



HPRA webinar on Regulation 2019/6

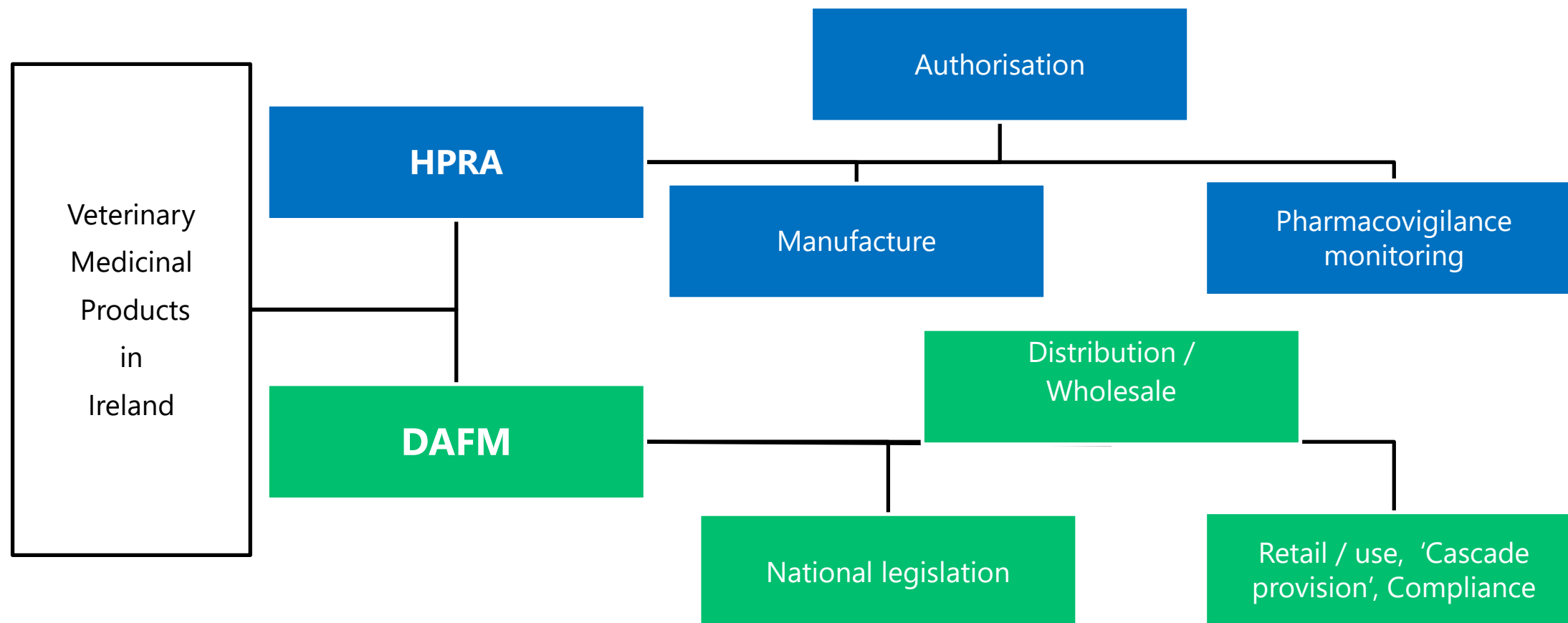
Introduction

J. Gabriel Beechinor
Director of Veterinary Sciences, HPRA

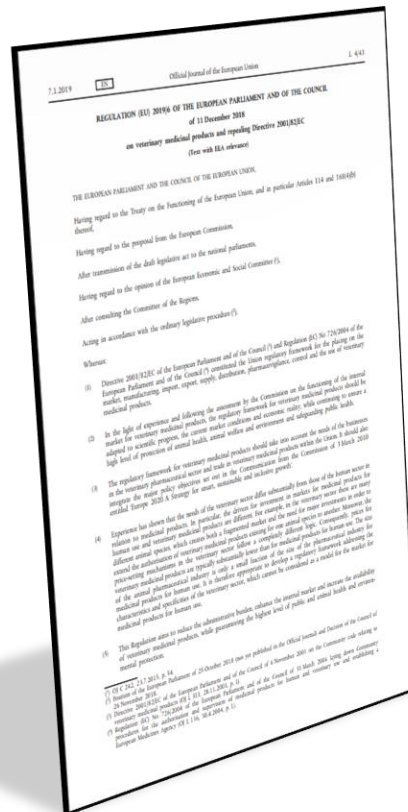
31 March 2021



