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.

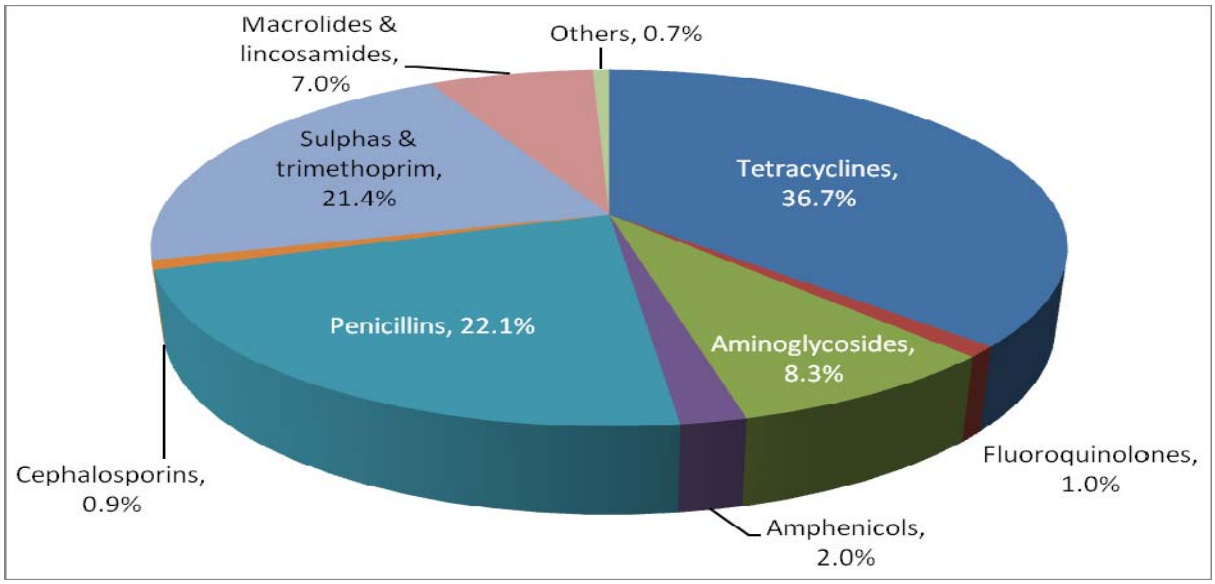
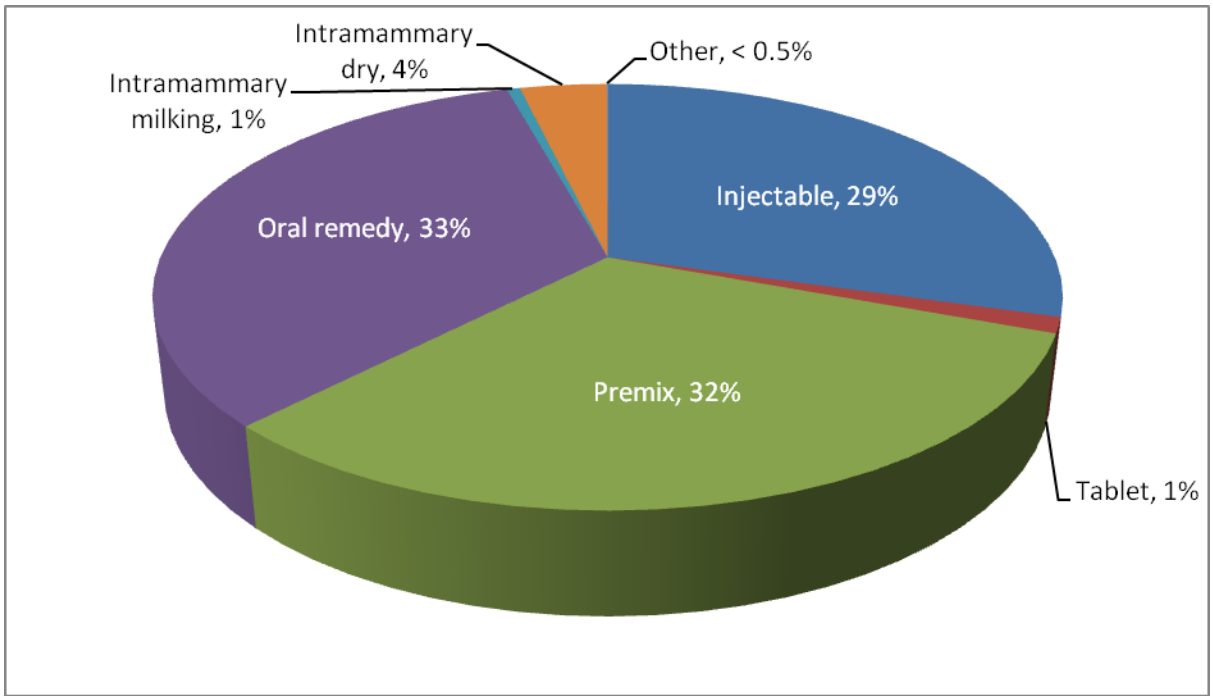


