EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EMA implementation activities and preparedness

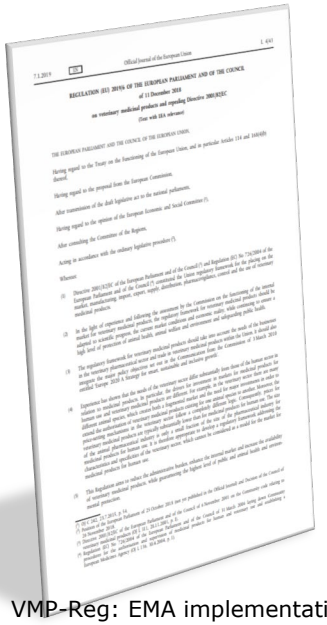
Veterinary Medicines Regulation (EU) 2019/6

Veterinary Medicines Info Day 2021

Presented by Ivo Claassen on 25 March 2021
Head of Veterinary Medicines Division

Regulation (EU) 2019/6 on veterinary medicinal products

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



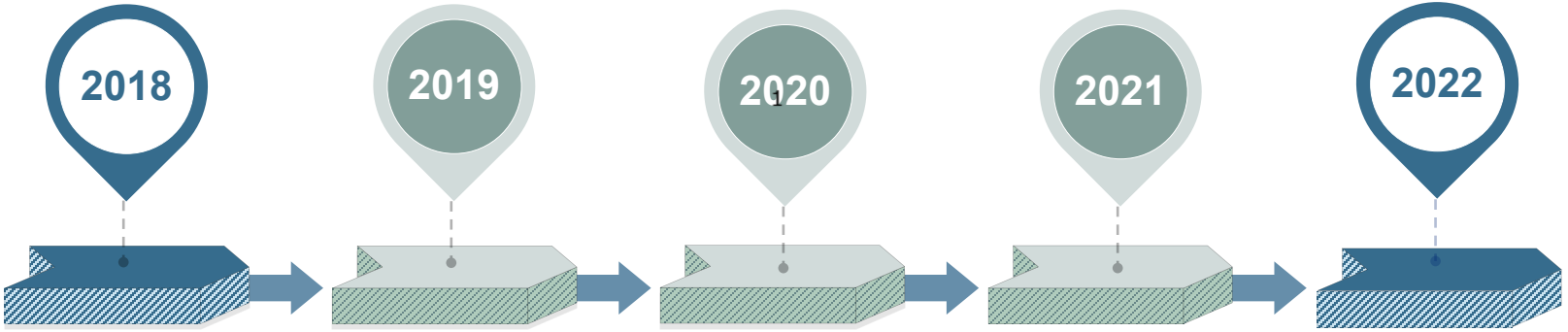
- *provides for a modern, innovative and fit for purpose legal framework*
- *gives incentives to stimulate innovation*
- *gives incentives to increase the availability of veterinary medicines*
- *strengthens the EU action to fight antimicrobial resistance*