Veterinary Medicinal Products Veterinary Medicines in Ireland



Regulation (EU) 2019/6 on veterinary medicinal products



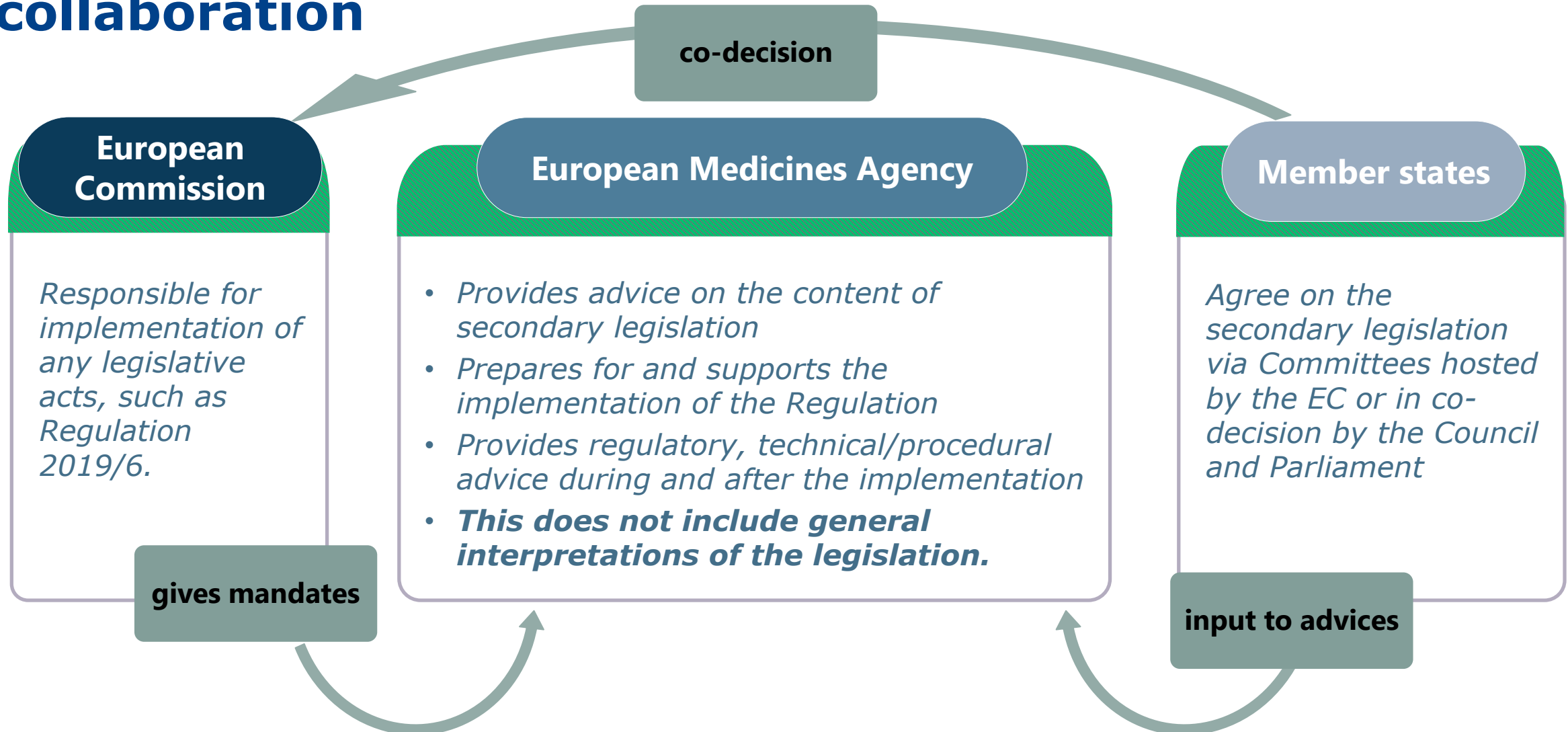
provides for a modern, innovative and fit for purpose legal framework

