The VMP Regulation in 2022 and beyond

Veterinary Medicines Info Day 2021

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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

AHL

F2F Strategy

Modern innovative

Fit-for-purpose

Fight against AMR

Easier and faster access to data

Limited Markets

Consumer confidence

More transparency and info on all VMPs in the Union

Reduce administrative burden

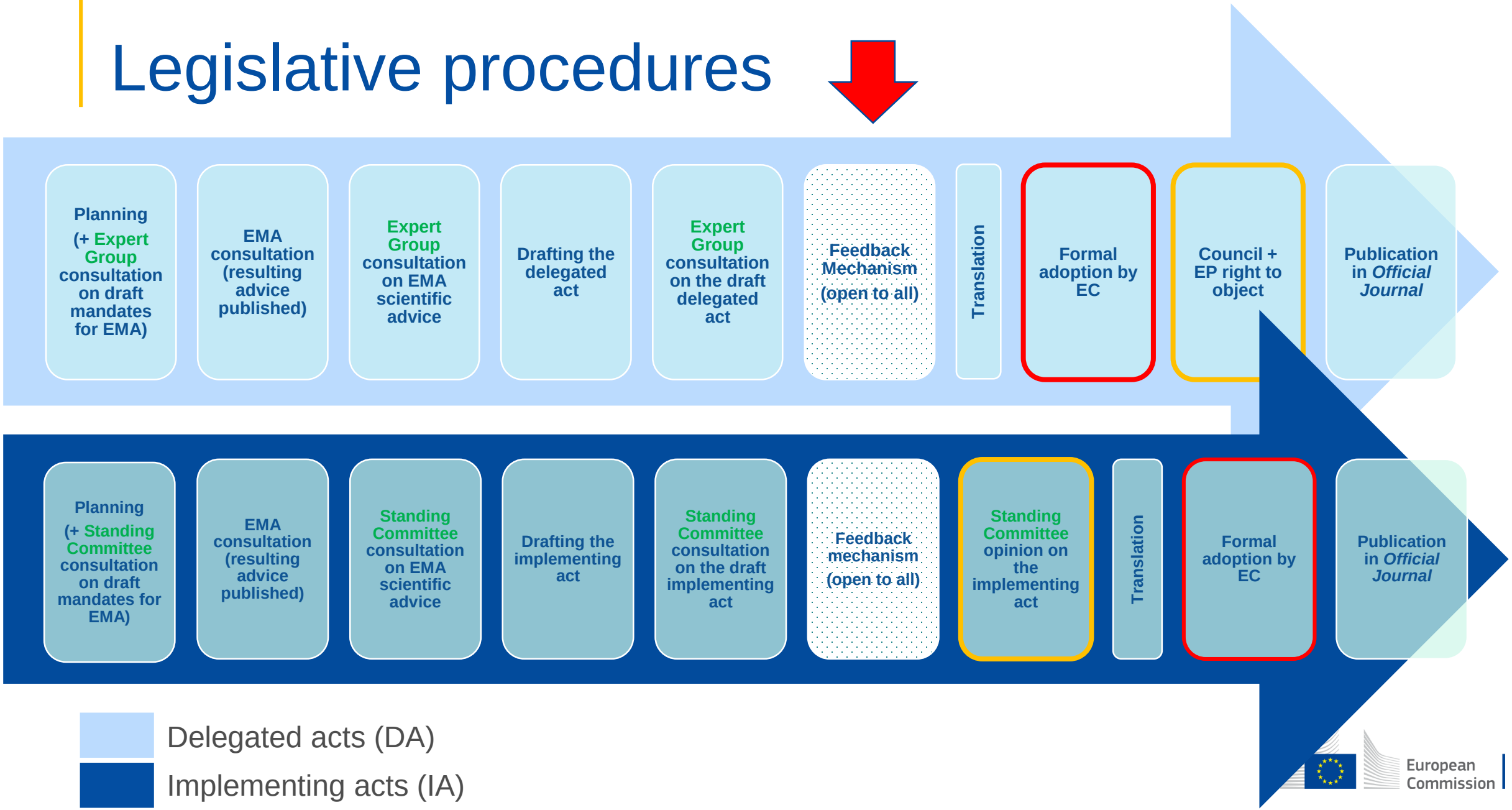
Stimulate innovation

Increase availability of VMPs

Streamlined procedures and processes

European Commission

Legislative procedures



European Commission

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

European Commission

Already in force
Applies 28/01/2022

VMP Regulation 2022

Union Product Database

Good Pharmacovigilance Practice & PSMF

Common logo for online sales

GDP Active substances

List of variations not requiring assessment

Annex II

GDP VMPs

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

Criteria to designate AM reserved for humans only

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

List of AM reserved for humans use only

Imports of animals and products of animal origin

12+2 legal acts

AHL

DA Horse passport

IA Horse passport

European Commission

To be adopted by 2025
or as necessary (*)

VMP Regulation Beyond 2022

List of substances for off-label use 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*

