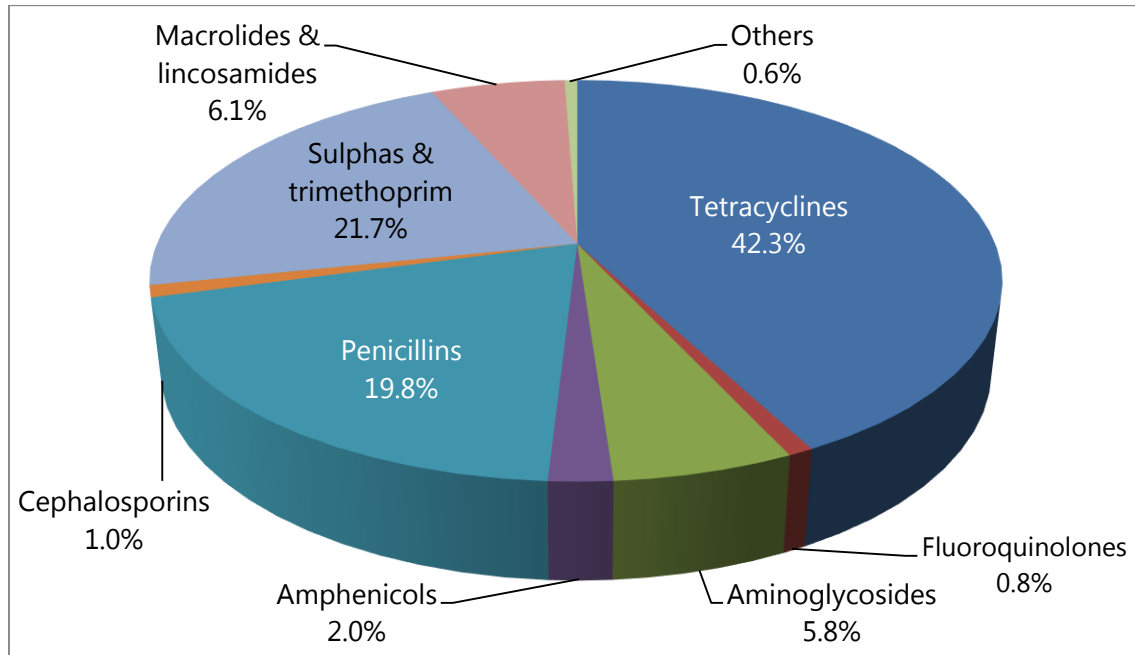
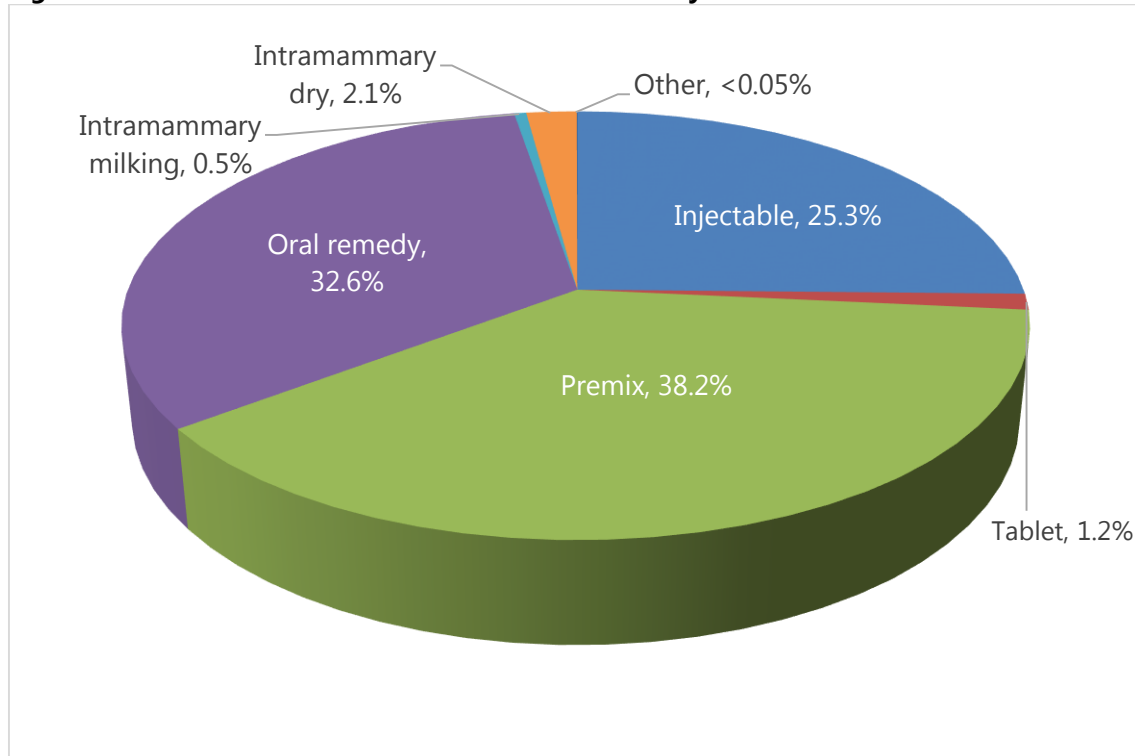


Figure 2. Pharmaceutical form breakdown of veterinary antibiotics sold in 2015 in Ireland.



1.3 Discussion

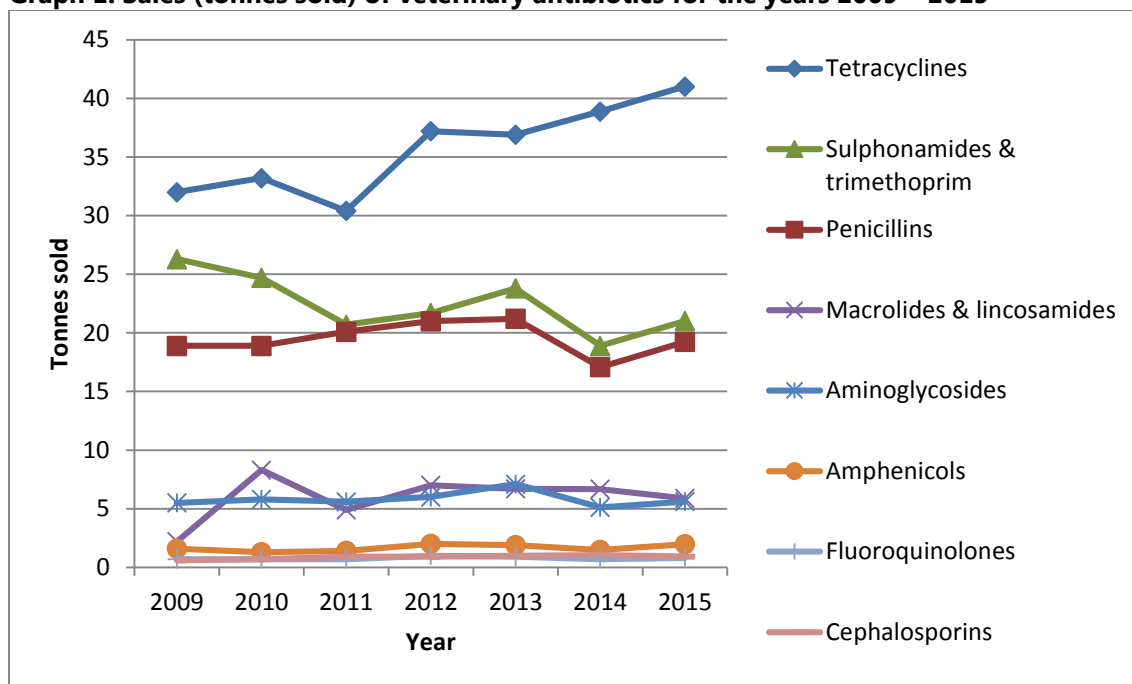
The data collected indicates that sales of veterinary antibiotics increased by approximately 6 tonnes in 2015 (Table 1). From the table below it can be seen that the overall tonnage fluctuates from year to year.

Table 1. Sales (tonnes sold) of veterinary antibiotics for the years 2009 - 2015

	2009	2010	2011	2012	2013	2014	2015
Tonnes sold	88.3	93.9	85.3	97.4	100.2	90.6	96.7

An investigation of sales on a class basis, highlights that tetracyclines comprise a substantial portion of overall tonnage, representing 42.3% of the total (Figure 1). This was marked by a continued increasing trend in sales when compared to previous years. The sales of sulphonamides and trimethoprim increased from those observed in 2014 but remained consistent with the general trend observed in the previous years. The overall proportion of sales based on tonnes sold remained relatively unchanged. In particular, the sales of the critically important antibiotics, 3rd & 4th generation cephalosporins, fluoroquinolones and macrolides remained within the ranges observed previously (Graph 1).

Graph 1. Sales (tonnes sold) of veterinary antibiotics for the years 2009 – 2015



The proportion of pharmaceutical forms (i.e. presentations of product) supplied to the market remained similar with previous years with only minor changes observed (Figure 2). Premixes and oral remedies (oral pastes, powders, solutions and boluses) accounted for 38.2% and 32.6% of sales, respectively. The next major group consisted of injectable products accounting for 25.3% of sales.

The range of veterinary antibiotic products in Ireland continues to expand with an additional 22 products authorised. This was offset by a small number of products being withdrawn. However, it should be noted that not all authorised products are marketed. These authorisations may support

the marketing of the products in international markets or may be held by the companies concerned for strategic or commercial purposes.

2 CONCLUSION

An increase in the overall sales of veterinary antibiotics was recorded for the year 2015, this remained within the historical range. As noted in previous reports, fluctuations in sales are expected, with factors such as seasonal disease prevalence, changes in the size of the national herd or product held in the supply chain between years among the many factors that can influence the changes.

