HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

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.

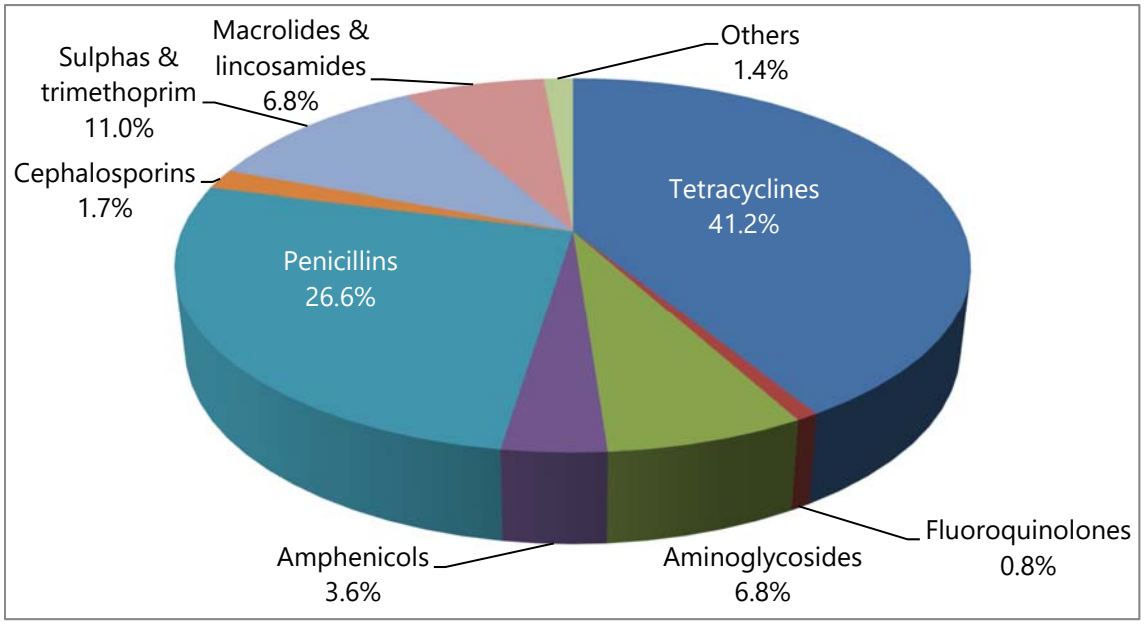
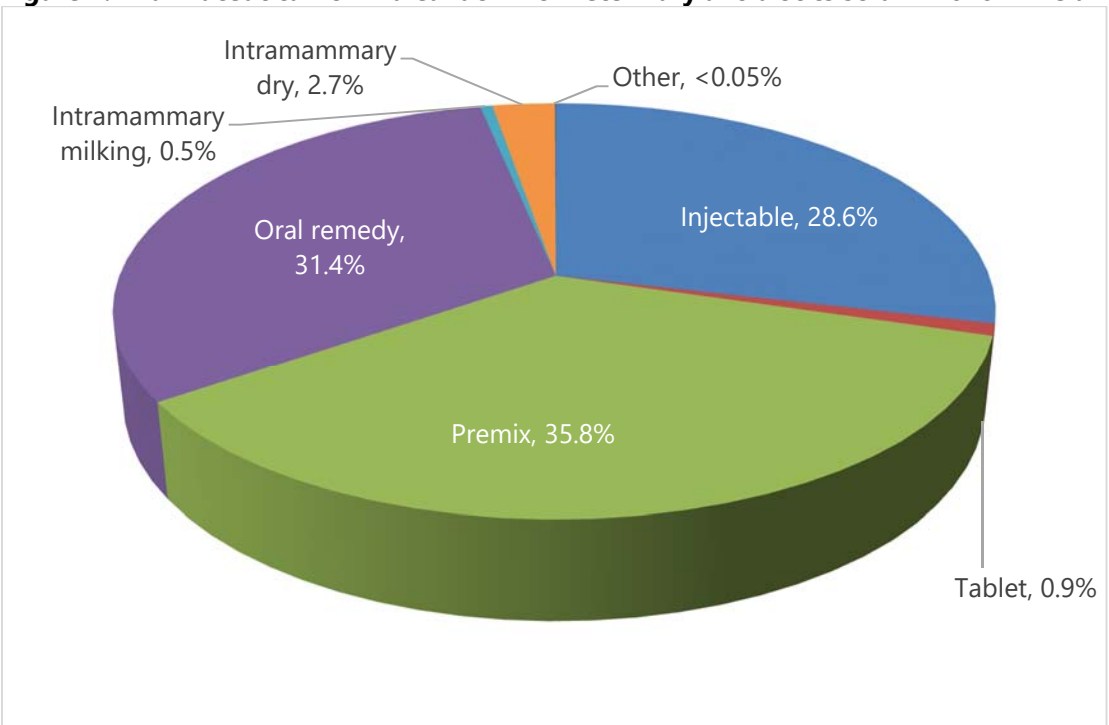


