

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.

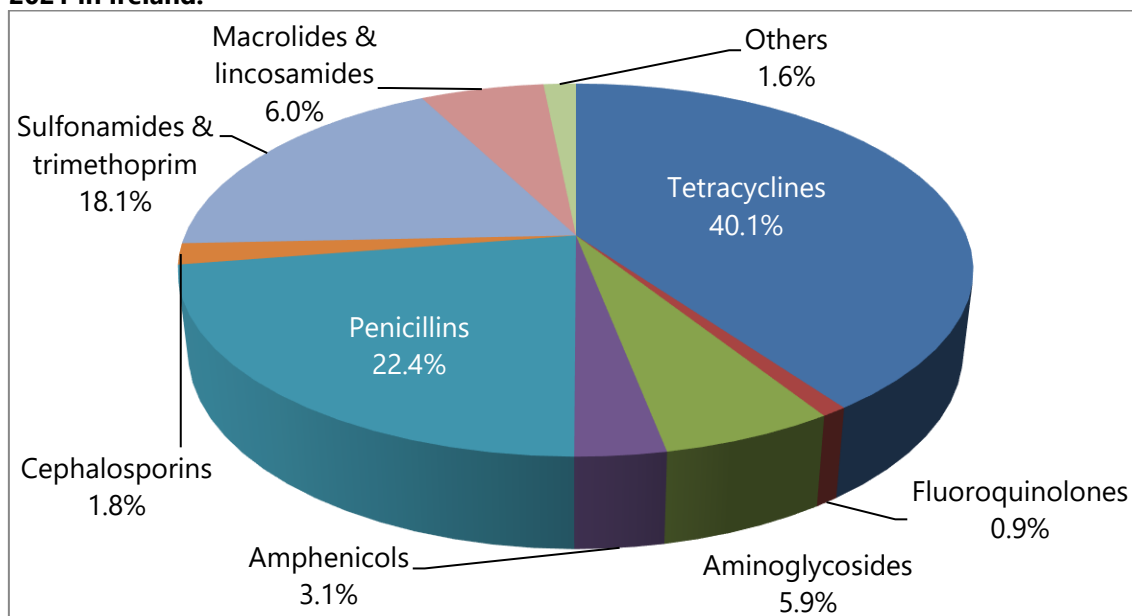
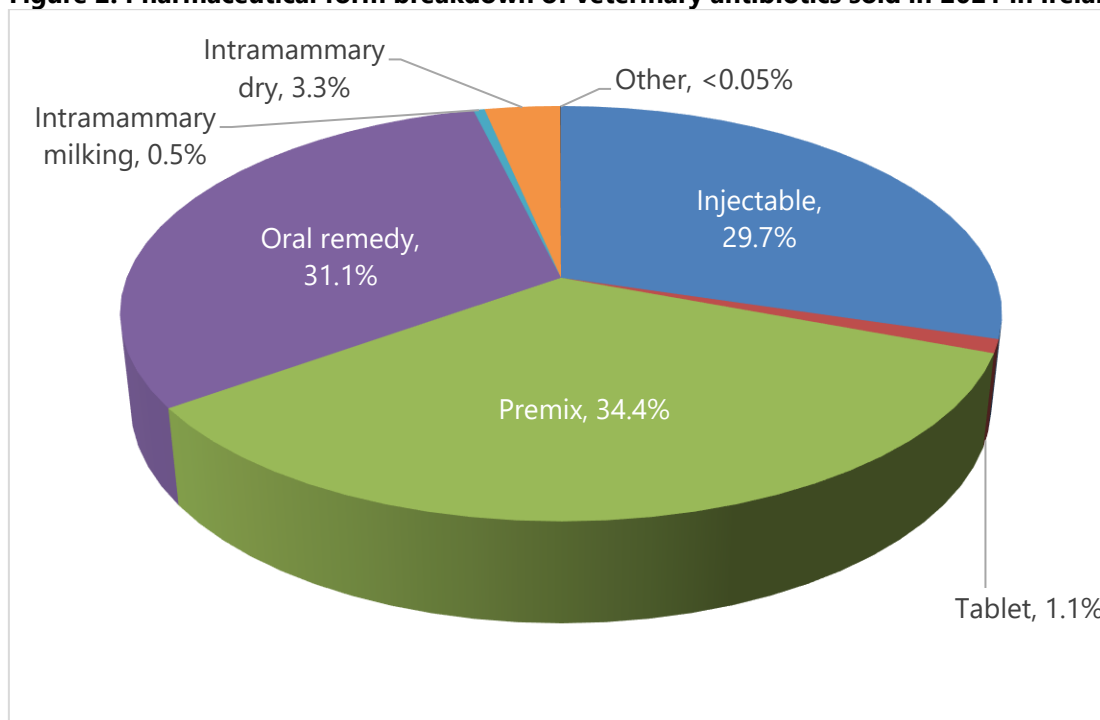


Figure 2. Pharmaceutical form breakdown of veterinary antibiotics sold in 2021 in Ireland.