Timeline

Approved on 11 December 2018

Published on 7 January 2019; effective since 27 January 2019

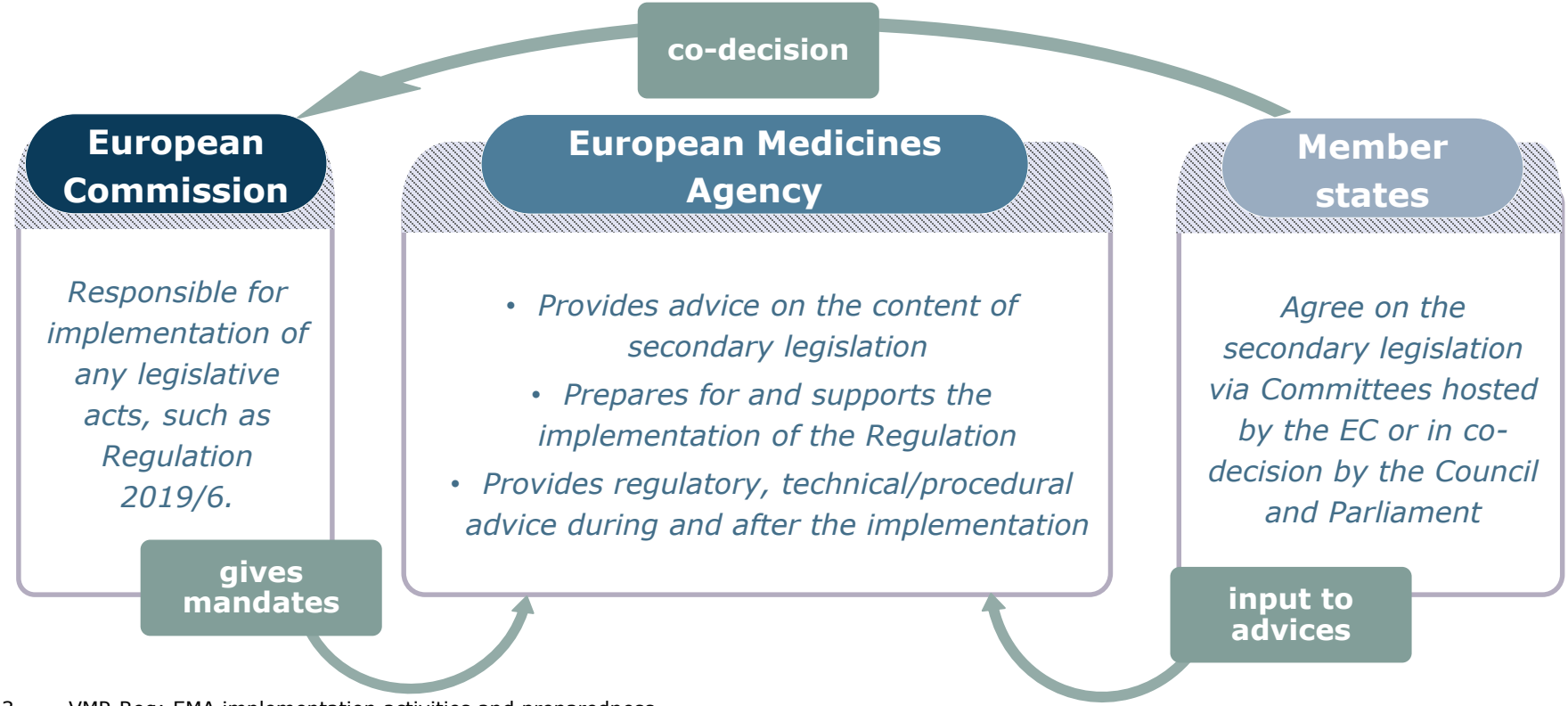
Becomes **applicable in January 2022**



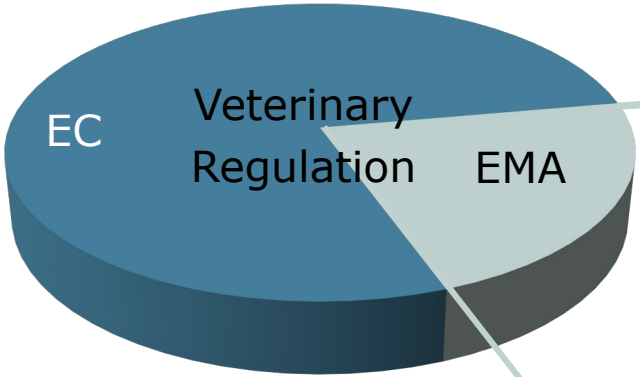
3-year implementation period

20 Implementing or Delegated Acts foreseen to be developed during the implementation period

EU network collaboration



The Agency's role in implementing the Regulation



IT systems

Revised regulatory procedures

Advice to support the drafting of several implementing /delegated acts

National competent authorities

Veterinary pharmaceutical industry

Veterinary Healthcare Professionals

General public

EU Network coordination

HMA Task Force on Coordination of the Implementation of the Veterinary Regulation (TF CIVR):

- Coordinating and facilitation body of the Network in its work on the implementation of the new regulation
- EC, NCAs, EMA
- Leading change management at national level
- Monthly meetings and regular exchange

Communication with industry (1)

February 2020, Klifovet – Expectations of the **Annex 2** proposal of Regulation 2019/6

KLIFOVET AG
ADDED VALUE TO ANIMAL HEALTH

TOPRA

October 2020, TOPRA – EMA activities on the **implementation of VMP-Reg**

2020 – Establishment of the **VMP-Reg Stakeholders Group** including industry representatives. Quarterly meetings

animalhealth europe
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EGGVP
European Group for Generic Veterinary Products

AVC
Association of Veterinary Consultants

Communication with industry (2)

- Veterinary Good Vigilance Practices Stakeholders meeting (**guidelines development**)
- **Union Product Database** (UPD), Product Owners Group
- **Union Pharmacovigilance Database** (EVV), Product Owners Group

Key challenges

- Complex programme of changes
- Short timeline
- Significant implications for MAHs and NCAs, which refer to EMA for clarifications
- Agile development – not all details are known, yet
- Implementation is a network effort involving multiple partners with different interests

The road ahead

VMP-Reg programme on track to deliver robust and sustainable systems compliant with legislative requirements

Paving the way for fine-tuning needed after January 2022

Timely communication with and active engagement of all stakeholders remains a priority

Status update VMP-Reg implementation - advices

- All submitted advices have been published on the EMA website

- The work on requests for 2 EMA advices is ongoing and on schedule to be submitted on time. This includes:
  - 1 advice on the list of antimicrobials to be reserved for human use;
  - 1 advice on list of substances not to be used or used subject to certain conditions under the so-called 'cascade'.

