



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

# Veterinary Medicinal Products: specificities and challenges

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Academia Info Day

Presented by Ana Vidal on 10 November 2023  
Veterinary Strategic Support Office

An agency of the European Union





# Outline

- Overview of what we do in the Veterinary division
- Marketing authorisation of VMPs in the EU – some specificities
- Key strategic areas and topics of interest in the veterinary domain
- Engagement with research activities
- The One Health approach



## What we do



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

## Protect human and animal health





# What is covered by “veterinary”?

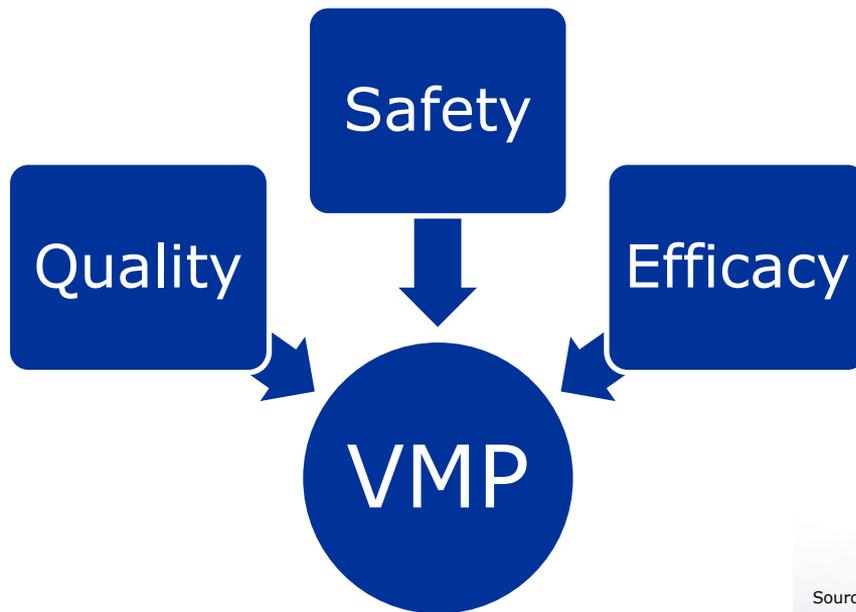
## Food-producing animals



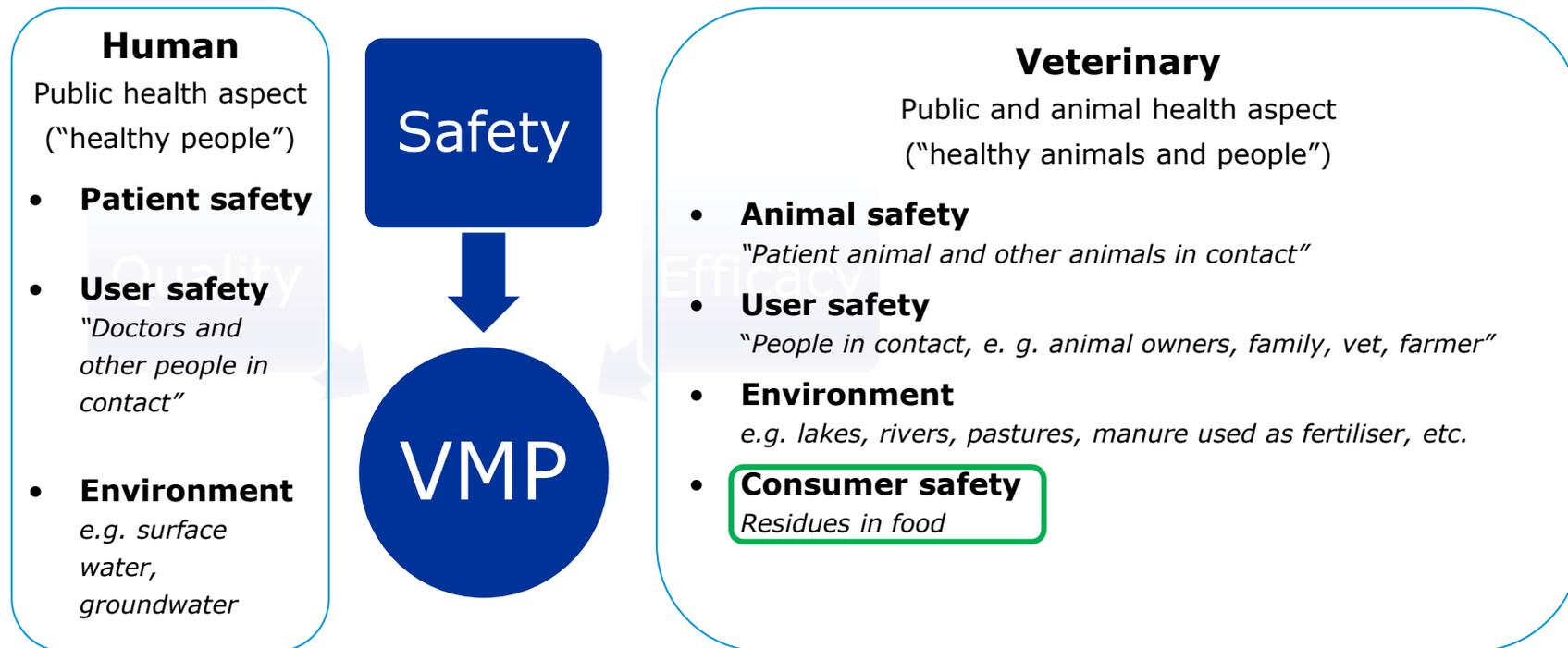
