



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Antimicrobial Resistance (AMR) initiatives

EMA's latest updates

EMA Veterinary Awareness Day, 12-13 September 2023

Presented by Zoltan Kunsagi
Veterinary Medicines Division





EMA's role in the global response to the threat of AMR

- Collecting antimicrobial consumption data to guide policy and research
- Promoting responsible use of existing antibiotics
- Providing advice to the European Commission





Collecting antimicrobial consumption data

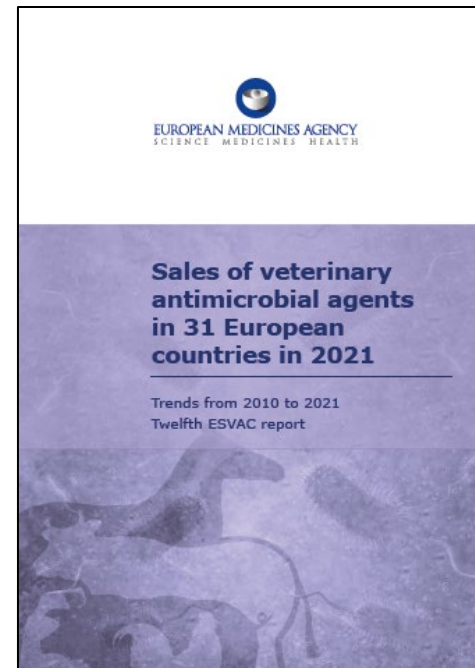
How we do it



ESVAC Network

Sales of antimicrobials for veterinary use

- The European Surveillance of Veterinary Antimicrobial Consumption (ESVAC), between 2009-2023, collected harmonised sales data of antimicrobials for veterinary use in the EU and EEA
- Important for:
 - Risk assessment
 - Trends in antimicrobial consumption
 - Monitoring of adherence to responsible use policies



Reference:
[The ESVAC project](#)



Trends in antimicrobial consumption from 2011 to 2021



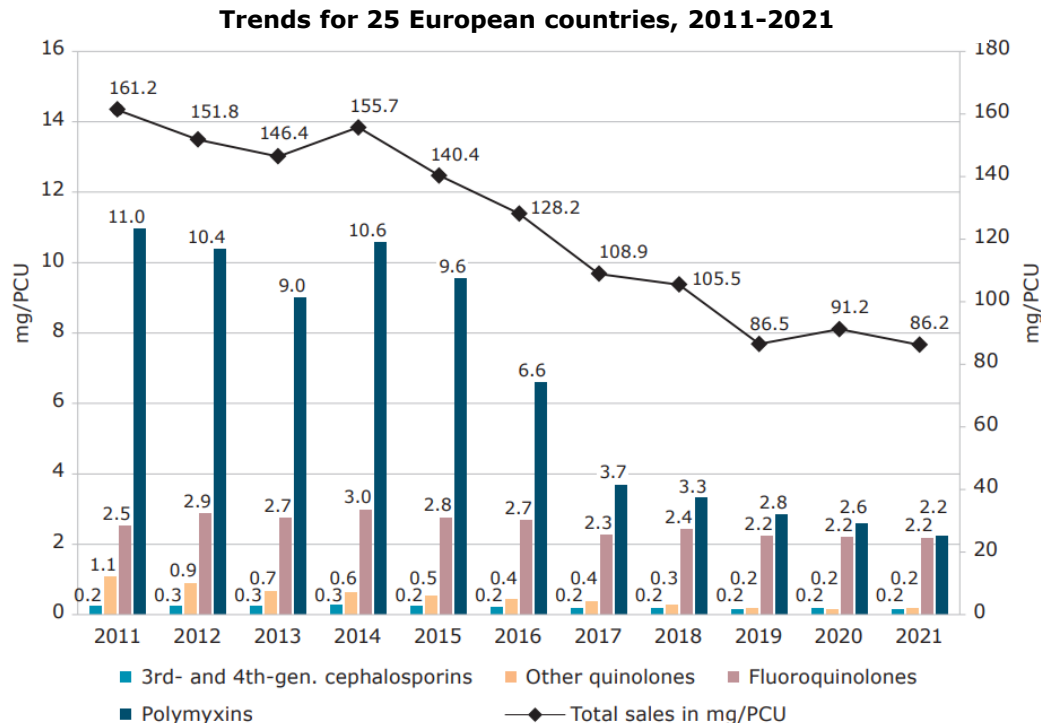
↓ **47% overall decrease**

↓ **38%** for 3rd-and 4th-gen. cephalosporins;

↓ **80%** for polymyxins;

↓ **14%** for fluoroquinolones;