Overview of ongoing work to support the implementation of the VMP-Reg (1)

- Art. 40(5) of Regulation (EU) 2019/6 (data protection for variations involving a change to the pharmaceutical form, administration route or dosage). Public consultation of concept paper now finished, reflection paper in progress.
- Article 18(7) Reflection paper on potential risks of generics to the environment to be published for public consultation by Q2 2021
- Draft of scientific guidelines and reflection paper on eligibility on Limited Markets ongoing (art. 23 and 24). Guidelines and reflection paper published for consultation until Mid May 2021.
- Revised QRD templates released on Monday 29 March for 7-wk public consultation.

Overview of scheduled work to support the implementation of the VMP-Reg (2)

- To update relevant scientific and regulatory guidelines according to legal basis and definitions
- To revise/update CVMP benefit:risk guidance
- To update guidance on eligibility of centrally authorisation products
- To develop guidance for Art 42(4) Enlarging the scope of the centralised procedure
- To update CVMP rules of procedure

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.

Database on Manufacturers and Wholesale Distributors database

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

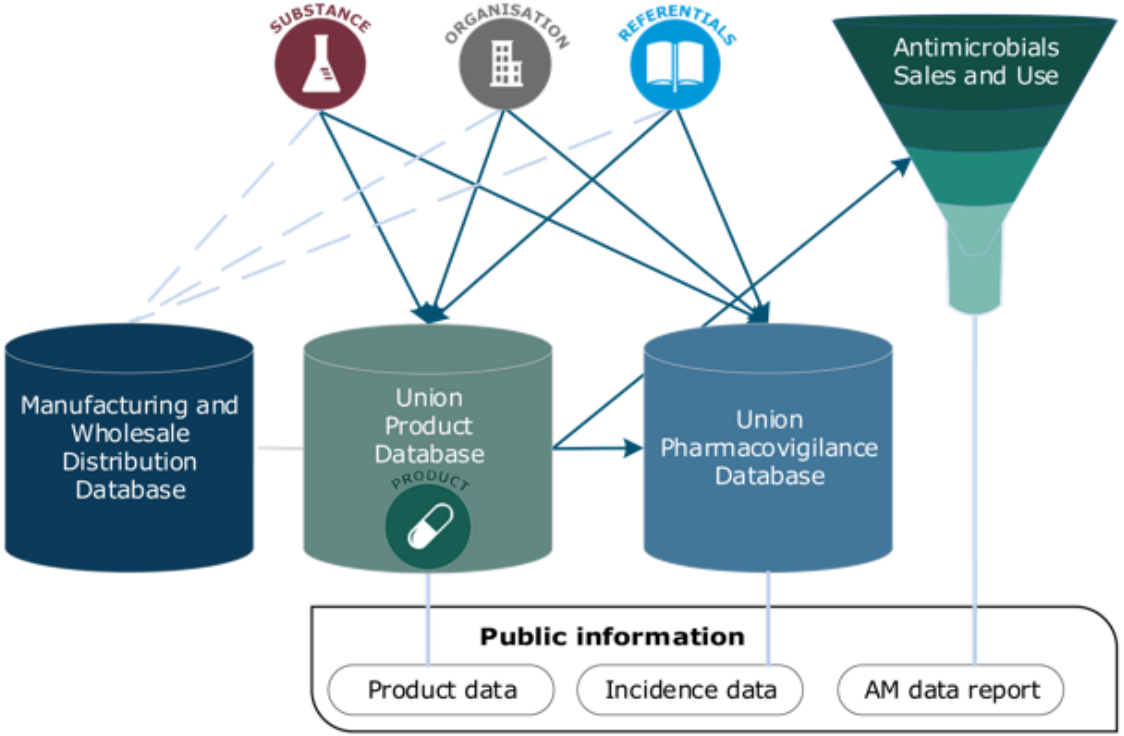
Collection of Antimicrobials Sales and Use data

