EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EMA and the EU network of veterinary medicines

The Agency’s perspective

EMA Veterinary Awareness Day

Presented by Dr Jordi Torren on 13 September 2023
Head of Evaluation and Innovation Support Department, Veterinary Medicines Division

The EU Regulatory network for veterinary medicines

Who are we?

- Is composed of:
  - 50 regulatory authorities from the 30 EEA countries (27 EU Member States plus Iceland, Liechtenstein and Norway)
  - European Commission
  - European Medicines Agency
- Is supported by more than 4000 experts across Europe

Who makes (part of) the EU Regulatory Network?

Innovation

Novel Therapies Working Party

- Veterinary monoclonal antibody products
- Potency tests for cell-based veterinary therapy products and the relation to clinical efficacy
- Phage therapy (quality, safety and efficacy)
- Nanomaterials
- Initial consideration on gene therapy veterinary medicinal products

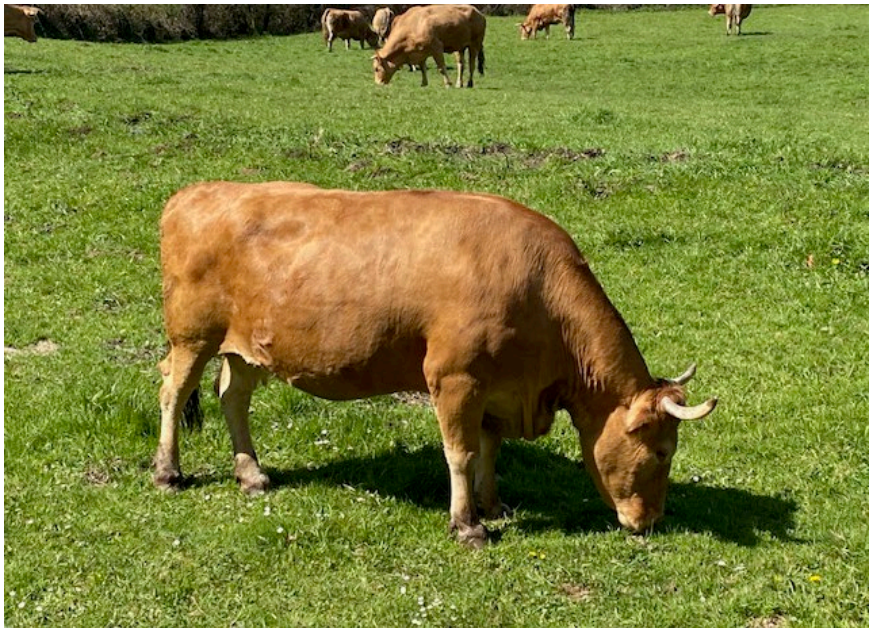
EU Network Training Centre (EU NTC)

Training platform

- Offers scientific and regulatory training opportunities to all EU network staff.
- Created with the purpose of:
  - sharing knowledge.
  - enhancing professional development.
  - Promoting the exchange of good practices across the EU network

Benefit risk and availability
Antimicrobial resistance and Environmental Risk Assessment

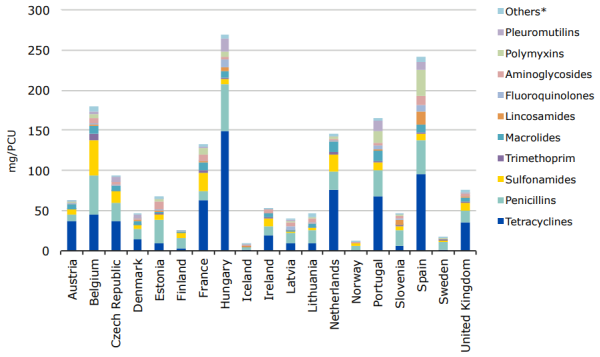
- Increase in society's concerns regarding antimicrobial resistance and environmental risk assessment.
- Legislation is demanding on use of antimicrobials in animals.
- Increasing concerns on impact of medicines in the environment.
  - Use of antiparasitics
  - Environmental Risk Assessment



Evolution of sales data

Sales of veterinary antimicrobial agents in 19 EU/EEA countries in 2010.
Second ESVAC report

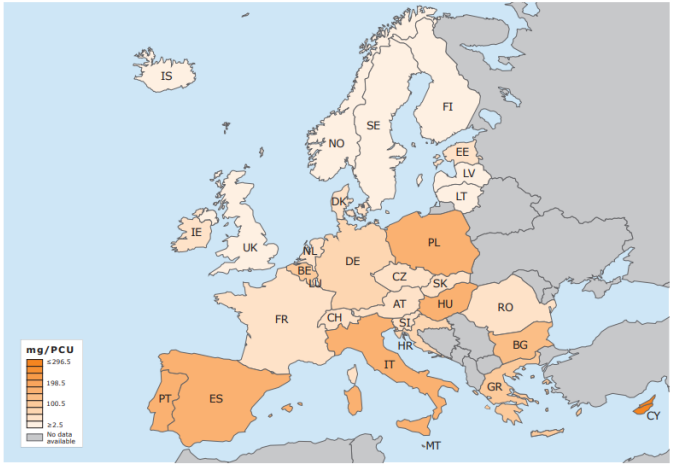
Figure 7. Sales for food-producing species, including horses, in mg/PCU, of the various veterinary antimicrobial classes, by country[1], for 2010



[1] Differences between countries can partly be explained by differences in animal demographics, in the selection of antimicrobial agents and in dosage regimes, among other factors. * Amphenicols, cephalosporins, other quinolones and other antibacterials (classified as such in the ATCvet system).

