VMP Regulation – State of Play of implementation and beyond January 2022

EMA Info day- 12 May 2022

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

Applicable as from 28/01/2022

12 acts due by 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

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

VET

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

12+2 legal acts

AHL

DA Horse passport

IA Horse passport

Commission Delegated Regulation (EU) 2022/524 of 27 January 2022 correcting Delegated Regulation (EU) 2021/577 as regards certain references to veterinary medicinal products

European Commission

COMMISSION IMPLEMENTING REGULATION (EU) …/...

of XXX

designating antimicrobials or groups of antimicrobials reserved for treatment of certain infections in humans, in accordance with Regulation (EU) 2019/6 of the European Parliament and of the Council

(6) The antimicrobials and group of antimicrobials listed in this Regulation should not be used in veterinary medicinal products. Thus, marketing authorisation applications for veterinary medicinal products that contain any of the antimicrobials or groups of antimicrobials listed in this Regulation should be refused. In addition, existing marketing authorisations of veterinary medicinal products containing such antimicrobials or groups of antimicrobials should cease to be valid.

(9) With a view to giving veterinarians, owners of animals and economic operators concerned the necessary time to adjust to the consequences referred to above, this Regulation should apply six months after its entry into force.

(10) The list of antimicrobials or groups of antimicrobials to be reserved for treatment of certain infections in humans, as provided for in this Regulation may be reviewed, as necessary, in the light of new scientific evidence or emerging information, including the emergence of new diseases, changes in the epidemiology of existing diseases, changes in antimicrobial drug resistance or changes in availability or patterns of antimicrobial use.

Ongoing :
Public feedback deadline 17 May
Notified to WTO/SPS for comments deadline 20 June
Next Steps :
Standing Committee, adoption and publication in the O.J

ANNEX

Antimicrobials or groups of antimicrobials reserved for treatment of certain infections in humans

(1) Antibiotics
- (a) Carboxypenicillins
- (b) Ureidopenicillins
- (c) Ceftobiprole
- (d) Ceftaroline
- (e) Combinations of cephalosporins with beta-lactamase inhibitors
- (f) Siderophore cephalosporins
- (g) Carbapenems
- (h) Penems
- (i) Monobactams
- (j) Phosphonic acid derivates
- (k) Glycopeptides
- (l) Lipopeptides
- (m) Oxazolidinones
- (n) Macrocycles
- (o) Plazomicin
- (p) Glycylcyclines
- (q) Eravacycline
- (r) Omadacycline

(2) Antivirals
- (a) Amantadine
- (b) Baloxavir marboxil
- (c) Celgosivir
- (d) Favipiravir
- (e) Galidesivir
- (f) Lactimidomycin
- (g) Laninamivir
- (h) Methisazone/metisazone
- (i) Molnupiravir
- (j) Nitazoxanide
- (k) Oseltamivir
- (l) Peramivir
- (m) Ribavirin
- (n) Rimantadine
- (o) Tizoxanide
- (p) Triazavirin
- (q) Umifenovir
- (r) Zanamivir

(3) Antiprotozoals
- (a) Nitazoxanide

EN

A single framework for official controls

Antimicrobial Resistance Prudent Use

Ban on imports of animals and products of animal origin treated with AMs from the list + growth promotion/yield increase

Targeted Amendment OCR Regulation (EU) 2021/1756 of the EP and of the Council

DA Imports of animals and products of animal origin

Scope: food producing animals and products of animal origin intended for exports to the Union / proposal: scope of the residues legislation as the starting point

IA: List of authorised third countries for imports into the Union

I A: Certificates

Ongoing:
Discussions Expert Group
Next steps:
Public feedback Notification WTO/SPS
Adoption by COM
Council /EP= objection period
Publication in O.J

Requirements:
Only consignments from listed countries
Accompanied by official certificates

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Transitional rules packaging and labelling (Article 152)

- Issue:
  - MAH of VMPs authorised or registered under Directive 2001/82/EC or Regulation (EC) No 726/2004 are **not able to comply, by 28 January 2022** with the requirements set out in Articles 10 to 16 of Regulation (EU) 2019/6.
  - CAs are not in a position to process all the **necessary variations** as defined in Article 4, point (39), of Regulation (EU) 2019/6 of Mas granted in accordance with either Directive 2001/82/EC or Regulation (EC) No 726/2004 to ensure compliance with Articles 10 to 16 of Regulation (EU) 2019/6 in a timely manner
- Solution to ensure the **continued availability of VMPs** in the Union and to establish **legal certainty**
  - Regulation of the EP and of the Council laying down transitional rules for the packaging and labelling of veterinary medicinal products authorised or registered in accordance with Directive 2001/82/EC and Regulation (EC) No 726/2004
  - VMPs which were authorised or registered in accordance with Directive 2001/82/EC or Regulation (EC) No 726/2004 and which comply with Articles 58 to 64 of Directive 2001/82/EC, as applicable on 27 January 2022, **can be placed on the market until 29 January 2027**, even if their labelling and, where applicable, package leaflet are not in compliance with Articles 10 to 16 of Regulation (EU) 2019/6 **APPLICABLE AS FROM 28 JANUARY 2022**

