



A new VMP Regulation: one year in operation

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A new VMP Regulation: one year in operation



Who are we?

**What.... and how are we
doing?**



**And..... why a new EU law on
Veterinary Medicinal Products?**





THE EUROPEAN COMMISSION

ec.europa.eu

Represents the EU common interests

Is made up of one President and a Commissioner from each EU country responsible for a specific topic

Proposes new laws and programmes

Is elected by the European Parliament for five years

Manages the EU policies and budget

Is the guardian of the EU Treaties



In a nutshell Commission's four main roles:

- **Legislative role** - proposing legislation to the Parliament and the Council;
- **Implementation role** - putting EU policies into effect;
- **Legal role** - enforcing EU law jointly with the Court of Justice;
- **Representative role** - representing the EU at international level.

General Services: Secretariat-General, DG Communication, European Anti-Fraud Office, etc.

22 DGs for Policies: AGRI, CLIMA, **SANTE (EFSA, EMA)**, etc.

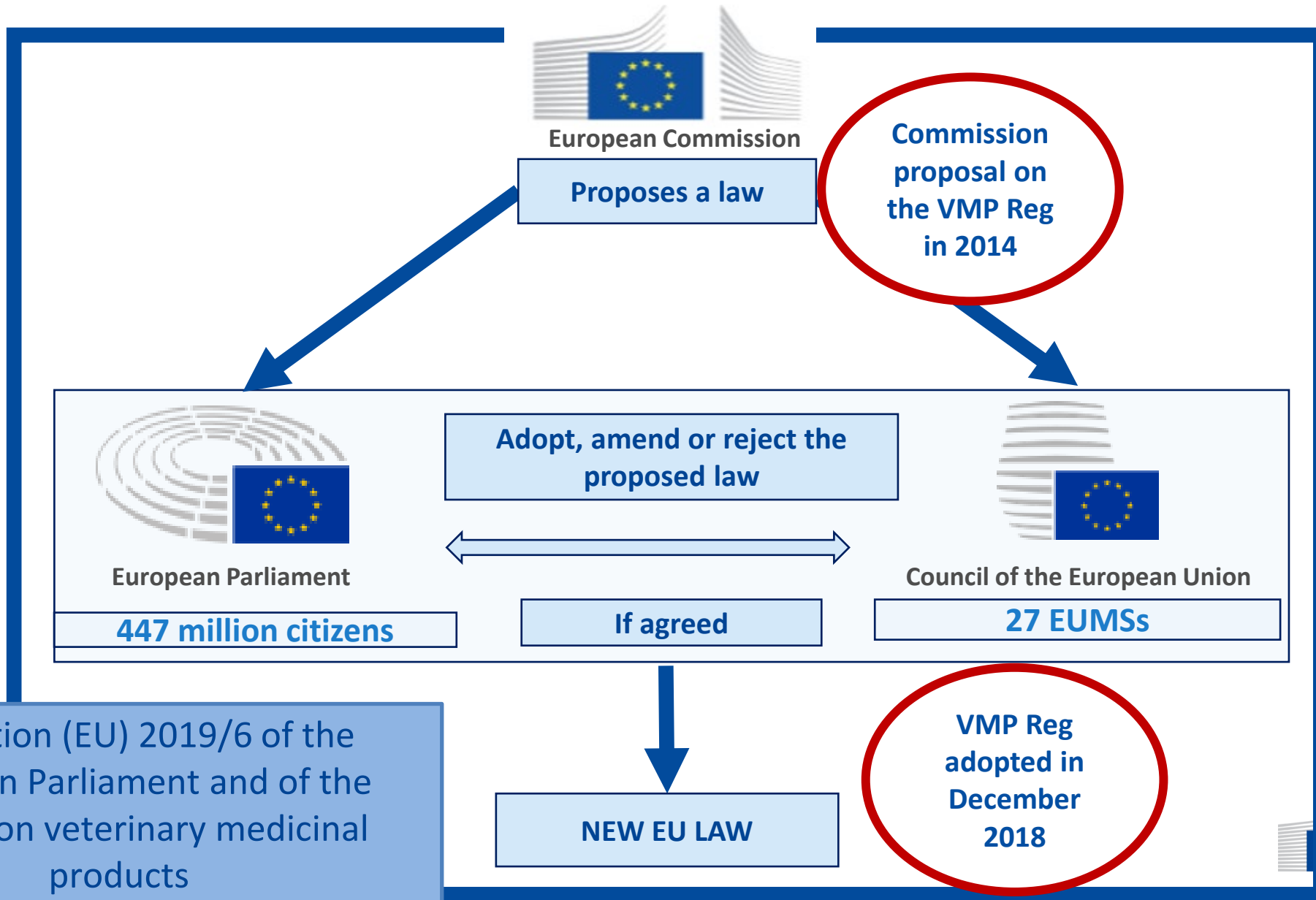
5 DGs for External relations: TRADE, Neighbourhood and Enlargement Negotiations, etc.

Internal Services: Legal Service, Budget, Interpretation, etc.

