EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Delivering EU Regulation 2019/6 - *Climbing the mountain together*

The road to 'V-Day' and beyond

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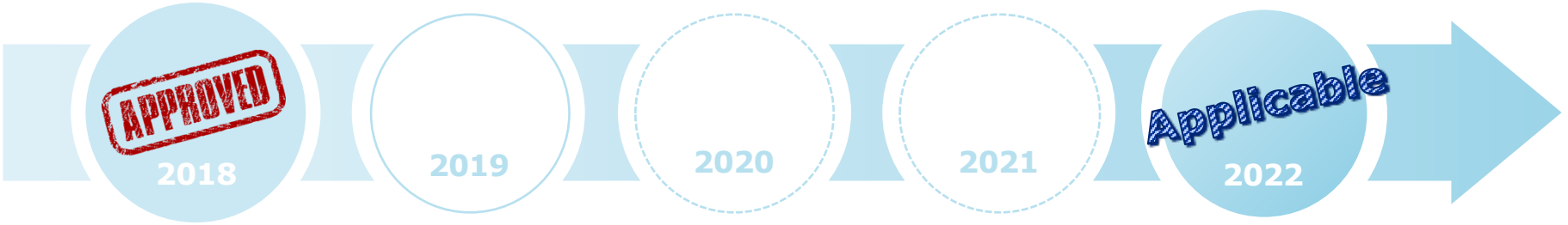
Head of Veterinary Medicines Division