Questions and answers on the requirements for active substances used as starting materials in veterinary medicinal products (Article 94)

- Fruitful discussions with MSs experts and EMA about the practical application of GMP requirements to ensure a harmonised approach on the interpretation of Article 94 (5)

- Questions and answers on the requirements for active substances used as starting materials in veterinary medicinal products published:

https://www.ema.europa.eu/en/human-regulatory/research-development/compliance/good-manufacturing-practice/guidance-good-manufacturing-practice-good-distribution-practice-questions-answers

Review of rules for environmental risk assessment

- Feasibility study under Article 156 (active-substance-based review system ('monographs') and possible alternatives) finalised and report published

https://op.europa.eu/en/publication-detail/-/publication/03055c4d-42a6-11ec-89db-01aa75ed71a1/language-en/format-PDF/source-243449059

- **Conclusion of the study team**: the monograph system would contribute to meeting the general objectives of the VMPR. In an initial implementation phase, the monograph system would probably be more cost- and resource-intensive than the current system. In the long term, however, the study authors expect that the efforts and costs would become lower and the benefits would outweigh the disadvantages. In addition, the monograph system would support the EU Strategic Approach to Pharmaceuticals in the Environment (COM(2019)128) and the Green Deal – zero emission – OS-OA approach (COM(2019)640)

- By 28/01/2022 Commission to draft a report to the EP and to the Council to be accompanied, **if appropriate**, by a legislative proposal

Other non-legislative actions/Implementation

- **Notice to applicants** - a tool valued by the network and stakeholders – we are considering how to continue to communicate key aspects of the interpretation of the legislation, involving also the network
- Questions in relation to the **interpretation** of new provisions
- **Feedback** on issues related to the implementation, identification of **possible issues** that would require an amendment of the tertiary legislation/ work ongoing (e.g. Annex II)

Ongoing Revision of the EMA Fee system

- Objective: creation of a cost-based fee system that will ensure the ongoing and future sustainability of the regulatory system through appropriate funding and flexibility to adapt to the fast changing sector in which it operates, while ensuring business continuity.

Study supporting the impact assessment completed and published: https://op.europa.eu/en/publication-detail/-/publication/f6b211b2-d9d4-11e9-9c4e-01aa75ed71a1/language-en

- Impact assessment ongoing

- Commission proposal expected **to be adopted by Q3 2022**

- **Co-decision (Council and EP) to start once Commission proposal is adopted**

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11 legal acts = work in progress 2 acts

VMP Regulation Beyond 28/01/2022

Shall by 28.01.2025

IA List of substances for off-label use in food-producing aquatic species

IA List of substances essential for equine species

IA Rules on the size of small immediate packaging units

IA Abbreviations and pictograms for labelling

IA GMPs VMPs & active substances

EMA advice issued

IA List of AM not to be used outside terms of MA

EMA advice in preparation

DA Rules for VMP oral administration via drinking water or top dressing

Work in progress

No legal deadline for adoption

IA Model format for prescriptions

IA Rules for the functioning of the worksharing procedure

DA Procedures for financial penalties for CAs VMP

IA Uniform rules on the identification code

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The VMP beyond 28/01/2022

Report to the European Parliament and to the Council on assessment of situation as regards the treatment with medicinal products of Equidae and their exclusion from the food chain, including regarding third country imports (Article 158)

Due by 2025

- 1st step: Study to support the Commission report
    - Start of initiative planned for early 2023 (money earmarked)
    - Study planned to last about a year after awarding it

The VMP beyond 28/01/2022

Report to the European Parliament and to the Council on traditional herbal products used to treat animals in the Union (Article 157)

Due by 2027

- 1st step: Study to support the Commission report
    - Start of initiative planned for 2024 (money earmarked)
    - Study planned to last about a year after awarding it

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

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Food Safety

Dear colleagues,

Please save the date of
20 June 2022
for celebrating the entry into application of Regulation (EU) 2019/6.

The event will take place physically in the morning.
It will be hosted by DG SANTE of the European Commission.

A web stream is also planned.

A formal invitation with further details will follow shortly.

We count on your continued commitment to make the implementation of the VMP Regulation our common success

Thank you

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