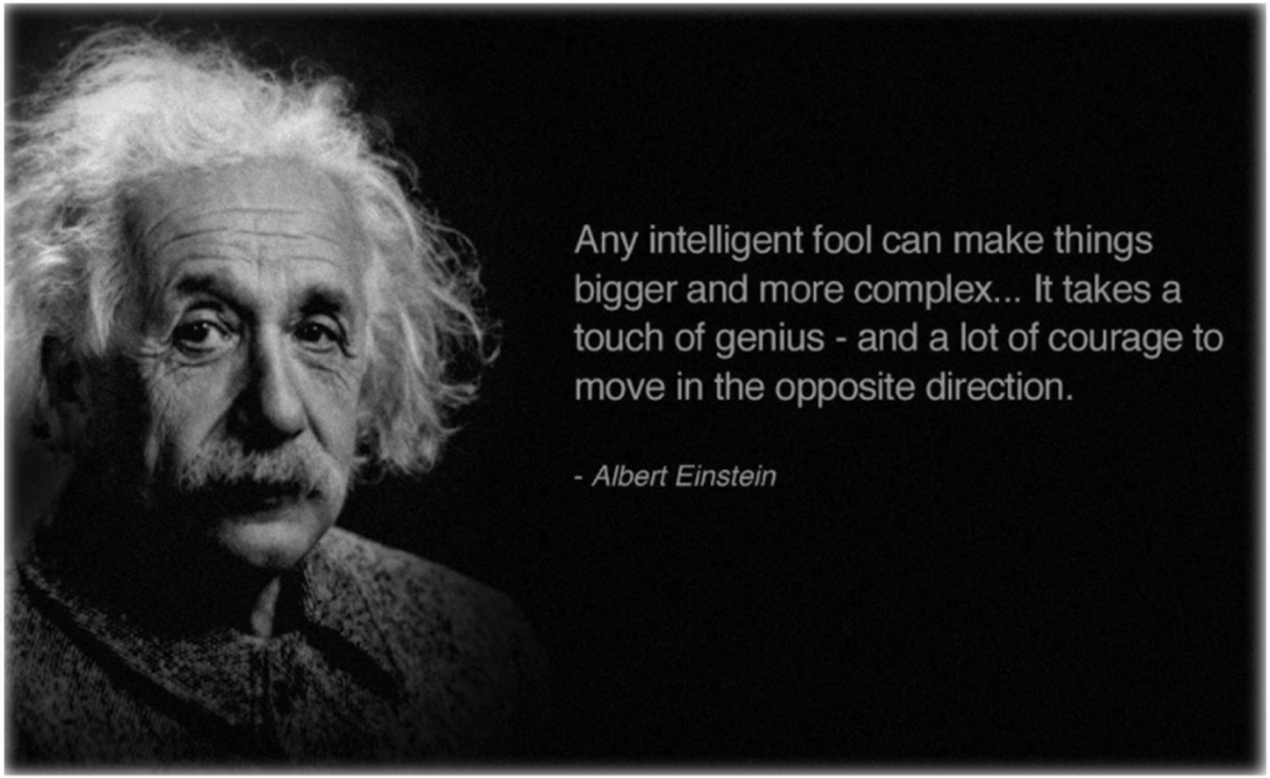
EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Updates on the implementation of VMP-Reg and secondary legislation

Veterinary Medicines Regulation (EU) 2019/6

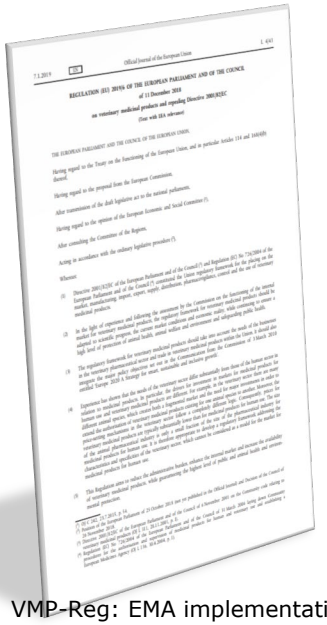
EMA Info Day II 2021

Presented by Ivo Claassen on 30 November 2021
Head of Veterinary Medicines Division



