



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

# EMA role and activities for veterinary medicines

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EMA Veterinary Awareness Day

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

An agency of the European Union





## 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 saňha  
 terveys sundhed  
 health hälsa sláinte  
 egézség'  
 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



**1995** EMA established

**7** Scientific Committees

- CHMP
- CVMP
- COMP
- HMPC
- PDCO
- CAT
- PRAC

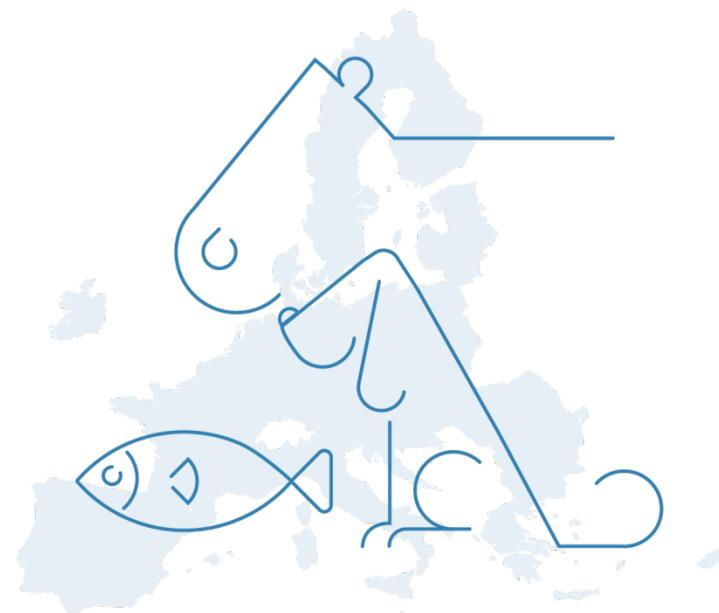
**1** Management Board

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

**~800** Staff members



# Human and veterinary medicines



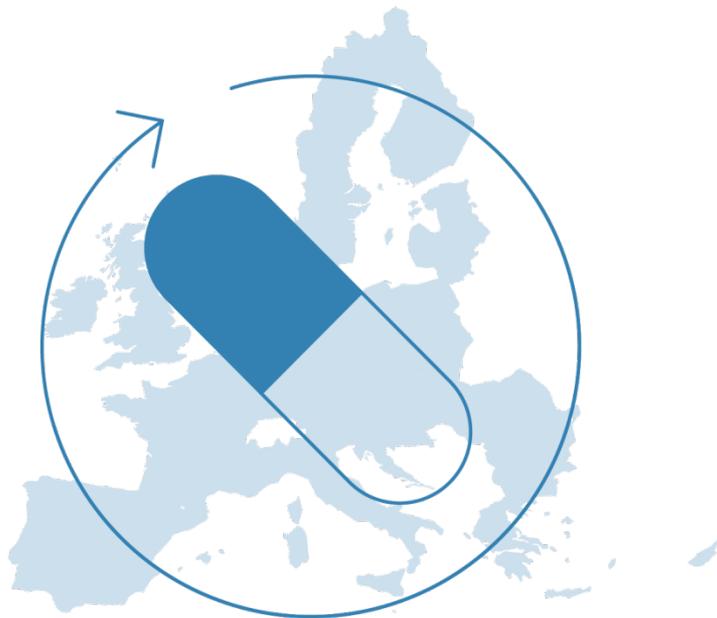
over **1300** medicines recommended for  
authorisation for use in humans  
EMA role and activities for veterinary medicines

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

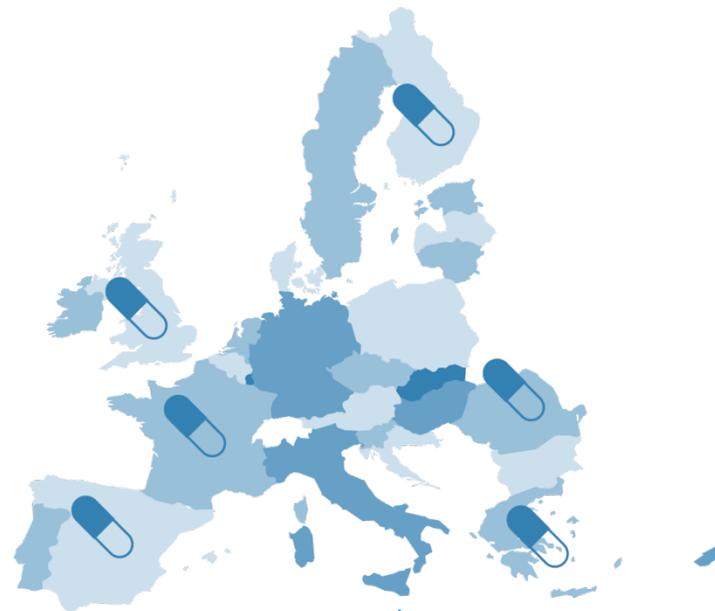


# How are medicines approved?

Different authorisation routes: one set of common rules



Centralised procedure (via EMA)