Procedures for financial penalties for CAs VMP

List of AM not to be used off label*

Model format for prescriptions*

Rules for VMP oral administration via drinking water or top dressing

GMPs VMPs & active substances

Rules on the size of small immediate packaging units

Abbreviations and pictograms for labelling

11 legal acts

European Commission

Applications

EP/Council

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

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

Public feedback

Criteria to designate AM reserved for humans only

List of AM reserved for human use

Imports of animals and products of animal origin

Drafting

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

Prohibition of certain uses or the use of certain AM applicable to imports from third countries

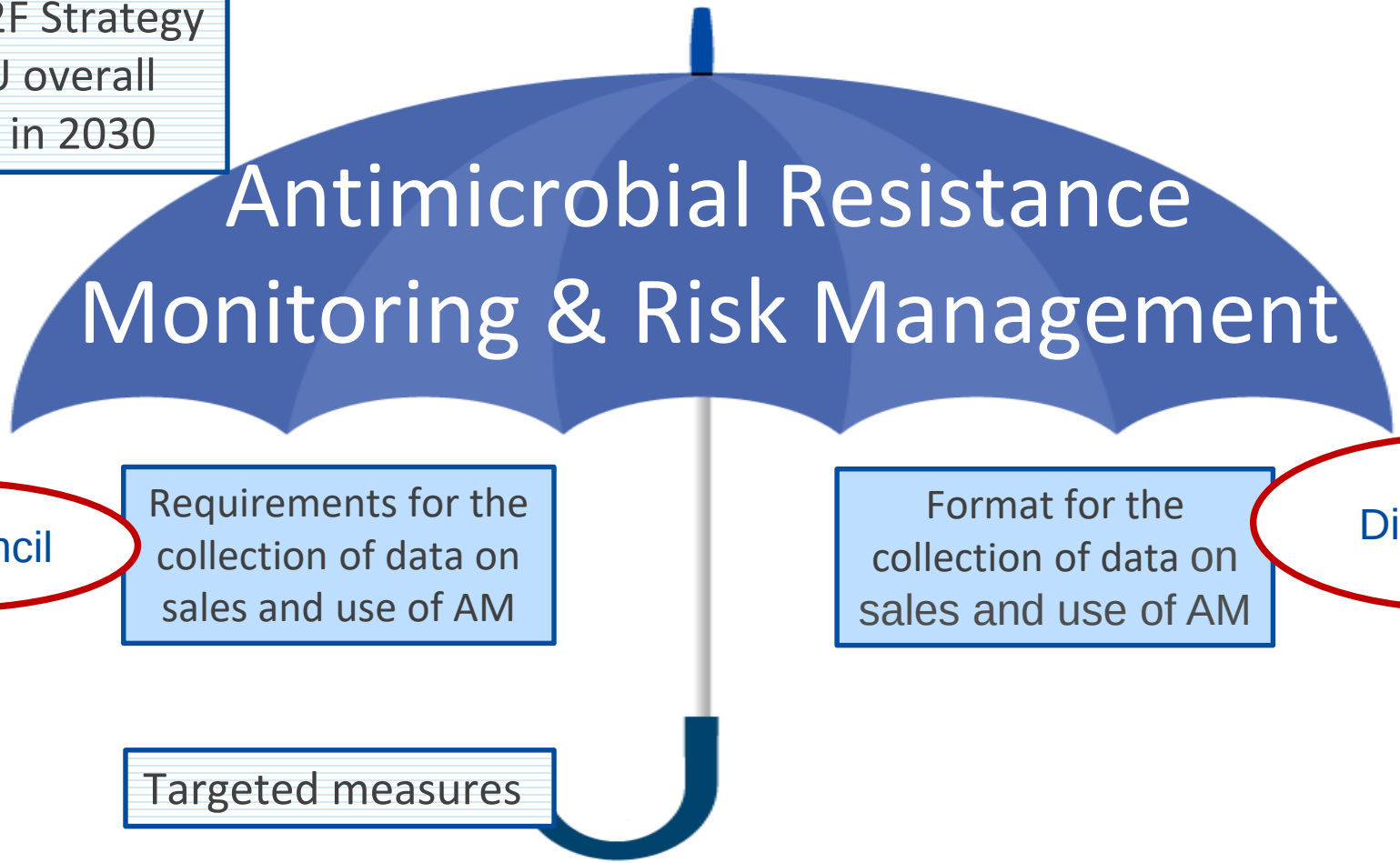
Medium term

Initiate discussions on new business models, economic or regulatory incentives that are financially sustainable for:

- **development of new AM/alternatives for the veterinary market**
- **maintenance of supply of existing AM for the veterinary market**

European Commission

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



EP/Council

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

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

Under Discussion MS

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

European Commission

Supply

Awaiting publication O.J.

registration of the logo as a trademark

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

GDP VMPs

GDP Active substances

Under discussion MS

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

Post-marketing authorisation measures

Published O.J.

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

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

Good Pharmacovigilance Practice & PSMF

Under discussion MS

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

UPDATE ON IMPLEMENTATION: OUTLOOK AND WAY FORWARD

- Overall, the work is progressing on time
- The Commission maintains its ambition for timely implementation
- The Commission relies on the continued commitment of the Agency, the Member States and stakeholders so that we can make the implementation of the VMP Regulation a success

European Commission

Thank you

European Commission