An agency of the European Union

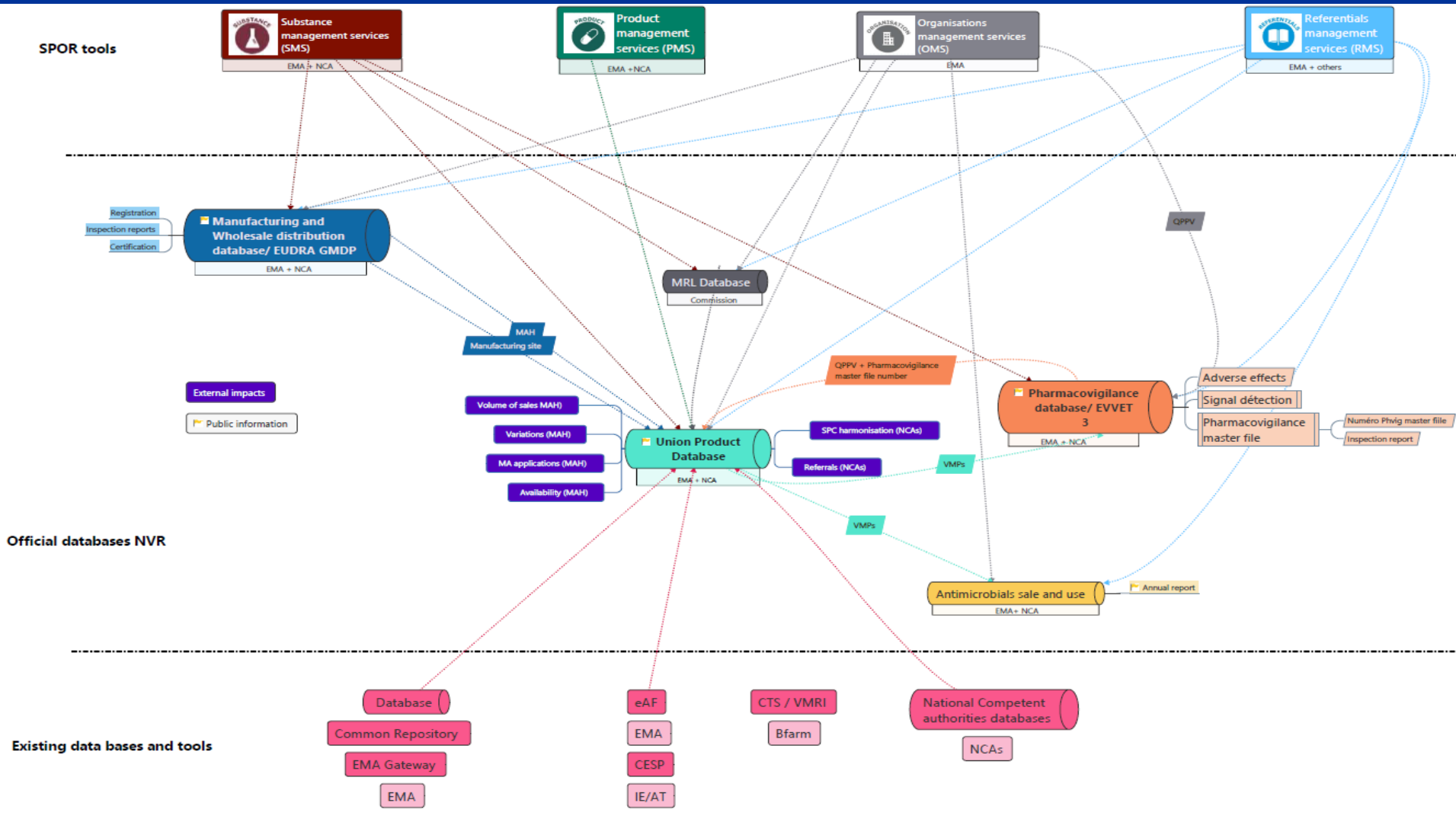
Regulation (EU) 2019/6

- published on 7 January 2019; effective since 27 January 2019; applicable since 28 January 2022
- secondary legislation on specific topics, such as pharmacovigilance and data collection on sale and use of antimicrobials developed in implementation period

