EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Introduction to the UPD

Veterinary Info Day for SMEs

Presented by Jana Schalansky on 28 October 2021
Head of Veterinary Strategic Support Office, Veterinary Medicines Division

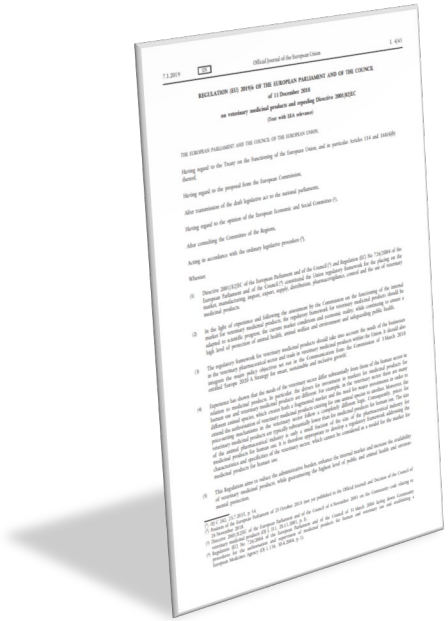
An agency of the European Union

Overview

- UPD programme and project context
- Project status

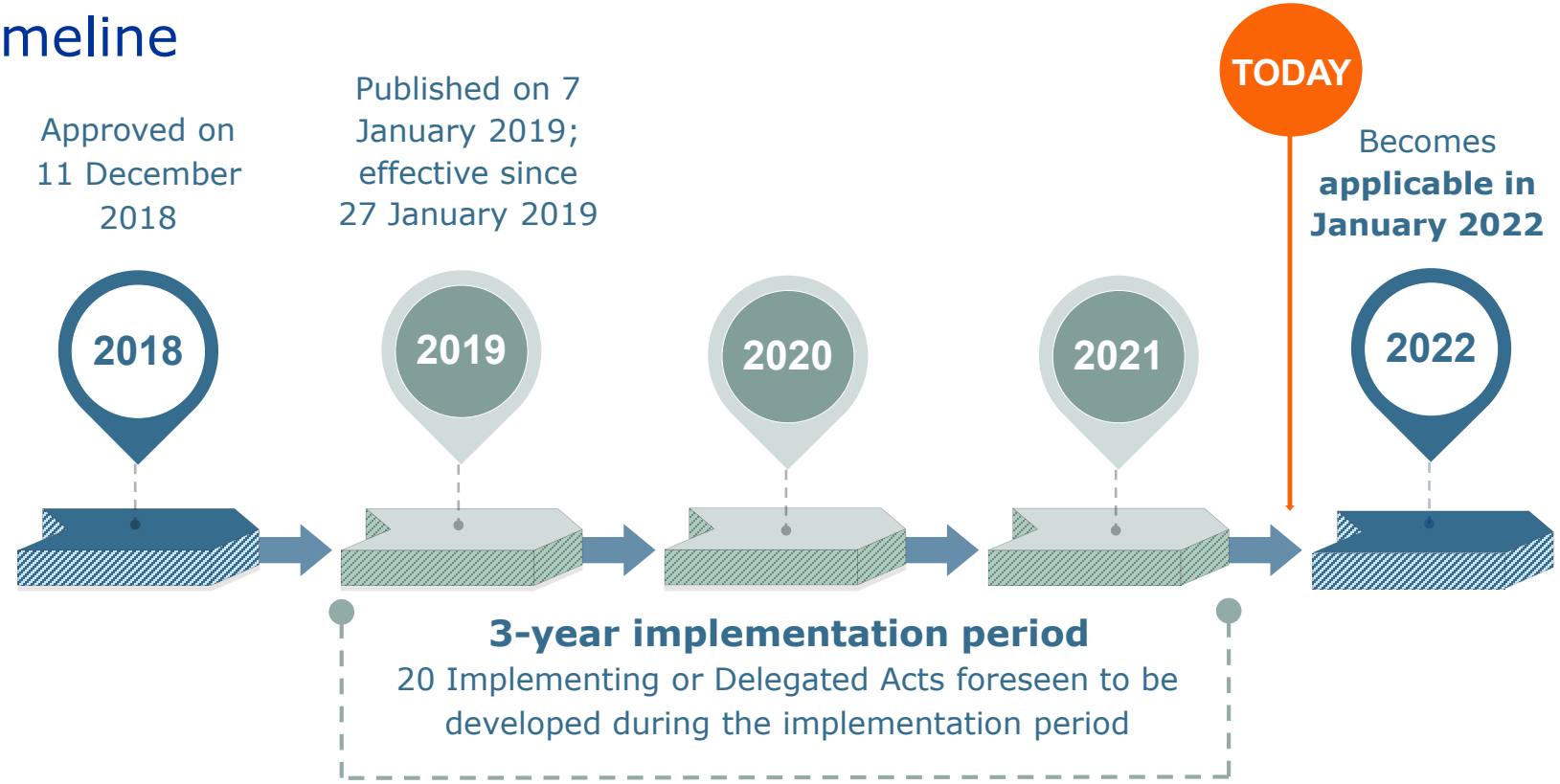
Regulation (EU) 2019/6 on veterinary medicinal products