Executive Agencies: European Research Executive Agency, European Health and Digital Executive Agency, etc.



EU LAW: WHO DOES WHAT?



Stakeholders/
citizens
Have your say

Commission proposal on the VMP Reg in 2014

Adopt, amend or reject the proposed law

European Parliament
447 million citizens

Council of the European Union
27 EUMSs

Regulation (EU) 2019/6 of the European Parliament and of the Council on veterinary medicinal products

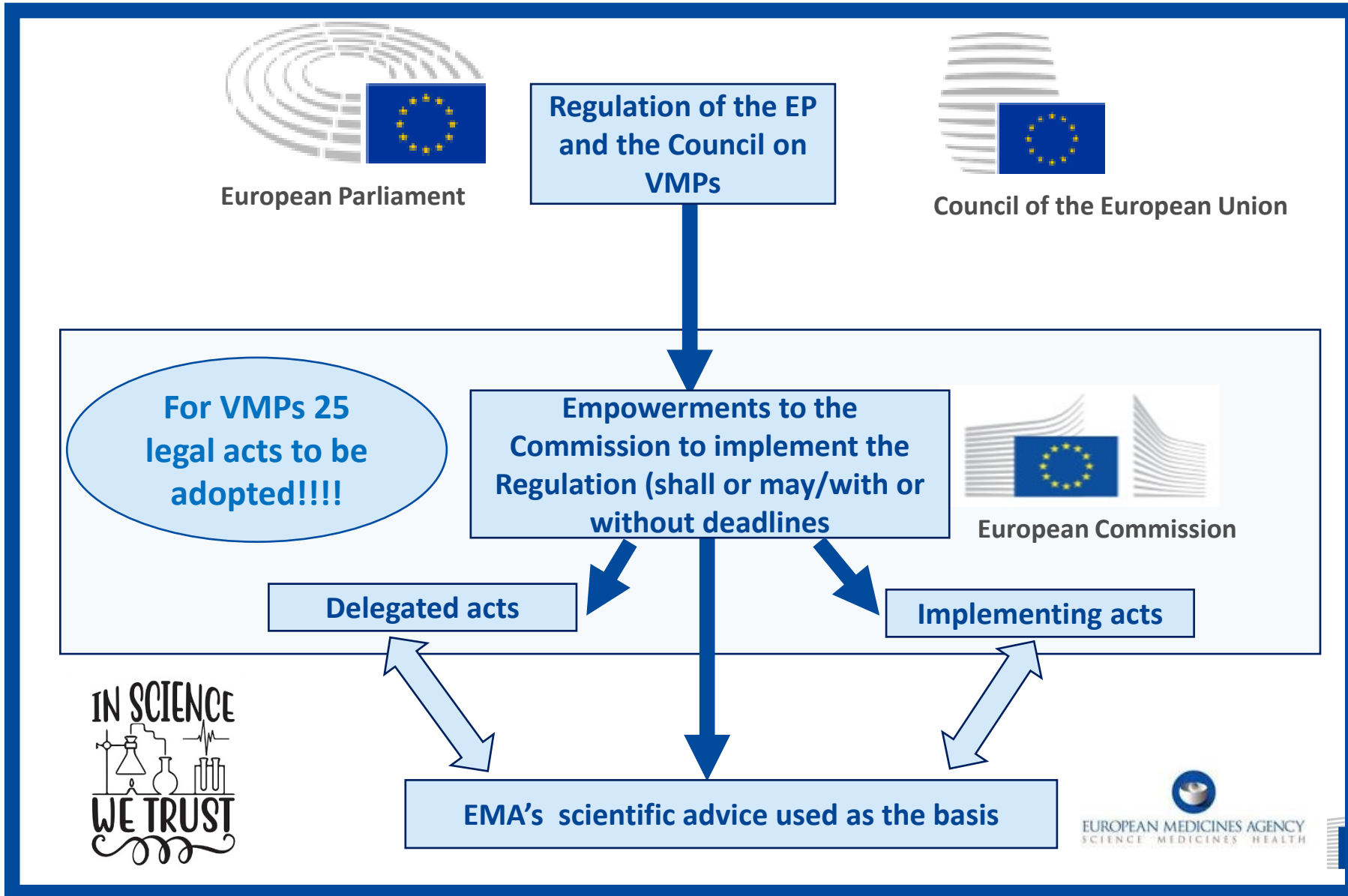
NEW EU LAW

VMP Reg adopted in December 2018



EU LAW: WHO DOES WHAT?