↓ **83%** for other quinolones





Farm-to-Fork Strategy

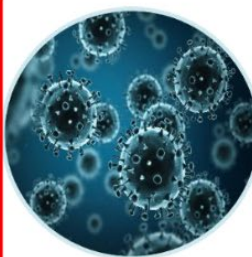
2030 targets for sustainable food production



Reduce by 50% the overall use and risk of **chemical pesticides** and reduce use by 50% of more hazardous **pesticides**



Reduce **nutrient losses** by at least 50% while ensuring no deterioration in soil fertility; this will reduce use of **fertilisers** by at least 20 %



Reduce sales of **antimicrobials** for farmed animals and in aquaculture by 50%



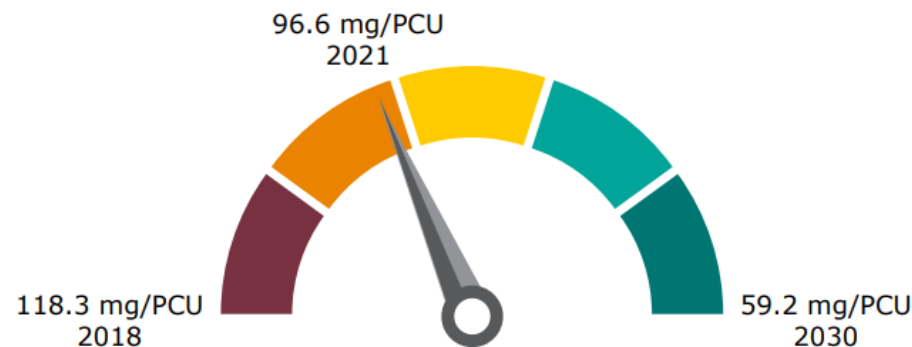
Achieve at least 25% of the EU's agricultural land under **organic farming** and a significant increase in **organic aquaculture**



Farm-to-Fork Strategy

50% target







- **Goal:** 50% reduction EU sales of antimicrobials
- **Species:** farmed animals and aquaculture
- **Timeline:** from 2018 to 2030



Between **2018-2021**, aggregated sales for 27 EU MSs decreased by **18%**

Sales and use data collection

From 2024

-  Requirement of Veterinary Medicines Regulation (EU) 2019/6
-  Collection and reporting of data on the **volumes of sales** per veterinary antimicrobial medicinal products
-  Collection and reporting of data on the **use per animal species** per antimicrobial medicinal products (both veterinary and human)
-  IT system for data reporting by MS to the EMA developed with MS representatives, available for testing since January 2023
-  Linked to the Union product database for veterinary medicines and the human Article 57 database
-  European Sales and Use of Antimicrobials for Veterinary Medicine Working Group established in 2023

Joint Interagency Antimicrobial Consumption and Resistance Analysis (JIACRA) report

Results of analyses to assess the relationship between antimicrobial consumption (AMC) and antimicrobial resistance (AMR) in animals and humans.



3rd JIACRA report published in 2021 based on data from years 2016-2018.

4th JIACRA report under preparation (publication by Dec 2023).

Reference:
[The JIACRA reports](#)



Responsible use of existing antibiotics

How we promote it



Categorisation of antibiotics in the EU

Prepared by AMEG (Antimicrobial Advice Ad Hoc Expert Group) on request of the Commission.
Published in 2020.

Category A: '*Avoid*'

Category B: '*Restrict*'

Category C: '*Caution*'

Category D: '*Prudence*'



Reference:
[The AMEG categorisation](#)



Supporting the European Commission

Providing advice

Antimicrobials to be reserved for human use

- No use in animals allowed, also applies to imports of animals and their produce
- Working group with a cross-sectoral One Health framework of experts (veterinarians, microbiologists and medical doctors specialising in infectious diseases + external experts)
- The evaluations are based on the best scientific evidence currently available
- **The advice recommends 11 antibiotic classes, 6 antibiotic substances and 18 antiviral substances to be reserved for humans**
- Ban on use = Strictest measure in veterinary context to address public health AMR issues



Reference:

[Advice by EMA](#)

[Regulation by Commission](#)



List of substances banned, or with restricted use, outside the directions on the product label

- Complements list of antimicrobials reserved for use in humans
- Working group with experts, including veterinary sector-specific, AMR experts and experts from human infectious diseases background
- Sources of evidence: existing recommendations, official reports, and surveillance data from EU agencies (>700 supporting references)
- Recommendations: conditions for use



Reference:
[Advice by EMA](#)

Summary

EMA plays a vital role in the global response to AMR through a 'One Health' approach:

- Collecting antimicrobial consumption data to guide policy and research
- Promoting responsible use of existing antibiotics
- Providing advice to the European Commission
- Supporting the development of new medicines and treatment approaches
- Inter-agency and international cooperation





Further information

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