



# HPRA webinar on Regulation 2019/6

#### Introduction

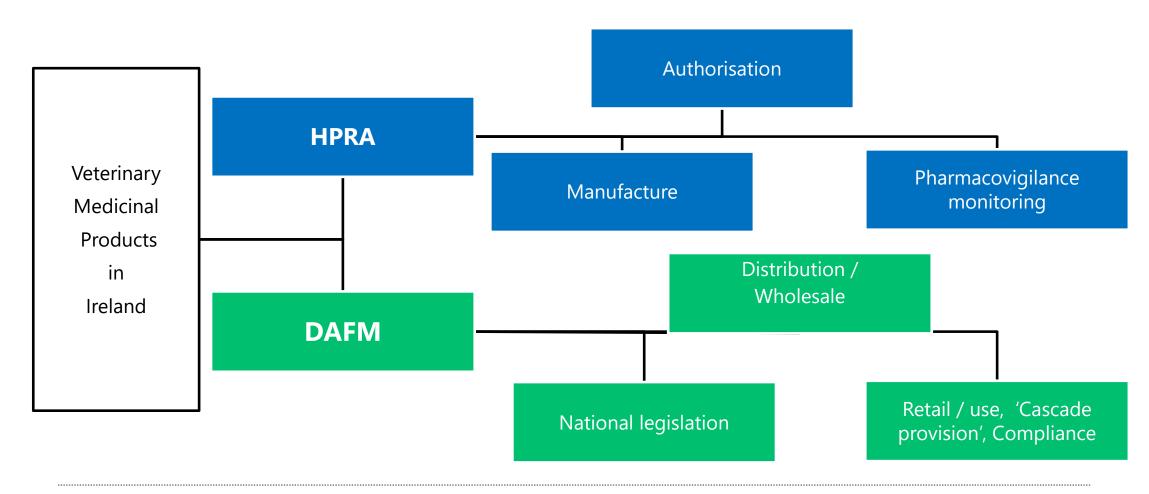
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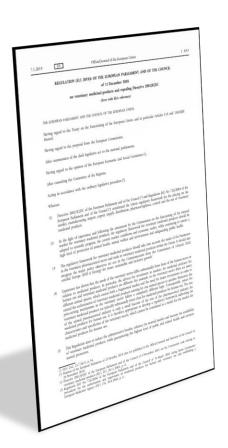


# Veterinary Medicinal Products Veterinary Medicines in Ireland





# Regulation (EU) 2019/6 on veterinary medicinal products



- provides for a modern, innovative and fit for purpose legal framework
- gives incentives to stimulate innovation
- gives incentives to increase the availability of veterinary medicines
- strengthens the EU action to fight antimicrobial resistance



# EU network collaboration

### **European Commission**

Responsible for implementation of any legislative acts, such as Regulation 2019/6.

gives mandates

#### co-decision

### **European Medicines Agency**

- Provides advice on the content of secondary legislation
- Prepares for and supports the implementation of the Regulation
- Provides regulatory, technical/procedural advice during and after the implementation
- This does not include general interpretations of the legislation.

#### **Member states**

Agree on the secondary legislation via Committees hosted by the EC or in codecision by the Council and Parliament

input to advices



### VMP-Reg programme – scope



#### **Union Product Database**

To store and make available information on different types of authorised veterinary medicinal products, at EU level.



#### Collection of data on Sales and Use of Antimicrobials in Animals

To store and make available information on the sales and use of antimicrobials.



#### Union Pharmacovigilance Database

To store and make available information on suspected adverse events for all veterinary medicinal products authorised in the Union.



#### Required interconnections



#### Union Database on Manufacturing and Wholesale Distribution

To store and make available information on manufacturing and wholesale distribution data in the European Union and will support the management of the information related to manufacturing authorisations and outcomes of inspections activities.

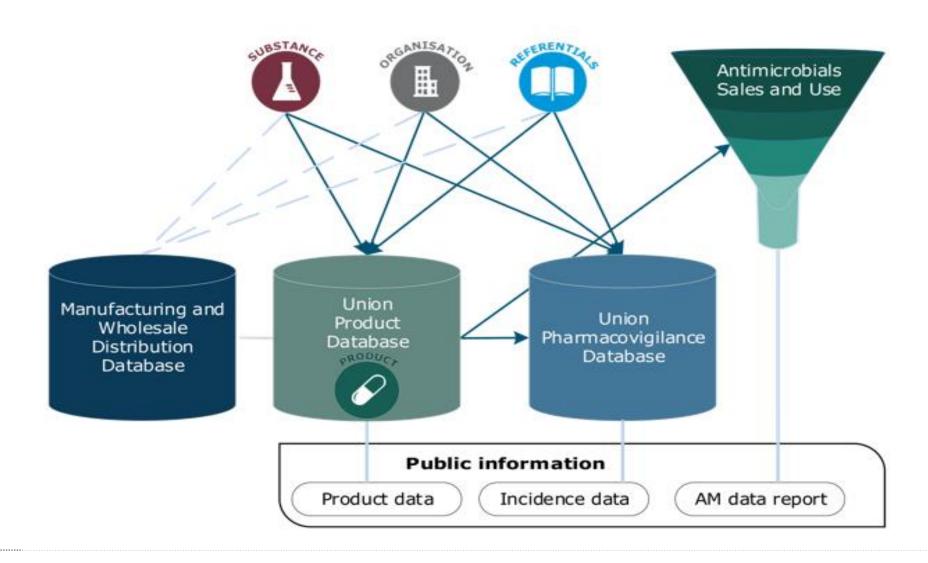


Any required changes to business processes that are not related to IT solutions, within the Agency

