The VMP Regulation

Antimicrobial Resistance

Dr. Eva ZAMORA ESCRIBANO
Head of Unit Animal Nutrition, Veterinary Medicines,
Health and Food Safety Directorate-General

Already in force
Applies 28/01/2022

VMP Regulation 2022

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

Ban on the preventive use of antibiotics in groups of animals

Restrictions on prophylactic and metaphylactic use

Veterinary prescriptions

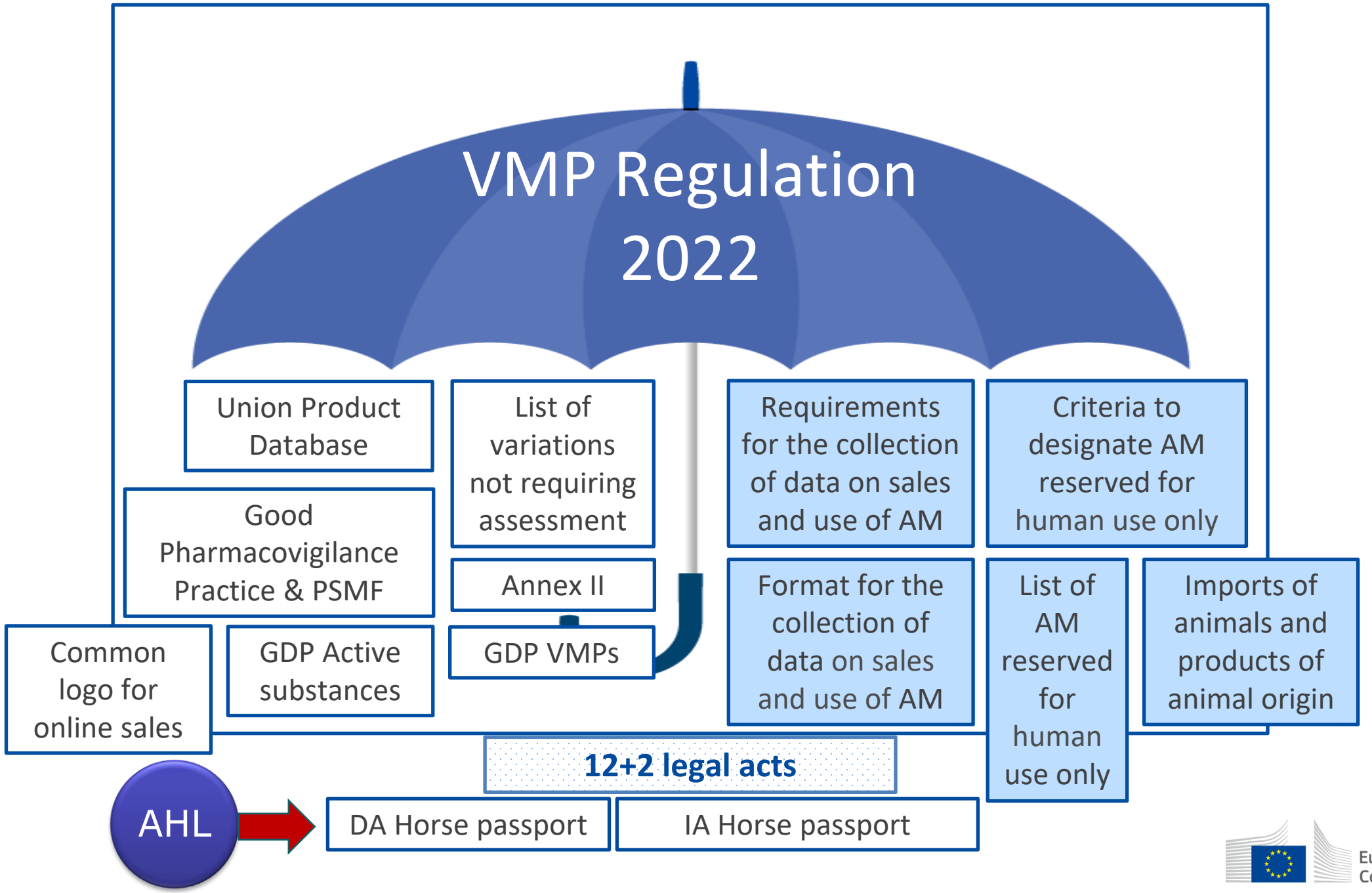
Ban on the use in animals of antimicrobials designated in the EU as reserved to human medicine

Enlarged ban on the use of antimicrobials for growth promotion and yield increase

Compulsory data collection on sales & use per species of antimicrobials

Ban on the preventive use of antimicrobials via medicated feed
(Regulation (EU) 2019/4 on medicated feed)

