EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EMA role and activities for veterinary medicines

EMA Veterinary Awareness Day

Presented by Ivo Claassen on 12 September 2023
Head of Veterinary Medicines Division

WHAT WE DO

Protect human and animal health

Facilitate development and access to medicines

Evaluate applications for marketing authorisation

Monitor the safety of medicines across their life cycle

Provide reliable information on human and veterinary medicines to patients and healthcare professionals

EMA in the EU

Who do we work for?

zdrowie zdravie
zdravlje Gesundheit
salud υγεία saúde
tervist veselība
salute здраве saħħa
terveys sundhed
health hälsa sláinte
egészség’
zdravje zdraví
gezondheid
sveikata
santé sănătate

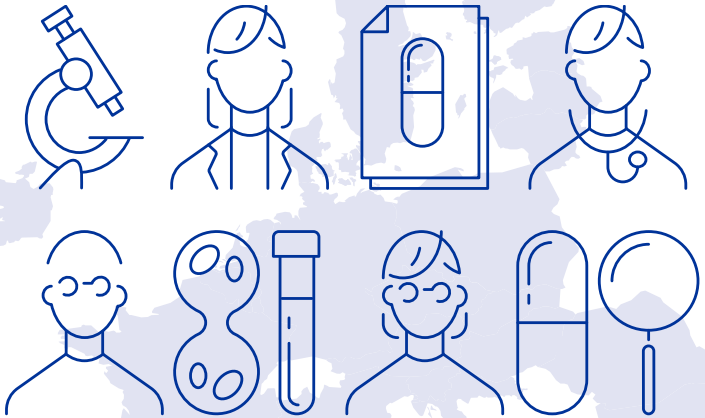
27 member states

21.5 % of global sales of medicines

24 official languages

Who we are

~4000 Scientific experts from across Europe



7 Scientific Committees

CHMP
CVMP
COMP
HMPC
PDCO
CAT
PRAC

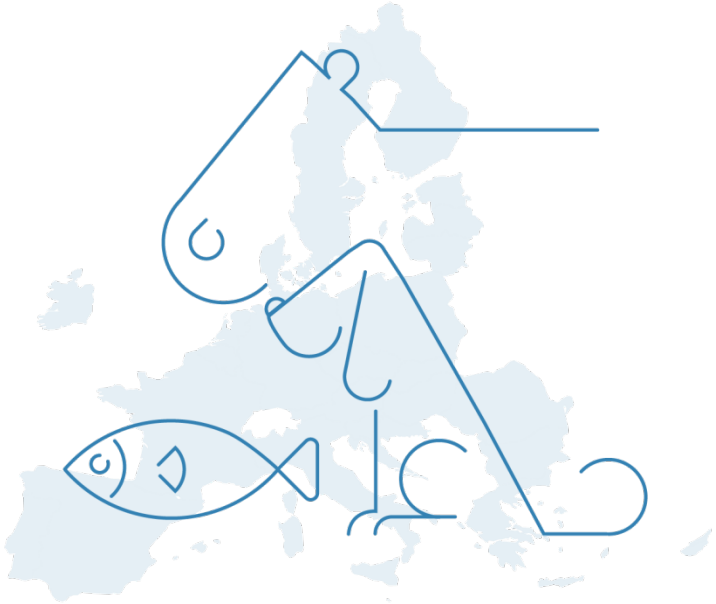
1 Management Board

27 Member States' representatives
4 Civil society representatives
2 European Commission representatives
2 European Parliament representatives

1995 EMA established

~800 Staff members

Human and veterinary medicines



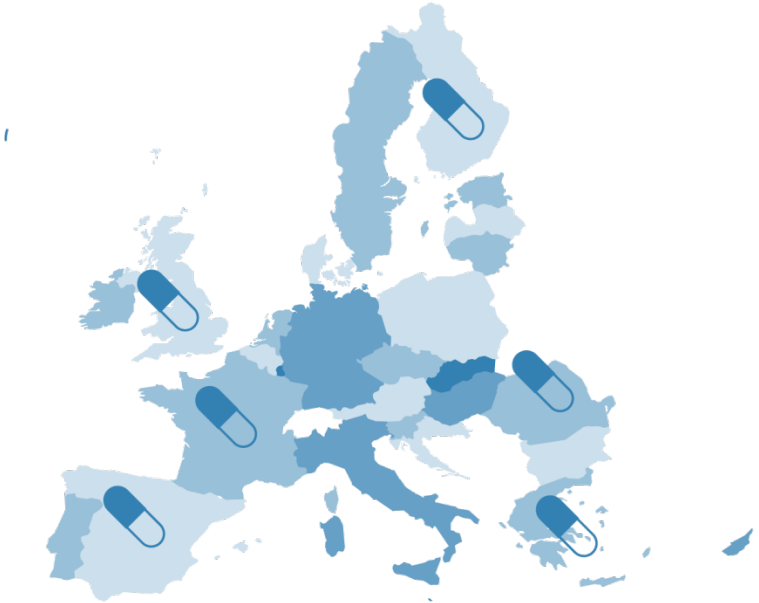
over **1300** medicines recommended for authorisation for use in humans

over **260** medicines recommended for authorisation for use in animals

How are medicines approved?