Figure 2. Pharmaceutical form breakdown (based on tonnes sold) of veterinary antibiotics sold in 2012 in Ireland.

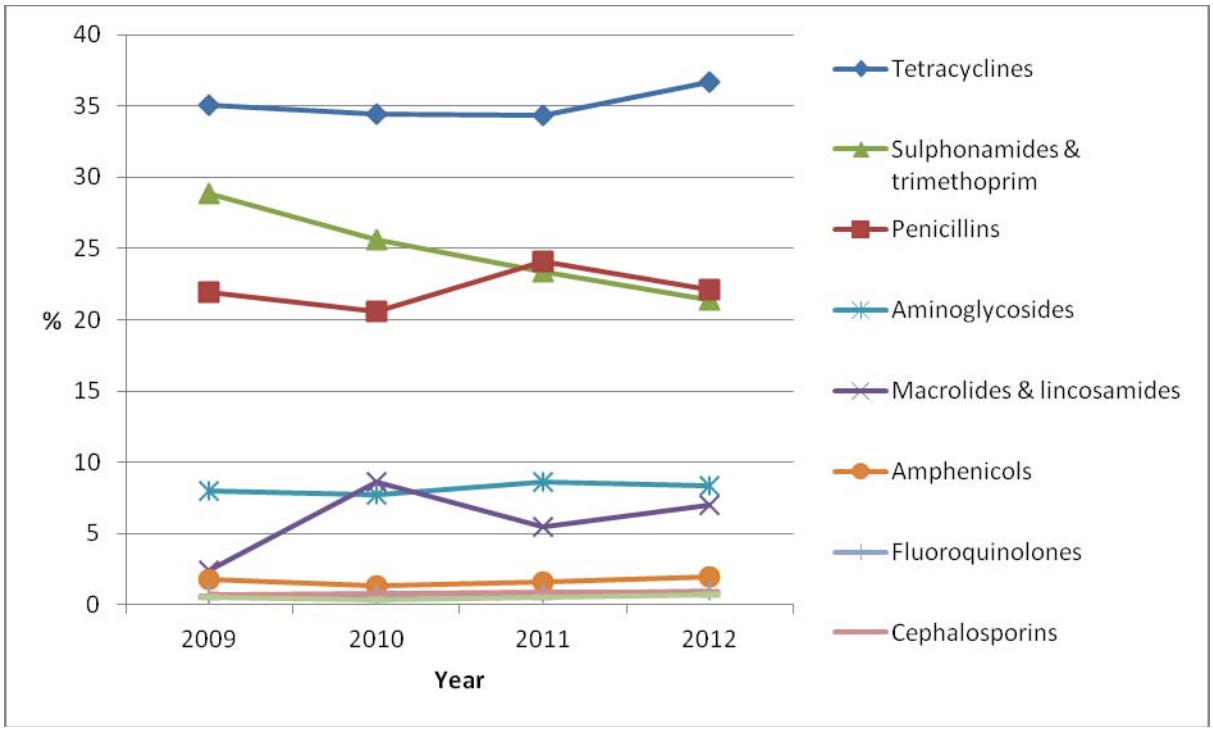


Discussion

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