Breaking New Ground with the VMP Regulation: Achievements and Challenges Ahead

High-level Event Celebrating the Application of the New Legal Framework on VMPs

Brussels, 20 June 2022

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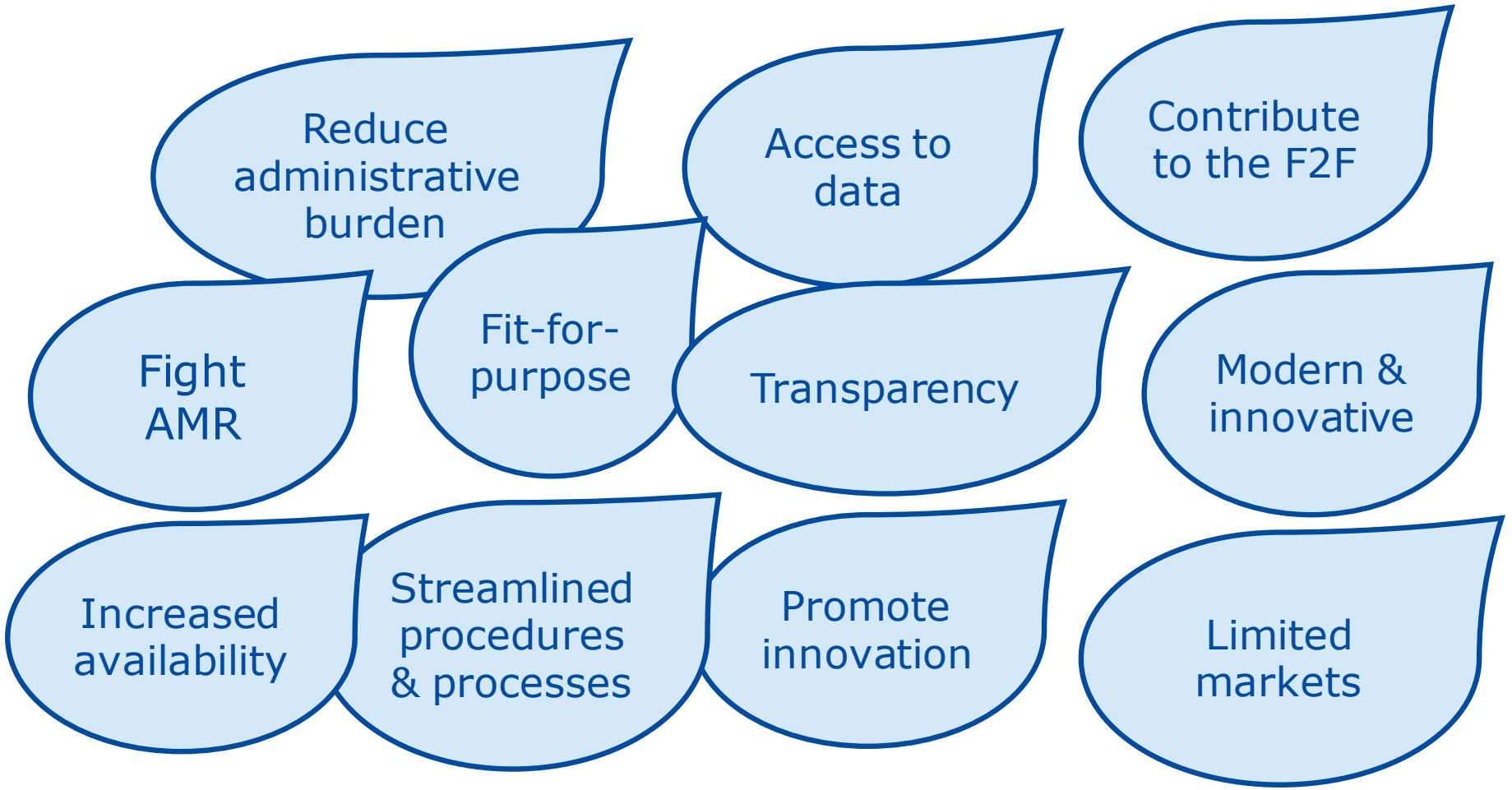
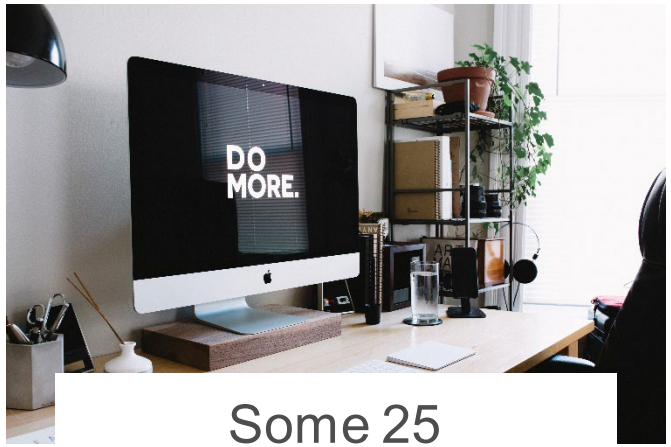
Breaking New Ground



