The VMP Regulation

Antimicrobial Resistance

Dr. Eva ZAMORA ESCRIBANO
Head of Unit Animal Nutrition, Veterinary Medicines, Health and Food Safety Directorate-General
VMP Regulation 2022

Already in force
Applies 28/01/2022


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)
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
- Common logo for online sales
- GDP Active substances
- GDP VMPs
- 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
- 12+2 legal acts
- DA Horse passport
- IA Horse passport

Good Pharmacovigilance Practice & PSMF

AHL

European Commission
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*
- Abbreviations and pictograms for labelling
- Rules for VMP oral administration via drinking water or top dressing
- Procedures for financial penalties for CAs VMP
- Rules on the size of small immediate packaging units

GMPs VMPs & active substances

11 legal acts

To be adopted by 2025 or as necessary (*)
Antimicrobial Resistance Monitoring & Risk Management

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

- 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
- Targeted measures

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)

COM adoption by 28/01/22

Under Discussion MS

Targeted measures

Under Discussion MS

EMA opinion

Commission Delegated Regulation (EU) 2021/578

Antimicrobial Resistance Monitoring & Risk Management

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)
Antimicrobial Resistance
Prudent Use

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

One Health approach

Under objection period in EP
COM adoption by 28/09/21

EMA opinion

DA Criteria to designate AM reserved for human use only

Applicable 28/01/22

DA Imports of animals and products of animal origin

Drafting

IA List of AM reserved for human use

EMA opinion

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 health 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
Thank you