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'.

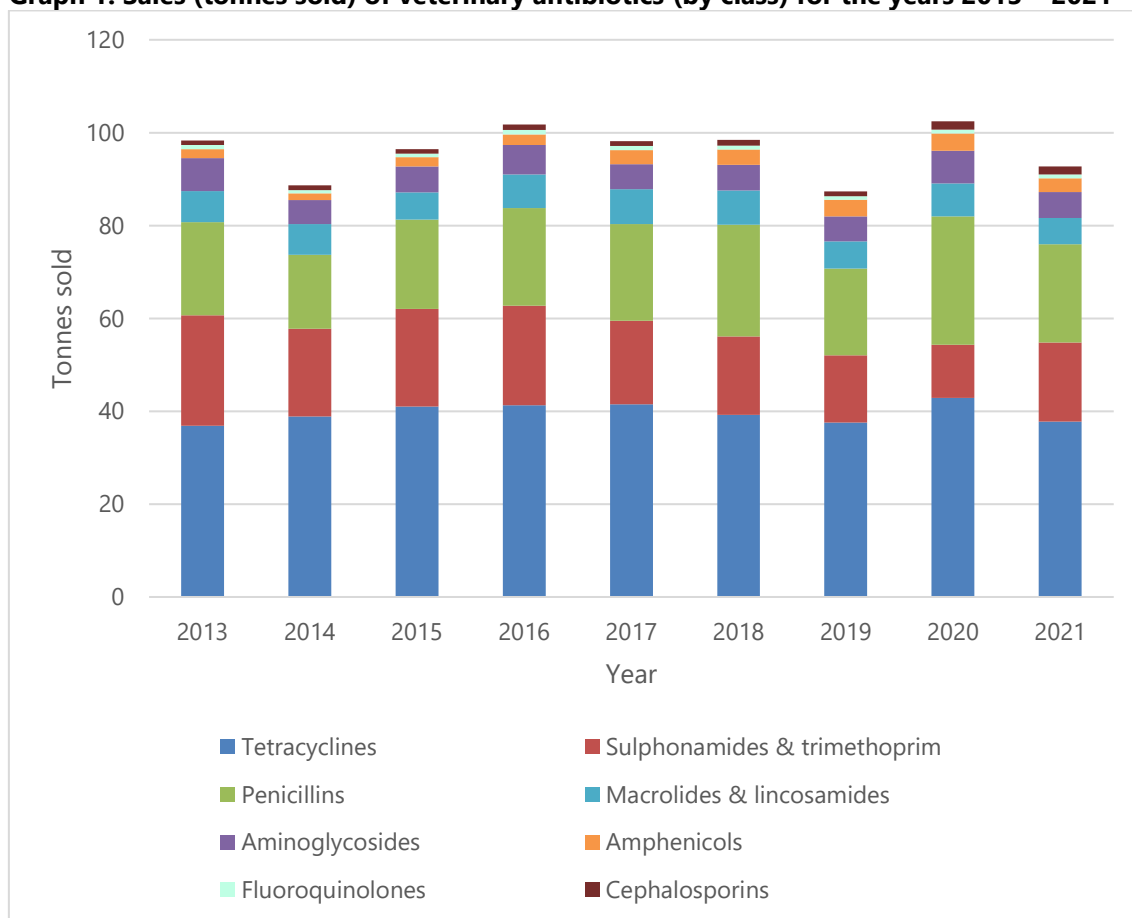
¹ Categorisation of antibiotics in the European Union. Answer to the request from the European Commission for updating the scientific advice on the impact on public health and animal health of the use of antibiotics in animals (https://www.ema.europa.eu/en/documents/report/categorisation-antibiotics-european-union-answer-request-european-commission-updating-scie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

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