Report on consumption of veterinary antibiotics in Ireland during 2014

INTRODUCTION

This sixth report presents the annual survey conducted by the Health Products Regulatory Authority (HPRA) on the sales of veterinary antibiotics in Ireland. This survey was conducted in conjunction with the European Surveillance of Veterinary Antimicrobial Consumption (ESVAC) project, a European Commission initiative coordinated by the European Medicines Agency (EMA).

As noted in the previous reports, the consumption data provided in this report should be interpreted with caution; annual consumption figures fluctuate and are subject to various extraneous factors, which are discussed in the body of this report. It should also be noted that the data are based on the voluntary declarations by marketing authorisation holders of supply of their products. Even though these declarations are made in good faith they are not subject to independent audit verification.

1.1 Methodology

Companies marketing veterinary antibiotics in Ireland were requested to submit annual returns for quantities of individual presentations of product supplied in the State during 2014. The data to be provided were described in a format prescribed by the ESVAC protocol (www.ema.europa.eu). Data were collected from a total of 54 individual antibiotic substances contained in over 800 product presentations which have been authorised for use in Ireland (including both medicines authorised nationally by the HPRA as well as those authorised centrally by the EU Commission). The data are based on self-declarations by applicant companies and have not been subject to independent verification or audit. It should be noted that certain other veterinary antibiotics (such as those authorised under special licence by the Department of Agriculture, Food and the Marine) and human antibiotics (which might be prescribed or used by veterinary practitioners where there is no suitable veterinary alternative authorised) were not included in this analysis. However, the contribution from these sources is likely to be very small.

The data were collated by the HPRA and reviewed for discrepancies before being entered into the ESVAC database for validation. This harmonised approach is followed in each of the European Member States. In conformity with ESVAC protocol, the analysis of the data in respect of individual substances of the same antibiotic classes have been grouped together and classified under the appropriate class headings. In this report the headings are as follows: penicillins, amphenicols, tetracyclines, fluoroquinolones, aminoglycosides, macrolides, lincosamides, sulphonamides & trimethoprim (TMP), cephalosporins and other classes.

1.2 Results

The total tonnage of veterinary antibiotics used in Ireland was 90.2 tonnes in 2014. These results are broken down by antibiotic classes supplied into the market in Figure 1 and by pharmaceutical form in Figure 2 below:

Figure 1. Distribution of sales (based on tonnes sold) of veterinary antibiotics supplied in 2014 in Ireland.

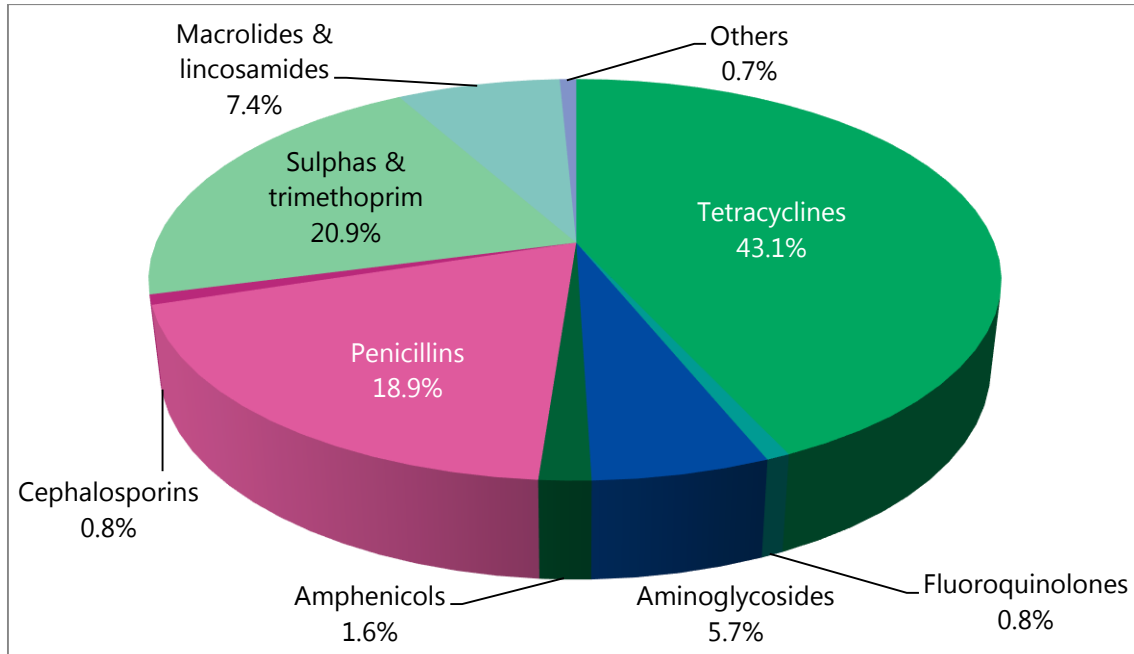
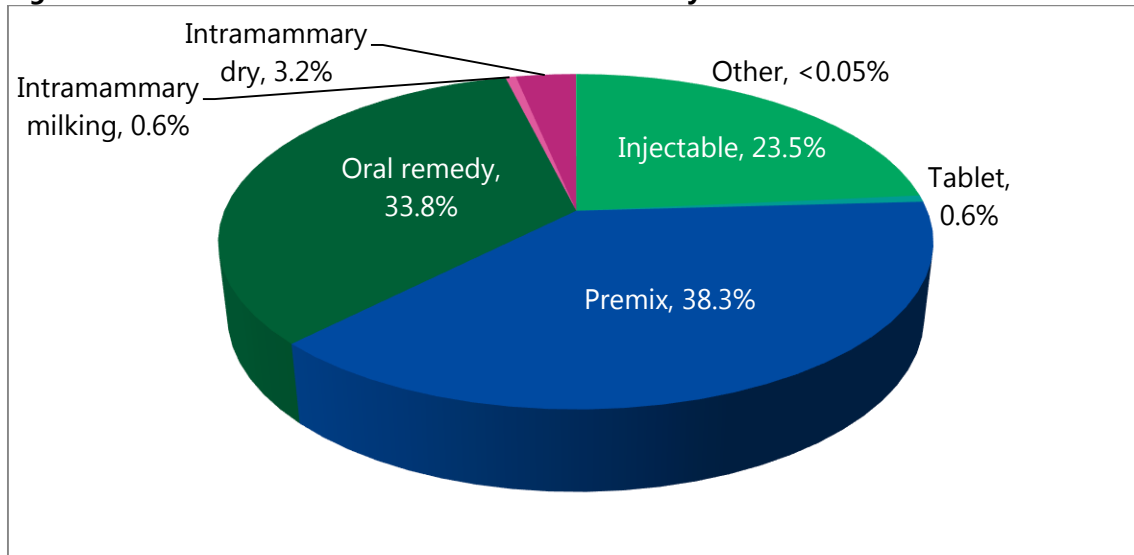


Figure 2. Pharmaceutical form breakdown of veterinary antibiotics sold in 2014 in Ireland.



1.3 Discussion

The data for 2014 indicates that antibiotic sales decreased by 10 tonnes when compared to 2013, and remain within the range recorded over the last 5 years (as indicated in Table 1). The reasons for the volatility in the annual consumption levels are unknown, and might be due to a number of factors, such as:

- Seasonal disease prevalence;
- The precise timing of end of year transactions for individual antibiotics;
- Quantities of product held in the supply chain (e.g. stored in veterinary practices, at feed mills or on farms);
- Changes in the size of the national herd;
- Export of veterinary medicines for use outside the State; or
- Changes in the class of antibiotic being prescribed. Some [newer] antibiotic classes are more potent [on a unit weight basis] than others and the dosage for these may be much lower than for other [older] antibiotic classes.

Table 1. Sales (tonnes sold) of veterinary antibiotics for the years 2009 - 2014

	2009	2010	2011	2012	2013	2014
Tonnes sold	88.3	93.9	85.3	97.4	100.2	90.2

When reviewing the data particular notice is given to the critically important antibiotics, namely 3rd and 4th generation cephalosporins, fluoroquinolones and macrolides. This is due to the fact that much smaller quantities of these antibiotics are required to treat animals and thus make up a much smaller percentage of the overall tonnage used. Graph 1 below shows that the sale of these critically important antibiotics have remained relatively unchanged.

Graph 1. Sales (tonnes sold) of veterinary antibiotics for the years 2009 – 2014



The overall proportion of antibiotic sales for the different classes remains generally similar to previous years. However, there was a significant increase in the sale of tetracyclines, while there were decreases in the sales of sulphonamides and trimethoprim, penicillins, and, to a lesser extent, the aminoglycosides.

The proportion of pharmaceutical forms (i.e. presentations of product) supplied to the market remained consistent with previous years with only minor changes observed (Figure 2). Premixes and oral remedies (oral pastes, powders, solutions and boluses) accounted for 38.3% and 33.8%

of sales, respectively. The next major group consisted of injectable products accounting for 23.5% of sales.

Of the over 500 authorised products where data was supplied, no sales were reported for 268 products. Ireland is a relatively small market for veterinary medicinal products and not all authorised products are marketed. Moreover, not all presentations of the authorised medicines are marketed (some presentations might not suit Irish market needs). The reason that certain products are authorised but not currently marketed may be due to individual company marketing plans, or logistical reasons or for strategic reasons (such as supporting the authorisation of the products concerned in international markets).

2 CONCLUSION

There has been a decline in the consumption of veterinary antibiotics in Ireland in 2014. Although welcome (as antibiotic use is seen as a key driver of antimicrobial resistance), the decline may be serendipitous and should be interpreted with caution as it is within the historical range which fluctuates significantly each year.