Stakeholders/
citizens
Have your say



DG Health and Food Safety - DG SANTE

Mission: "Making healthy and safe EU citizens the engine of sustainable economic growth"

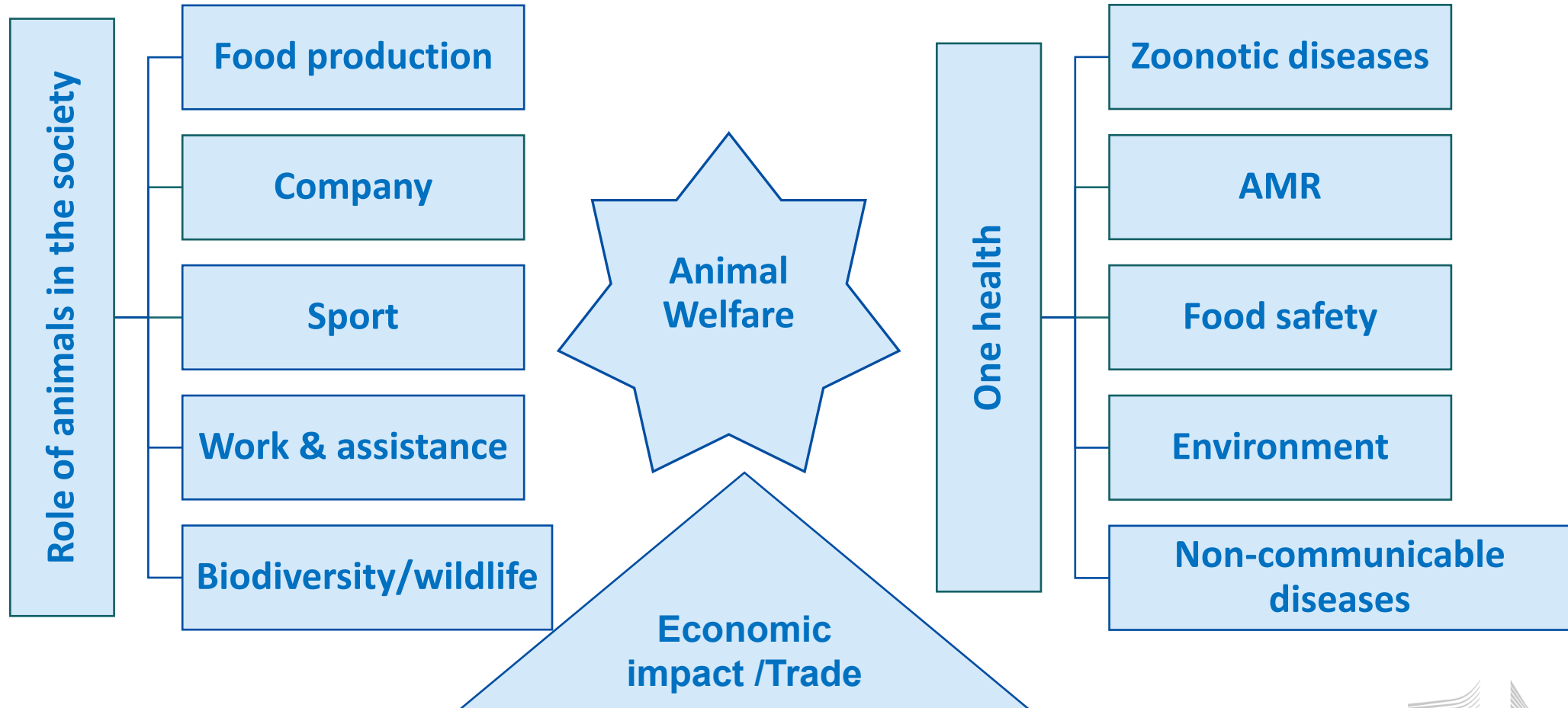
In practice, our mission requires that we:

- improve and protect human health
- ensure that all food and medicinal products are safe
- protect animal health and welfare, and plant health

Why is veterinary care important?

How the VMP Regulation contributes to these general objectives?

Why is Veterinary care important?



VMPs are an essential tool in veterinary care!



Between animal and human medicine, there is no dividing line—nor should there be.

(Rudolf Virchow)

One health

- Zoonotic diseases
- AMR
- Food safety
- Environment
- Non-communicable diseases