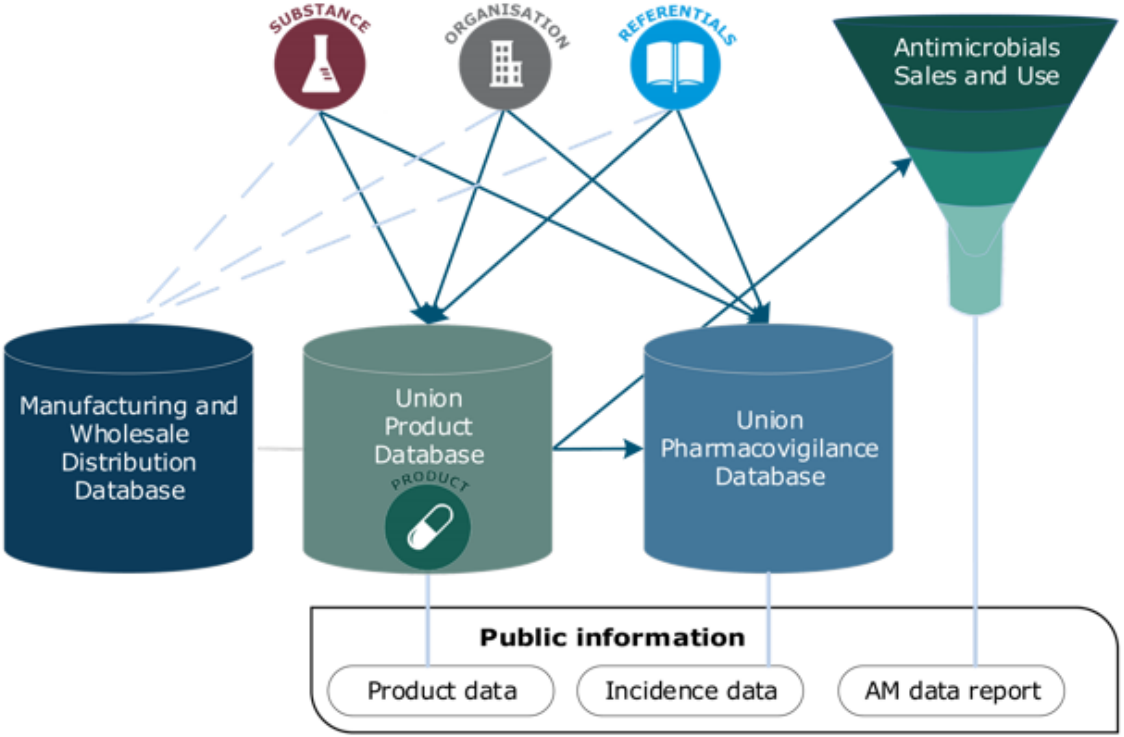


Flashback to 2019/2020

- VMP-Reg programme **established** to deliver on the IT systems required by Regulation (EU) 2019/6
- In the midst of a pandemic, the programme success remained a **priority** for EMA
- Excellent **collaboration** was key
  - National competent authorities (e. g. HMA Task Force on the Coordination of the Implementation of the Veterinary Regulation, HMA TF CIVR)
  - Pharmaceutical Industry (AnimalhealthEurope, Access VetMed)
  - Federation of Veterinarians of Europe (FVE)


SPOR tools
Substance management services (SMS)
EMA + NCA
Product management services (PMS)
EMA +NCA
Organisations management services (OMS)
EMA
Referentials management services (RMS)
EMA + others
Registration
Inspection reports
Certification
Manufacturing and Wholesale distribution database/ EUDRA GMDP
EMA + NCA
MRL Database
Commission
QPPV
MAH
Manufacturing site
External impacts
Public information
QPPV + Pharmacovigilance master file number
Pharmacovigilance database/ EVVET 3
EMA + NCA
Adverse effects
Signal détection
Pharmacovigilance master file
Numéro Phvig master file
Inspection report
Volume of sales MAH)
Variations (MAH)
MA applications (MAH)
Availability (MAH)
Union Product Database
EMA + NCA
SPC harmonisation (NCAs)
Referrals (NCAs)
VMPs
VMPs
Official databases NVR
Antimicrobials sale and use
EMA+ NCA
Annual report
Database
Common Repository
EMA Gateway
EMA
eAF
EMA
CESP
IE/AT
CTS / VMRI
Bfarm
National Competent authorities databases
NCAs
Existing data bases and tools

