

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.

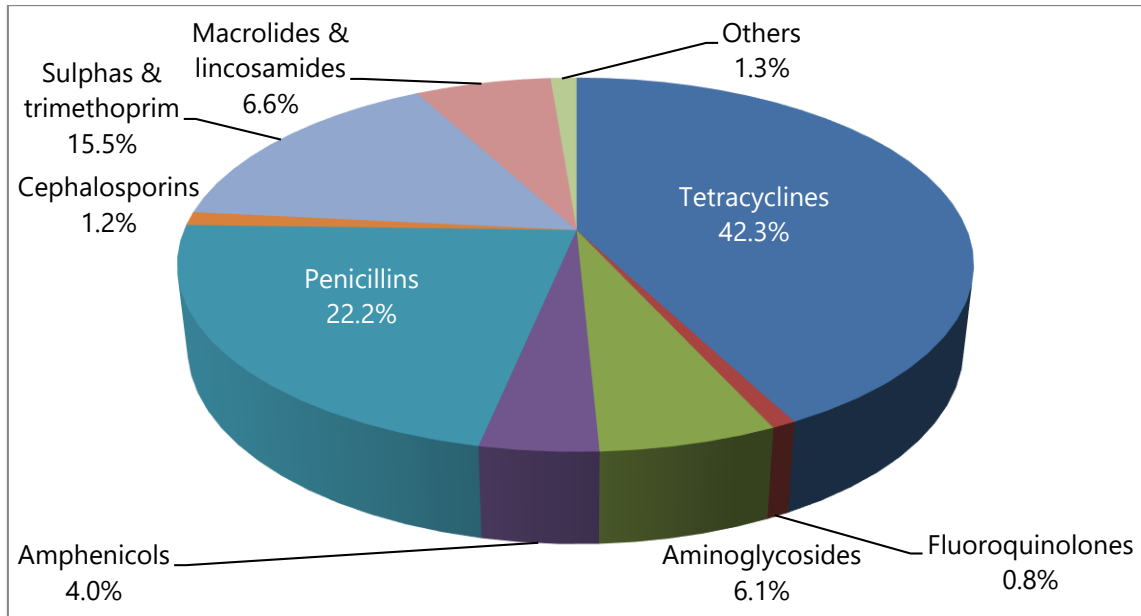
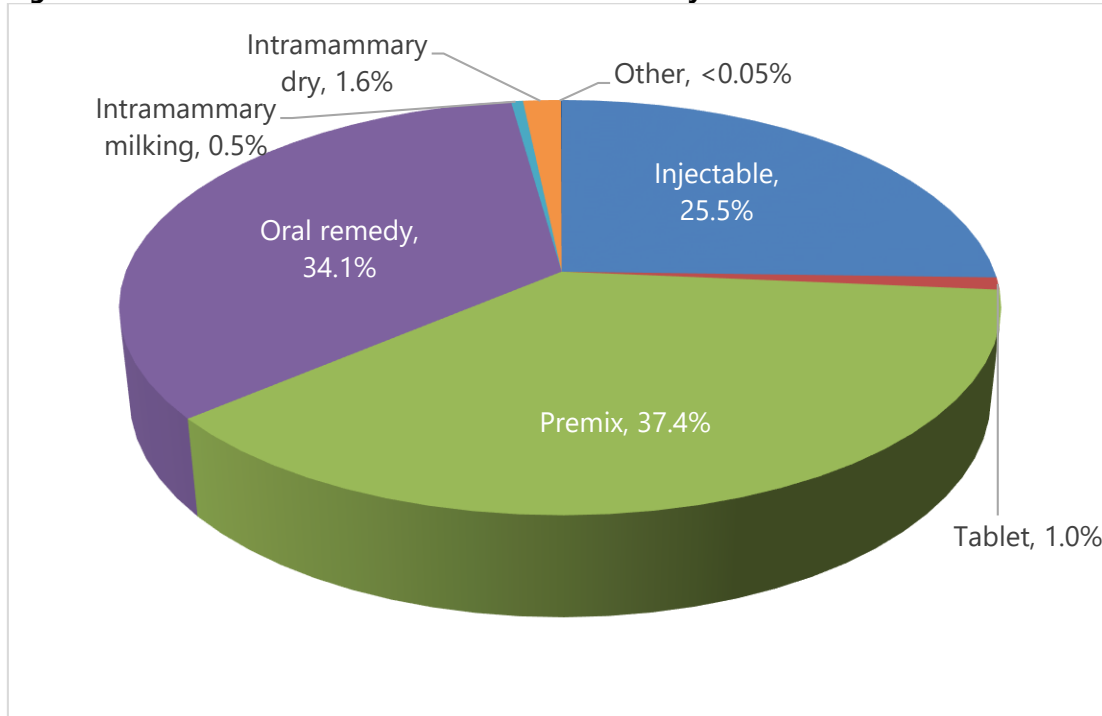


Figure 2. Pharmaceutical form breakdown of veterinary antibiotics sold in 2019 in Ireland.



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).

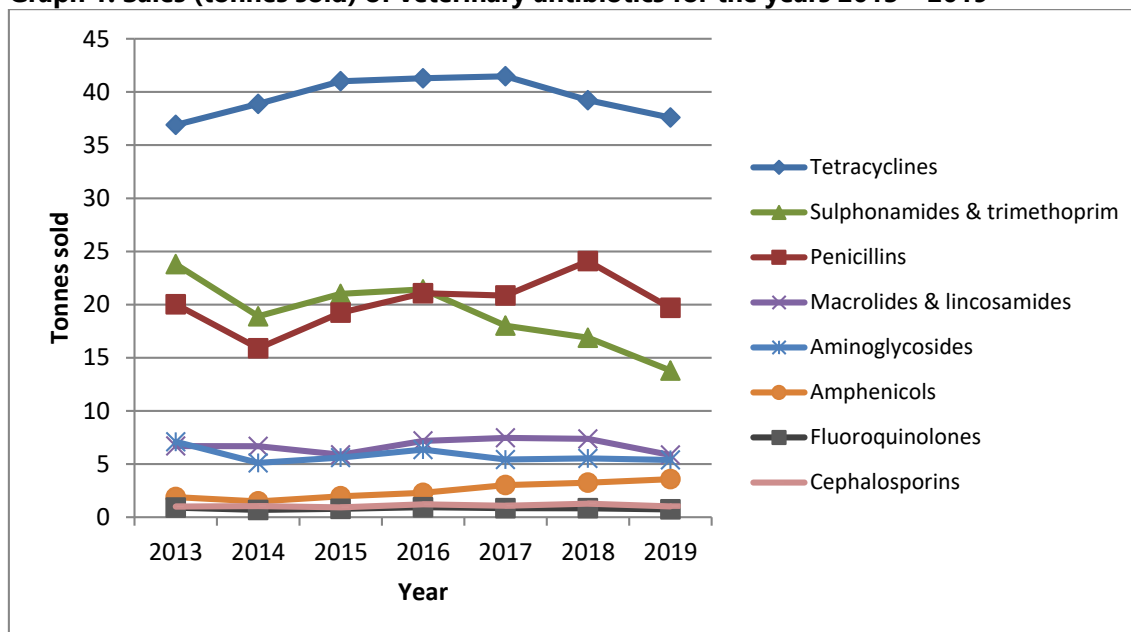
Table 2. Sales (tonnes sold) of veterinary antibiotics for the years 2013 - 2019

	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.

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