National procedures (via Member States)





# '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

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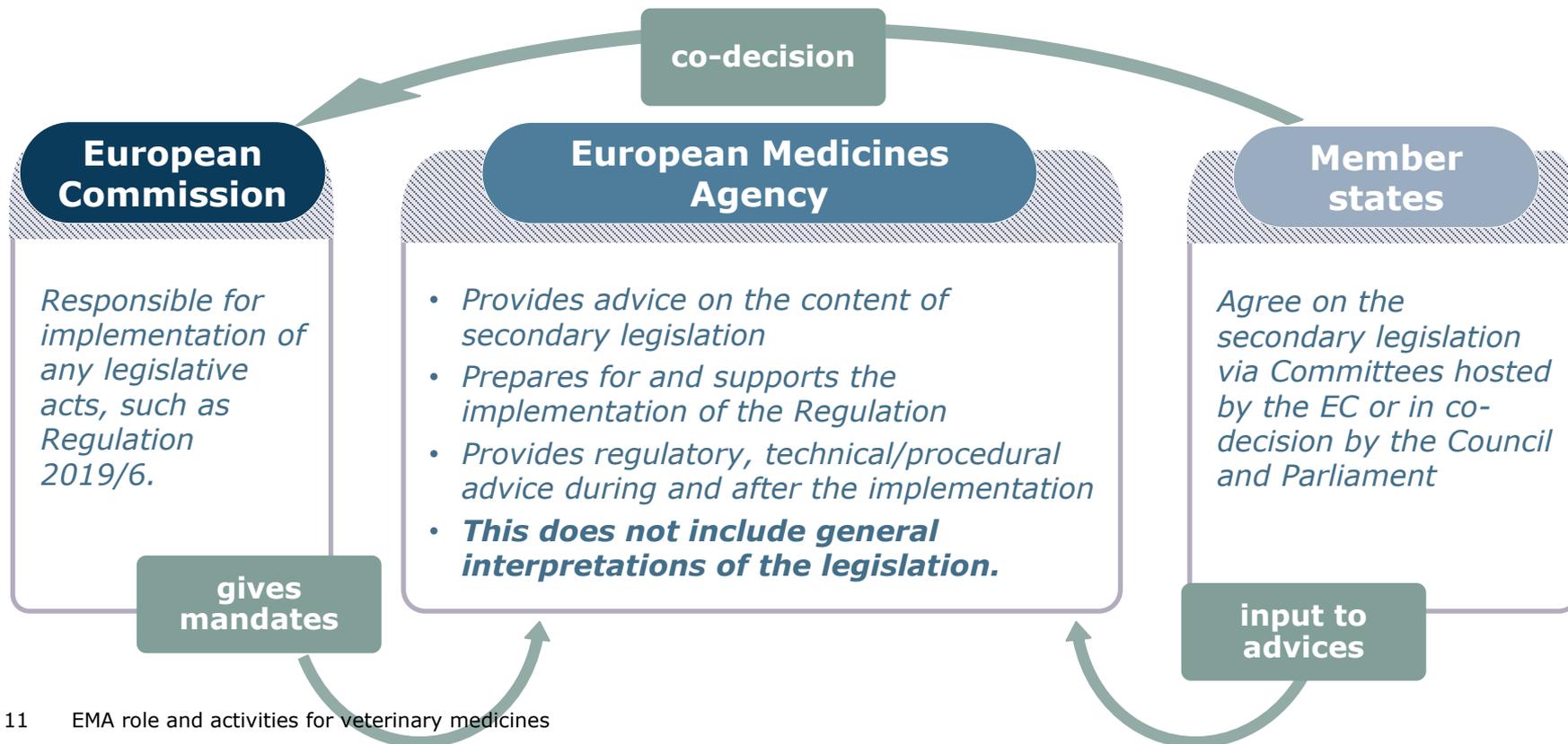
- ✓ Improved pharmacovigilance reporting and evaluation system
- ✓ Public access to safety profile of each product, including incidence of suspected adverse events reported each year, broken down by product, animal species and type of suspected event (incl. reactions in animals and humans, lack of efficacy 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?

## Further information

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Send a question to the European Medicines Agency

**Official address** Domenico Scarlattilaan 6 • 1083 HS Amsterdam • The Netherlands

**Send us a question** Go to [www.ema.europa.eu/contact](http://www.ema.europa.eu/contact)

**Telephone** +31 (0)88 781 6000

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