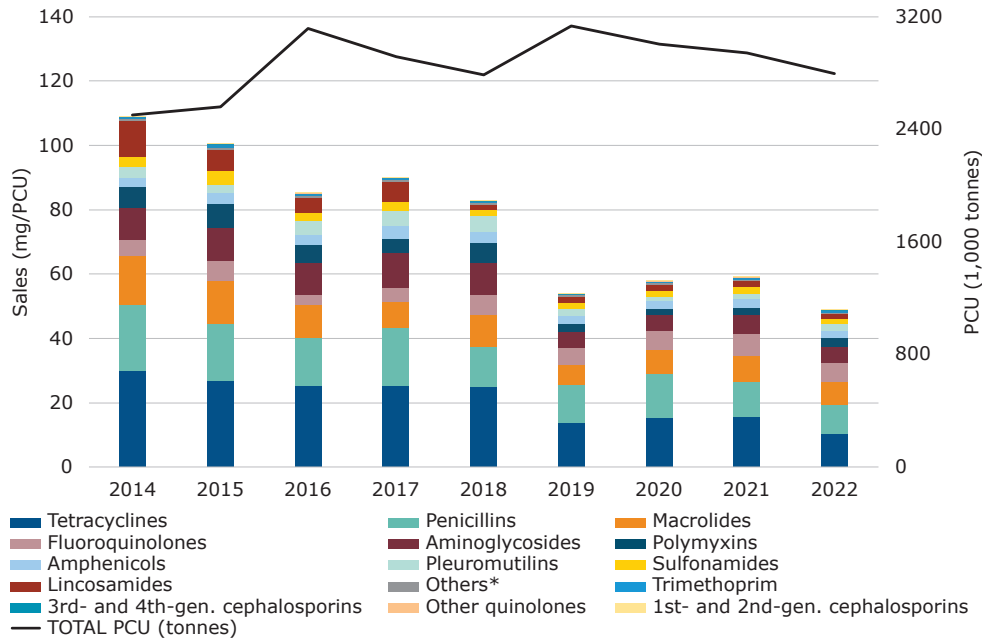


Sales trends (mg/PCU) of antibiotic VMPs for food-producing animals

Sales trends by antibiotic class (mg/PCU) from 2014 to 2022^{1,2}



¹ Sales data sorted from highest to lowest in 2022.

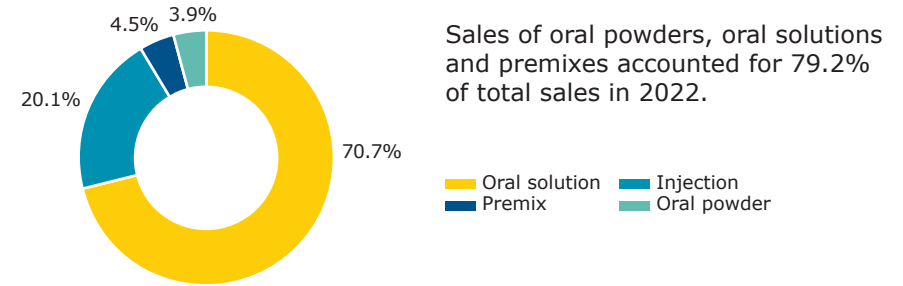
² In 2021 and 2022, some of the tablets sold were indicated for food-producing or non-food-producing birds. Tablets are not included in the mg/PCU analysis.

* The class 'Others' includes sales of the following sub-classes: imidazole derivatives (metronidazole), nitrofurantoin derivatives (furazolidone) and other antibacterials (bacitracin, fosfomicin, furaltadone, novobiocin and spectinomycin). Of note is that some of the sales could be for non-food-producing animals.

Since 2014:

- ⬇️ 55.2% overall annual sales (from 109.0 mg/PCU to 48.8 mg/PCU in 2022)
- ⬆️ 165.2% 3rd- and 4th-generation cephalosporin sales (from 0.05 mg/PCU to 0.13 mg/PCU in 2022)
- ⬆️ 5.4% fluoroquinolone sales (from 5.3 mg/PCU to 5.5 mg/PCU in 2022)
- ⬇️ 72.0% other quinolone sales (from 0.23 mg/PCU to 0.07 mg/PCU in 2022)
- ⬇️ 58.4% polymyxin sales (from 6.5 mg/PCU to 2.7 mg/PCU in 2022)
- ⬆️ PCU increased by 11.7% between 2014 and 2022

Proportion of sales (mg/PCU) by product form in 2022^{1,2}

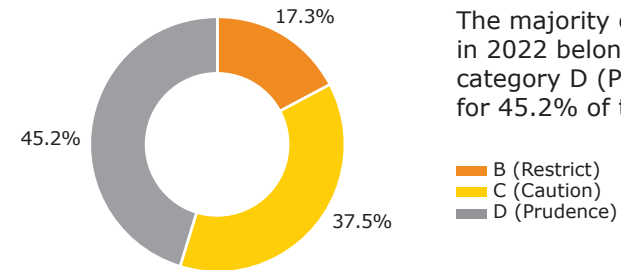


Sales of oral powders, oral solutions and premixes accounted for 79.2% of total sales in 2022.