The Implementation Challenge

In force: 3 years, 4 months, 25 days

Applicable: 144 days



Some 25 empowerments:

13 before or by the date of application

6 by 2025

1 by 2027

6 no legal deadline

Focus on the implementation & completing the implementation & implementing

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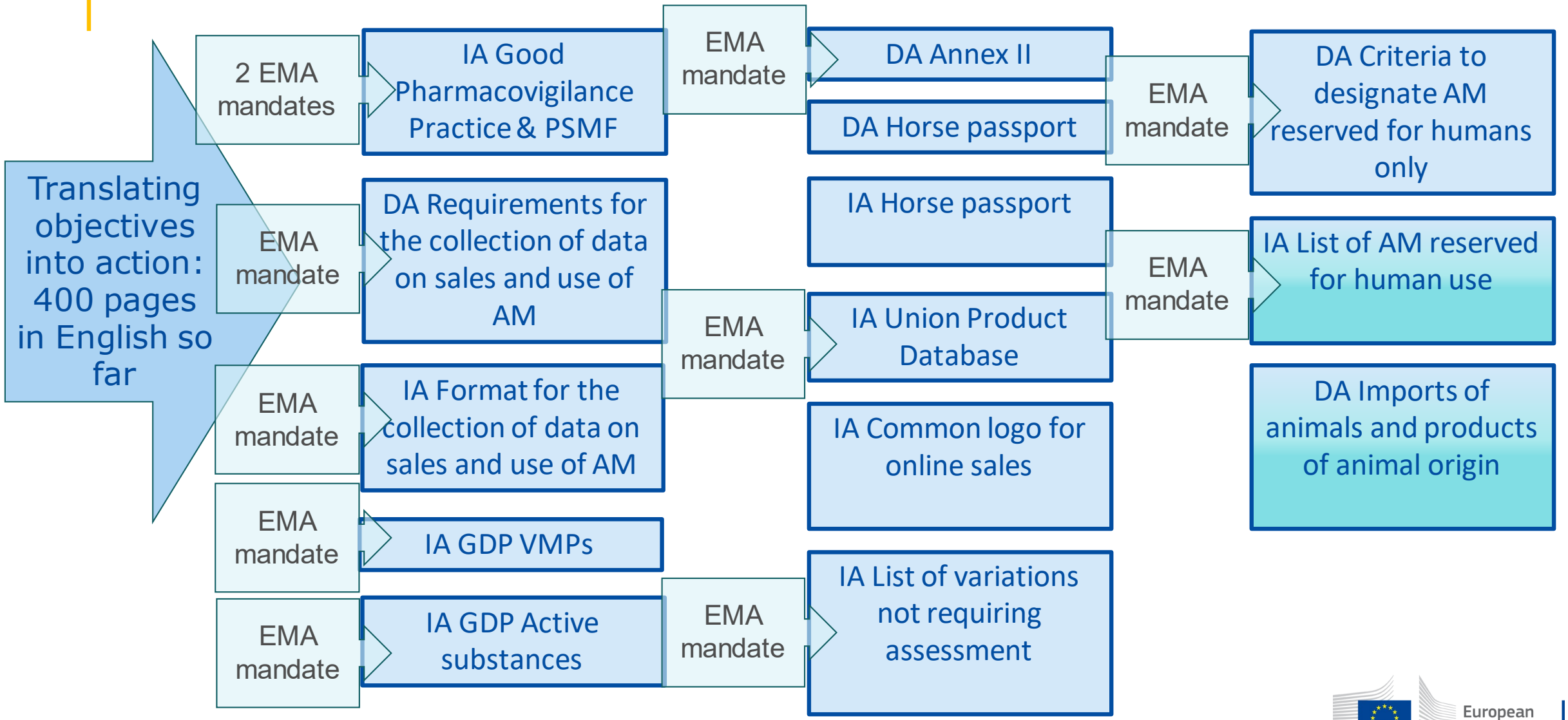
Achievements