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

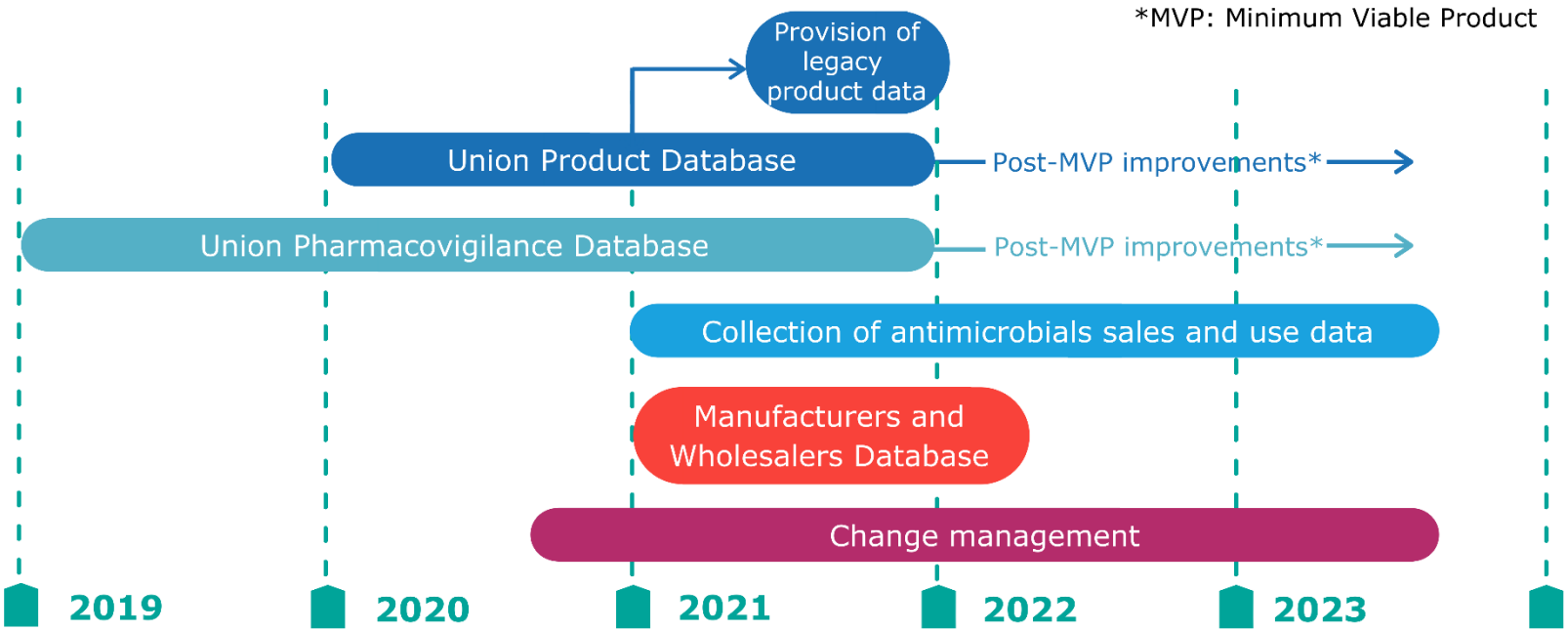
Required interconnections

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

VMP-Reg programme – IT systems overview

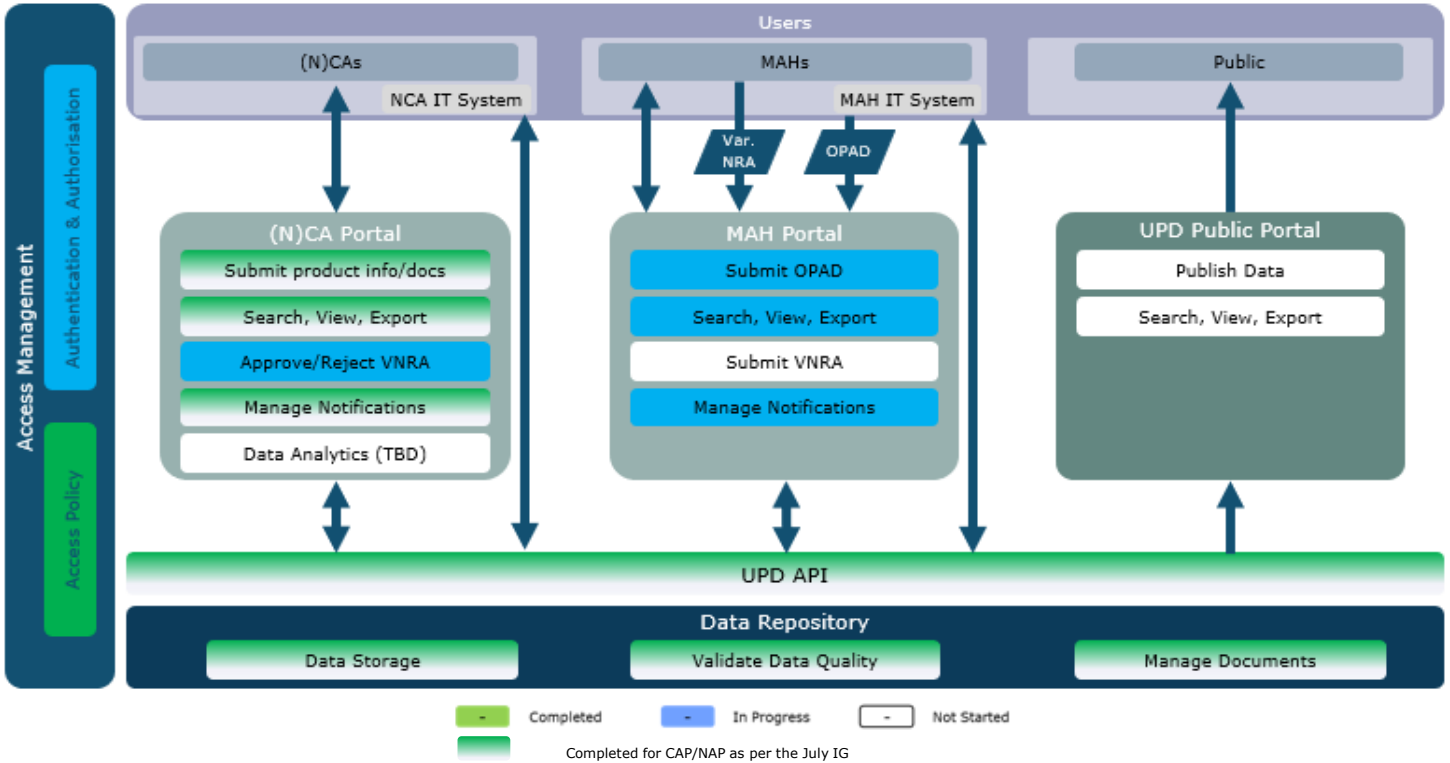


VMP-Reg programme – IT systems timeline

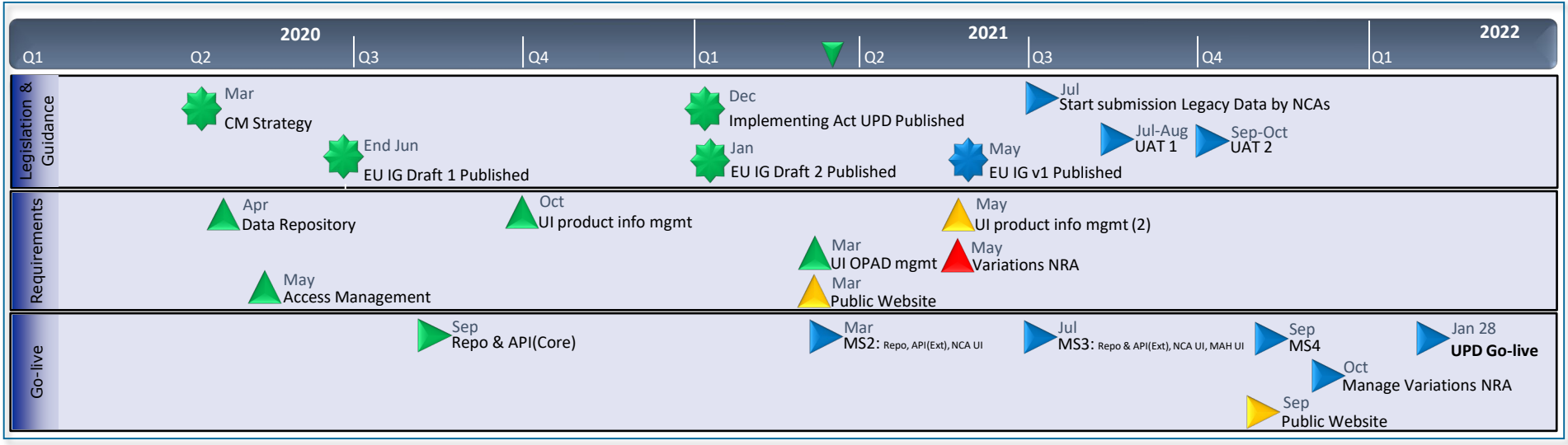


Union Product Database (UPD)

UPD project update: scope



UPD project: timeline



The project is on track to deliver the MVP by Jan 2022, as currently understood from the Implementing Act.

UPD project: delivery (1)

- Most recent go-live on 16 March 2021 (release notes)
- Ongoing alignment of legislative requirements and technical feasibility (of some elements), following version of Implementing Act on UPD specifications
- Ongoing user research for public website; usability testing on NCA user interface starting
- Start gathering of detailed requirements for variations not requiring assessment
- Industry represented in Product Owners group

UPD project: delivery (2)

- Continuation informal user acceptance testing with NCAs of the UPD data repository and API; preparation of end-to-end user acceptance testing initiated
- UPD Access Policy published
- EU Vet Implementation Guide published for 2 months consultation, concluded on 21 March

Union Pharmacovigilance Database (EVV)

