MINISTERIO DE SANIDAD, POLÍTICA SOCIAL E IGUALDAD

agencia española de medicamentos y productos sanitarios

# Sales of veterinary antimicrobial agents in Spain in 2009

Date of publication: 18th April 2011

Data generated from monitoring of the use of antimicrobial agents in animals are essential to identify and quantify risk factors for the potential development and spread of antimicrobial resistance in animals. This is acknowledged by the Council of the European Union through the Council Conclusions on Antimicrobial Resistance (AMR) of 10 June 2008 that (point 8) "Stresses the importance of effective surveillance systems from both human health and veterinary sectors for collecting comparable data on AMR and antibiotic use". In response to the Council Conclusions the Commission asked the European Medicines Agency (EMA) to take a lead in the collection of harmonized data on use of veterinary antimicrobial agents and the EMA launched the European Surveillance of Veterinary Antimicrobial Consumption (ESVAC) project in September 2009.

The ESVAC project established a Technical Consultative Group (TCG) that advised the Agency setting up the ESVAC) project in order to obtain harmonized data across EU, including which antimicrobial agents to be included (see Table 1) and which of variables to be collected for each product. Also an ESVAC Data Collection Form (ESVAC Template) has been provided by the project. Several countries in parallel have started this project at national level, as a pilot phase; among these is Spain.

In July 2010, the project on collecting sales data was presented to the pharmaceutical company that has registered or dispenses veterinary antimicrobial agents in Spain. The Spanish veterinary medicine industry provided the data for 2009 on a voluntary basis and data were collected and provided by use of the ESVAC Template.

**Table 1. Groups of veterinary antimicrobial agents included in the data**

| Groups of antimicrobial agents | ATCvet codes |
|---|---|
| Antimicrobial agents for intestinal use | QA07AA; QA07AB |
| Antimicrobial agents for intrauterine use | QG51AA; QG51AC; QG51AE; QG51AX<br>QG51BA; QG51BC; QG51BE |
| Antimicrobial agents for systemic use | QJ01 |
| Antimicrobial agents for intramammary use | QJ51 |
| Antimicrobial agents used as antiparasitic agents | QP51AG |

## 1. Material and methods

### a. Distribution of veterinary medicines in Spain.

In Spain all veterinary medicinal products (VMPs) containing antimicrobials are prescription only medicines, so they can only be dispensed under veterinary prescription. All suppliers to final VMPs' users (retailers, pharmacies and farmers' co-

* *It has been included the name "centro de vigilancia sanitaria veterinaria (VISAVET)"*

CORREO ELECTRÓNICO
smuvaem@aemps.es



C/ CAMPEZO, 1 – EDIFICIO 8
28022 MADRID
TEL: 91 822 54 01
FAX: 91 822 54 43

operatives) are authorised according to national law and benefit from a mandatory pharmacist control service, being the retailers the most frequent dispensing way. Vets in Spain are allowed to use VMPs in their daily practice, but they can not sell VMPs to animal owners.

Medicated feeds containing antimicrobial premixes have also to be prescribed by a veterinarian and manufactured only by feed mills authorized by regional competent authorities according to the specific legislation and the feed hygiene regulation as well (HACCP principles).

### b. Veterinary antimicrobial agents included in the material

Sales data were collected for the groups of veterinary antimicrobial agents included in Table 1.

### c. Data sources

Annual sales data were collected from the veterinary medicine industry.

### d. Collection of the data.

The Spanish monitoring of sales of antimicrobial agents used in veterinary medicine has been coordinated by Agencia Española de Medicamentos y Productos Sanitarios (AEMPS) in collaboration with the Spanish Veterinary Antimicrobial Resistance Surveillance Network (VAV) of antimicrobial resistance in bacteria, Centro de Vigilancia Sanitaria Veterinaria (VISAVET) de la Universidad Complutense de Madrid.

The ESVAC template (Excel file) was distributed to all veterinary laboratories to be filled on with data of sales of veterinary medical products containing antimicrobials.

### e. Data coverage

These figures were supplied for the period of 1st January to 31st December of the 2009. 48 of the 50 N companies returned data (two of them did not marketed AM).The data coverage is assumed to be 90-100%.