VMP-Reg programme – IT systems overview



Today

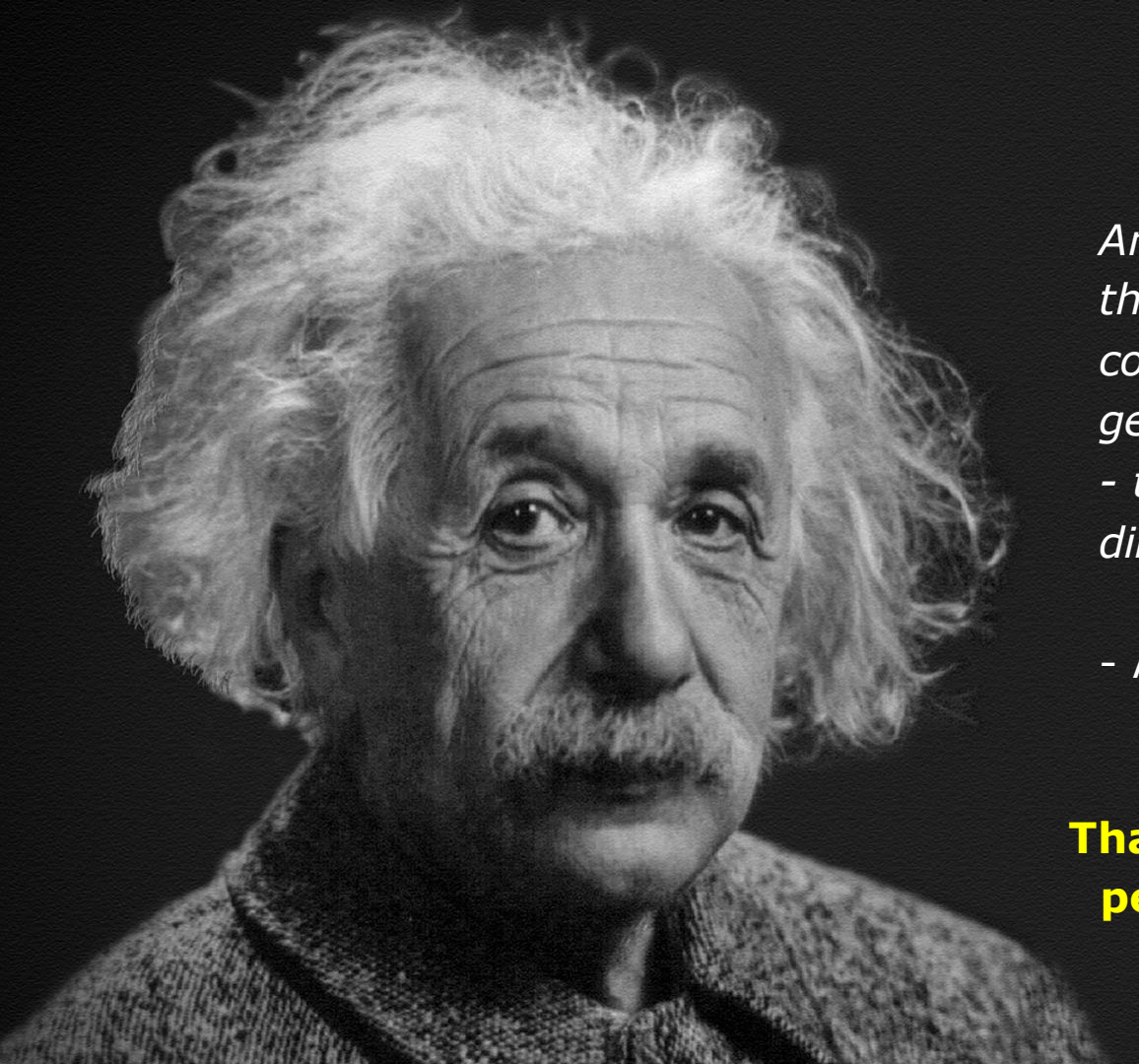
- Major regulatory changes → towards **"better administration"** in EU
- VMP-Reg programme delivered **on time** - three IT systems live since 28 January
  - **UPD**: Union Product Database is the first **central** database on veterinary medicinal products; also **first** network IT system compatible with ISO IDMP
  - **EVV**: Union Pharmacovigilance Database connected to UPD, compliant with **VICH** standards, new procedure for signal management
  - **MWD**: EudraGMDP aligned with veterinary requirements
- First public website with information on **all veterinary medicines** authorised in EU/EEA

Today

- **Pharmacovigilance**: significant reduction in administrative burden, signal management is designed to be less resource-intensive, more effective process
- Increased monitoring in **antimicrobial sales and use**: project initiated and is delivering according to schedule; first submission under new rules in 2024
- Programme paved the way for continued **improvements in functionality and data quality**
- Reduction of administrative burden expected after current change/**transition** period

Lessons learnt

- **Scope management** - focus on must-have functionalities for January 2022
- **Collaboration** – deliver together with network, industry & veterinary professionals
- **Governance** – ensure roles, responsibilities and decision lines are clear
- **Expectation management** as a continuous exercise:
  - Not all benefits will be realized immediately
  - Everyone needs to learn how to operate in the new normal
  - Continuous processes improvement needed
- Potential **efficiency gains** depend on how successful we ALL are in the implementation and our willingness to adopt new ways of working



Any intelligent fool can make things bigger and more complex…It takes a touch of genius – and a lot of courage - to move in the opposite direction.

- Albert Einstein

Thank you for your courage & persistence on this journey with us!

Further information

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