The sales data collected provide a broad picture on which antibiotics are being used for the treatment of animals in Ireland and serve as a benchmark for future analysis on the impact of European risk management measures that are intended to address the global challenge of antimicrobial resistance. Currently it is not possible to link the national consumption data with usage in the different target species (many products are indicated for use in two or more species), but this challenge is being further considered and initiatives to address this data gap are expected to be developed by the European Commission in the future.

The HPRA will continue to collect and report on the national sales of veterinary antibiotics as well as contributing to the work conducted by ESVAC and to the elaboration and implementation of risk management measures deemed necessary by the European Commission. The ultimate goal is to ensure the responsible use of antibiotics so that they can continue to be used for animal treatment when necessary but preserving their efficacy into the future. This must be achieved in the context of responding to the global threat of antimicrobial resistance.

Report on consumption of veterinary antibiotics in Ireland during 2013.

INTRODUCTION

This report details the fifth annual survey conducted by the HPRA on the usage of veterinary antibiotics. This survey was conducted in conjunction with the European Surveillance of Veterinary Antimicrobial Consumption (ESVAC) project, a European Commission initiative coordinated by the European Medicines Agency (EMA).

As noted in the previous reports, the consumption data provided in this report should be interpreted with caution; annual consumption figures may be affected by the precise timing of end of year sales, some veterinary medicines might be exported for use outside the State, and there might occasionally be inaccuracies in the voluntary declarations made in good faith by marketing authorisation holders. Indeed, during the preparation of this year's report an inaccuracy involving one product was discovered in the data entry which had gone unnoticed in previous years. This had the effect of overstating the actual usage in previous years by between 2.8 to 3.8 tonnes in each year. Although significant in its own right, the HPRA believes this should not detract from the general trends observed.

1.1 Methodology

Companies marketing veterinary antibiotics in Ireland were requested to submit annual returns for quantities of individual presentations of product supplied in the State during 2013. The data to be provided were described in a format prescribed by the ESVAC protocol (www.ema.europa.eu). Data were collected from a total of 52 individual antibiotic substances contained in over 800 product presentations which have been authorised for use in Ireland (including both medicines authorised nationally by the HPRA as well as those authorised centrally by the EU Commission). The data are based on self-declarations by applicant companies and have not been subject to independent verification or audit. It should be noted that certain other veterinary antibiotics (e.g. those authorised under special licence by the Department of Agriculture, Food and the Marine) or human antibiotics which might be prescribed or used by veterinary practitioners where there is no suitable veterinary alternative authorised were not included in this analysis. However, the contribution from these sources is likely to be very small.

The data were collated by the HPRA and reviewed for discrepancies before being sent to the EMA for validation and entry into the ESVAC database. This harmonised approach is followed in each of the European Member States. In conformity with ESVAC protocol, the analysis of the data in respect of individual substances of the same antibiotic classes have been grouped together and classified under the appropriate class headings. In this report the headings are as follows: penicillins, amphenicols, tetracyclines, fluoroquinolones, aminoglycosides, macrolides, lincosamides, sulphonamides & trimethoprim (TMP), cephalosporins and other classes.

1.2 Results

The total tonnage of veterinary antibiotics used in Ireland is 100.2 tonnes in 2013. These results are broken down by chemical classes supplied into the market in Figure 1 and by dose form in Figure 2 below:

Figure 1. Distribution of sales (based on tonnes sold) of veterinary antibiotics supplied in 2013 in Ireland.

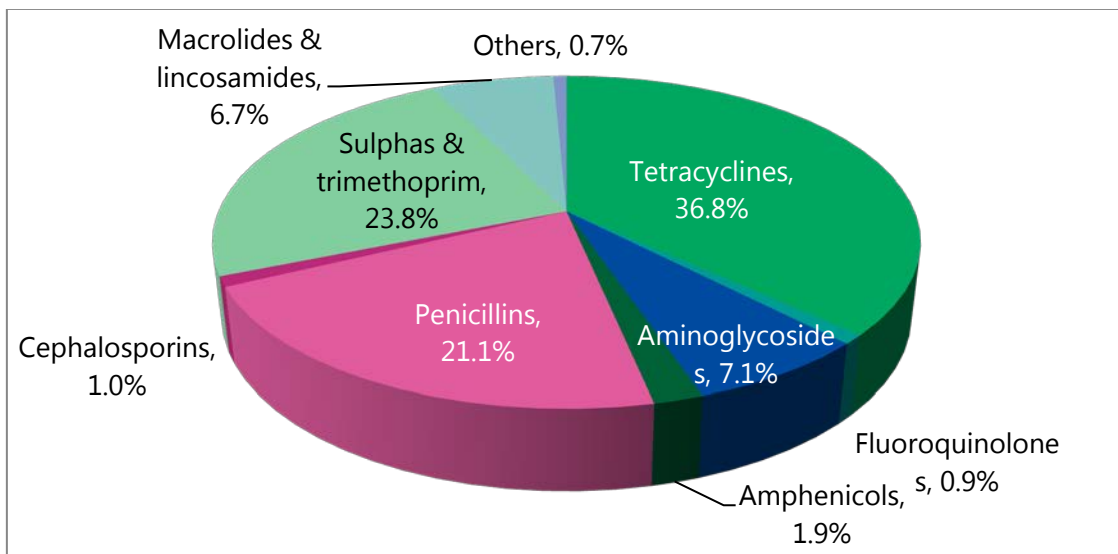
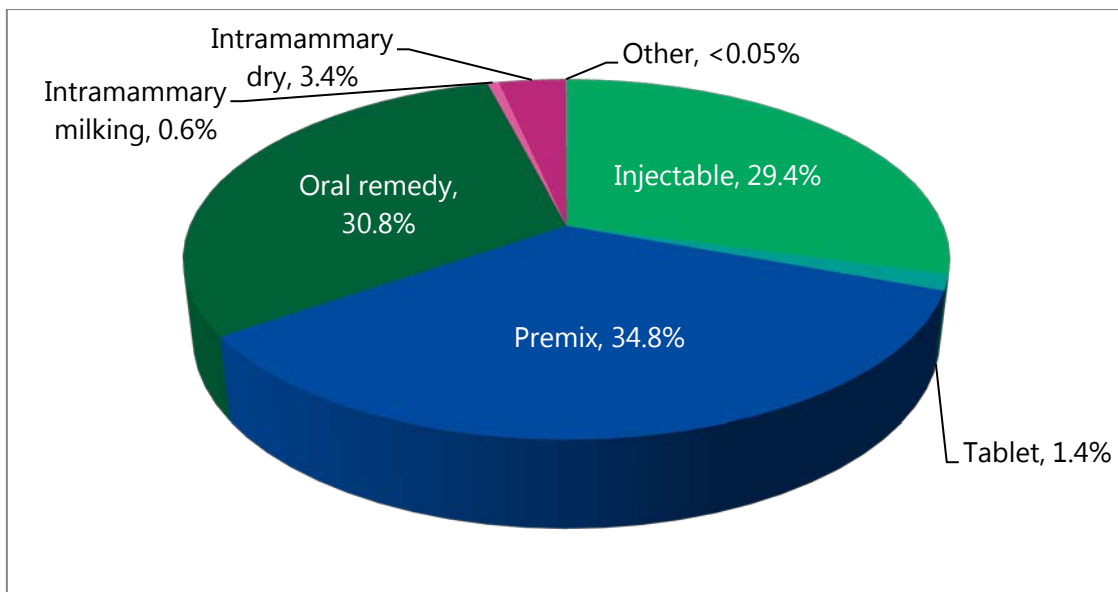


Figure 2. Pharmaceutical form breakdown of veterinary antibiotics sold in 2013 in Ireland.



1.3 Discussion

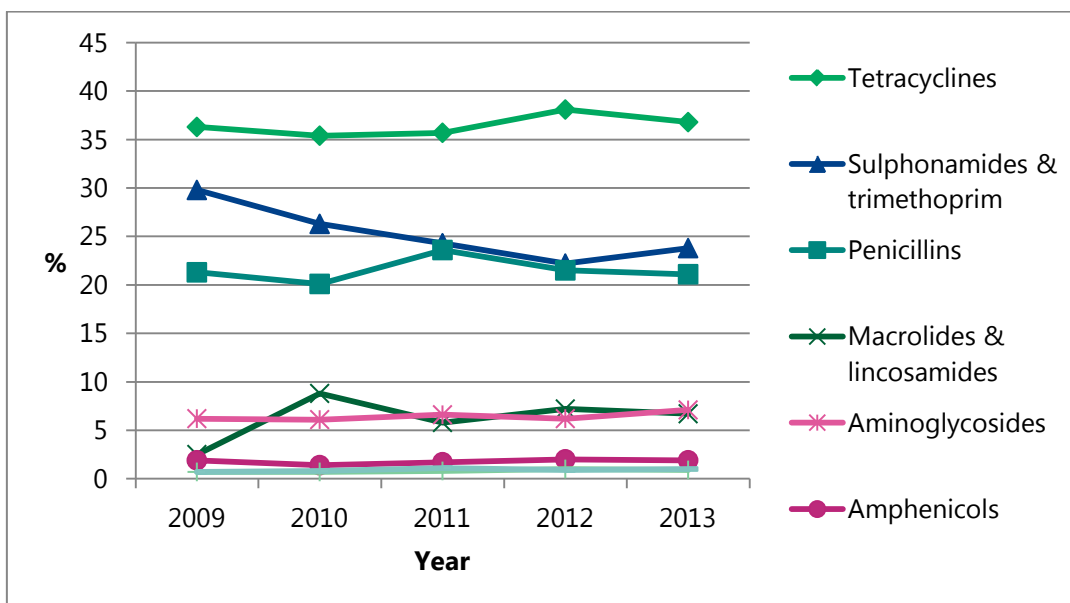
The total sales of veterinary antibiotics for the period 2009 – 2013 are reported in Table 1. The available data indicate an increase in antibiotic sales for the year 2013 compared with previous years. Whether this is due to seasonal factors, an increase in animal numbers bred in Ireland or a true increase in individual animal consumption in the market place is unclear.