¹ Sales of other forms (intramammary and intrauterine) are not represented in this figure and account for 0.7% of total sales.

² No sales of bolus and oral paste products in 2022.

Proportion of sales (mg/PCU) by AMEG categories in 2022¹



The majority of antibiotic VMP sales in 2022 belonged to the AMEG category D (Prudence), accounting for 45.2% of total sales.

¹ Novobiocin is not included in the AMEG categorisation and accounts for 0.02% of overall sales.

2022 sales data

In 2022, overall sales decreased by 17.3% in comparison to 2021 (from 59.0 mg/PCU to 48.8 mg/PCU). The three highest selling antibiotic classes were tetracyclines, penicillins and macrolides, which accounted for 21.8%, 17.8% and 15.3% of total sales, respectively.

Country information

In Romania, data on sales of antimicrobial VMPs are collected from MAHs. This started in 2014 and since then has been reported annually to ESVAC and WOA. H.

Since 2015, the Reports on Antimicrobial Sales for Romania have been posted on the Institute for Control of Biological Products and Veterinary Medicines website.

The collection of sales and use data of the antimicrobials are based on national legislation on the implementation of Regulation (EU) 2019/6 regarding data collection on the volume of sales and the use of medicinal products in animals.

Based on EU guidelines regarding the prudent use of antimicrobials, a National Guide for the prudent use of antimicrobial substances in veterinary medicine was published on the National Sanitary Veterinary and Food Safety Authority website in 2016 and is periodically updated. The purpose of this guide is to provide practical guidance to veterinarians, farmers, authorities, the veterinary industry, the pharmaceutical industry, associations and academia on the prudent use of antimicrobials in animals and various ways to limit the development of AMR.

In 2018, the national legislation on biosecurity in poultry holdings included special requirements for the prudent use of antimicrobials, namely:

- Antimicrobial VMPs may be administered only after a diagnosis has been established based on an analysis report issued by an approved veterinary and food safety laboratory attesting the presence of a pathogen and justifying their administration in compliance with sanitary veterinary legislation in force;
- Antimicrobials of critical importance for humans may be administered to animals only if a laboratory diagnosis has been established and after the antibiogram has been performed, or a laboratory diagnosis correlated with the epidemiological history has been established to demonstrate that the other classes of antimicrobial are not effective.

The overall decrease in sales of antimicrobials in 2022 was influenced both by the evolution of African swine fever and by the COVID-19 pandemic. However, animals exported to third countries and live goats are not taken into account when the PCU indicator is calculated. Romania, on the eastern border of the EU, continues commercial activities with live animals both on the common market and directly (export only) to third countries, according to the specific legislation. Animal movements within the EU, including transit related to export in third countries, are recorded in TRACES, but taking into account the geographical position of Romania, exports carried out through border inspection points directly to the third countries are not recorded in TRACES. Therefore, animals exported directly via border inspection points (cattle and sheep), directly influence the calculation of mg/PCU. Moreover, in Romania, the number of live goats is significant and its non-inclusion in the calculation of the PCU directly influences the calculation of the mg/PCU indicator.

Currently, at the national level, the National Strategy for the prevention and limitation of healthcare-associated infections and combating the phenomenon of antimicrobial resistance in Romania for the period 2023–2030 has been developed and is in the process of being approved.

To develop and monitor the National Strategy to combat AMR, the National Committee for Limiting Antimicrobial Resistance was established in 2018, with representatives from central authorities and non-governmental professional organisations, under the coordination of the Ministry of Health¹.

In Romania, AMR surveillance in the veterinary field is based on the isolation of indicator microorganisms and the phenotypic characterisation of strains isolated from clinical specimens, environmental samples or food. Monitoring and reporting of antimicrobial resistance in zoonotic and commensal bacteria are performed annually in accordance with Commission Implementing Decision (EU) 2020/1729.

¹ Government Decision No. 879/2018 regarding the establishment of the National Committee for Limiting Antimicrobial Resistance, with amendments.