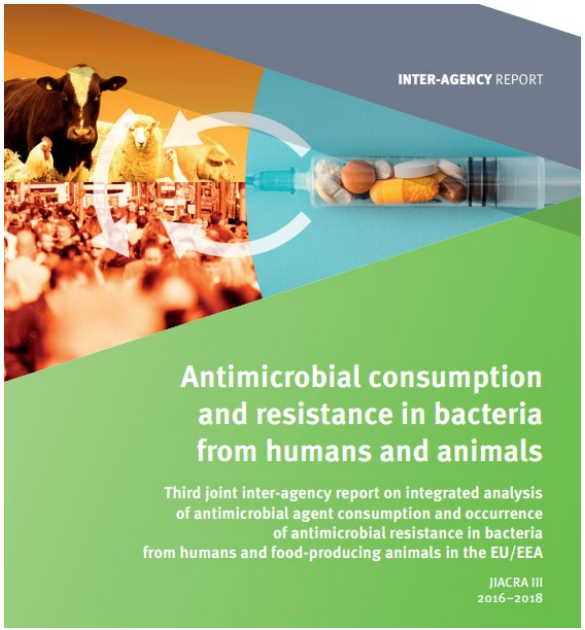
Sales of veterinary antimicrobial agents in 31 EU/EEA countries in 2021.
Twelfth ESVAC report

Figure 2. Spatial distribution of overall sales, in mg/PCU, of antibiotic VMPs for food-producing animals in 31 European countries in 2021[1]



[1] ESVAC-participating countries codes according to ISO 3166 — Codes for the representation of names of countries and their subdivisions.

Joint assessments EMA/EFSA, JIACRA



Ref. Ares(2022)277241 - 14/01/2022

EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Director-General

Brussels,
SANTE/E4/MW/gb(2021)8786383

Subject: Request for a Scientific Report on the impact of the use of azole fungicides, other than as human medicines, on the development of azole-resistant *Aspergillus spp*.

Dear Dr Url,
Dear Mr Hansen,
Dear Ms Cooke,
Dear Ms Ammon,
Dear Mr Bruyninckx

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Reduce pollution to combat ‘superbugs’ and other anti-microbial resistance

[Reduce pollution to combat ‘superbugs’ and other anti-microbial resistance | UN News]

Photo by Johannes Plenio

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

17 February 2021
EMA/CVMP/ERA/632109/2014
Committee for Medicinal Products for Veterinary Use (CVMP)

Reflection paper on antimicrobial resistance in the environment: considerations for current and future risk assessment of veterinary medicinal products

Draft agreed by the Environmental Risk Assessment Working Party (ERAWP)	30 April 2018
Draft agreed by the Antimicrobials Working Party (AWP)	30 May 2018
Adopted by CVMP for release for consultation	8 November 2018
Start of public consultation	16 November 2018
End of consultation (deadline for comments)	31 August 2019
Draft agreed by Environmental Risk Assessment Working Party (ERAWP)	6 January 2021
Draft agreed by the Antimicrobials Working Party (AWP)	6 January 2021
Adoption by CVMP	17 February 2021

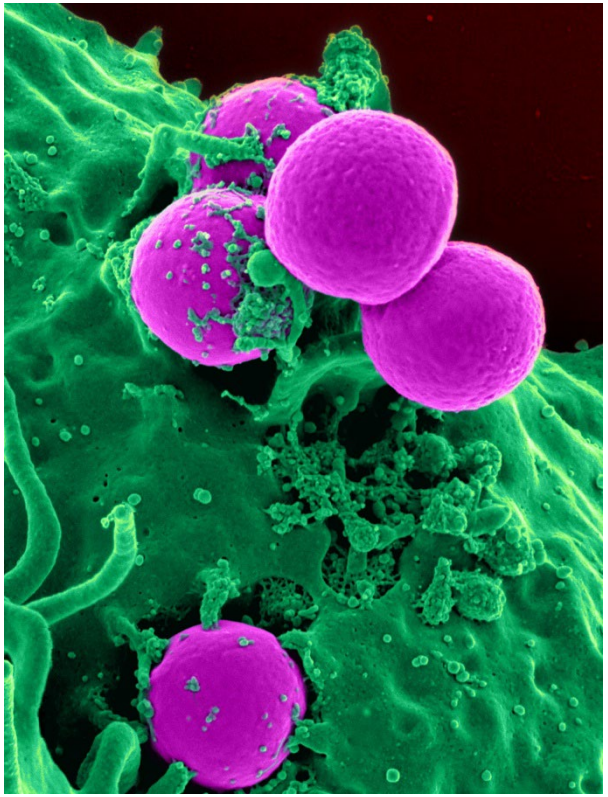


Photo from Pixabay

Need for a more refined environmental risk assessment of ectoparasites in companion animals?