## Non-food-producing animals



# Aim of the VMP authorisation process



# Aim of the VMP authorisation process





# How are veterinary medicinal products regulated in the EU?

In order to be marketed in the EU, VMPs must have a **Marketing Authorisation (MA)**

- The **Veterinary Medicines Regulation (EU) 2019/6**, repealing Directive 2001/82/EC, came into application on 28 January 2022.
  - The regulation sets the standards to ensure authorisation of **safe, effective and quality VMPs**, and includes provisions governing their monitoring, manufacture, use, distribution, advertising etc.

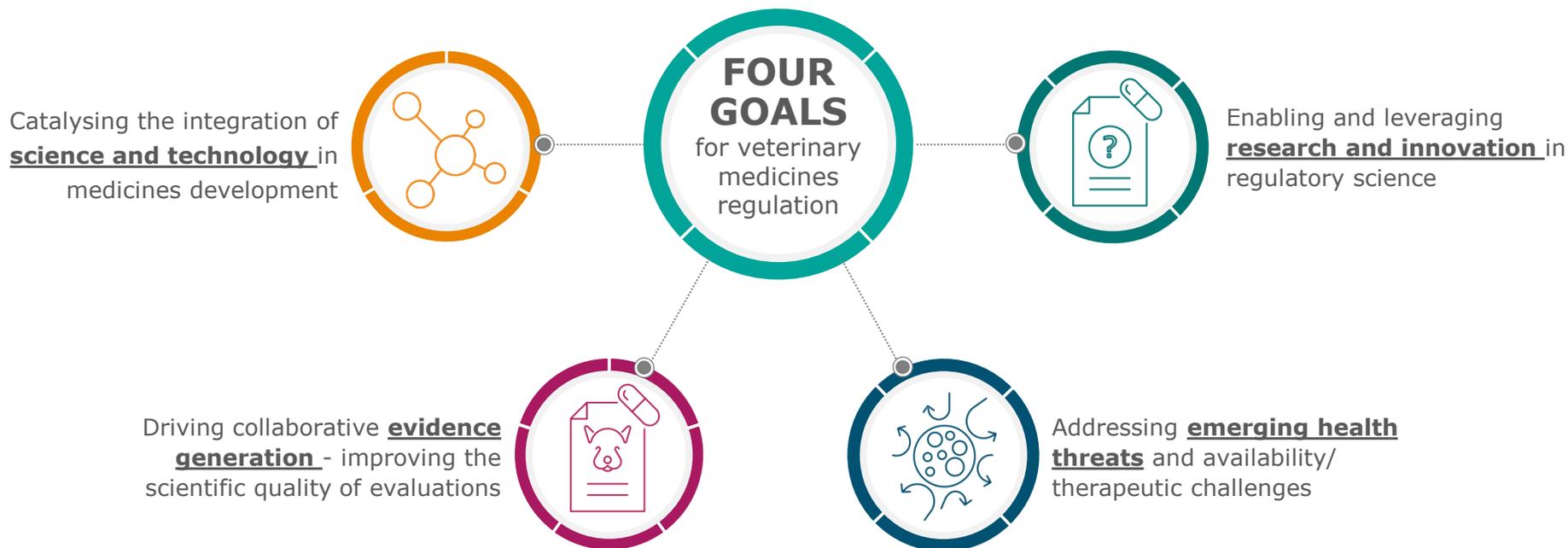
In addition, pharmacologically active substances that are used in **VMPs for food-producing animals** that may leave potentially harmful residues in foodstuffs, must have **Maximum Residue Limits (MRLs)**