TABLE 1. Sales (tonnes sold) of veterinary antibiotics for the years 2009 – 2013*	2009	2010	2011	2012	2013
	Tonnes sold	88.3	93.9	85.2	97.4

*The sales figures for 2009-2012 have been adjusted to correct for an inaccuracy which resulted in over reporting of the tonnage sold during this period.

A similar trend in the proportion of antibiotic sales for the different classes for the period 2009 – 2013 can be seen in the Graph 1 below.

Graph 1. Proportional sales (% , based on tonnes sold) of veterinary antibiotics for the years 2009 - 2013



Tetracyclines, penicillins and sulphonamides/trimethoprim again accounted for the highest proportion of antibiotic sales. It should be noted that the dose required of each antibiotic class to treat an animal can vary significantly. For example it can require up to 70 times more tetracycline to treat a disease in an individual animal when compared to treatment with a fluoroquinolone (new classes of antibiotic tend to be more potent on a per kg basis). Animal demographics will also influence the quantity required with different animal species requiring different dosing patterns.

With regard to the proportion of pharmaceutical forms supplied during 2013, the proportions are similar to those of previous years. Premixes continued to dominate the usage in Ireland accounting for 34.8% of all antibiotic sales. This was followed by oral remedies at 30.8%, consisting of oral powders, pastes and solutions. Injectable antibiotics accounted for 29.4% of sales. These three groups accounted for 95% of all antibiotic sales.

All antibiotic products carry label/package leaflet warnings relating to the responsible use of antibiotics; those considered critically important contain additional precautionary phrases so as to highlight the fact that they should only be used when necessary, usually following precise diagnosis using confirmatory diagnostic tests. All veterinary antibiotics are subject to veterinary prescription control, meaning that they require the prescription of a veterinary practitioner before they can be used.

CONCLUSION

Even if slightly increased compared to previous years, the overall pattern of antibiotic sales for 2013 shows a similar pattern compared with previous years. As in previous years large fluctuations in the sales of some individual products were observed, however, when compared with historical data this may be attributed to market volatility.

The HPRA is continuing to collect antibiotic sales data for Ireland as part of a broader European surveillance initiative, itself being an initiative to inform risk-management strategies to fight antibiotic resistance. Work is underway by ESVAC to develop a methodology to refine the data based on the different target species, daily dose and duration of treatment. This is expected to help in identifying the areas where antibiotic usage can be refined and risk-management measures can be targeted.

HPRA
1 December 2014



IRISH MEDICINES BOARD

REPORT ON CONSUMPTION OF VETERINARY ANTIBIOTICS IN IRELAND DURING 2012.

1 INTRODUCTION

Antimicrobial resistance (AMR) is considered to be a major global public health concern and a potential food safety issue. This issue has been reviewed by many European and global bodies, including the European network of medicines agencies, known as HMA (<http://www.hma.eu/283.html>) which has published a strategic plan to address the issue. One component of this plan refers to a European Commission initiative (known as the European Surveillance of Veterinary Antimicrobial Consumption (ESVAC)). The task of ESVAC (http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/document_listing/document_listing_000302.jsp) is to collect and report on the use of antibiotics in European Member States. The information gained is deemed by the expert bodies to be essential to the identification of possible risk factors that could lead to the development and spread of antimicrobial resistance in animals. In accordance with the plan the Irish Medicines Board (IMB) has completed its fourth annual survey on the usage of veterinary antibiotics in Ireland.

It should be noted that even if the term AMR is widely used, this term is not always appropriate as the word 'antimicrobial' encompasses anti-viral and anti-fungal drugs in addition to antibiotics. In this report, the word 'antibiotic' is therefore used.

2 METHODOLOGY

Companies marketing veterinary antibiotics in Ireland were requested to submit annual returns for quantities of individual presentations of product supplied in the State during 2012. The data to be provided were described in a format prescribed by the ESVAC protocol (www.ema.europa.eu). Data were collected for a total of 51 individual antibiotic substances contained in 699 product presentations which have been authorised for use in Ireland (including both medicines authorised nationally by the IMB as well as those authorised centrally by the EU Commission). The data are based on self-declarations by applicant companies and have not been subject to independent verification or audit. It should be noted that certain other veterinary antibiotics (e.g. those authorised under special licence by the Department of Agriculture, Food and the Marine) or human antibiotics which might be prescribed or used by veterinary practitioners where there is no suitable veterinary alternative authorised were not included in this analysis.

The data were collated by the IMB and reviewed for discrepancies before being sent to the European Medicines Agency (EMA) for entry into the ESVAC database. This approach is followed in each of the European Member States. In conformity with ESVAC protocol, data in respect of individual substances of the same antibiotic classes have been grouped together and are presented under the appropriate class headings.

In this report the headings are as follows: penicillins, amphenicols, tetracyclines, fluoroquinolones, aminoglycosides, macrolides, lincosamides, sulphonamides & trimethoprim, cephalosporins and 'other classes'.

As noted in the previous reports, the consumption data provided in this report should be interpreted with caution; annual consumption figures may be affected by the precise timing of end of year sales, some veterinary medicines might be used outside the State, and there might occasionally be errors in the voluntary declarations made in good faith by marketing authorisation holders. However, while experience has shown that errors in the data can arise after the data have been analysed and published, this should not detract from the general trends observed.

Results

The total tonnage of veterinary antibiotics used in Ireland was reported to be 101.2 tonnes in 2012. In comparison, 88.5 tonnes was reported in 2011 and 96.7 tonnes in 2010. These results are broken down by antibiotic classes sold (Figure 1) and by dose form (Figure 2):

Figure 1. Distribution of sales (based on tonnes sold) of veterinary antibiotics supplied in 2012 in Ireland.

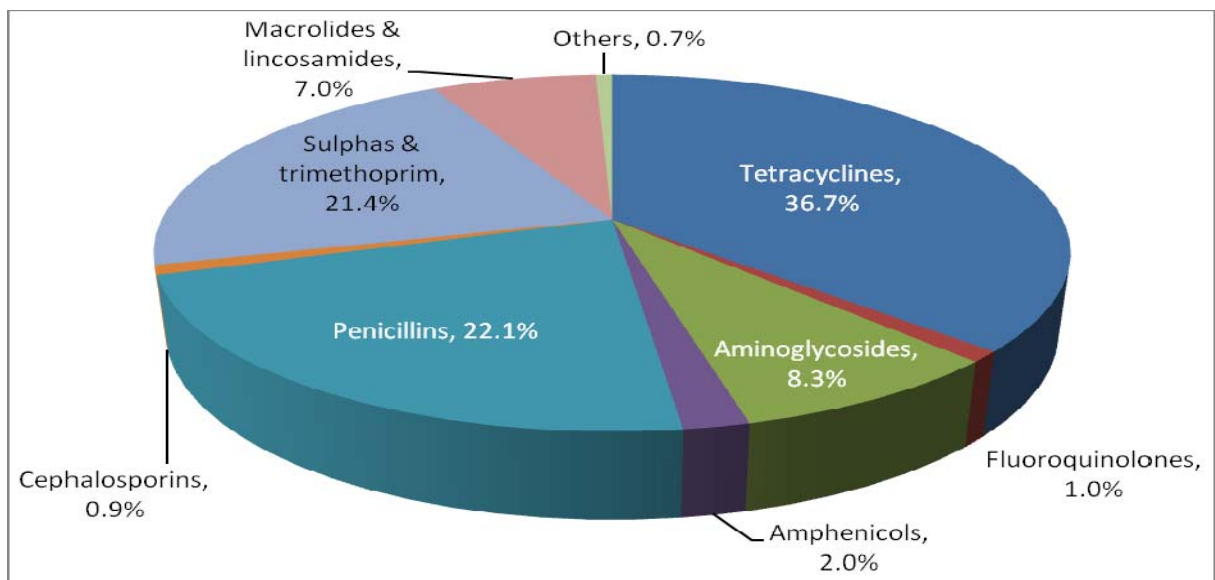
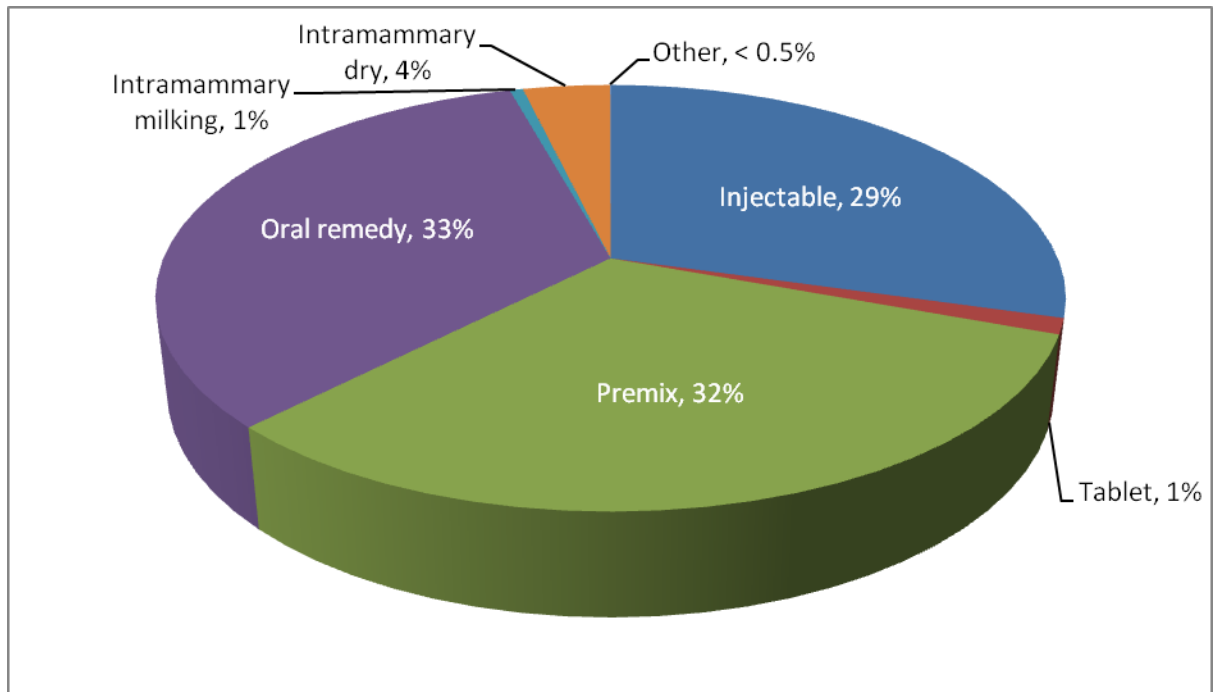