Photo by Lloyd Dirks

16 December 2022
EMA/CVMP/ERA/31905/2021
Committee for Veterinary Medicinal Products (CVMP)

Reflection paper on the environmental risk assessment of ectoparasiticidal veterinary medicinal products used in cats and dogs

Draft

Draft agreed by ERAWP	23 September 2022
Adopted by CVMP for release for consultation	8 December 2022
Start of public consultation	16 December 2022
End of consultation (deadline for comments)	31 March 2023

One substance, One assessment

Also working on:

- Nitrosamines
- Titanium dioxide
- PFAS

  (Per- and polyfluoroalkyl substances)

Ref. Ares(2022)5249691 - 19/07/2022

European Commission

CALL FOR EVIDENCE
FOR AN INITIATIVE (without an impact assessment)

TITLE OF THE INITIATIVE	Chemical safety – better access to chemicals data for safety assessments
LEAD DG – RESPONSIBLE UNIT	ENV B.2
LIKELY TYPE OF INITIATIVE	Proposal for a Regulation
INDICATIVE TIMING	Q1 2023
ADDITIONAL INFORMATION	Implementation of the chemicals strategy – Implementation (europa.eu).

This document is for information purposes only. It does not prejudge the final decision of the Commission on whether this initiative will be pursued or on its final content. All elements of the initiative described by this document, including its timing, are subject to change.

A. Political context, problem definition and subsidiarity check

Political context

The EU has a comprehensive framework for regulating chemicals, involving over 40 legislative instruments. These instruments often require assessments of chemicals by a number of regulatory bodies or agencies. As part of the chemicals strategy for sustainability (CSS) under the **European Green Deal**, the Commission will move towards a 'one substance – one assessment' approach and implement the following three key actions as part of this approach.

- It will remove legislative obstacles to the re-use of data and better streamline the flow of data on chemicals between EU and national authorities.
- It will extend the principle of 'open data' and the relevant transparency principles from the EU's food safety sector to other pieces of legislation on chemicals.
- It will enable EU and national authorities to commission the testing and monitoring of chemical substances as part of the regulatory framework when further information is considered necessary.

The initiative will also: (i) facilitate access to monitoring data to support the framework for zero-pollution monitoring and zero-pollution outlook; and (ii) help implement the EU data strategy in the area of chemicals.

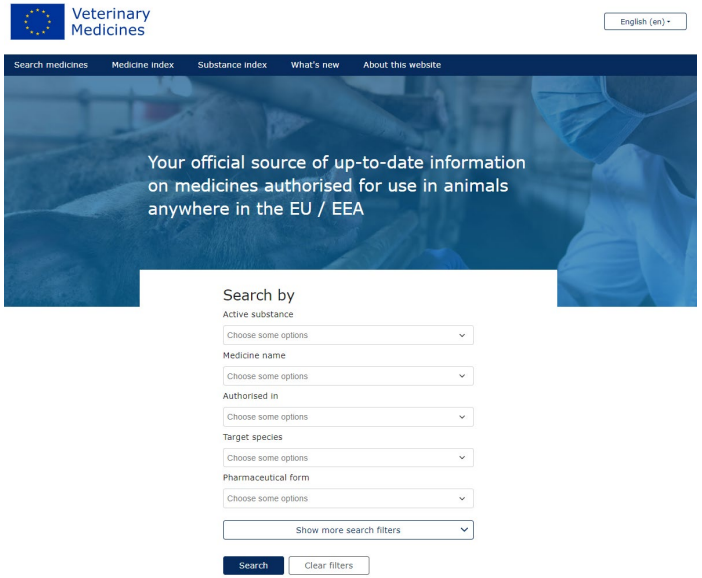
Transparency and publication of guidelines for consultation

- One of the founding values of the EMA is transparency.
- Guidelines, and other guidance documents, are published for consultation and comments received are published and guidelines revised.
- Workplans of the CVMP and its working parties are regularly published as well as other relevant documents.

Pharmacovigilance: detecting, consolidating and publishing relevant findings

Veterinary Medicines Information website

- https://medicines.health.europa.eu/
- Public face of the Union Product Database
- Information on all authorised veterinary medicinal products in the EU/EEA



Conclusions

- The European Medicines Agency, with more than 25 years of history, provides the institutional support for the scientific assessment of veterinary medicines.
- The process includes a rigorous assessment of quality, safety and efficacy of veterinary medicinal products as performed by the scientists of the EU Member States.
- With an increasing number of new technologies (mRNA vaccines, bacteriophages, stem cells…) there is a need to rapidly adapt to those changes.
- The Veterinary Medicine Regulation, combined with other factors (Brexit, Covid, remote telework) has obliged the Agency, and the network, to adapt rapidly.
- New tools from the legislation to be further fine-tuned to take advantage of its full potential could result in a more innovative, more one health orientated, authorisation of veterinary medicinal products.

Any questions?

Further information

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