



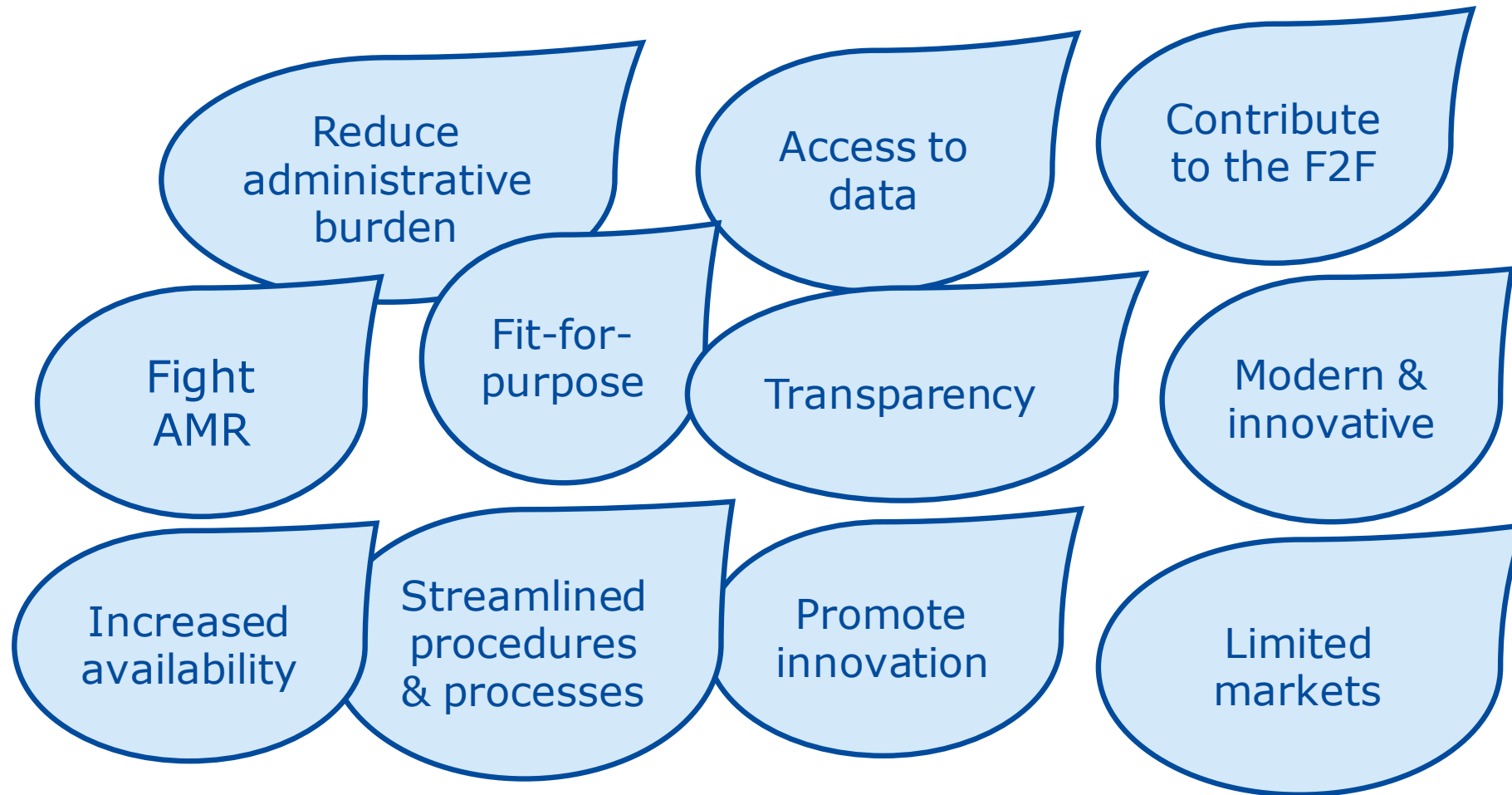
Breaking New Ground with the VMP Regulation: Achievements and Challenges Ahead