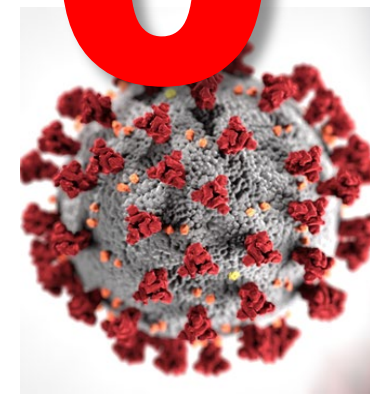
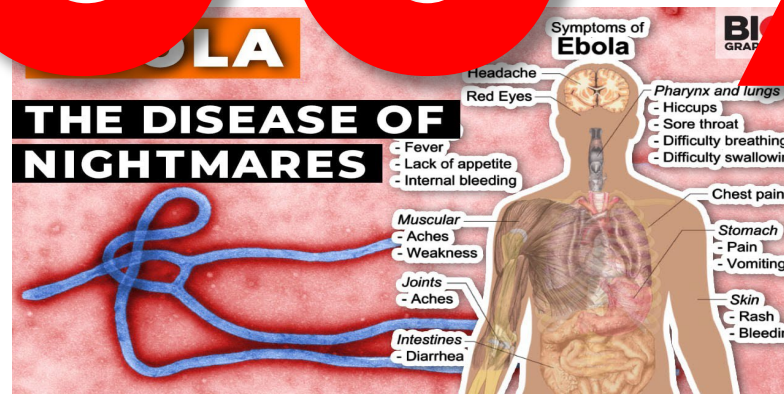
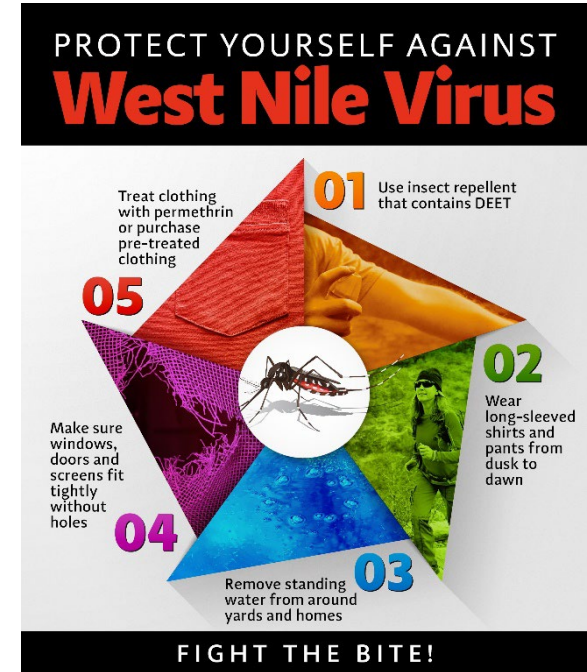
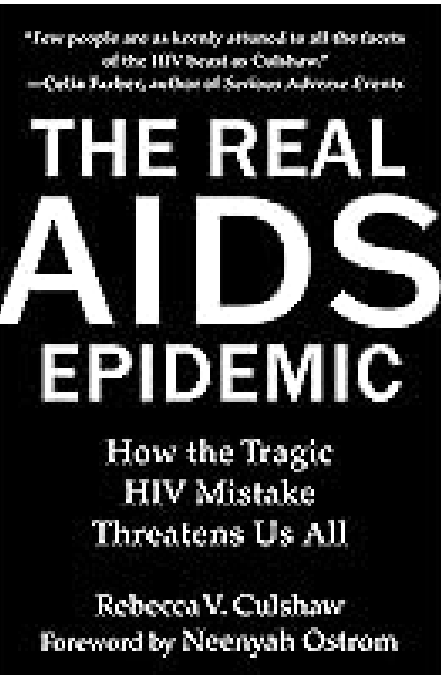


“livestock hygiene is the people’s health”