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



VMP-Reg programme – scope



Union Product Database

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



Union Pharmacovigilance Database

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



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.



Collection of data on Sales and Use of Antimicrobials in Animals

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



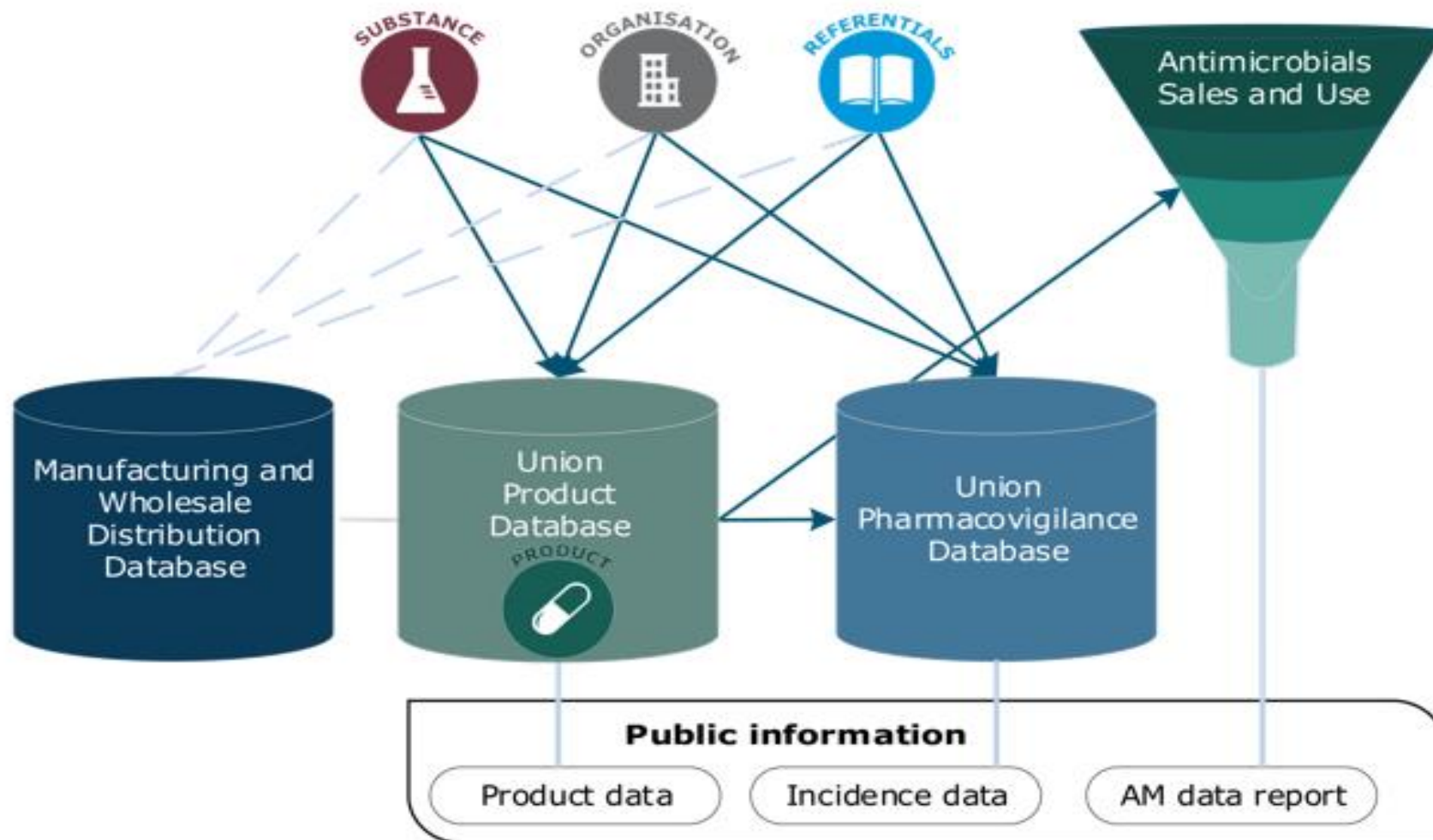
Required interconnections

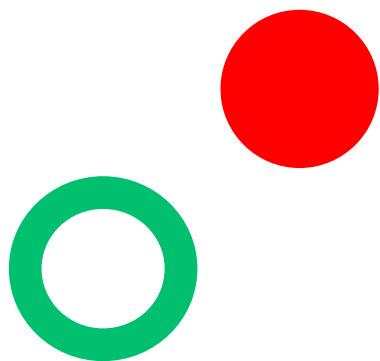


Any required changes to business processes that are not related to IT solutions, within the Agency