Figure 2. Pharmaceutical form breakdown (based on tonnes sold) of veterinary antibiotics sold in 2012 in Ireland.

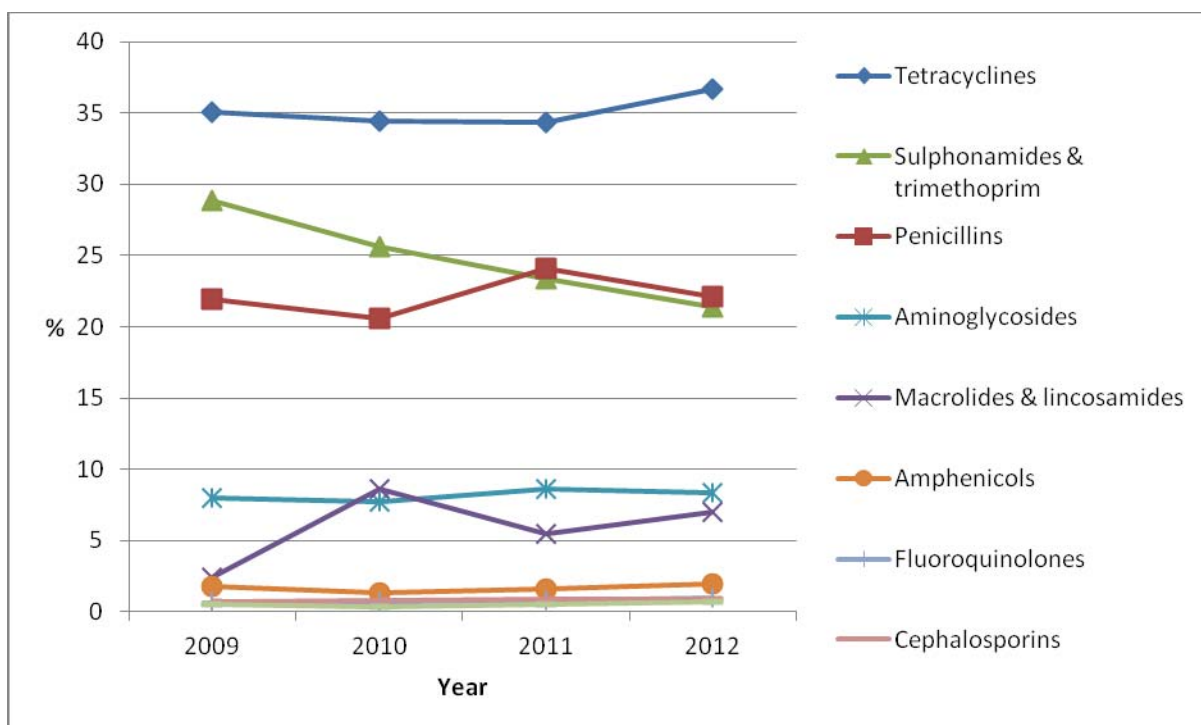


Discussion

The reported data for 2012 indicates an increase in antibiotic sales of approximately 12.7 tonnes when compared to 2011 and 4.5 tonnes when compared to 2010. This apparent increase should be interpreted with caution as it has been the experience of the IMB in the collection of data that the overall tonnage sold can fluctuate from year to year. This could be due to seasonal factors, or to a change in the numbers of animals kept or to other reasons.

In Figure 3 below, it can be seen that tetracyclines, penicillins and sulphonamides/trimethoprim accounted for the largest proportion of antibiotic sales. This pattern remains consistent with previous years. Of note is the continued reduction in sulphonamides/trimethoprim usage as a proportion of overall antibiotic sales.

Figure 3. Proportional sales (% , based on tonnes sold) of veterinary antibiotics for the years 2009 – 2012



The primary driver in the apparent increase in tonnage sold for 2012 may be primarily attributable to increased sales of tetracyclines and macrolides. The reasons behind this are not known to the IMB.

The mix of pharmaceutical presentations sold during 2012 was similar to that seen in previous years. Medicated premixes and other oral dosage forms (soluble powders, oral solutions and pastes) remained the most common pharmaceutical forms, accounting for 65% of all antibiotic sales. Injectable antibiotics accounted for 29%, broadly in line with that observed in 2011. The reported use of intramammary formulations also remained consistent at approximately 5% of total sales.

It should be noted that although the number of veterinary antibiotic products authorised in Ireland has increased over recent years, approximately half of the all authorised products are not currently marketed in the State. These authorisations may support the marketing of the products in international markets or may be held by the companies concerned for strategic or commercial purposes.

In line with EU risk management decisions over recent years to help control antibiotic resistance, the IMB has updated the labelling of the newer antibiotic classes, including the fluoroquinolones, 3rd and 4th generation cephalosporins and macrolide antibiotic classes to include so-called 'responsible use' warnings. However, it is possible that the labelling of some batches of existing products on the market that are within their use shelf life might not contain the updated warnings (they will be updated at the next production run).

For definitive information on the warnings and use instructions on any authorised veterinary medicine, visit the IMB web listing of authorised products on <http://www.imb.ie/EN/Medicines/VeterinaryMedicines/VeterinaryMedicinesListing.aspx>.

As all veterinary antibiotics are subject to veterinary prescription, the IMB expects that they are being prescribed appropriately in this country.

It should also be noted that refinements in the data collection system are expected to be developed in the coming years, to allow for more meaningful comparisons on usage between European Member States and thereby to provide for usage reduction strategies. Currently, given the fact that many antibiotic veterinary medicines are indicated for use in several species and that animals may be exported outside the State prior to slaughter in another country, it is difficult to obtain precise and meaningful usage data in respect of each species.

3 CONCLUSION

The IMB continues to collect and report on data on the use of antibiotics in animals in Ireland. The data for 2012 show that there has been an apparent increase in the overall usage of veterinary antibiotics of 14% (although the 2011 baseline might be seen as low by historical standards). Medicated premixes and other oral formulations that are used primarily for the medication of pigs and poultry account for about two thirds of total consumption. This consumption pattern is relatively consistent with that of previous years, although the use of the tetracycline and macrolide antibiotic classes shows an increase.

Responsible use of antibiotics is a key goal in the ongoing activities of controlling antibiotic resistance for both human and veterinary medicine. Antibiotic resistance genes circulate readily in the environment and readily transfer amongst animals and between humans and animals. Raising awareness of the issue and of where antibiotics are being used is expected to be helpful to inform policy makers in developing appropriate risk management strategies. Each time an antibiotic is used it may contribute to the creation of a population of resistant bacteria which may spread. Therefore every antibiotic intervention should be the subject of careful thought and responsible use.

IMB

November 2013



IRISH MEDICINES BOARD REPORT ON CONSUMPTION OF VETERINARY ANTIBIOTICS IN IRELAND DURING 2011

Dr. J.G. Beechinor, Director of Veterinary Sciences, IMB
22 April 2013

Introduction

In response to the European Commission's initiative known as the European Surveillance of Veterinary Antimicrobial Consumption (ESVAC), the IMB has completed its third annual survey on the usage of veterinary antibiotics. The 2011 report follows those previously published by the IMB in respect of the years 2009 and 2010.

As noted in the previous reports, the consumption data provided in this report should be interpreted with caution; experience from other countries shows that it can take a number of years of collecting such information to establish true baseline values and to be able to analyse trends in the data. The information provided is based on voluntary declarations by marketing authorisation holders. It is expected that the long-awaited modification to the Veterinary Directive governing the authorisation, usage and monitoring of veterinary medicines in the Community will provide useful additional tools to help strengthen the data collection system in the future.

Methodology

During 2011 companies marketing veterinary antibiotics in Ireland were requested to submit annual returns for quantities of dose forms sold, at package level. The data to be provided were described in the ESVAC protocol (www.ema.europa.eu). Data were collected from a total of 51 individual antibiotics contained in 634 product presentations which have been authorised for use in Ireland (including both medicines authorised nationally by the IMB as well as those authorised centrally by the European Commission). The sales data were self-declared by the companies responsible for marketing the products. It should be noted that certain other antibiotics which might be legitimately prescribed by veterinary practitioners (e.g. human antibiotic formulations where there is no suitable veterinary alternative licensed, as well as antibiotics authorised under special import licence by the Department of Agriculture, Food and the Marine) were not captured in this analysis.