- **Regulation (EC) 470/2009** sets out the Union rules for the establishment of MRLs
- **Commission Regulation (EU) 37/2010** sets out the classification of pharmacologically active substances regarding MRLs ('allowed substances' are listed in an Annex)





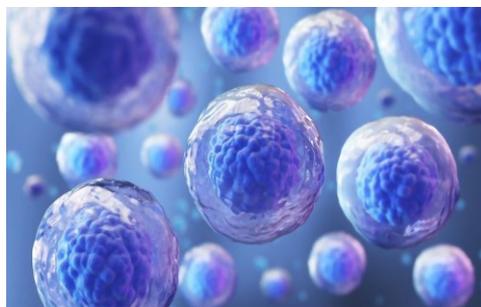
# EMA Regulatory Science Strategy to 2025



[#RegScience2025](#)



# Catalysing the integration of science and technology in medicines development



## Novel Therapies

- ❑ Cell-based veterinary therapy products
- ❑ Phage therapy (quality, safety and efficacy)
- ❑ VMPs issued from nanotechnologies



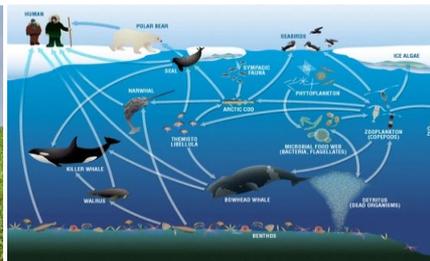
# Driving collaborative evidence generation

## Environmental Risk Assessment (ERA)

- ERA for VMPs in aquaculture
- Impact of parasiticides for cats and dogs



Source: Matthias Zomer  
<https://www.pexels.com/photo/group-of-black-and-white-cows-near-river-422207/>



Source: Darnis et al. Clim Change. 2012;115:161-78

## Big Data & RWE

EMA  
EUROPEAN MEDICINES AGENCY

Big data strategy for veterinary medicine 2021-2027

EUROPEAN MEDICINES AGENCY

Third Veterinary Big Data Stakeholder Forum  
23 November 2023  
EMA building, Amsterdam + virtual meeting



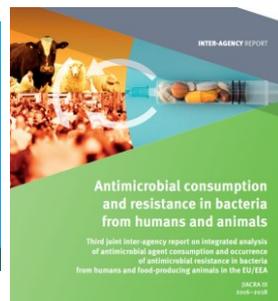
## Addressing emerging health threats

### ❑ Antimicrobial resistance

- Collecting antimicrobial **consumption data**
- Promoting **responsible use** of existing antibiotics
- Providing **advice** to the European Commission
- Supporting **development of new medicines**
- Fostering inter-agency and international **cooperation**

### ❑ Vaccines & alternatives to antimicrobials

- Reflection paper on promoting the authorisation of **alternatives to antimicrobial veterinary** medicinal products in the EU



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# Enabling and leveraging research and innovation in regulatory science

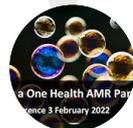
**EMA engagement in external Vet research initiatives**



AVANT: Alternatives to veterinary antimicrobials



EU Partnership for Animal Health and Welfare



EU Partnership for One Health AMR



Curing EU aquaculture by co-creating health and welfare innovations



EU Thematic Network for beekeeping modernisation



## Why?

- To **increase understanding of EMA’s public health role** among academic stakeholders
- To ensure that EMA can have **access to the expertise of its academic partners** to inform its decision-making
- To **collaborate on advancing the field of regulatory science** by fostering the development of methodologies and tool.
- To **facilitate the translation of academic research into novel methodologies and products** which meet EMA’s standards and address public and animal health needs

**#RegScience2025**

# EMA procurement mechanism to support research



## Lot 2: Veterinary studies



### What

1. Studies on the use, efficacy and safety of vet medicines
2. Observational studies
3. Descriptive studies
4. Using of existing data sources
5. Impact research
6. ....