Zoonotic diseases



RABIES



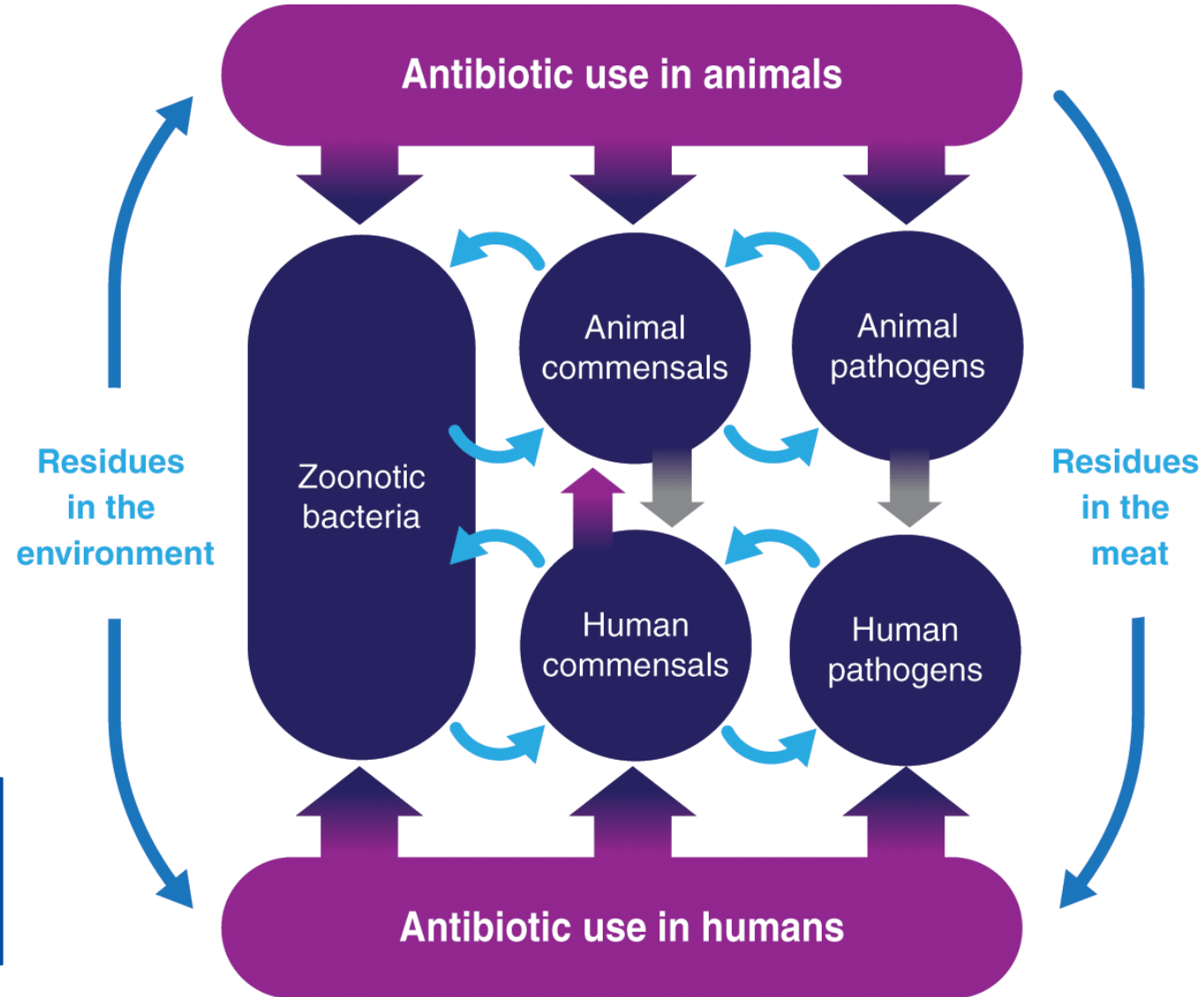
COVID-19

CORONAVIRUS DISEASE 2019

AMR: "is the ability of micro-organisms to survive or grow in the presence of a concentration of an antimicrobial agent which is usually sufficient to inhibit or kill microorganisms of the same species"



>35.000 deaths/year in EU/EEA



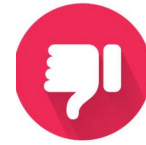
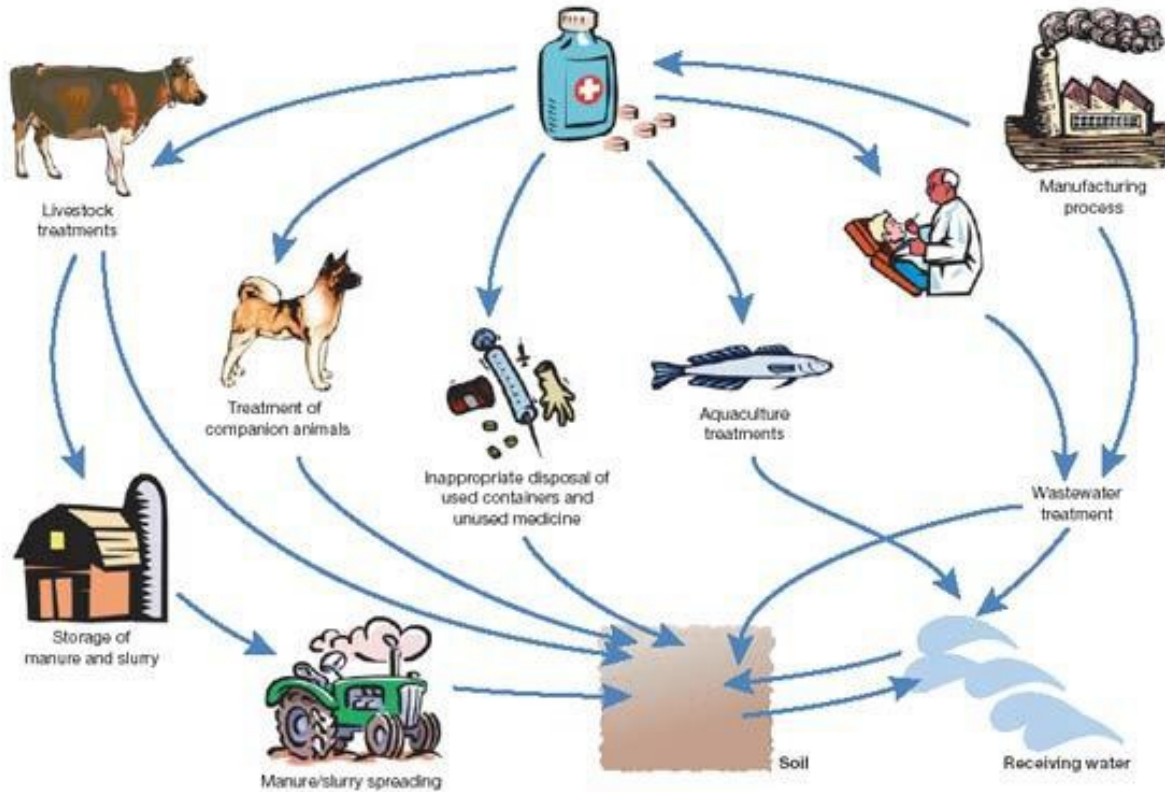
Food safety