### f. Analysis of the data

The sales data were processed by support of the ESVAC data manager and analysed and validated by the AEMPS in collaboration with the VAV Network.

## 2. Results

**Table2. Sales of veterinary antimicrobial agents in Spain in 2009 (in Tons).**

| Group of substances | 2009 |
|---|---|
| **Tetracyclines** | 344,36 |



MINISTERIO DE SANIDAD, POLÍTICA SOCIAL E IGUALDAD
Agencia Española de Medicamentos y Productos Sanitarios

| Group of substances | 2009 |
|---|---|
| **Amphenicols** | 8,02 |
| **β-lactams (penicillins)** | 179,62 |
| **1st and 2nd gen. cephalosporins** | *0,57* |
| **3rd and 4th gen. cephalosporins** | *1,41* |
| **Sulfonamides and Trimethoprim (total)** | 245,73 |
| **Macrolides** | 77,50 |
| **Lincosamides** | 93,17 |
| **Aminoglycosides** | 24,52 |
| **Fluoroquionolones** | *51,19* |
| **Other quinolones** | *4,13* |
| **Polymyxins** | 0,10 |
| **Pleuromutilins** | 54,53 |
| **Others** | 17,50 |

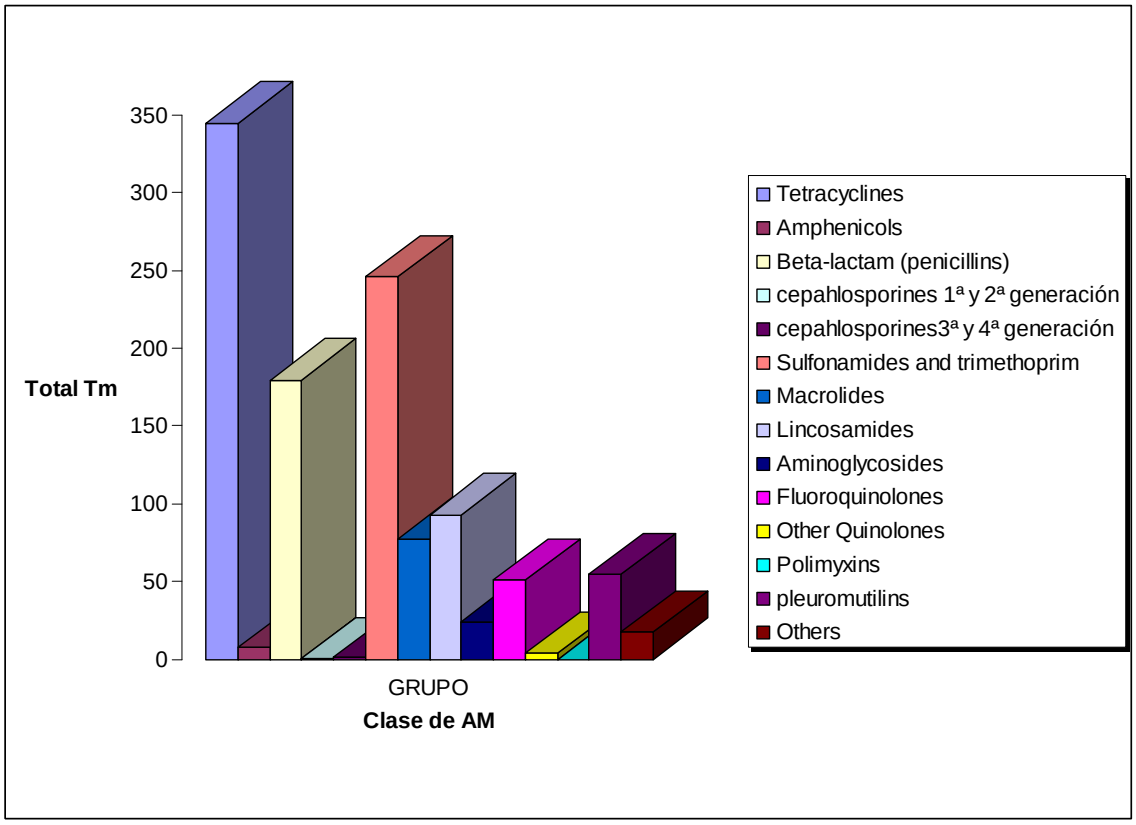


Fig.1 total sales of antimicrobial reported for 2009.