European Commission


VMP Regulation 2022
Union Product Database
List of variations not requiring assessment
Requirements for the collection of data on sales and use of AM
Criteria to designate AM reserved for human use only
Good Pharmacovigilance Practice & PSMF
Annex II
Format for the collection of data on sales and use of AM
List of AM reserved for human use only
Imports of animals and products of animal origin
Common logo for online sales
GDP Active substances
GDP VMPs
12+2 legal acts
AHL
DA Horse passport
IA Horse passport

To be adopted by 2025
or as necessary (*)

VMP Regulation Beyond 2022

List of substances for use outside the terms of the MA in food-producing aquatic species

List of substances essential for equine species

Uniform rules on the identification code

Rules for the functioning of the worksharing procedure*

List of AM*: not to be used outside the terms of the MA, or that can be used subject to certain conditions

Model format for prescriptions*

Rules for VMP oral administration via drinking water or top dressing

GMPs VMPs & active substances

Procedures for financial penalties for CAs VMP

Abbreviations and pictograms for labelling

11 legal acts

Rules on the size of small immediate packaging units

European Commission

Contribution to the F2F Strategy
Reduction of the EU overall sales of AM by 50% in 2030

Antimicrobial Resistance Monitoring & Risk Management

EMA opinion

Commission Delegated Regulation (EU) 2021/578

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

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

Under Discussion MS

COM adoption by 28/01/22

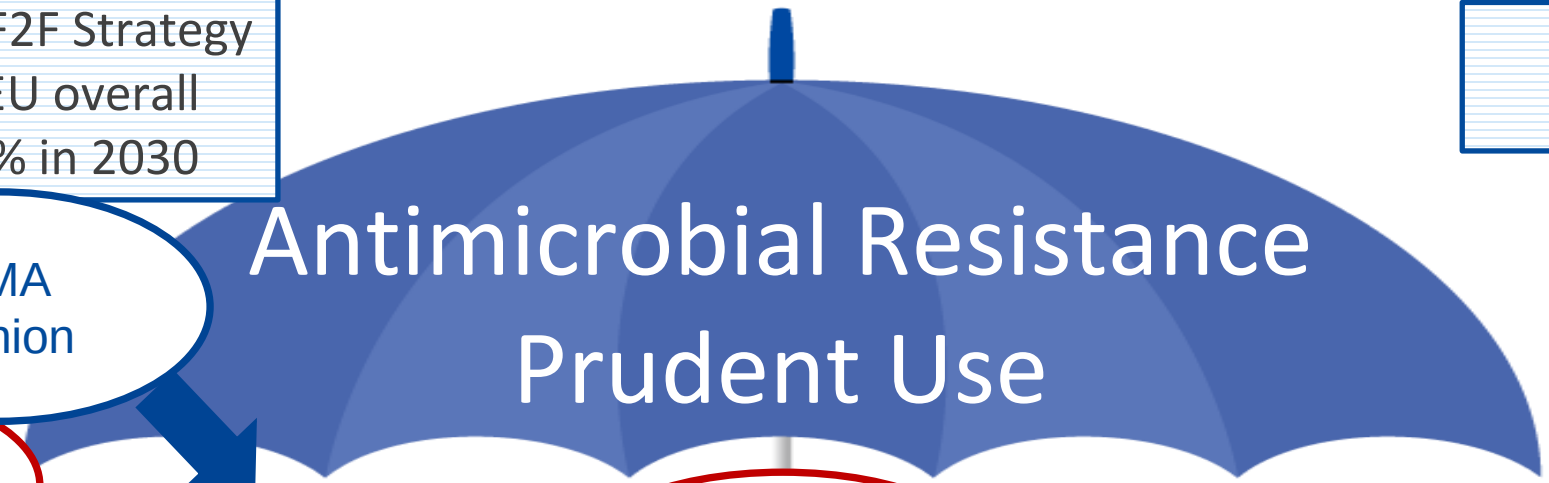
Provides a good overview of the EU market landscape, overall EU and per Member State, on sales of AM used in animals and on use of AM per animal species (food producing animals and other animals kept or bred)

Targeted measures

European Commission

Contribution to the F2F Strategy Reduction of the EU overall sales of AM by 50% in 2030

One Health approach



EMA opinion

Under objection period in EP

COM adoption by 28/09/21

DA Criteria to designate AM reserved for human use only

Applicable 28/01/22

DA Imports of animals and products of animal origin

Drafting

EMA opinion

IA List of AM reserved for human use

COM adoption by 28/01/22

Ban to use antimicrobials as growth promoters
Ban to use antimicrobials in the list reserved for human use

Art 37.2(f) Marketing authorisation shall be refused if the risk for public heath in case of development of AMR or antiparasitic resistance outweighs the benefit of the VMP to animal health

Where can you follow progress?

On our dedicated web page:

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

European Commission

Thank you

European Commission