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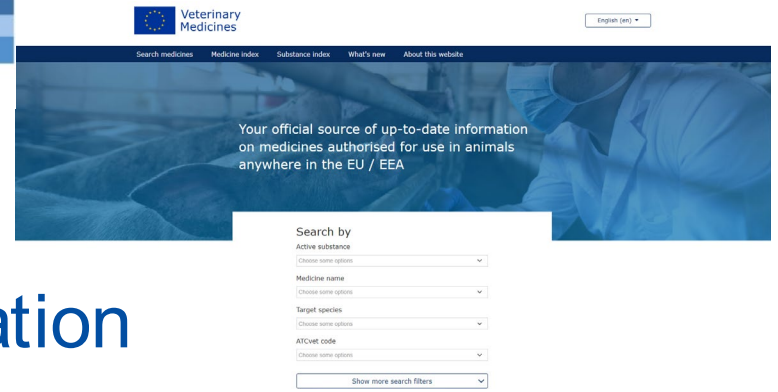
Challenges Turned Achievements

Common logo: worth the long wait



UPD: useful tool to find available VMPs

Some VMPs already have unlimited authorisation

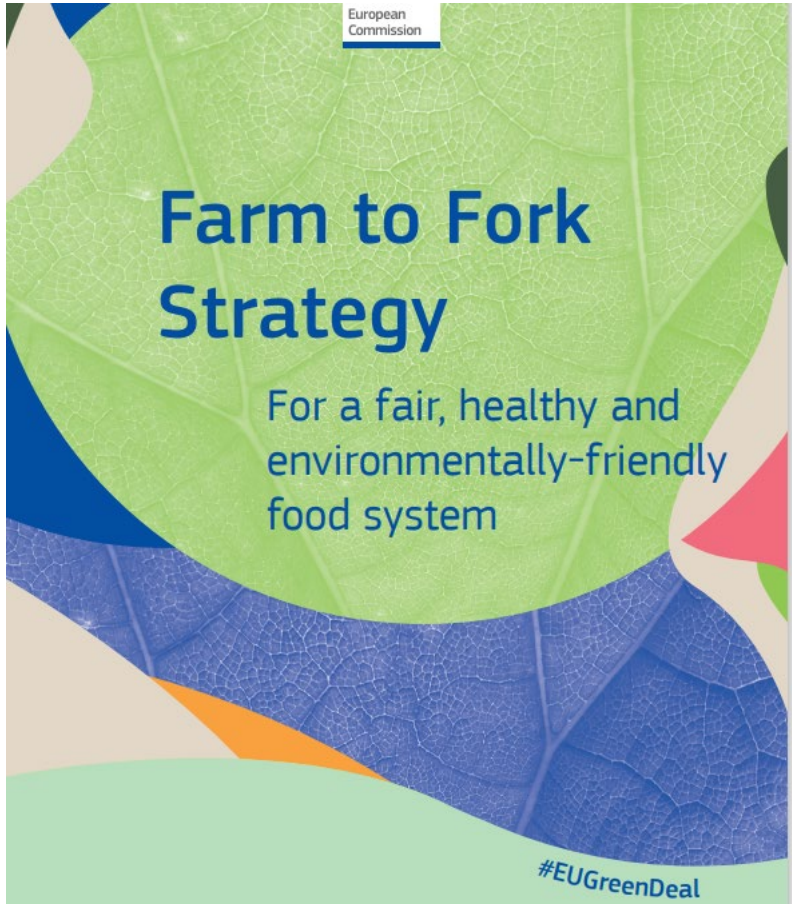
Harmonised system for collection of data on sales and use of antimicrobials