- Healthy animals, free from diseases
- Maximum residue levels of VMP residues in food

Healthy animals
Safe food



Environment



- Excretion of residues in the environment by:
 - humans
 - companion animals
 - farming animals
- Inappropriate disposal
- Manufacturing



- Preventing the spread of pathogens

Non-communicable diseases

- Horse/pet therapy for depression, anxiety, autism,...
- Detection of carcinoma
- Diabetic assistance dogs
- Collaborative medicine/sharing of common knowledge



K9 MEDICAL DETECTION NZ

PAWS 4 CANCER **Dogs Saving Lives**
Training dogs for the early non-invasive detection of cancer
Fund-raising Event

Speaker - Pauline Blomfield
K9MD Founder & CEO
'Dogs Detecting Cancer'

Speaker - Gary Wulff
Dog Obedience Trainer
'Training dogs for Search & Rescue Work'

Entertainment by
'Tim and Janie Shaw'

Refreshments available for purchase

Bannockburn Hall
July 31st - 7pm

Tickets available from Reception at 'The Gate' in Cromwell
Cost \$15.00



Dogs & Science Working Together



Specificities of the veterinary medicine market

The market is fragmented

Food producing animals

- Cost-sensitive - High prices not affordable, under pressure from EU/global competition
- Setting Maximum Residues Limits increase costs
- Food safety (withdrawal periods)
- Impact on the environment (ERA)

Companion animals

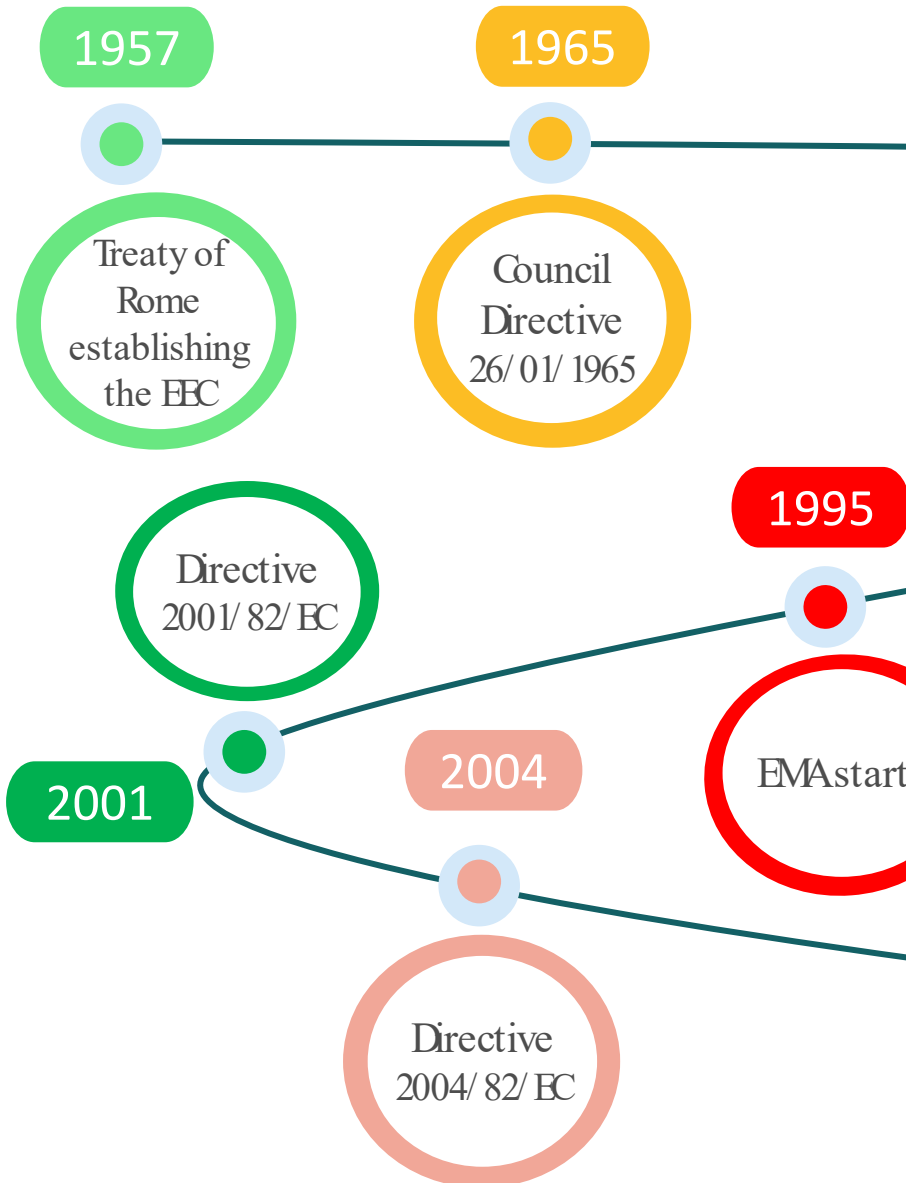
- Market prices affected by the consumer's purchasing power

Specificities of the veterinary medicine market

- Some veterinary formulations different to human formulations
- Lack of reimbursement
- Smaller market for rare diseases and for species where the number of animals is comparatively small
- Need for additional investments to extend the authorisation of veterinary medicinal products from one animal species to another.