Different authorisation routes: one set of common rules

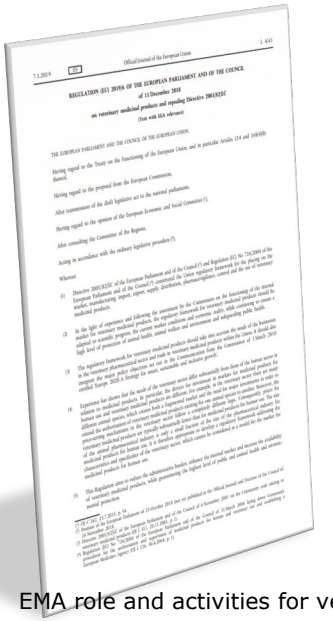
Centralised procedure (via EMA)



National procedures (via Member States)

Regulation (EU) 2019/6 on veterinary medicinal products

Replaced Directive 2001/82/EC within the overall aim of achieving 'Better Regulation' in the EU



REGULATION (EU) 2019/6 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL
of 11 December 2018
on veterinary medicinal products and repealing Directive 2001/82/EC

- *provides for a modern, innovative and fit for purpose legal framework*
- *gives incentives to stimulate innovation*
- *gives incentives to increase the availability of veterinary medicines*
- *strengthens the EU action to fight antimicrobial resistance*

‘Better Regulation’ in veterinary medicines

Better availability of veterinary medicines

Accessible information on veterinary medicines available in the EU

Reducing the risks of antimicrobial resistance

Encouraging pharmacovigilance reporting

- Legal framework to stimulate innovation (new medicines)
- Increased flexibility of prescription cascade
- Easier import of medicines from other EU Member States; prescriptions valid throughout the EU
- Online sales (certified online pharmacies) for non-prescription medicines

Easier access to more treatment options

‘Better Regulation’ in veterinary medicines

Better availability of veterinary medicines

Accessible information on veterinary medicines available in the EU

Reducing the risks of antimicrobial resistance

Encouraging pharmacovigilance reporting

- Union Product Database provides information on all veterinary medicines authorised in any EU Member State
- Information includes, but not limited to:
  - Name, active substance(s), strength
  - Summary of product characteristics (SPC), package leaflet, public assessment reports (EPAR) – to give more information on the scientific background of the content of the SPC
  - Dates of placing on the market in a Member State
  - Information on availability for each veterinary medicinal product

Easier access to information about treatment options

‘Better Regulation’ in veterinary medicines

Better availability of veterinary medicines

Accessible information on veterinary medicines available in the EU

Reducing the risks of antimicrobial resistance

Encouraging pharmacovigilance reporting

- Certain antimicrobials to be restricted to human use
- Restrictions in use of antimicrobials under the cascade
- Preventative use prohibited, metaphylaxis only under specific conditions
- Member States shall collect information on the use of antimicrobials in food-producing animals at farm level; but later also for companion animals (phased implementation)