EVV project: scope and progress

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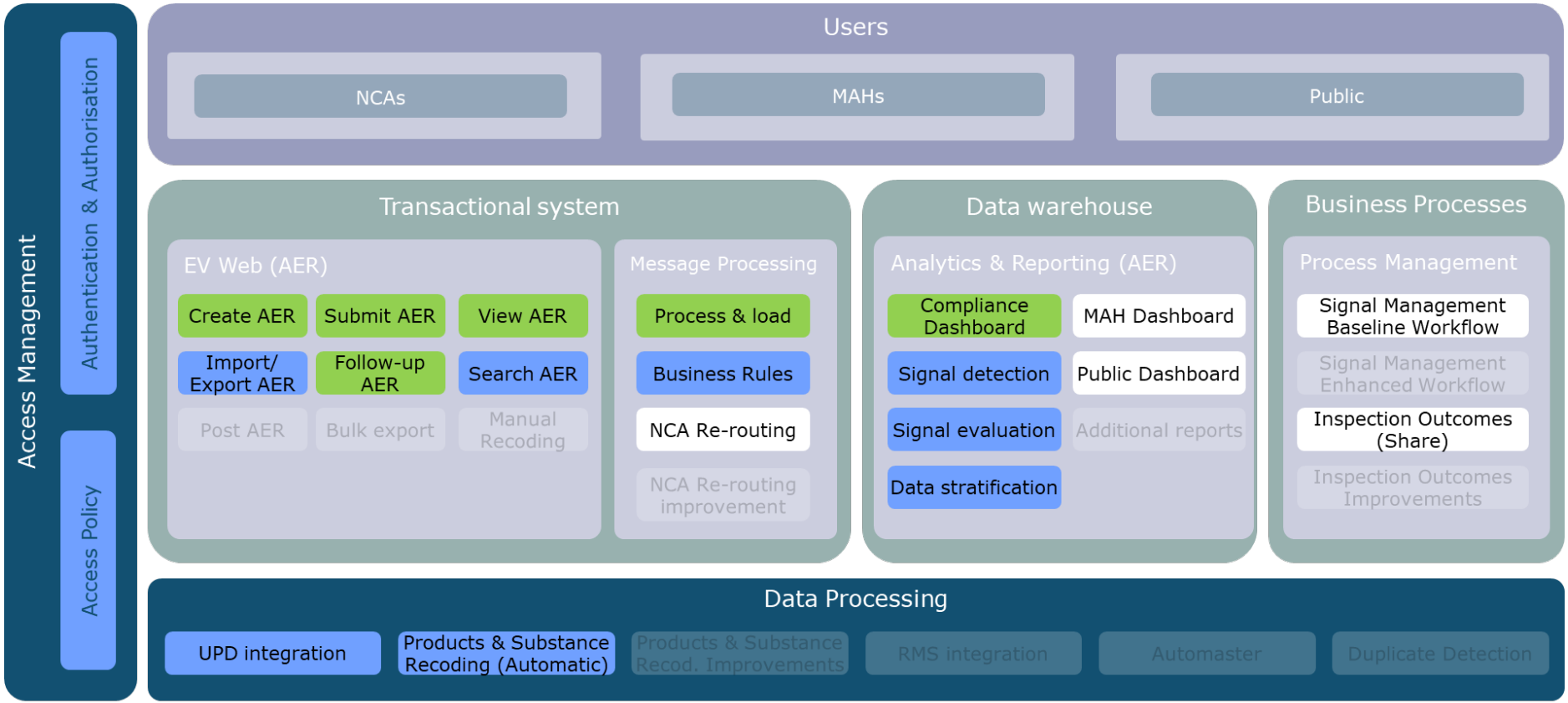


EVV project: delivery (1)

- EVVet Access Policy revision published for consultation until 12 March (https://www.ema.europa.eu/documents/regulatory-procedural-guideline/eudravigilance-access-policy-medicines-veterinary-use-revision-2_en.pdf)
- Drafting of implementation guide for EVV ongoing in Product Owners Group (which included industry representatives)
- Analysis of signal management initiated

EVV project: delivery (2)

- **Common messaging platform**: additional issues resolved on documentation of VICH message; continued implementation of the business rules; continued development of UPD integration and automatic recoding (data quality)
- **Data Warehouse:** mock-ups for all dashboards of previous work package reviewed, continued implementation of signal evaluation, data stratification, authentication and authorisation
- **EVWEB:** Completed user acceptance testing of download/export, import DEG and access policy; some issues outstanding in relation to mappings between DEG and VICH; continued implementation of search AER, access policy, authentication and authorisation

