VMP Regulation–State of Play

EMA Info day- 30 November 2021

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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

In March only 2 acts published in the O.J
Today 12 acts + amendment OCR

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

12+2 legal acts

AHL

DA Horse passport

IA Horse passport

European Commission

To be adopted by 2025 or as necessary (*)

11 legal acts = work in progress 2 legal acts

VMP Regulation Beyond 2022

Other priorities to be identified

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

IA List of substances essential for equine species

IA Uniform rules on the identification code

IA Rules for the functioning of the worksharing procedure *

EMA advice issued

DA Procedures for financial penalties for CAs VMP

IA Rules on the size of small immediate packaging units

IA Abbreviations and pictograms for labelling

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

IA GMPs VMPs & active substances

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

IA Model format for prescriptions*

EMA advice in preparation

European Commission

Applications

Commission Delegated Regulation (EU) 2021/578

Requirements on technical documentation necessary for demonstrating the quality, safety and efficacy of VMPs – Annex II

Updated requirements for dossier for marketing authorisations

Reduction of administrative burden and increasing the availability

New rules for biological and novel therapy VMPs – to promote product innovation and development

Addresses issues related to the development of AMR

New/updated provisions for:

- Vaccine antigen master file
- Vaccine platform technology*
- Multi-strain dossier (viral & bacterial)

Defines reduced data requirements for limited markets and applications in exceptional circumstances

Next Steps

- Consolidate Regulation 2019/6
- Considering a correcting act: (AHE-'pre-clinical safety studies')

European Commission

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

Antimicrobial Resistance Prudent Use

One Health approach

Commission Delegated Regulation (EU) 2021/1760

Criteria to designate AM reserved for humans only

IA List of AM reserved for human use

DA Imports of animals and products of animal origin

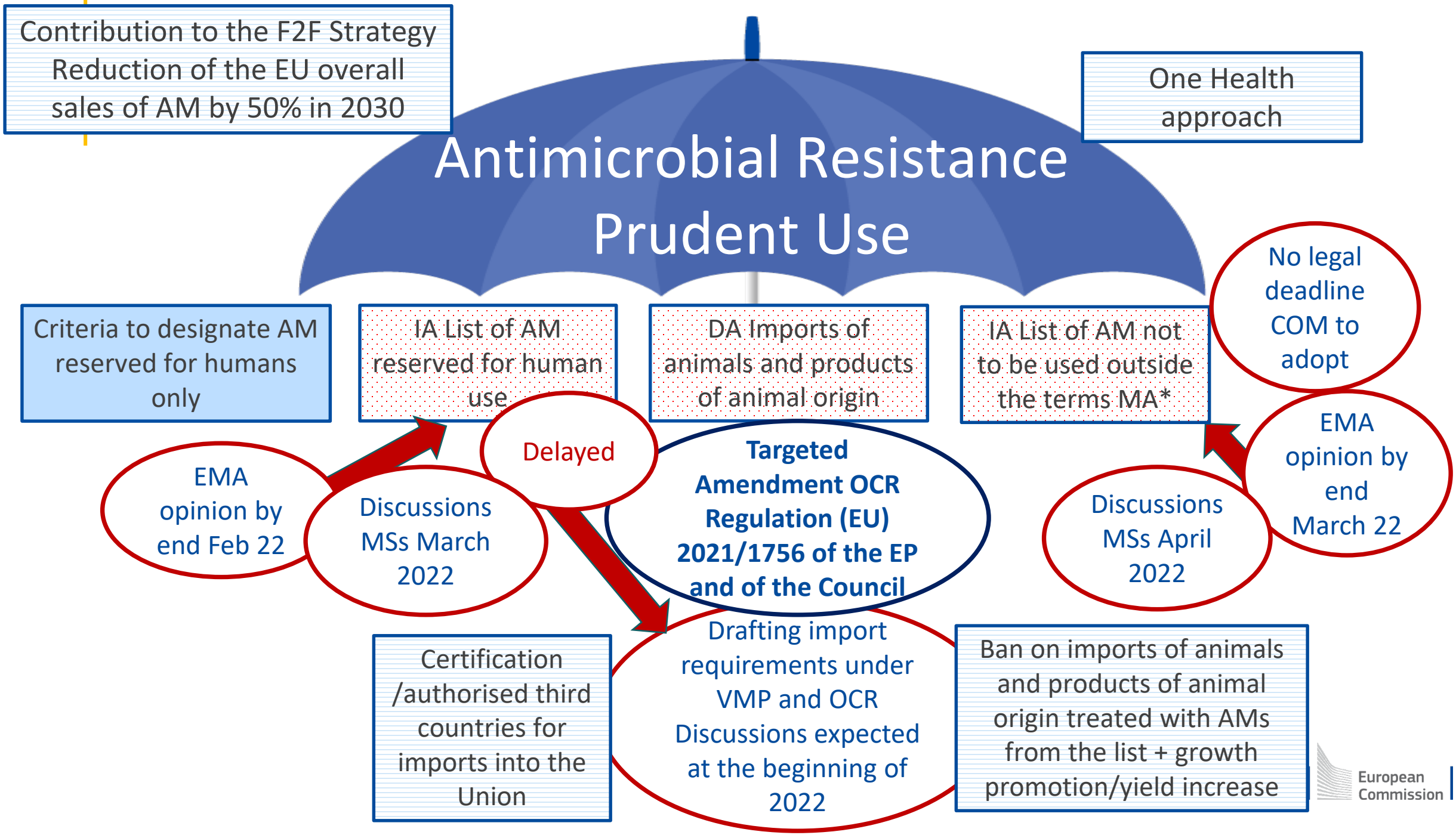
IA List of AM not to be used outside the terms MA*