Replaces Directive 2001/82/EC within the overall aim of achieving 'Better Regulation' in the EU

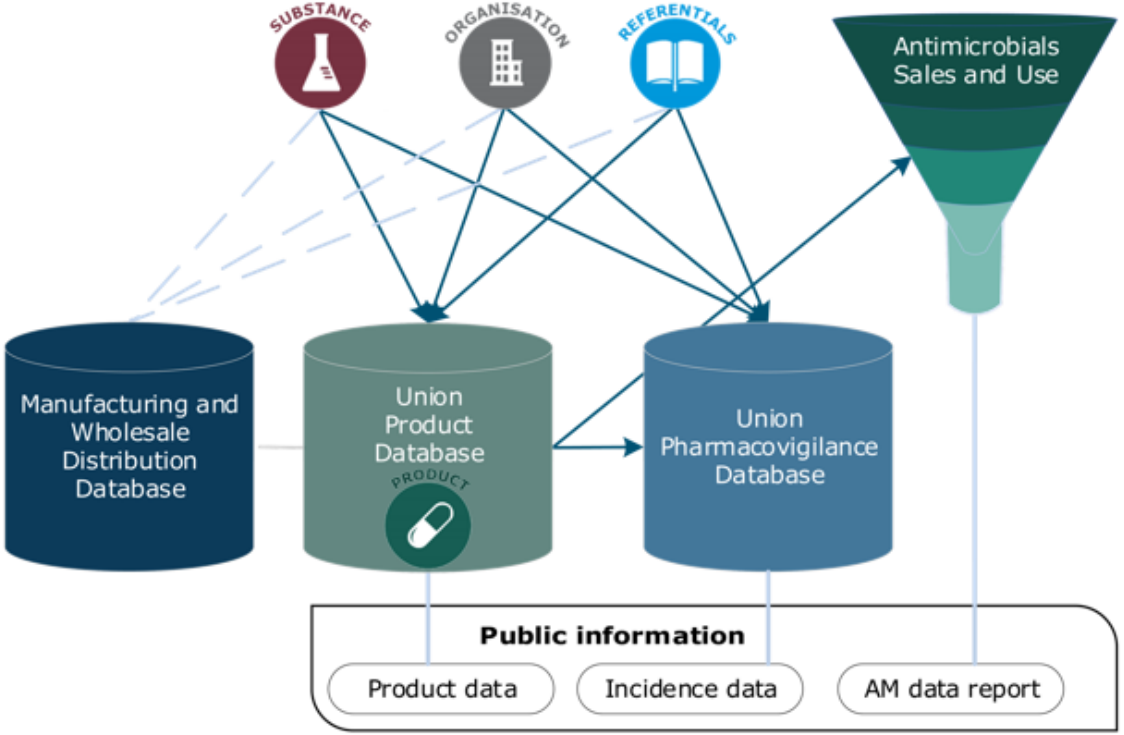


- *provides for a modern, innovative and fit for purpose legal framework*
- *gives incentives to stimulate innovation*
- *gives incentives to increase the availability of veterinary medicines*
- *strengthens the EU action to fight antimicrobial resistance*