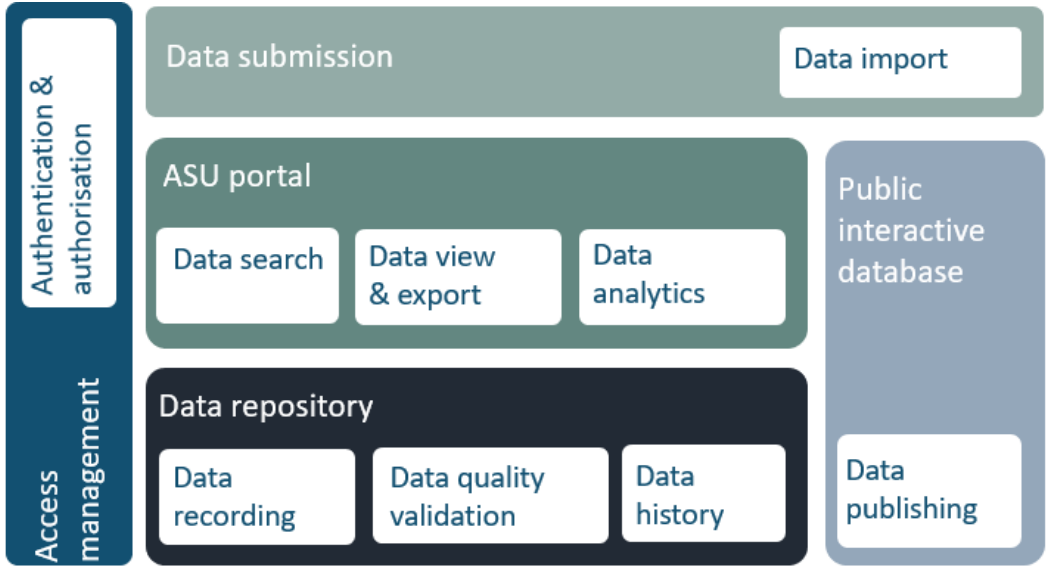
EVV – DEG/VICH formats

- Submission of DEG (old standard) reports will be possible during a transition period – tentatively for at least 6 months; however
- Download of reports from EVWEB will be in VICH format only (DEG format potentially possible only for reports received in DEG format)

➢ **Everyone (MAHs and NCAs) must be able to *read* VICH standard messages from go-live onwards!**

Collection of Antimicrobials Sales and Use (ASU) Project

ASU project: concept



ASU concept

ASU project: update

- ASU project established and Project Group operational since January 2021
- Current scope until end of April 2021: preparation of business case to obtain approval for delivery of collection system
- Drafting of project vision ongoing
- Drafting of high-level business requirements (based on known/draft legislative requirements) ongoing
- Project timeline and options analysis under discussion

Manufacturers and Wholesale Distributors database (MWD)

MWD project status update

- MWD project initiated; Project Group to be established soon
- Objective: to bring EudraGMDP in line with legislative requirements arising from Regulation (EU) 2019/6
- Current scope until end of April 2021: preparation of business case to obtain approval for delivery of changes to EudraGMDP system
- Drafting of project vision initiated
- Drafting of high-level business requirements (based on known/draft legislative requirements) initiated

Change management approach

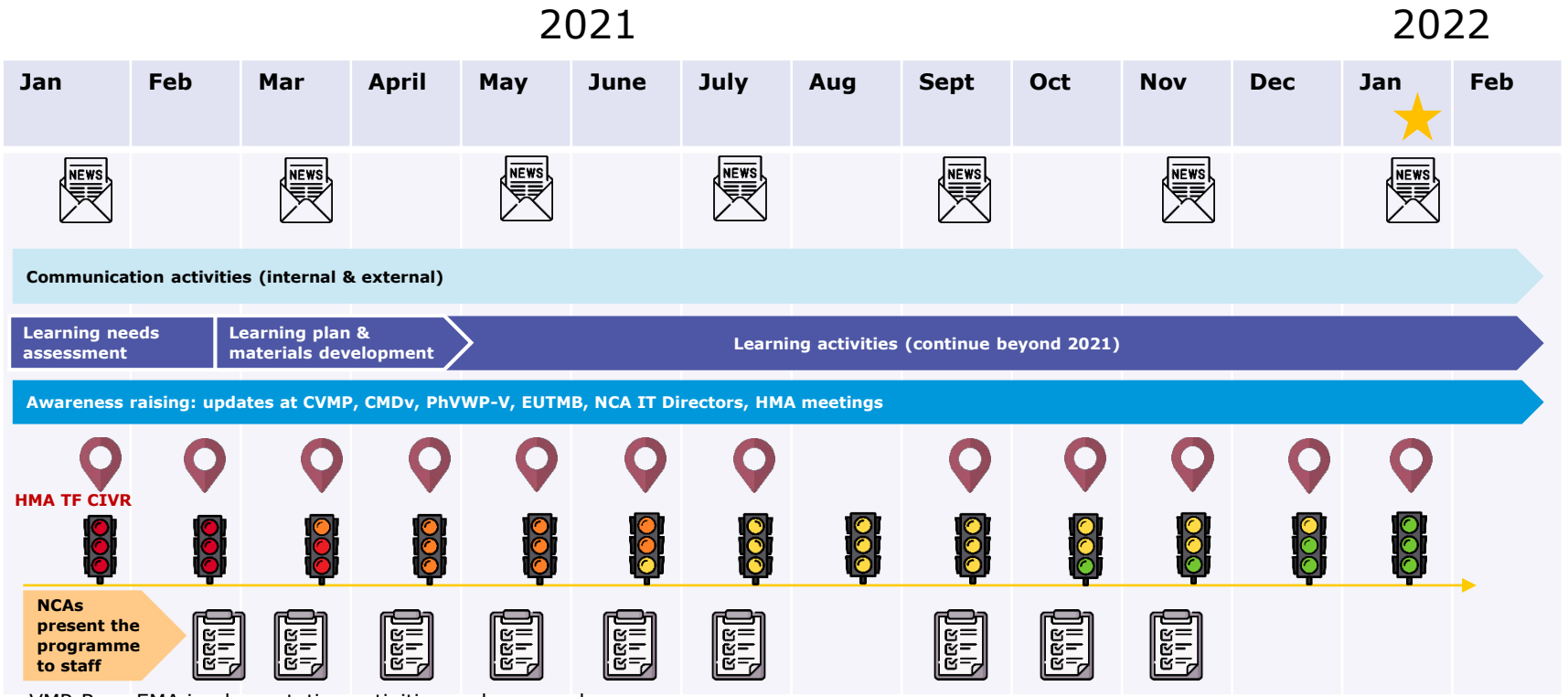
Change management: goal, scope & governance