Encourage and monitor prudent use of antimicrobials

‘Better Regulation’ in veterinary medicines

Better availability of veterinary medicines

Accessible information on veterinary medicines available in the EU

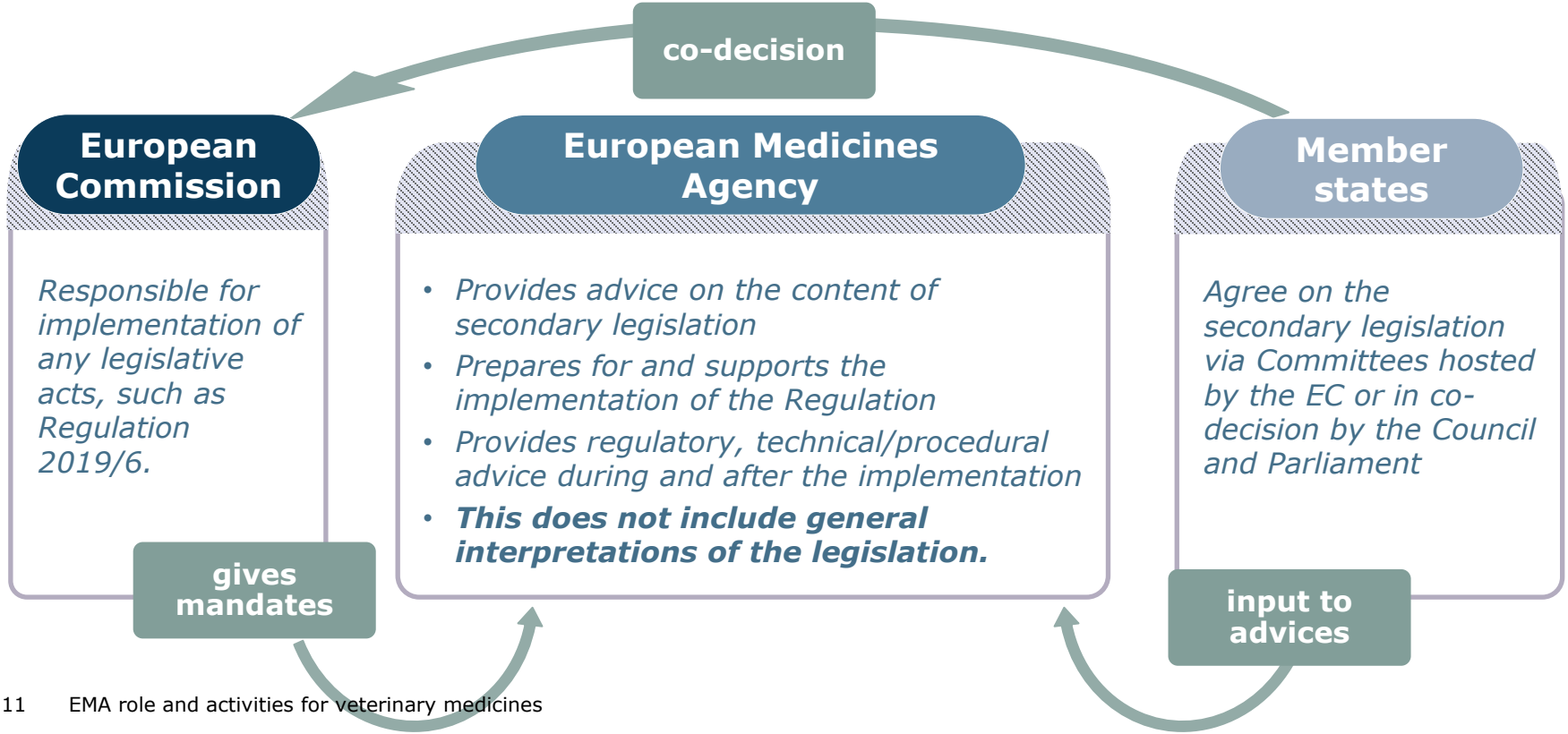
Reducing the risks of antimicrobial resistance

Encouraging pharmacovigilance reporting

- Improved pharmacovigilance reporting and evaluation system
- Public access to safety profile of each product, including incidence of suspected adverse events reported each year, broken down by product, animal species and type of suspected event (incl. reactions in animals and humans, lack of efficacy and environmental issues)
- Possibility to impose specific requirements for veterinarians in relation to reporting of suspected adverse events
- Agency may organise meetings for groups of veterinary healthcare professionals in case of a specific need for collecting, collating or analysing specific pharmacovigilance data

Improved information on safety profile of specific products, and a chance to get involved

EU network collaboration



New Regulation: digitalisation and transparency

Union Product Database

To store and make available information on different types of authorised veterinary medicinal products, at EU level.

Union Database on Manufacturing and Wholesale Distribution

To store and make available information on manufacturing and wholesale distribution data in the European Union and will support the management of the information related to manufacturing authorisations and outcomes of inspections activities.

Union Pharmacovigilance Database

To store and make available information on suspected adverse events for all veterinary medicinal products authorised in the Union.

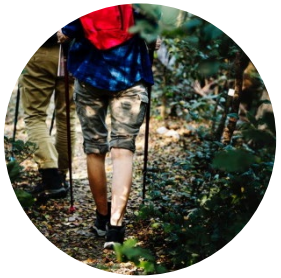
Collection of data on Sales and Use of Antimicrobials in Animals

To store and make available information on the sales and use of antimicrobials.

Action potential for Europe

We must increase awareness of social and economic relevance of work in veterinary medicines – most of what we do impacts people

- Healthy livestock for food production industry
- Safety of food derived from animals through evaluation of MRLs & setting of withdrawal periods for veterinary medicines to be used in food-producing animals
- Foster prudent use of antibiotics in animals
- Safeguarding antibiotics so that they continue to work for humans
- Healthy pet animals have a positive effect on human health
- Protecting the environment from harmful substances in veterinary medicines
- Animal welfare (through 3Rs policies and veterinary medicines)



Where to find information on the topics presented

- EMA website: https://www.ema.europa.eu/en; for example
  - Regulatory Science Strategy: https://www.ema.europa.eu/en/about-us/how-we-work/regulatory-science-strategy
  - Veterinary Big Data: https://www.ema.europa.eu/en/veterinary-regulatory/overview/veterinary-big-data
- Veterinary medicinal products: https://medicines.health.europa.eu/veterinary/en
- Reported suspected adverse events after use of a veterinary medicine: https://www.adrreports.eu/vet/en/index.html
- Veterinary antimicrobial sales in the EU: https://www.ema.europa.eu/en/veterinary-regulatory/overview/antimicrobial-resistance/european-surveillance-veterinary-antimicrobial-consumption-esvac#interactive-esvac-database-section
- Subscribe to our newsletter! https://ec.europa.eu/newsroom/ema/newsletter-archives/47420

Any questions?

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