Availability of veterinary medicines is essential

History of veterinary medicines regulations in the EU



Why a regulation on veterinary medicinal products is essential?



Quality

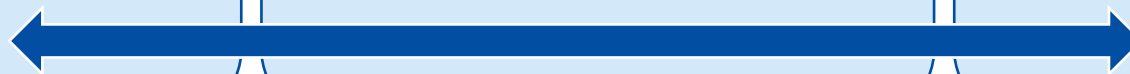


Efficacy



Safety

Animal
User
Consumer
Environment



Why a regulation on veterinary medicinal products is essential?

Objectives of the Regulation on VMPs

Safeguarding public- and animal health and environmental protection +

Tackle AMR

**Increase
availability**

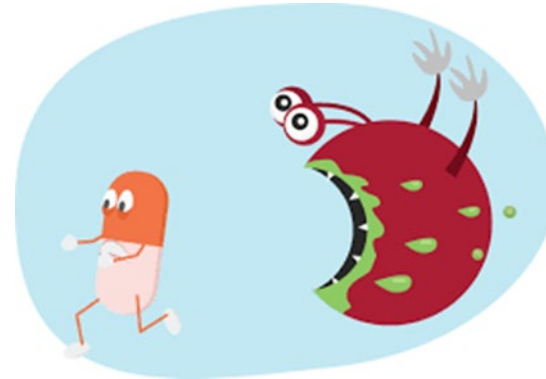
**Foster
innovation**

**Enhance
the
internal
market**

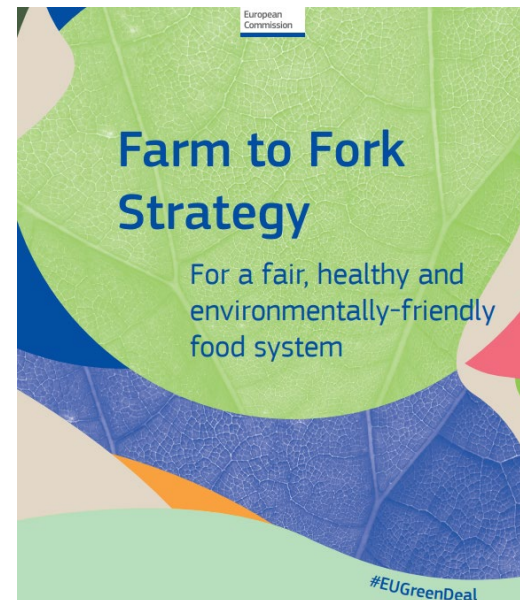
**Reduction
of admin
burden**

Tackling AMR: world's leaders

- A forward-looking regulation
- Ground-breaking policy measures to ensure prudent and responsible use of antimicrobials
- Major tool to achieve the Strategy objective of cutting by half overall Union sales of antimicrobials for farmed animals and in aquaculture by 2030
- First to take action ensuring prudent and responsible use for animals and products imported into the Union



**Hands-on training targeted to farmers and veterinarians working with food-producing animals about to start
Budget 2.790.000**



**Financial support to MSs for data collection on sales and use of antimicrobials
Budget > 30 mill**

Challenges Turned Achievements...few examples

An enlarged ban on the use of antimicrobials to promote growth and increase yield

New measures in place to ensure a responsible and prudent use (e.g. restrictions on prophylactic and metaphylactic uses)

Harmonised system for collection of data on sales and use of antimicrobials

EU list of antimicrobials reserved for human use and criteria to designate those antimicrobials

New marketing authorisations requiring a AMR risk benefit balance

Additional data protection for variations demonstrating a reduction in the antimicrobial or antiparasitic resistance

Requirements for imports of animals and products of animal origin from third countries into the union banning the use of certain antimicrobials

+ other EU policies and actions: e.g. animal health law, medicated feed, national action plans, etc.

Challenges Turned Achievements...few examples

No expiration of marketing authorisations

A new system in place for Pharmacovigilance

Additional protection of technical documentation

Common Logo



List of variations not requiring assessment

No requirement of ERA for generics (unless the marketing authorization of the reference VMP was given before 1/10/2025)



Centrally authorised products: open to all new authorisation applications, generics centrally authorised (possible when the reference VMP is authorised nationally in a Member State)

First ever harmonised GDP requirements for active substances and VMPs

Specific provisions for marketing authorisations for limited markets and applications in exceptional circumstances



VMP Regulation

Transitional rules for packaging and labelling (Art 152)!!!!