Timeline



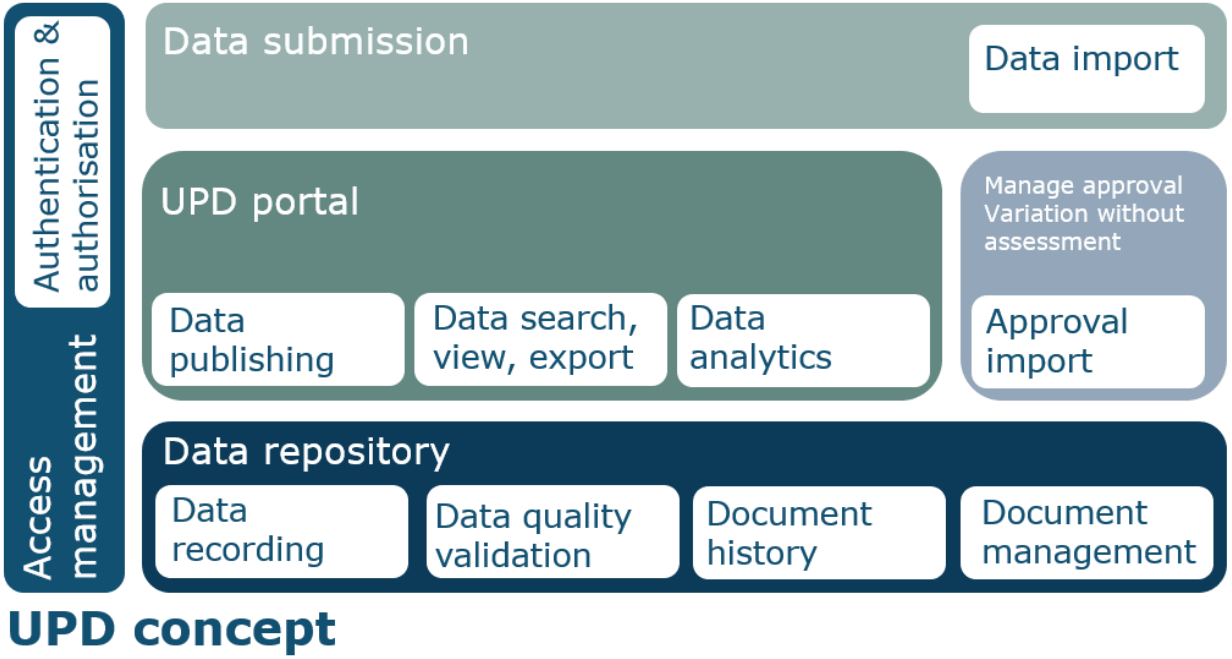
VMP-Reg programme – IT systems overview



Objectives arising from legislative requirements

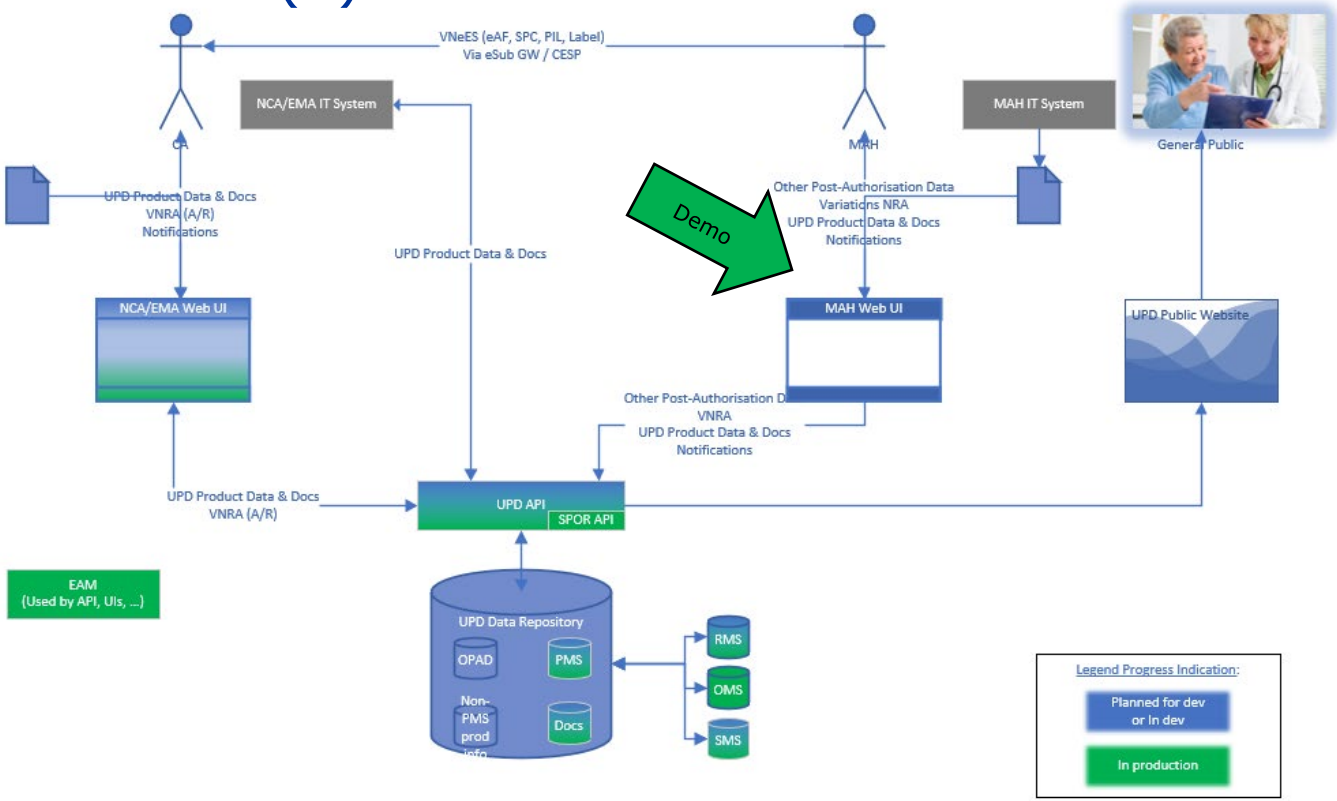
- To be the common database to collect, store and provide information about veterinary medicinal products within scope of NVR to both individual users and other, centralised/NCA systems
- To be the common database to collect, store and provide information on availability of veterinary medicinal products (VMP)
- To use structured data and controlled vocabularies in the UPD; to foster the use of controlled vocabularies for improved data quality in the regulatory processes
- To allow integration of the UPD in the activities of the regulatory network
- To support electronic exchange of product data between competent authorities and the Agency