Figure 2. Pharmaceutical form breakdown of veterinary antibiotics sold in 2020 in Ireland.



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 polymixins (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
3rd & 4th 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

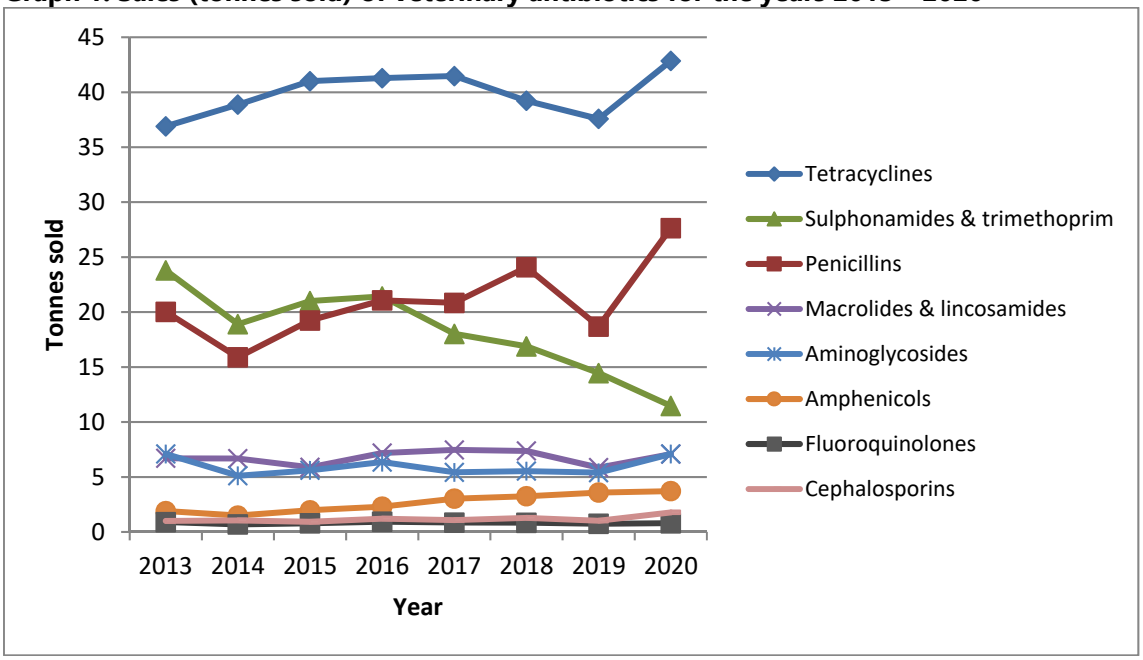
The antibiotic sales data reported for 2020 indicates that sales of veterinary antibiotics increased by approximately 15.6 tonnes when compared to the previous year (Table 2).

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