The data were inputted into an IMB database and were also transmitted to the European Medicines Agency (EMA) for input into an ESVAC database. The data were validated by the EMA using the ESVAC data program in order to harmonise the information in respect of veterinary antibiotics with those in other European countries. In conformity with the ESVAC protocol, the analysis of the data in respect of individual substances of the same antibiotic classes have been grouped together and classified under the appropriate class headings. In this report the headings are as follows: penicillins, amphenicols, tetracyclines, fluoroquinolones, aminoglycosides, macrolides, lincosamides, sulphonamides & trimethoprim (TMP), cephalosporins and other antibiotic classes.

Results

The total tonnage of veterinary antibiotics used in Ireland was 88.4 tonnes in 2011. This figure compares favourably with 93.2 tonnes in 2010 and 91.1 tonnes in 2009. These results are broken down by chemical classes used in Figure 1 and by dose form in Figure 2 below:

Figure 1. Proportional sales (based on tonnes sold) of the various classes of veterinary antibiotics supplied in 2011 in Ireland

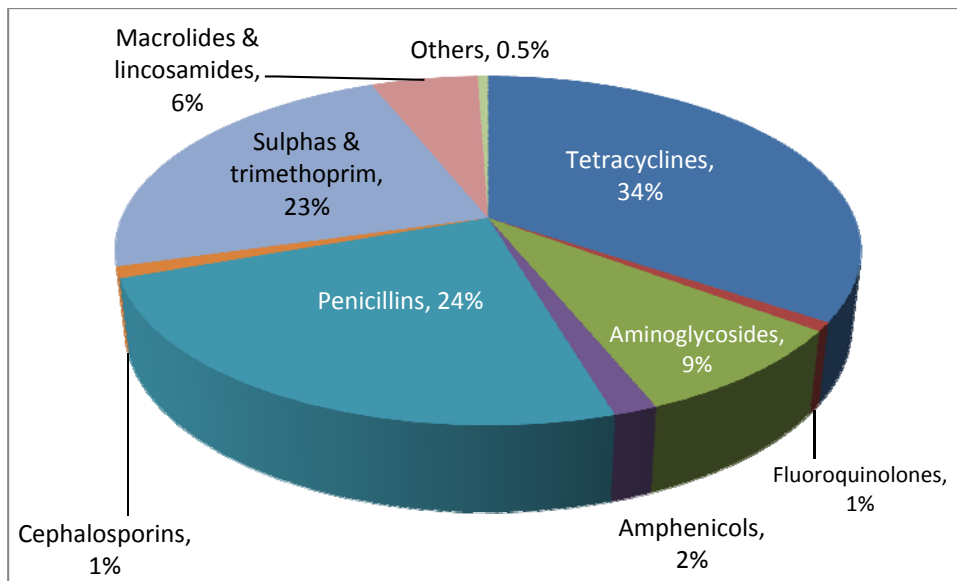
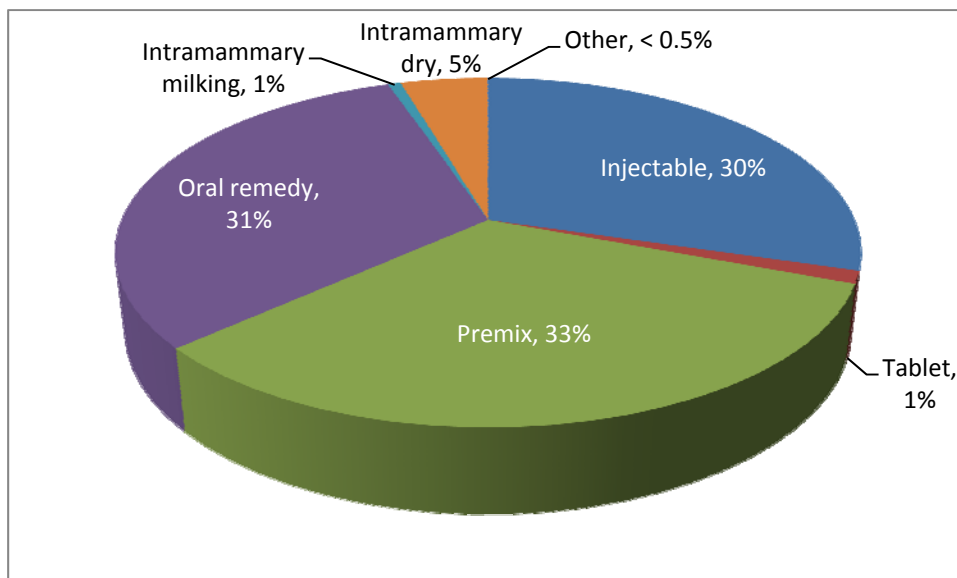


Figure 2. Dose form breakdown of veterinary antibiotics sold in 2011 in Ireland



Discussion

There has been a reduction of nearly 5 tonnes in the reported usage of veterinary antibiotics for 2011 compared to 2010. During this time, the numbers of animals farmed in Ireland is expected to have increased slightly, in line with government expansion plans.

The sales data for 2011 are relatively consistent with those reported for previous years. It appears that the usage of premixes has reduced from 40% in 2009, to 33% in 2011. However, the use of other oral forms of antibiotics has increased from 28% to 31% during this period. Injectable antibiotic formulations have also seen an increased usage, up from 26% in 2009 to 30% in 2011. Use

of intramammary formulations and other pharmaceutical forms has remained relatively consistent at approximately 5% and less than 0.5% respectively.

Tetracyclines, penicillins, aminoglycosides and trimethoprim/sulphonamide drugs account for 90% of the reported use of veterinary antibiotics during 2011. This is similar to their usage in previous years (2010:88%, 2009:94%). The reported use of cephalosporins, fluoroquinolones, macrolides and other antibiotic classes amounts to approximately 10% of the total for 2011, being similar to that for 2010 (12%).

The Irish pattern of use for 2011 follows a largely similar pattern to the EU average as reported in the 2010 ESVAC report; from the 19 participating countries (including Ireland) approximately 90% of the sales were for products used for herd treatment, i.e. premixes (49%), oral powders and solutions (42%), and 9% sold as injectable preparations. However, the distribution of sales of the antibiotic classes varies considerably between countries, being attributed to differences in:

- The relative proportion of the various animal species in different countries,
- Animal production systems,
- The mix of different products on national markets,
- Prices in different countries,
- The general situation with regard to infectious diseases,
- Veterinarians' prescribing behaviour.

The sales of tetracyclines, penicillins and sulphonamides in the 19 countries surveyed in 2010 were 39%, 23% and 11%. The sales of those antibiotics defined as the most critically important by the World Health Organisation, i.e. the 3rd and 4th generation cephalosporins, fluoroquinolones and macrolides accounted for approx 8.1% of the total.

Conclusion

International efforts to ensure the responsible use of antibiotics in the European Community are continuing. The availability of data that can be used to make informed, evidenced-based decisions is critical to the elaboration of appropriate national strategies to help fight antibiotic resistance, whether in humans or animals. This report serves to provide such data in respect of veterinary antibiotic sales in Ireland during 2011.

As was the case in previous years, the 2011 data show that medicated premix and other oral dosage forms continue to make up the bulk of veterinary usage of antibiotics (being approximately 65% of total consumption for 2011). The older classes of antibiotics account for 90% of all veterinary usage, with the newer, more potent substances, being used more judiciously. All veterinary antibiotics are subject to prescription control in Ireland; this is a key control point in ensuring their responsible use.

International comparisons with other European countries is difficult currently given the species, animal population, as well as differences in prescribing and dispensing practices and other confounding factors. Many authorised veterinary antibiotics have indications for more than one species, and this adds a further complexity to any analyses. The ESVAC programme foresees refinements in the collection of data in the future, with the goal of being able to collect the data by animal species, production category and age class. However, these tools might not become available until the European legislation has been adapted. In the interim, the IMB will continue to work with its partners within the European Medicines network to improve the situation.

ENDS



IRISH MEDICINES BOARD REPORT ON CONSUMPTION OF VETERINARY ANTIMICROBIALS IN IRELAND DURING 2010

Dr. J.G. Beechinor, Director of Veterinary Medicines, IMB
15 November 2011

Introduction

Further to the roll out of the European Commission's monitoring initiative throughout the Community in 2009 in a project known as the European Surveillance of Veterinary Antimicrobial Consumption (ESVAC), the IMB has completed its survey on the usage of veterinary antimicrobials for the year 2010. This report follows an earlier report provided by the IMB in respect of the 2009 situation and which is updated in this document.

As pointed out in the 2009 report, the consumption data provided in this report should be interpreted with caution; experience from other countries shows that it can take a number of years of collecting such information to establish absolute baseline values and to be able to analyse trends in the data. Indeed, on investigation of discrepancies between the 2009 and the 2010 returns, a number of errors in the returns of the companies involved came to light. The investigation of these errors has delayed the finalisation of this report by several months. While the IMB cannot rule out that further errors might come to light as more experience of the data analysis is gained, nevertheless, the report provides a useful benchmark from which trends can be derived.

Methodology

Companies marketing veterinary antimicrobial products in Ireland were requested to submit annual returns for quantities of dose forms sold at package level during 2010. The data to be provided were described in the ESVAC protocol (www.ema.europa.eu). Data were collected from a total of 40 individual antimicrobial substances contained in 517 product presentations which have been authorised for use in Ireland (including both medicines authorised nationally by the IMB as well as those authorised centrally by the EU Commission). The data are based on self-declarations by the companies responsible for marketing the products. It should be noted that certain other antimicrobial products (e.g. those authorised under special licence by the Department of Agriculture) or human antimicrobial medicines which might be prescribed by veterinary practitioners where there is no suitable veterinary alternative licensed were not included in this analysis.