Preserving the efficacy of AM – public health / animal health
Longer "viability" on the market

DELAYED

DA Criteria
Adopted by COM 26/05
Supported by Council
Extension of the objection period by EP 26/09 following a motion by the Greens
VOTE EP 15/09
Motion rejected
205 votes in favor
450 votes against
32 abstentions

European Commission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IA List of AM reserved for human use
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IA List of AM not to be used outside the terms MA*
No legal deadline COM to adopt
EMA opinion by end Feb 22
Discussions MSs March 2022
Delayed
Targeted Amendment OCR Regulation (EU) 2021/1756 of the EP and of the Council
EMA opinion by end March 22
Discussions MSs April 2022
Certification /authorised third countries for imports into the Union
Drafting import requirements under VMP and OCR
Discussions expected at the beginning of 2022
Ban on imports of animals and products of animal origin treated with AMs from the list + growth promotion/yield increase
European Commission

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

Antimicrobial Resistance Monitoring & Risk Management

Commission Delegated Regulation (EU) 2021/578

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

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

Legal deadline COM to adopt by 27/02/22

Public consultation ongoing: deadline 21/12/21

Standing Committee in January 22

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)

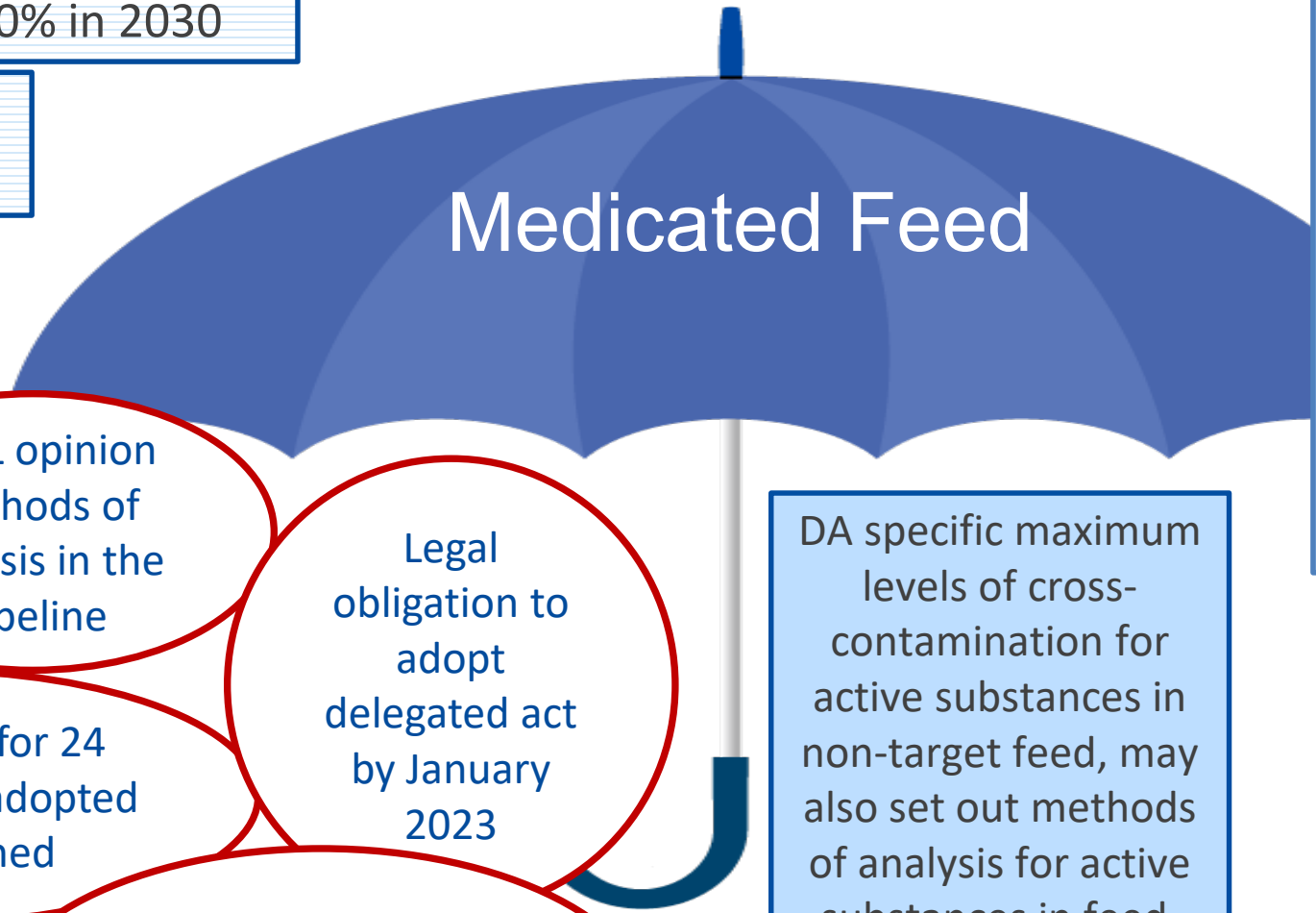
⇨ Valuable information for the industry

Common approach for data collection across the EU will ensure data quality and comparability⇨ monitoring

European Commission

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

One Health approach



EURL opinion methods of analysis in the pipeline

Legal obligation to adopt delegated act by January 2023

EFSA opinion for 24 antimicrobials adopted and published

Presentation of EFSA opinion in Expert Group in December/ discussions next year

DA specific maximum levels of cross-contamination for active substances in non-target feed, may also set out methods of analysis for active substances in feed.

Regulation (EU) 2019/4 of the European Parliament and of the Council of 11 December 2018 on the manufacture, placing on the market and use of medicated feed, amending Regulation (EC) No 183/2005 of the European Parliament and of the Council and repealing Council Directive 90/167/EEC

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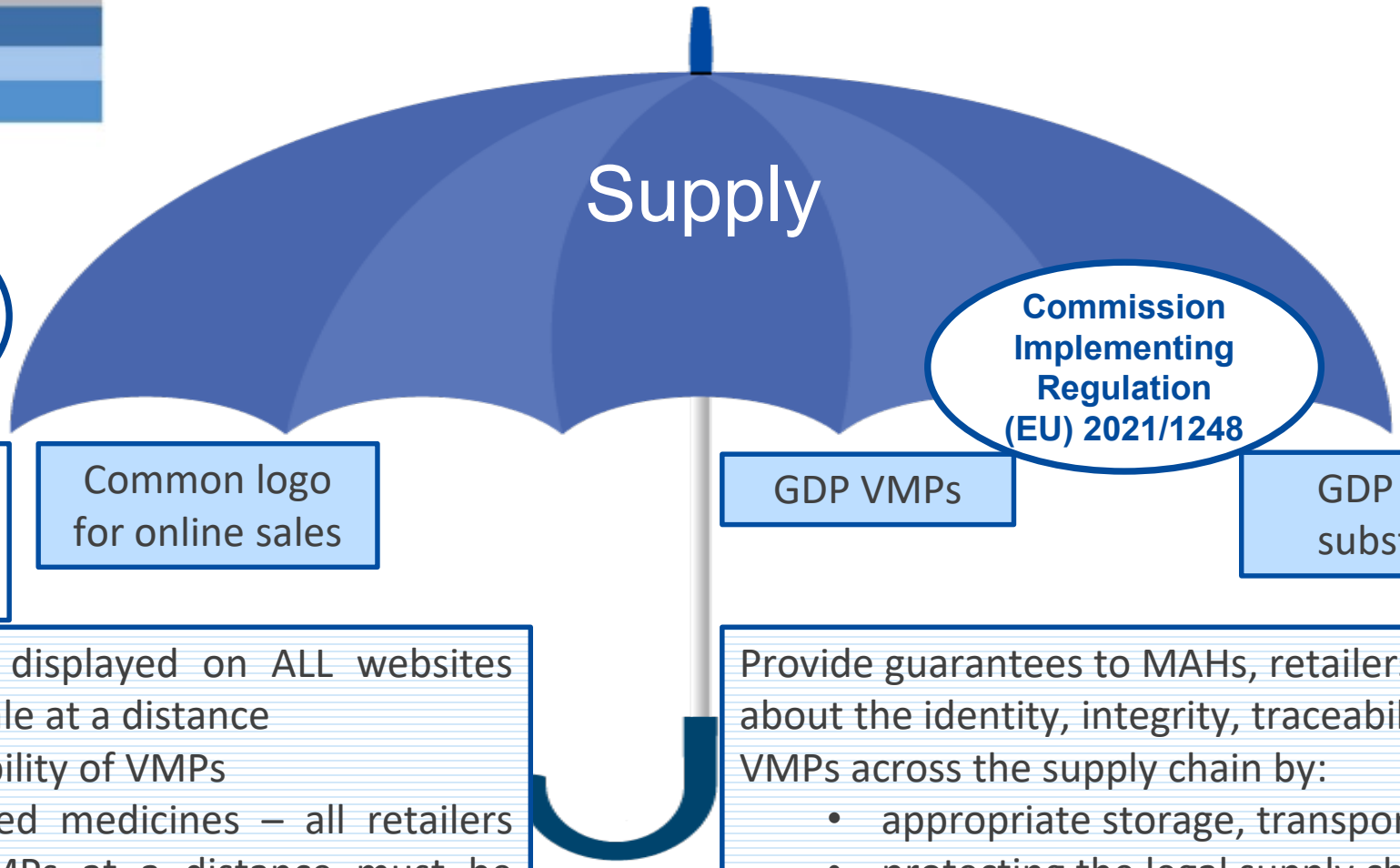
Supply