First ever harmonised GDP requirements for active substances and VMPs

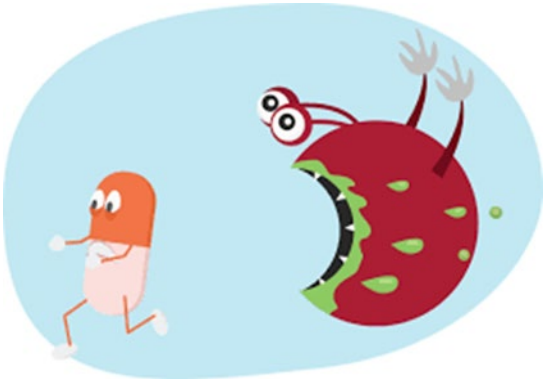
List of VNRAs to reduce admin burden

Antimicrobial Resistance: the Bigger Picture

- A forward-looking regulation
- Ground-breaking policy measures to ensure prudent and responsible use of antimicrobials
- Major tool to achieve the Strategy objective of cutting by half overall Union sales of antimicrobials for farmed animals and in aquaculture by 2030



Antimicrobial Resistance: the Mother of all Challenges



Combating AMR

First in the world to ask ourselves:

To list or not to list

that is the question?

often different views

but always

our common goal

Resources also needed

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Antimicrobial Resistance: the International Dimension

We are not only world leaders in asking ourselves the big question, but also the first to take action ensuring prudent and responsible use for animals and products imported into the Union

Making Article 118 work in practice a major challenge:

- The VMP Regulation does not provide for a legal basis for controls

Article 1

Regulation (EU) 2017/625 is amended as follows:

(1) in Article 1(4), point (c) is replaced by the following:

'(c) Regulation (EU) 2019/6 of the European Parliament and of the Council (*1); however, this Regulation shall apply to official controls for the verification of compliance with Article 118(1) of that Regulation.

Solution:

- The Official Controls Regulation was amended by Regulation (EU) 2021/1756
- Article 118 will now use the EU's official control framework

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Article 152 – packaging and labelling

Or…

what happens when the panic bottom is pushed

The fix: a co-decision in record time

L 148/6 EN Official Journal of the European Union 31.5.2022

REGULATION (EU) 2022/839 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of 30 May 2022

laying down transitional rules for the packaging and labelling of veterinary medicinal products authorised or registered in accordance with Directive 2001/82/EC or Regulation (EC) No 726/2004

(Text with EEA relevance)

Challenges Ahead

Finalise legal acts & report on ERA + embark on new legal acts + draft guidance to applicants

Implementation of new provisions

Matters of interpretation

Fixing errors

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More Challenges Ahead

Work in progress

EMA mandate

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

EMA mandate

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

Shall by 28.01.2025

- IA Rules on the size of small immediate packaging units
- IA List of substances essential for equine species
- IA GMPs VMPs & active substances
- IA Abbreviations and pictograms for labelling

Shall by 28.01.2027

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

No legal deadline

- IA Model format for prescriptions
- IA Rules for the functioning of the work-sharing procedure
- DA Procedures for financial penalties for CAs VMP
- IA Uniform rules on the identification code

Reports

- Report on assessment of situation as regards the treatment of Equidae and their exclusion from the food chain, including regarding 3rd country imports (by 2025)
- Report on traditional herbal products used to treat animals in the Union (by 2027)

This would not have been possible without you

We would like to continue this fruitful cooperation

We thank you very much for your commitment and dedication!

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