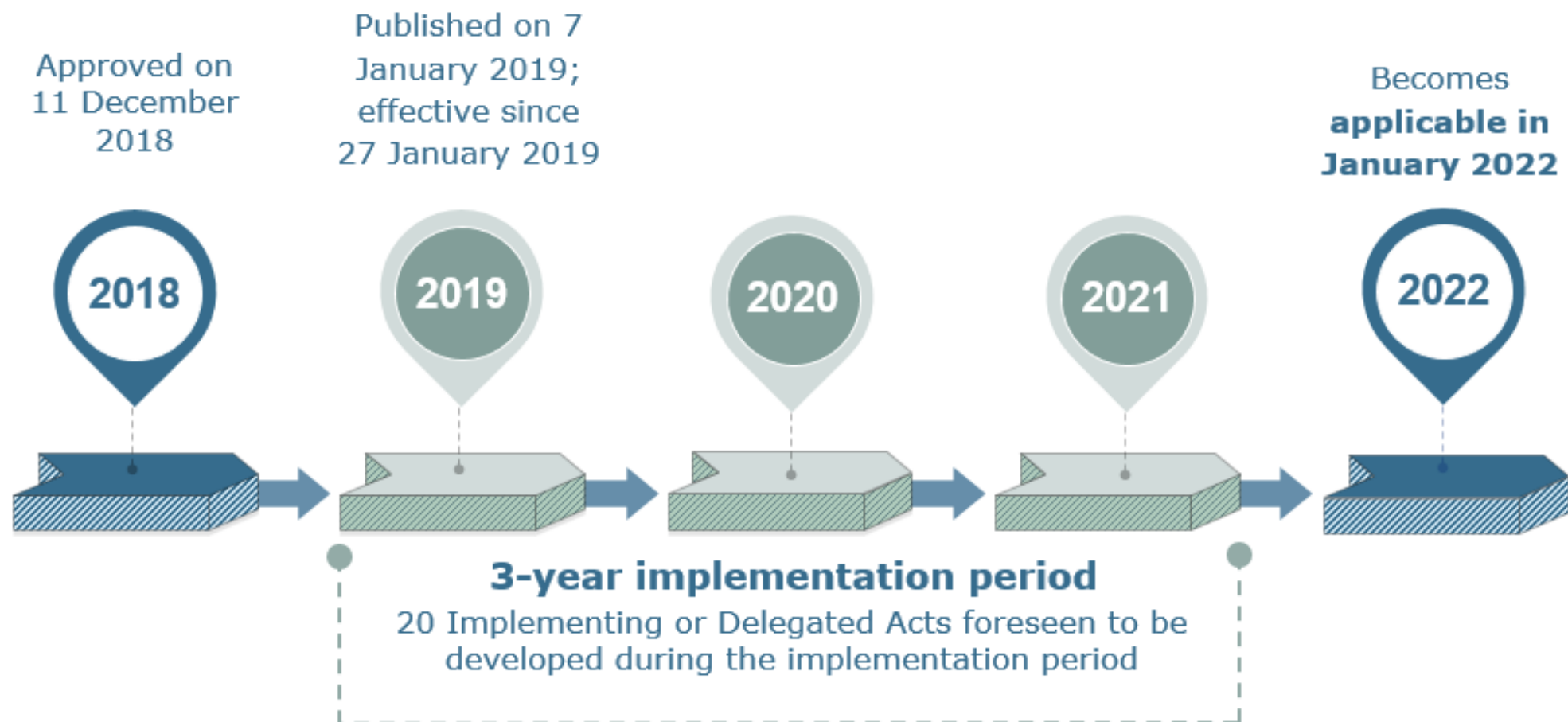


VMP-Reg programme – EU IT systems overview





Timeline



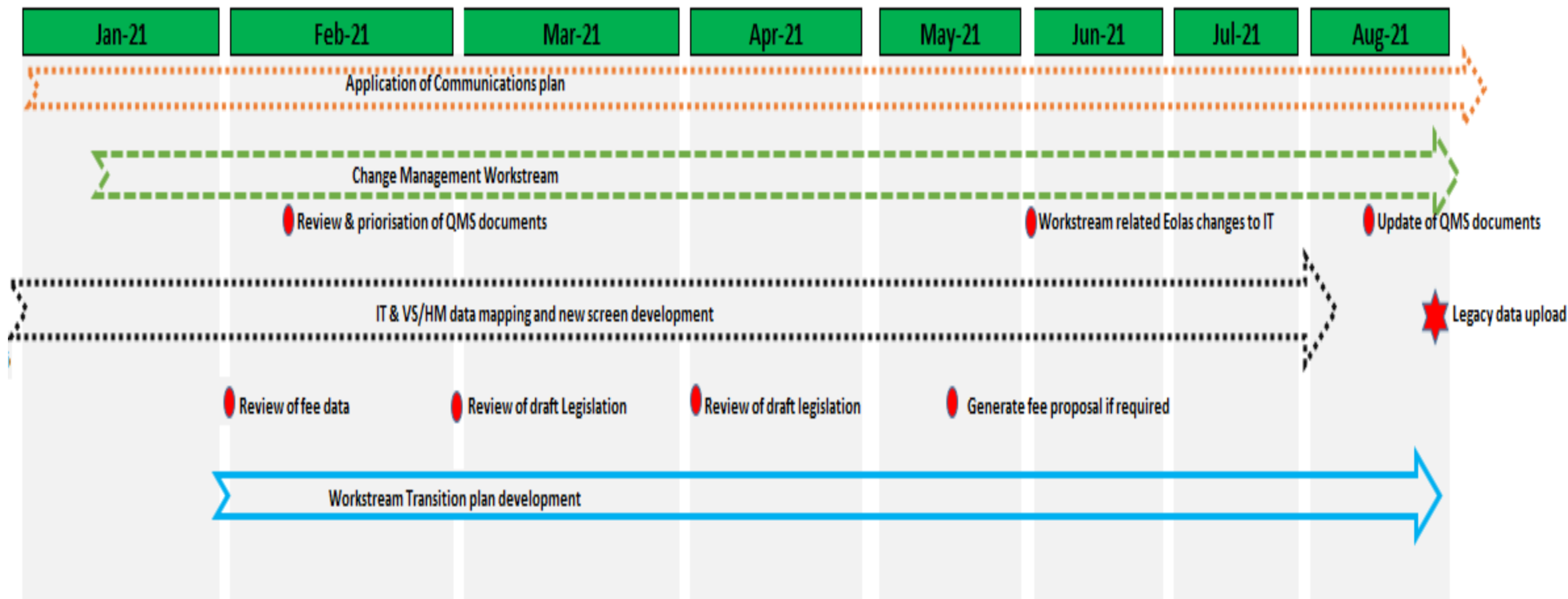