The data were inputted into an IMB database and were also transmitted to the European Medicines Agency (EMA) for input into an ESVAC database. The data were validated by the EMA using the ESVAC data program in order to harmonise the data with the data on the sales of veterinary antimicrobial agents in other EU Member States. In conformity with the ESVAC protocol, the analysis of the data in respect of individual substances of the same antimicrobial classes have been grouped together and classified under the appropriate class headings. In this report the headings are as follows: penicillins, amphenicols, tetracyclines, fluoroquinolones, aminoglycosides, macrolides, lincosamides, sulphonamides & trimethoprim (TMP), cephalosporins and other classes.

Prompted by the identification of discrepancies in the data returns in relation to certain individual products between the years 2009 and 2010, the IMB sought further clarification from the marketing authorisation holders (MAHs) involved. These investigations, which involved a number of cases, led to a revision of the overall consumption data for both years.

Results

The total tonnage of veterinary antimicrobials used in Ireland was 93.2 tonnes in 2010 and 91.1 tonnes in 2009. These results are broken down by chemical classes used in Figures 1 and 2 and by dose form in Figures 3 and 4 below:

Figure 1. Proportional sales (based on tonnes sold) of the various classes of veterinary supplied in 2010 in Ireland

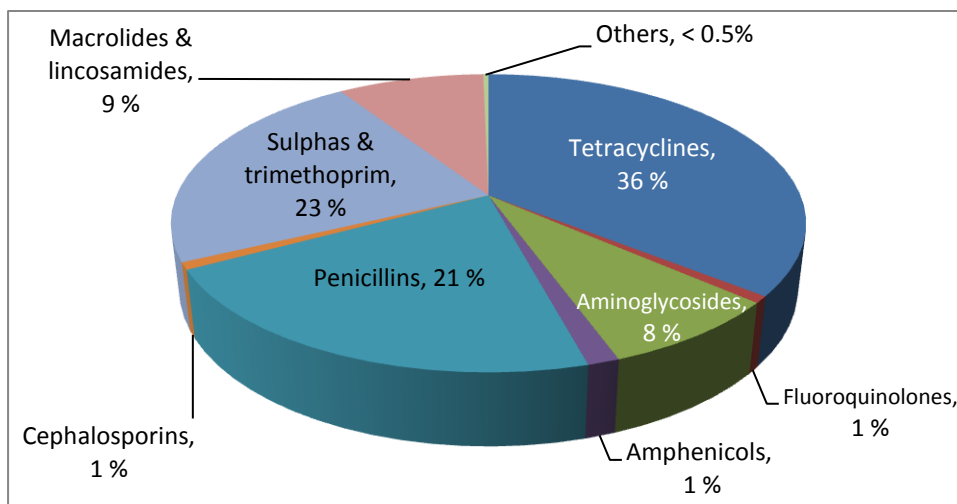


Figure 2. Proportional sales (based on tonnes sold) of the various classes of veterinary supplied in 2009 in Ireland

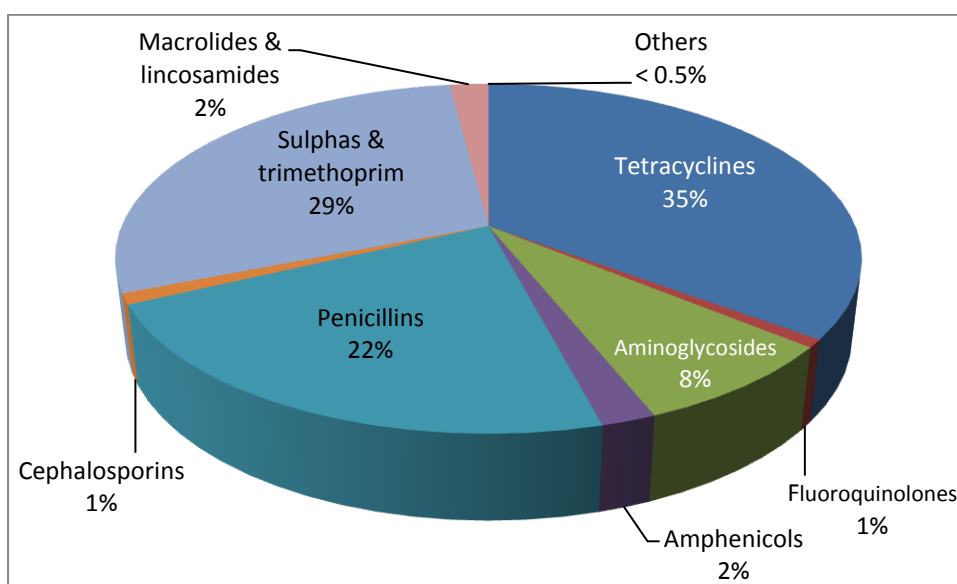


Figure 3. Dose form breakdown of veterinary antimicrobial substances sold in 2010 in Ireland

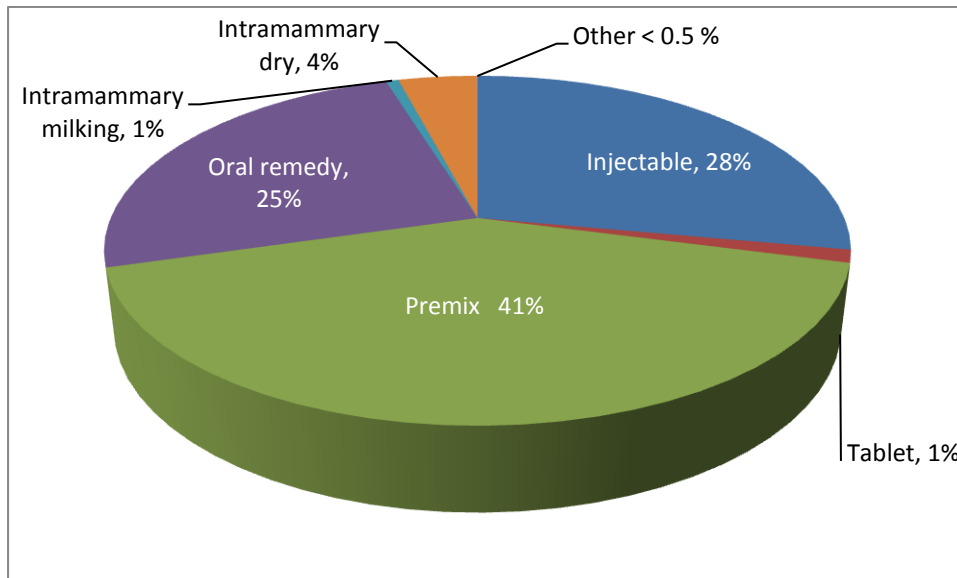
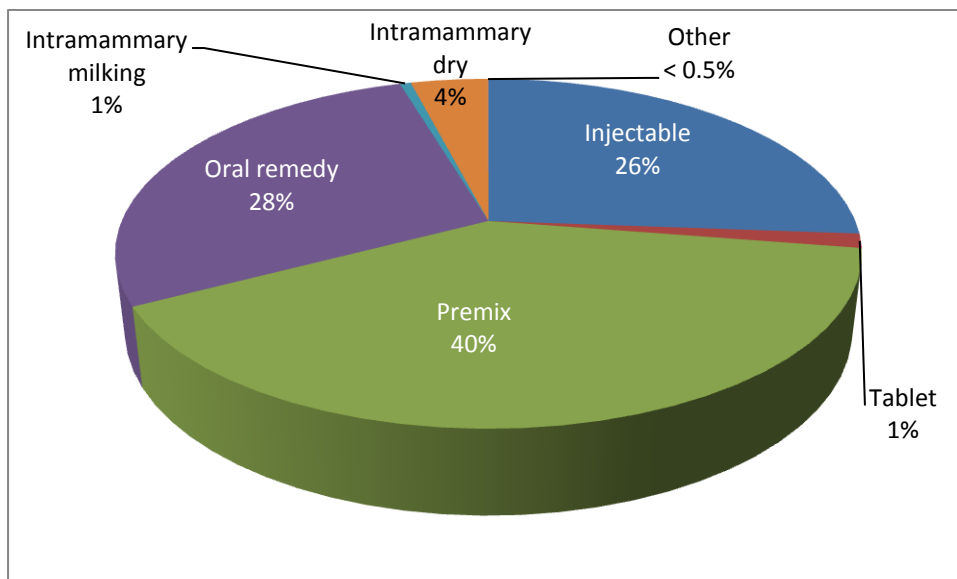


Figure 4. Dose form breakdown of veterinary antimicrobial substances sold in 2009 in Ireland



Discussion

Based on the experience of other European countries, it is expected that usage data in respect of three or more years are ideally needed to establish reliable trends in baseline values for usage of veterinary antimicrobial agents. That stated, the data are quite consistent between the two years, with an overall increase of 2% for 2010.

Tetracyclines, penicillins, aminoglycosides and trimethoprim/sulphonamide drugs account for 88% of the reported use of veterinary antimicrobials during 2010. This is similar to their usage in 2009 (94%). The reported use of cephalosporins, fluoroquinolones, macrolides and other antimicrobial classes amounts to approximately 12% of the total for 2010, being a significant change from the 6% declared for 2009. One possible explanation is that it might be due to underreporting of veterinary antimicrobial agents for 2009; the position will be monitored further in the coming years.