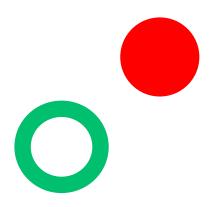


### **VMP-Reg programme – EU IT systems overview**





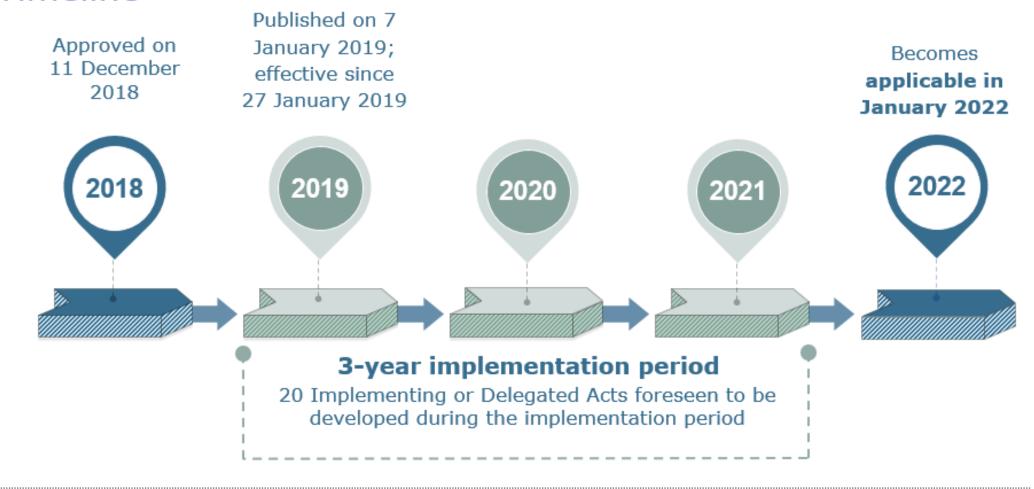








### **Timeline**







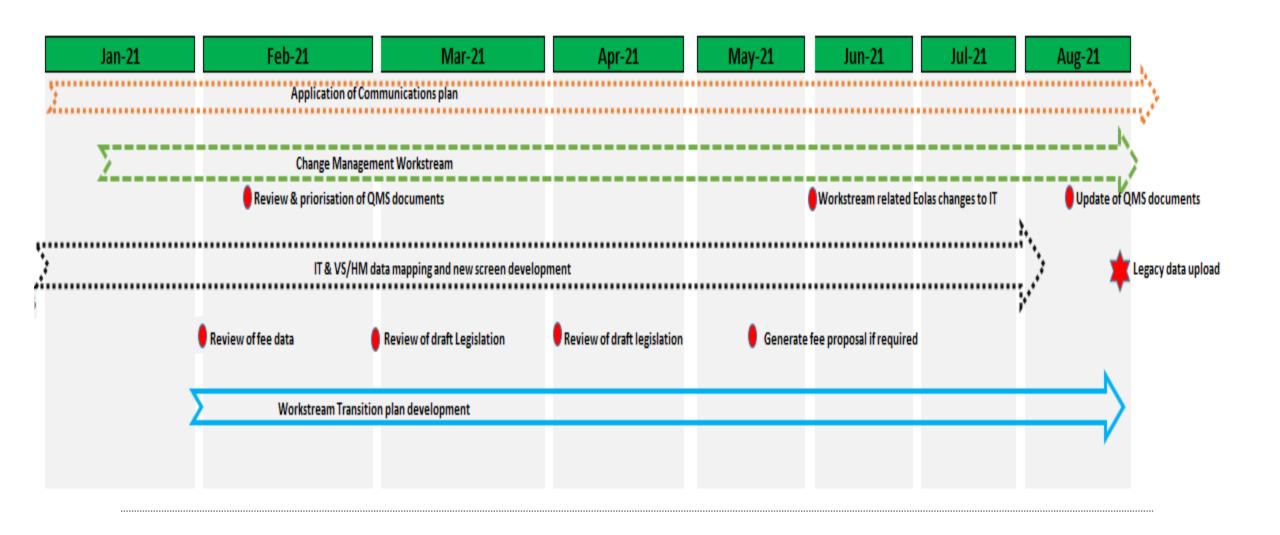
### **Update from EU Commission on legislative packages**

- Overall, the work is progressing on time
- The Commission maintains its ambition for timely implementation
- 2021 will be the busiest in terms of finalisation and adoption of delegated and implementing acts
- The Commission relies on the continued commitment of the Agency and the Member States so that we can make the implementation of the VMP Regulation a success









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







## Thank you

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