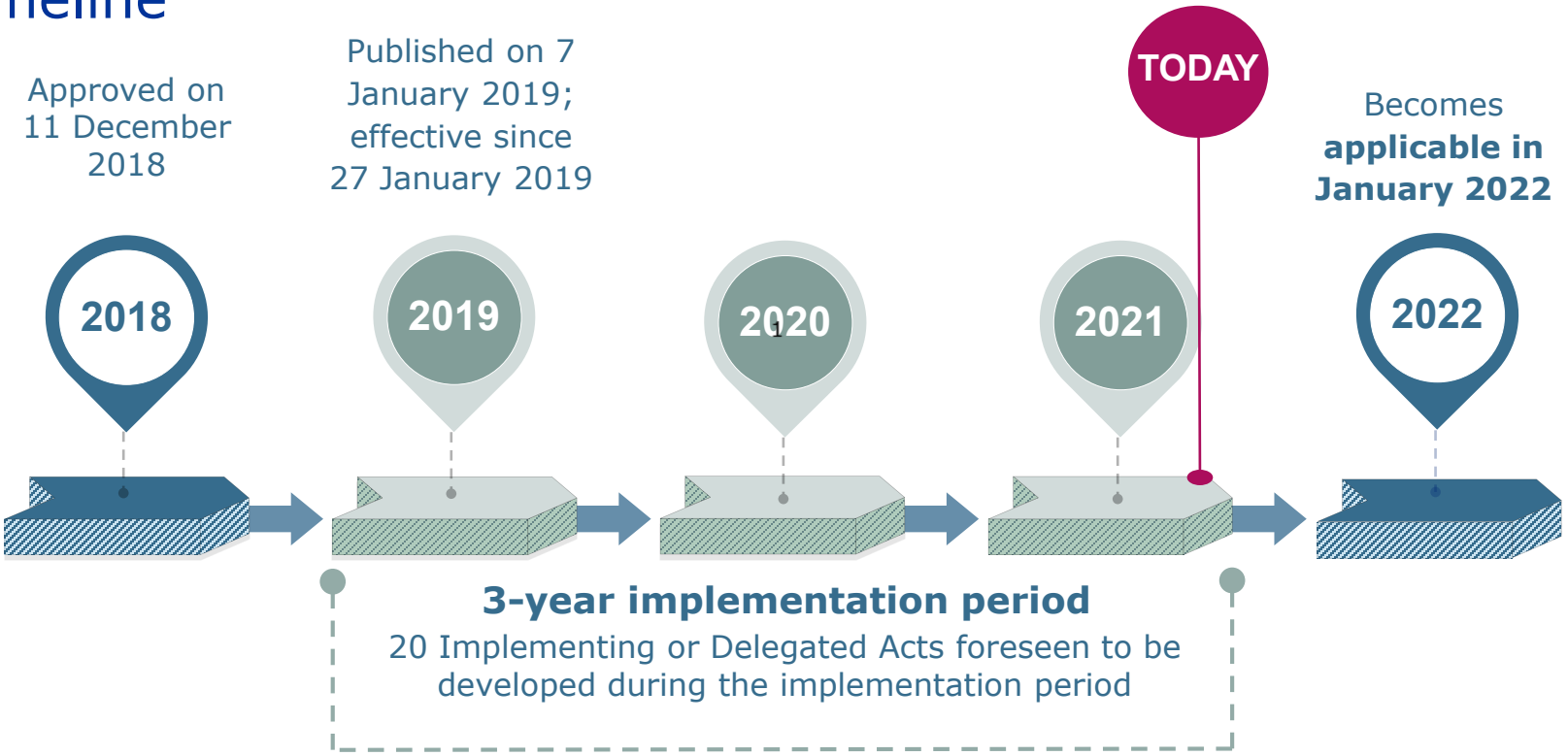
Regulation (EU) 2019/6 on veterinary medicinal products

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



EU Network coordination

EMA/HMA Task Force on Coordination of the Implementation of the Veterinary Regulation (TF CIVR) since September 2018:

- 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 stakeholders

- UPD/EVV Product Owners groups
- Newsletters, mailings via industry associations
- Webinars/trainings
- Focus groups (guideline development)

TOPRA – EMA activities on the implementation of VMP-Reg and veterinary data strategy

VMP-Reg Stakeholders Group

Quarterly meetings

animalhealth europe – THE VOICE OF THE ANIMAL MEDICINES INDUSTRY

Access VETMED

AVC – Association of Veterinary Consultants

FVE – Federation of Veterinarians of Europe

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; first improvements have been prioritised

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:
  - 1 advice on the list of antimicrobials to be reserved for human use (by February 2022);
  - 1 advice on list of substances not to be used or used subject to certain conditions under the so-called 'cascade' (by March 2022).