System overview (1)



UPD concept

System overview (2)



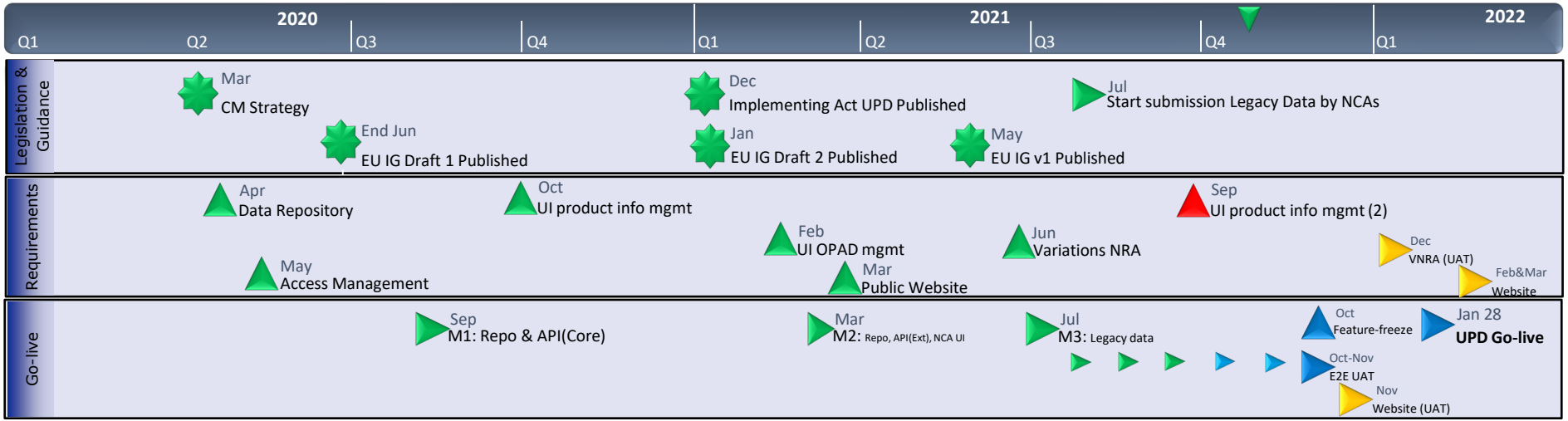
Main functionalities

- Provision of product information by NCAs
  - Manual or via provision of a file with the product information (via a Web UI or an API; FHIR standard)
  - Stored in PMS
  - Including provision of all legacy data held by NCAs (Art. 155)
- Provision of sales and availability information by MAHs via a Web UI (or an API; post-MVP)
- Support the processing of variations not requiring assessment by MAHs and NCAs
- Provide access to product information:
  - Public website for general public
  - Restricted area for NCAs and MAHs
- Access management via EMA Account Management
- Usage of SPOR controlled vocabularies & organisation data

Content

- Veterinary medicinal products authorised within the Union by the Commission and by the competent authorities
- Homeopathic veterinary medicinal products registered in accordance with Chapter V within the Union by the competent authorities
- Veterinary medicinal products allowed to be used in a Member State in accordance with Article 5(6): "… for animals which are exclusively kept as pets…" (*Note: this is not part of the Jan 22 release*)
- Information in the UPD:
  - Product information
  - Documents: SPC, PL, Labelling, Public AR
  - Information on the annual volume of sales and information on the availability of each veterinary medicinal product
  - Information related to the processing of variations without assessment: Approval/rejection by NCAs, …

Schedule and progress



Resources

- Vet EU Implementation Guide on VMP data in the UPD, Chapter 7: guidelines for MAHs
- UPD release notes
- UPD webinar for MAHs (15 September 2021) – recording, presentation, Q&As
- UPD webpage – linking to training activities for MAHs

Any questions?

Further information

vetchange.programme@ema.europa.eu

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Telephone +31 (0)88 781 6000
Send us a question Go to www.ema.europa.eu/contact

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Overview functionalities UPD Portal