Update from EU Commission on legislative packages

- 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

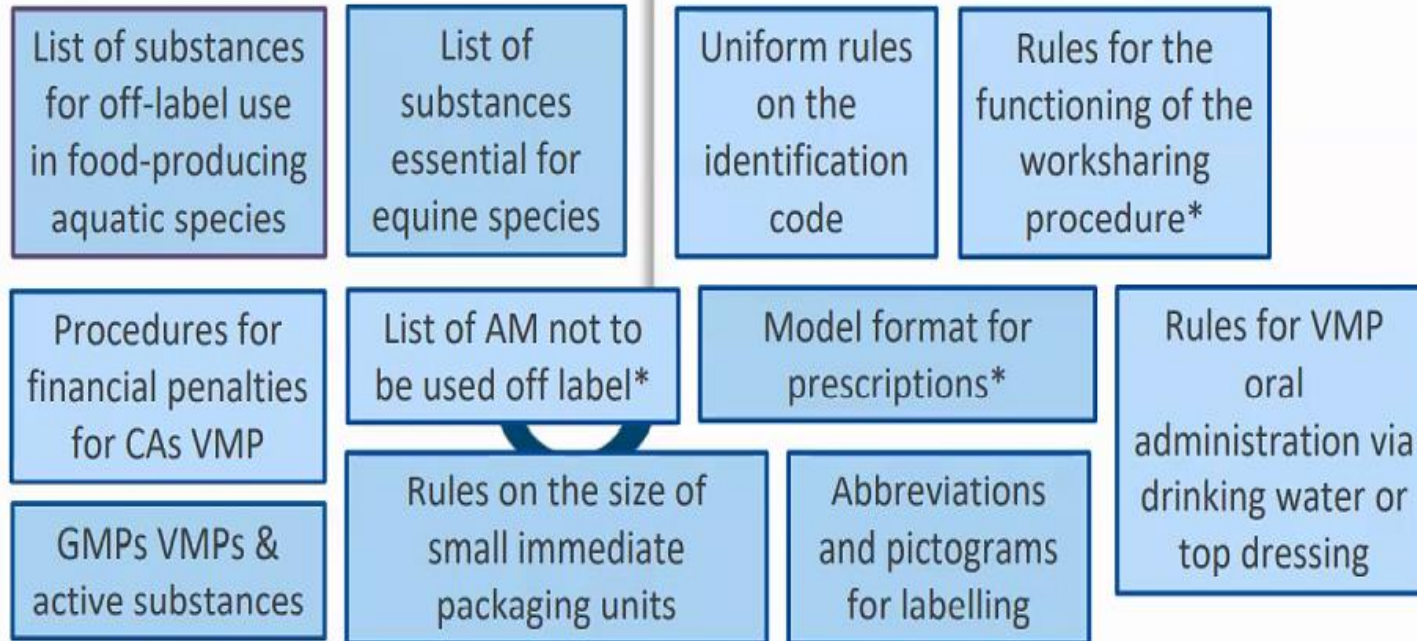


HPRA project plan overview



or as necessary (*)

VMP Regulation Beyond 2022



11 legal acts



Thank you

- Follow @TheHPRA 
 - newvetreg@hpra.ie 
 - www.hpra.ie
-