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

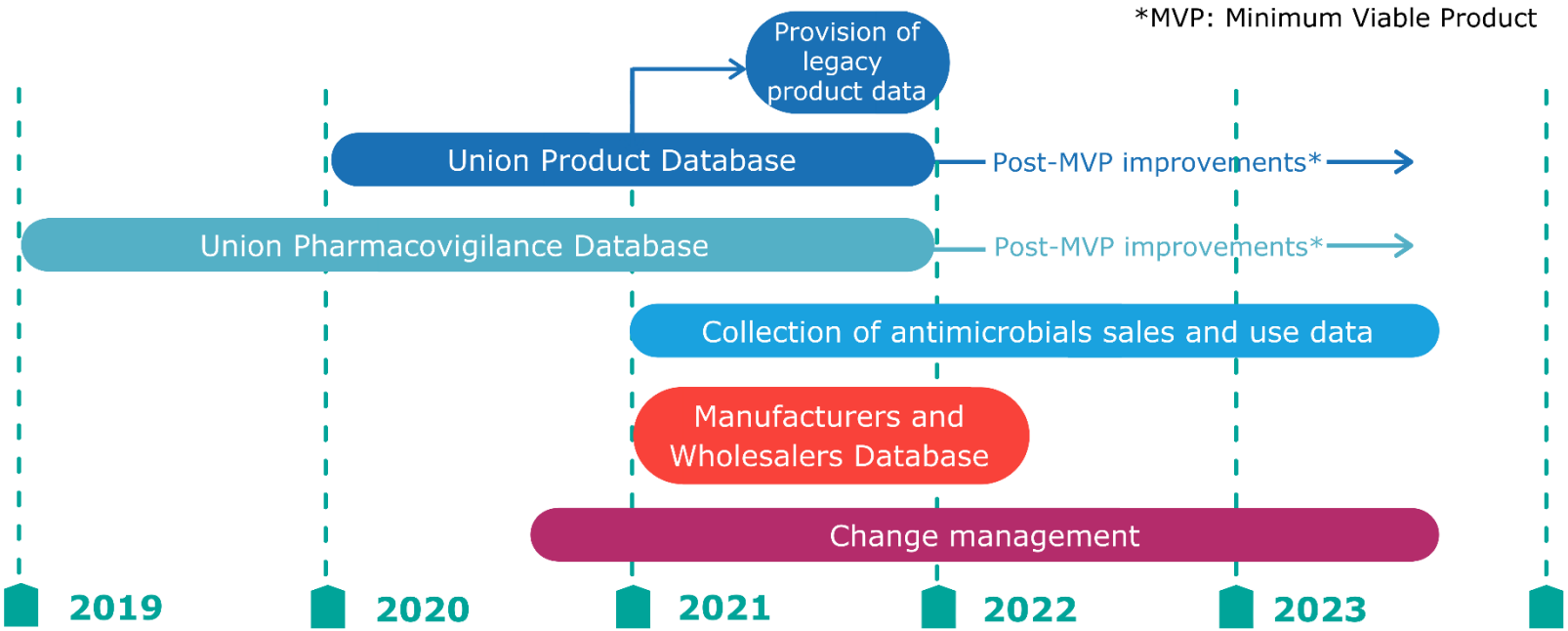
- Art. 40(5) of Regulation (EU) 2019/6 (data protection for variations involving a change to the pharmaceutical form, administration route or dosage): concept paper public, reflection paper is being drafted for public consultation
- Reflection paper on the interpretation of Article 18(7) published for public consultation on 17 September
- Guidelines and reflection paper on eligibility on Limited Markets (art. 23 and 24) revised after consultation. Work on products for Limited Markets that do not comply with Article 23 ongoing
- Revised QRD templates published

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

- Revised implementing rules to EMA's **Fee Regulation** will apply from 28 January 2022, to take account of the Veterinary Medicines Regulation. For more information, see Fees payable to the European Medicines Agency
- Guidance on Veterinary Good Pharmacovigilance Practice: published
- Guidance on variations: published

Keep consulting the EMA website and newsletter: additional guidance is being published continuously (incl. updated Q&As)

VMP-Reg programme – IT systems timeline



UPD project

- Most recent go-live on 29 October 2021 (release notes)
- EU Vet Implementation Guide: new Chapter 7 describing MAH actions
- Progress on product data upload: over 2,500 product entries in UPD production

EVV project

- Revised EVVet Access Policy published
- EVV implementation guide published
- On track for go live on 28 January 2022

MWD project

- Objective: bring EudraGMDP in line with legislative requirements arising from Regulation (EU) 2019/6
- 3 modules (MIA, GMP and API-Reg) completed and in User Acceptance testing
- 1 module (WDA) in development, user acceptance with NCAs scheduled for January
- GDP module alignment: no legislative requirement but will be delivered in Q1 2022
- Webinar for industry on integration of EudraGMDP with OMS (12 October, recording, presentations, Q&As on event page)

Change management

- Training sessions for industry on UPD, EVV, MWD published
- Q&As on UPD for industry users published
- Q&As on EVV for industry to be published shortly
- Rolling assistance via vetchange.programme@ema.europa.eu
- VMP-Reg newsletter

Dedicated helpdesk

- Agency ready to support stakeholders after 28 January go live for UPD, EVV, MWD
- Dedicated staff for post go-live support – technical and business
- Initially for 6 months

Almost in 2022

- The VMP-Reg implementation journey will not end on 28 January
- In 2022, we will all learn how to live our ‘new normal’
- Flexibility and workarounds
- Multi-stakeholder collaboration will remain key.

Any questions?

Further information

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