Amendment of the Official Controls Regulation

IA Union Product Database

IA List of variations not requiring assessment

DA Requirements for the collection of data on sales and use of AM

DA Criteria to designate AM reserved for humans only

IA Good Pharmacovigilance Practice & PSMF

DA Annex II

IA Format for the collection of data on sales and use of AM

IA List of AM reserved for human use only

DA Imports of animals and products of animal origin

IA Common logo for online sales

IA GDP Active substances

IA GDP VMPs

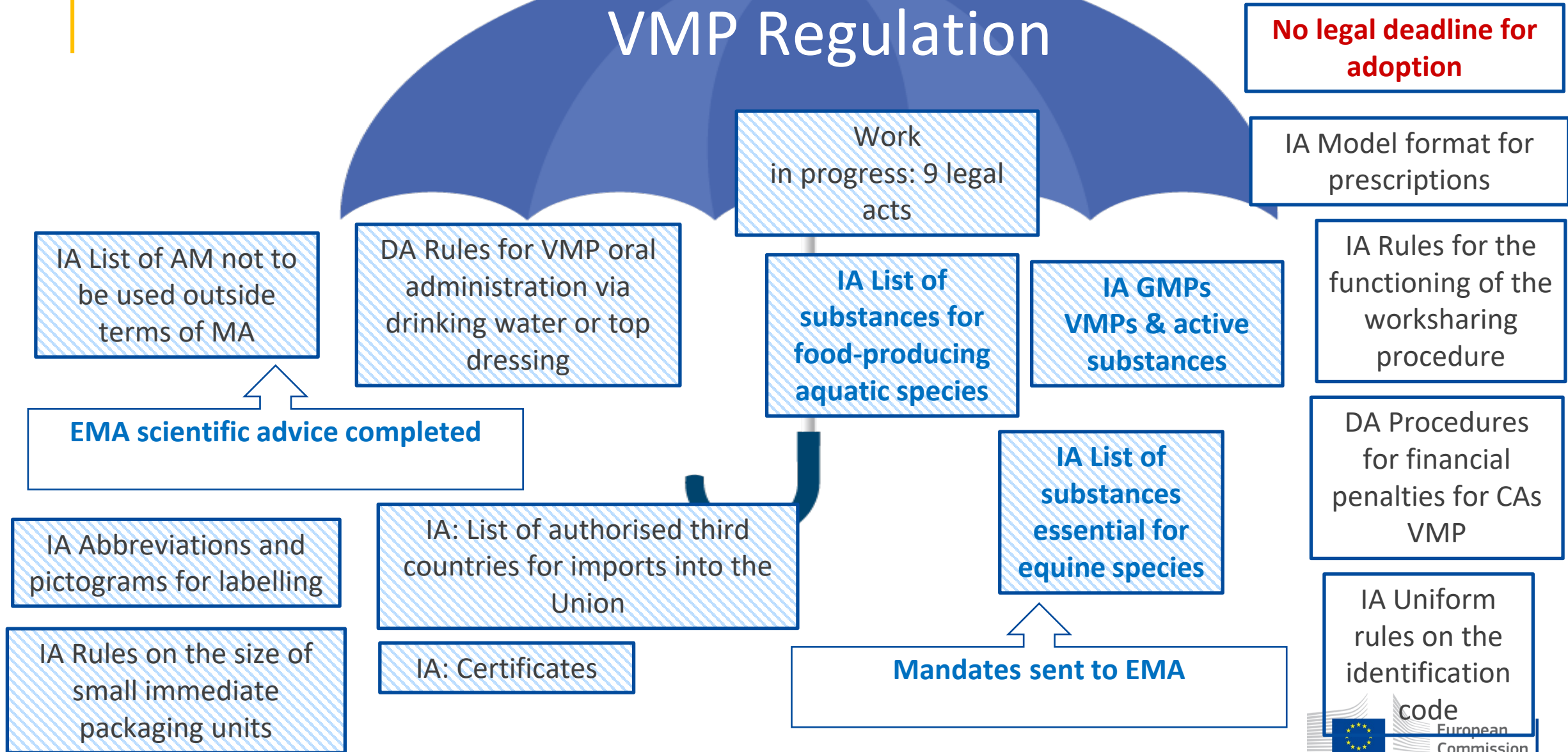
AHL

DA Horse passport

IA Horse passport

VET

VMP Regulation



The Implementation Challenge...continues



Have all the necessary EMA's scientific advices, legal acts and databases, etc in place well on time to allow the implementation of the VMP Regulation in January 2022

A challenge for all!!!



Put in place 28 legal acts within the required deadline to complete the implementation of the Regulation:

16 legal acts published

Work in progress: 9 legal acts



Focus on the implementation & finalising legal acts & interpreting



Where can you follow progress?

On our dedicated web page:

<https://europa.eu/!rJ63kT> or QR code →



Where can you provide feedback?

On the Have Your Say platform:

<https://ec.europa.eu/info/law/better-regulation/have-your-say>

Regulation 2019/6: more than 1 year of implementation

All we have achieved was thanks to the efforts/contributions of:

EMA

National Competent Authorities

Stakeholders/citizens

Experts/scientists

Council

European Parliament