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

Brussels, 20 June 2022

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Breaking New Ground

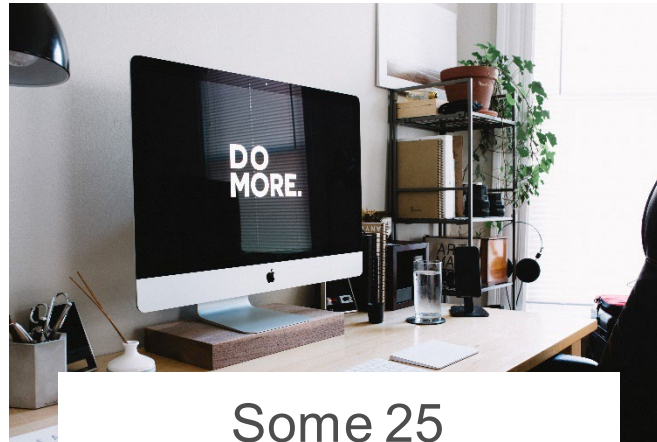


The Implementation Challenge



In force: 3 years, 4 months, 25 days

Applicable: 144 days

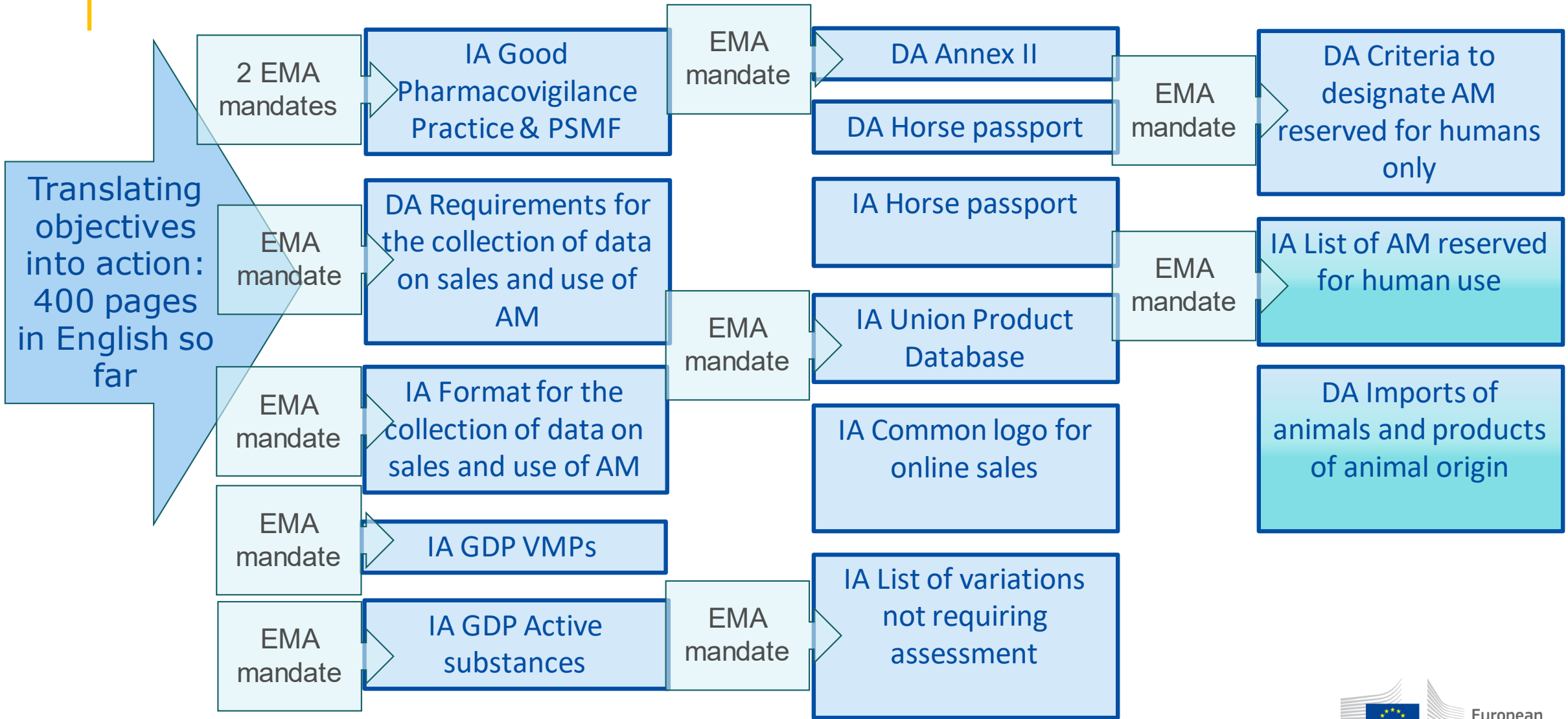


Some 25
empowerments:
13 before or by the
date of application
6 by 2025
1 by 2027
6 no legal deadline