As was the case for 2009, the 2010 data show that medicated premix and other oral dosage forms continue to dominate (being approximately 67% of total consumption for 2010 and 69% for 2009). The declared usage of injectable forms was 28% in 2010 (comparable to 26% in 2009). The reported use of intramammaries appeared to be consistent between both years (4% for dry cow products, 1% for lactating cow products).

The IMB investigations of inconsistencies and dramatic changes in the declared consumptions for individual products yielded positive results. In one case a transcription error in the 2010 returns was found. In another, the MAH stated that they had included returns for both Ireland and the UK in their returns to the IMB. In other cases, the MAHs restated their returns for both years. These investigations led to a significant delay in the finalisation of this report.

The available analytical tools provided under the ESVAC project do not, at present, provide for direct comparisons between the position of Ireland relative to other EU Member States (as the data will be affected by the relative livestock species populations, production systems etc.). However, such a methodology (known as the 'Population Correction Factor') is in development by the EMA and is expected to become available over the coming months. To facilitate contextualisation of the Irish data, the reported sales of antimicrobials for several European countries for the year 2009¹ are given in Table 1 hereunder:

Table 1. Consumption of veterinary antimicrobials in nine European countries during 2009

Country	Tonnes sold
Czech Republic	82
Denmark	130
Finland	17
France	1064
Netherlands	514
Norway	6
Sweden	15
Switzerland	70
United Kingdom	403

In a recent report from Belgium², which states that that country has the third highest consumption of antimicrobial agents per kg biomass produced (behind the Netherlands and France), the consumption of antimicrobial agents in 2009 was stated to be some 304 tonnes.

Conclusion

As advised previously at time of project initiation in 2010, it can be difficult to ensure the reliability of the consumption data provided by MAHs on a self-declared basis. Nevertheless, the data provided for the years 2009-2010 indicate some overall trends:

- Overall consumption patterns were consistent between 2009 and 2010, with a 2% increase being reported.

¹ European Medicines Agency, 2011. 'Trends in the sales of veterinary antimicrobial agents in nine European countries (2005-2009)' (EMA/238630/2011)

² Belgian Veterinary Surveillance of Antimicrobial Consumption, National consumption report 2007-2009, http://www.belvetsac.ugent.be/pages/home/BelvetSAC_report_2007-8-9%20finaal.pdf. [accessed 15 November 2011]

- Medicated premixes are the biggest contributor to the overall usage, followed by other oral dose forms and by injectable presentations.
- The older classes of antimicrobial substances are responsible for nearly 90% of all veterinary usage.
- More sophisticated analytical tools are being developed which will facilitate international comparison of usage between EU Member States.

The IMB will continue to work with its partners within the European Medicines network to enhance the reliability and utility of future such reports.

END



Report on Consumption of Veterinary Antimicrobial Drugs in Ireland in 2009

14 June 2011

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Background

As part of an EU-wide initiative, known as the European Surveillance of Veterinary Antimicrobial Consumption (ESVAC) project, being coordinated by the European Medicines Agency, the IMB compiled a review of usage of veterinary antimicrobials for the year 2009. This initiative is expected to be repeated annually henceforth.

The consumption data provided in this first report should be interpreted with caution; EU Member States with long experience in collecting similar data is that it can take a number of years of collecting such information to establish reliable baseline values and to be able to analyse trends in the data. Results can be influenced by once-off transactions which affect year-end sales or other influences which could lead to under- or over-estimation of actual consumption and spurious individual results.

Methodology

Companies marketing veterinary antimicrobial products in Ireland were requested to submit annual returns for quantities of dose forms sold in 2009. The data to be provided were described in the ESVAC protocol (www.ema.europa.eu). Data were collected from a total of 40 individual antimicrobial substances contained in 475 product presentations which have been authorised for use in Ireland. The data are based on self-declarations by applicant companies. It should be noted that certain other antimicrobial products (e.g. those authorised under special licence by the Department of Agriculture) or human antimicrobial medicines which might be prescribed by veterinary practitioners where there is no suitable veterinary alternative licensed were not included in this analysis.

In conformity with the ESVAC protocol, the analysis of the data in respect of individual substances of the same antimicrobial classes have been grouped together and classified under the appropriate class headings. In this report the headings are as follows: penicillins, amphenicols, tetracyclines, quinolones, aminoglycosides, macrolides & lincosamines, sulphonamides & trimethoprim (TMP), cephalosporins and other classes.

Results

Noting the cautionary remark that given this is the first time that veterinary antimicrobial data have been collected in Ireland and that the data should be interpreted with caution, the overall reported usage of veterinary antimicrobials for the year 2009 was 104 tonnes approximately.

The results are provided graphically in Figures 1 and 2 below:

Figure 1. Breakdown of veterinary antimicrobial substances by their chemical class

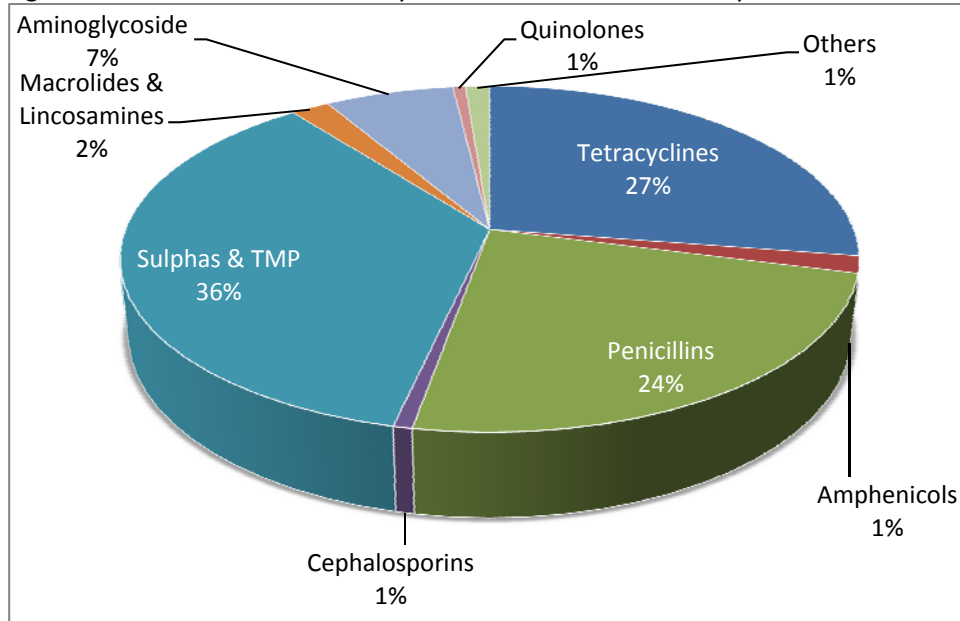
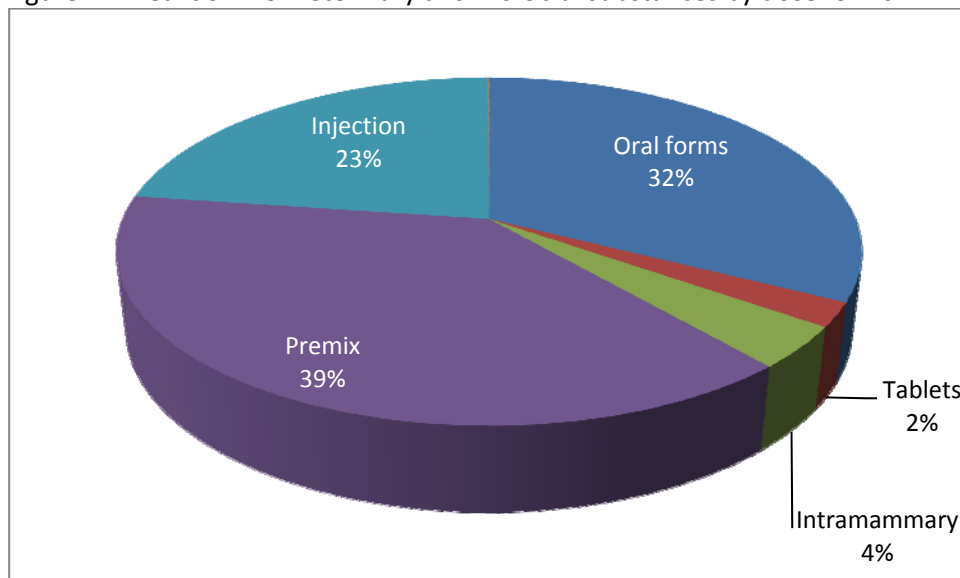


Figure 2 . Breakdown of veterinary antimicrobial substances by dose forms



Discussion and conclusion

Tetracyclines, penicillins, aminoglycosides and trimethoprim/sulphonamide drugs account for 94% of the reported use of veterinary antimicrobials during 2009. The use of cephalosporins, quinolones, macrolides and other drug classes amounts to less than 6% of the total. This breakdown contrasts to that reported by McGowen *et al*, 2011¹ in respect of antimicrobial usage in human usage in community care in Ireland in 2005 where penicillins, macrolides, tetracyclines, cephalosporins and quinolones accounted for 49%, 16%, 12%, 10% and 5% respectively.

¹ McGowen, B., Bergin, C., Bennett, K., and Barry, M. 2011. Utilisation of Antibiotic Therapy in Community Practice, *Irish Medical Journal*, 104(4).

Medicated premix and other oral dosage forms including tablets account for some 73% of the reported use, with injectable forms accounting for a further 23% approximately. Intramammary formulations are reported to account for some 4% of total usage.

This report is expected serve as a benchmark by which future trends in veterinary antimicrobial consumption can be gauged. The currently available analytical tools do not allow for direct comparisons between the position of Ireland relative to other EU Member States (as the data will be affected by the relative livestock species populations, production systems etc.). It is expected that a methodology to enable such comparisons will become available in due course.