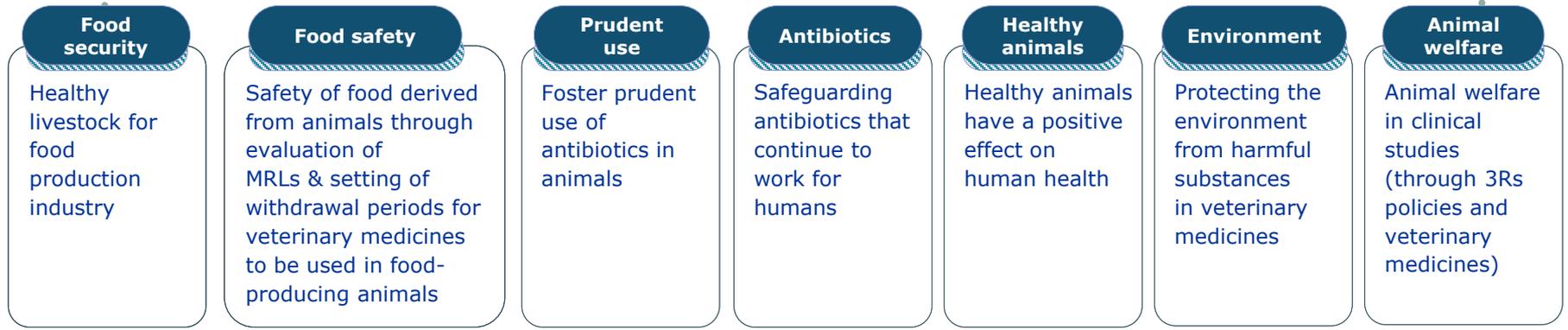
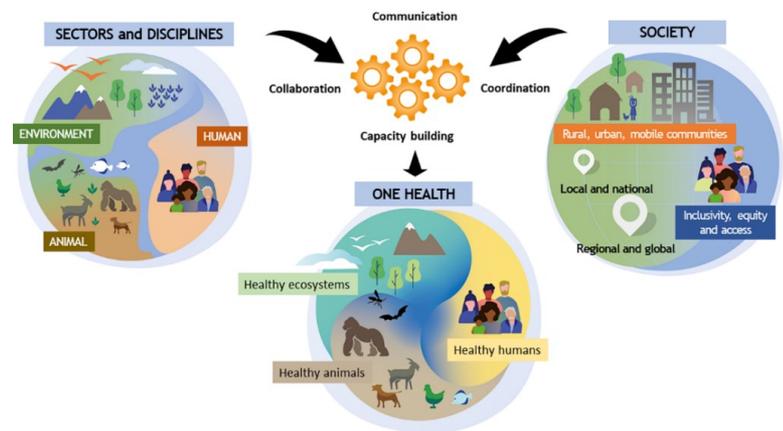
### Who

1. **Royal GD** BV (Gezondheidsdienst voor Dieren BV )
2. **PKPDM consortium** (Utrecht University - Faculty of Veterinary Medicine & Ecole Nationale Vétérinaire de Toulouse)
3. Stichting **Wageningen Research** (WR)

[TED Tenders Electronic Daily](#)

# The One Health approach

Most of what we do has an effect on people!





### Veterinary Medicines Highlights



Quarterly news, activities and interviews from  
EMA Veterinary Medicines Division



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#### Editorial

Welcome to the 13th edition of the Veterinary Medicines highlights and to its new format! As previously announced, we are expanding the content to cover news and updates on all activities of the Veterinary Medicines Division.



*“ We asked your opinion, and your feedback was fundamental in re-shaping the newsletter to a format that better suits your interests.”*



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### EMA Veterinary Awareness Day

12-13 September 2023  
European Medicines Agency, Amsterdam

[EMA Veterinary Awareness Day](#)



### Third Veterinary Big Data Stakeholder Forum

23 November 2023  
EMA building, Amsterdam + virtual meeting

[Third Veterinary BigData Stakeholder Forum - agenda](#)

# Any questions?

## Further information

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