Focus on the
implementation &
completing the
implementation &
implementing

Achievements



Challenges Turned Achievements

Common logo: worth the long wait



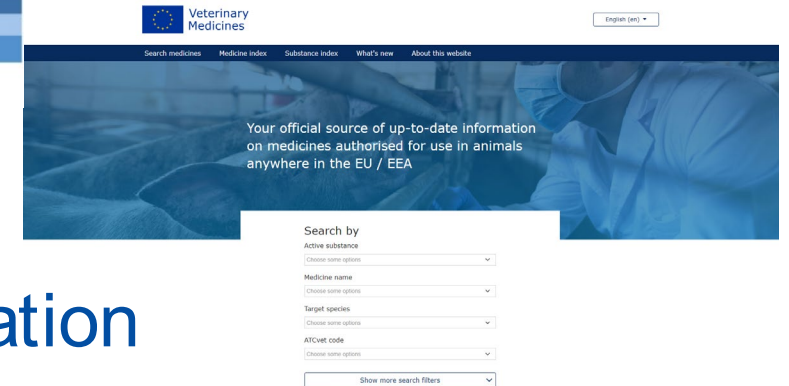
UPD: useful tool to find available VMPs

Some VMPs already have unlimited authorisation

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

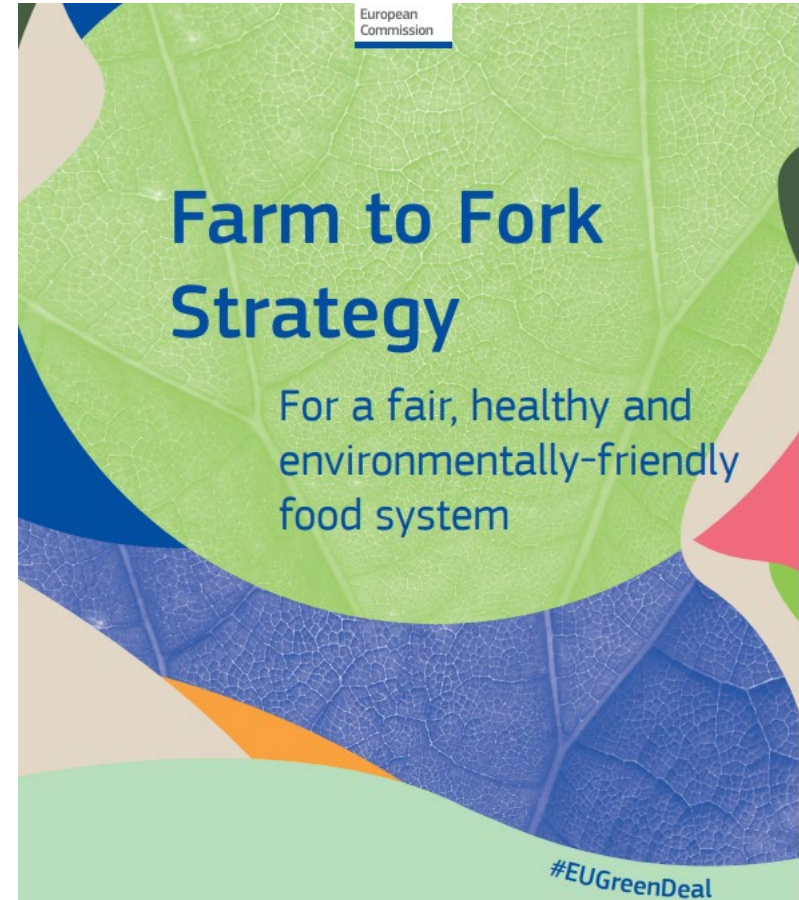
First ever harmonised GDP requirements for active substances and VMPs

List of VNRAAs 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

often different views

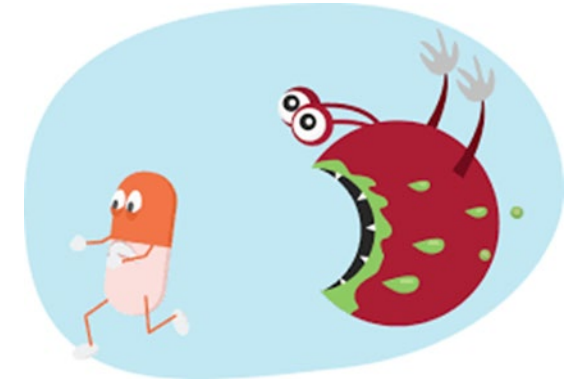
but always

our common goal

First in the world to ask
ourselves:



*To list or not to list
that is the question?*



Resources also needed



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

Article 152 – packaging and labelling

Or...

what happens when the panic button
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

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)

**AWESOME
& AMAZING** | **GRATEFUL**

THANK YOU!

*Couldn't
have
DONE IT
without you!*

THANKS
so much

YOU ARE GREATLY APPRECIATED



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!*