MINISTERIO DE SANIDAD, POLÍTICA SOCIAL
E IGUALDAD
Agencia Española de Medicamentos y Productos Sanitarios

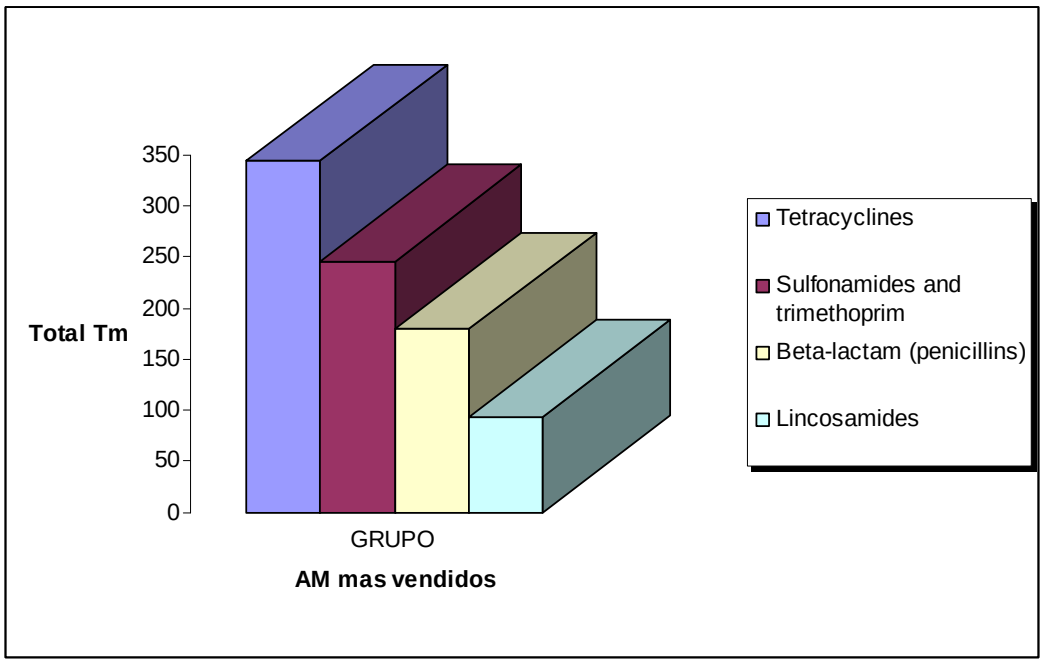


Fig.2 the most important groups by sales.

**3. Comments on the data** (Main developments/interpretation of the data - total sale, groups of substances)

Table 2 presents the results of sales of antimicrobial used in veterinary medicine by class; Total sales of antimicrobials reported for 2009 are 1102, 35 Tn. As 2009 is the first year that these data have been collected, no comparative in deep analysis could be drawn.

Approximately 80% of the total amount sold come from four groups of antimicrobials: tetracycline (31, 23%, Sulphonamides and trimethoprim (22,29%) Beta-lactams (16, 29%) and lincosamides (8,45%).

The total sales figures should be interpreted with great care as the data are not corrected neither for biomass of animals “at risk” for being treated, including differences in animal demographics and transport of animals for slaughter in other countries, nor for differences in dosages that are due differences in potency, pharmacokinetic characteristic, formulation, MIC values and disease.

This is of particular importance since Spain is one of the major farm animals’ producers in the EU (2nd for swine, broilers and small ruminants; 3rd for laying hens and rabbits; 4th for dairy cows and 5th for beef meat). Furthermore dogs and cats also involved a high consumption.

Finally, it should also be considered that Spain has historically imported from EU MSs young animals for fattening in our country (mainly piglets and calves) and also sent live fattened animals for slaughter in other MSs and third countries. These facts, together with an increasing number of live animals exported for reproductive purposes, make of trade flow a key issue to be taken into account in the interpretation of the sales volume data.



MINISTERIO DE SANIDAD, POLÍTICA SOCIAL
E IGUALDAD
Agencia Española de Medicamentos y Productos Sanitarios