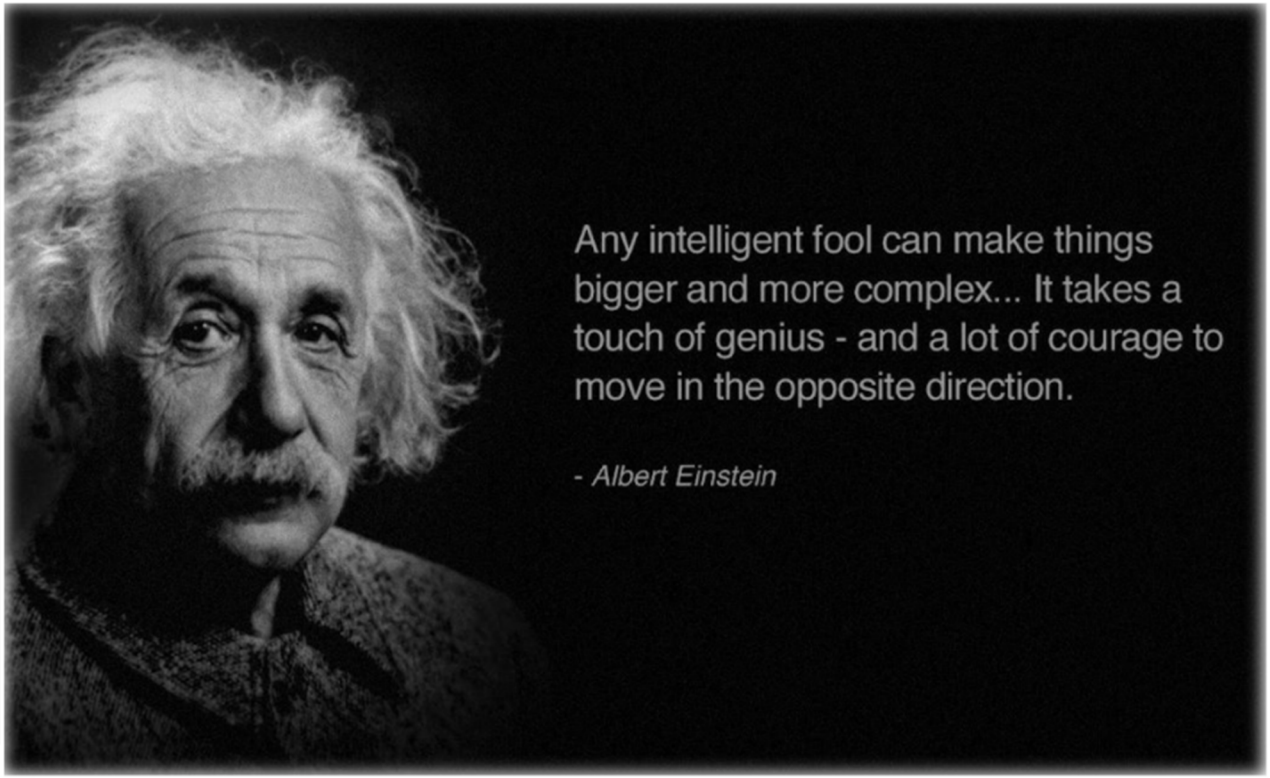
Goal: optimise the implementation and **adoption** of IT and corresponding business changes resulting from delivery of new IT systems that EMA is delivering to support the implementation of the VMP-Reg

Scope: planning and delivery of communications, engagement and training activities to partners and stakeholders across the programme

Governance: Involvement and participation in the change management effort across stakeholder and partner network -- **VMP-Reg Stakeholders Group** established to channel information to the industry and veterinarians community

Change management timeline





Any questions?

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