Commission Implementing Regulation (EU) 2021/1904

registration of the logo as a trademark completed

Common logo for online sales

- The logo must be displayed on ALL websites offering VMPs for sale at a distance
- Will increase availability of VMPs
- Fight against falsified medicines – all retailers offering sale of VMPs at a distance must be listed on the corresponding national website
- Increase in consumer confidence

Commission Implementing Regulation (EU) 2021/1248

GDP VMPs

Commission Implementing Regulation (EU) 2021/1280

GDP Active substances

Provide guarantees to MAHs, retailers and consumers about the identity, integrity, traceability and quality of VMPs across the supply chain by:

- appropriate storage, transport and handling
- protecting the legal supply chain during storage and transport

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Post-marketing authorisation measures

Commission Implementing Regulation (EU) 2021/16

Union Product Database

- Enhance the Single market by providing info on existing VMPs and their availability per Member State
- Help vets elaborate treatment alternatives
- Future-proof by continuous evolution involving MAH feedback
- Aimed at avoiding duplicate input of info
- Reducing admin burden, e.g. by allowing grouping changes

Commission Implementing Regulation (EU) 2021/17

Variations not requiring assessment

- New category of "variations"
- Easy procedure for recording changes to a VMP that do not need to be assessed by NCAs
- Reduction of administrative burden

Commission Implementing Regulation (EU) 2021/1281

Good Pharmacovigilance Practice & PSMF

- Create an efficient system of continuous surveillance
- Pharmacovigilance database
- Better info for users (SPC+PL)
- Increased consumer confidence in safe VMPs

European Commission

Horse Passport

Rules for and a model of the single lifetime identification document that must accompany equine animals

Commission Delegated Regulation (EU) 2021/577

DA rules identification, incorporating the model forms for entering the information necessary to apply AHL, VMP and zootecnics

IA content and format of the information y

Commission Implementing Regulation (EU) 2021/963

Content and format of information on the use of veterinary medicinal products and on the possibility to exclude animals of equine family from the food chain

Next Steps

- Regulation correcting Delegated Regulation (EU) 2021/577 as regards certain references to veterinary medicinal products in the pipeline: erroneous use of the word 'veterinary' where the text is to be related both to veterinary medicinal products and medicinal products for human use

Art. 158: Review of measures regarding animals of equine species-by **29/01/25** EC to present report to Council/EP- assessment on the situation and their exclusion from food chain

Other non-legislative actions/Implementation

Commission Notice on marketing authorisations for veterinary medicinal products for which the expiry of the 5-year period of validity falls on or after the date of entry into application of Regulation (EU) 2019/6

- To inform stakeholders on how the Commission intends to deal with **centrally authorised veterinary** medicinal products for which the expiry of the 5-year period of validity of the marketing authorisation falls on or after 28 January 2022. The Notice also addresses certain questions that may arise in relation to **nationally authorised** products

- Q&A for both centrally and nationally authorised products and for centrally authorised products only

- Publications Office (europa.eu)

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: 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

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Ongoing Revision of the EMA FEES – Study Supporting the Impact Assessment

- 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.
- Targeted consultations: NCAs, EMA, industry, broader stakeholders (14 June - 23 August)
- Contractor currently double checking calculations and **analyzing feed-back received**, in parallel to preparing interim study deliverables

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

Thank you

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