



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Updates on the implementation of VMP-Reg and secondary legislation

Veterinary Medicines Regulation (EU) 2019/6

Veterinary Medicines Info Day 2022

Presented by Ivo Claassen on 12 May 2022
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An agency of the European Union





VMP-Reg programme status update

- Manufacturer and Wholesale Distributors database: live since **28 January 2022**
- Union Product Database: live since **28 January 2022**
 - Subsequent monthly releases of fixes, improvements and additional functionality
 - Functionality still pending for parallel traded products (planned for late June/July)
- Union Pharmacovigilance Database: live since **28 January 2022**
- Antimicrobial Sales and Use data collection: development started in January 2022



Legacy data submission status update

	Product in UPD (Permanent IDs)	National dataset in UPD	National dataset completeness Rate (%)
Decentralised Procedure	25222	14922	
Mutual Recognition Procedure	3556	3472	
National Procedure	12150	12150	
Centralised Procedure	592	592	
Subsequent Recognition Procedure	313	95	
Total	41833	31231	75

- **41,833** product entries in UPD Production (out of ca. 42,000 expected as per estimates from NCAs in November 2020 $\approx$ 100%);
- “National data” only applies to MRP/DCP/SRP products where the data has to be completed by the CMS
- NCAs are being contacted and supported individually in final push towards completion



Several helpdesk channels available

- Dedicated user support via EMA service desk for:
 - UPD: <https://servicedesk.ema.europa.eu/jira/servicedesk/customer/portal/283/group/506>
 - EVV: <https://servicedesk.ema.europa.eu/jira/servicedesk/customer/portal/283/group/505>
 - EudraGMPD:
<https://servicedesk.ema.europa.eu/jira/servicedesk/customer/portal/283/group/507>
- Other EMA system-related issues: <https://servicedesk.ema.europa.eu/>;
- Regulatory questions via Ask EMA: <https://www.ema.europa.eu/en/about-us/contact/send-question-european-medicines-agency>;
- Other questions via functional mailbox: vetchange.programme@ema.europa.eu.



Change management update

- Priority remains to support NCAs to complete legacy data upload and support all users of the systems released
- Several webinars for NCAs and industry organised since December (UPD, EVV, MWD); recordings, presentations, Q&As available on EU NTC (for NCAs) and EMA website (for industry), respectively
- VMP-Reg newsletters adjusted to quarterly frequency



Veterinary IT systems improvements advisory group (VSIAG)

- Group to prioritise requirements after the programme has closed: kick-off meeting held on 5 April 2022;
- VSIAG members:
 - **MSs:** 8 representatives
 - **Industry:** C. Anton, T. Simon, B. Beutel, M. Colmorgen, R. Bhui and V. Vinot (AhE) S. Schwab and J. Petrič (Access VetMed)
 - **Animal Healthcare professionals:** 3 representatives
 - **EC:** 2 representatives
 - **EMA:** 2-3 representatives & participation of further EMA staff as needed
- Prioritisation of system improvements continues in current governance until summer
- Next VSIAG meeting in June to familiarise members with product backlogs



Status update VMP-Reg implementation - advices

- All submitted advices have been published on the [EMA website](#)
- The work on requests for one EMA advice is ongoing and on schedule to be submitted on time: 1 advice on list of substances not to be used or used subject to certain conditions under the so-called 'cascade'
- Further requests for advice expected later in 2022 (e. g. on GMP)

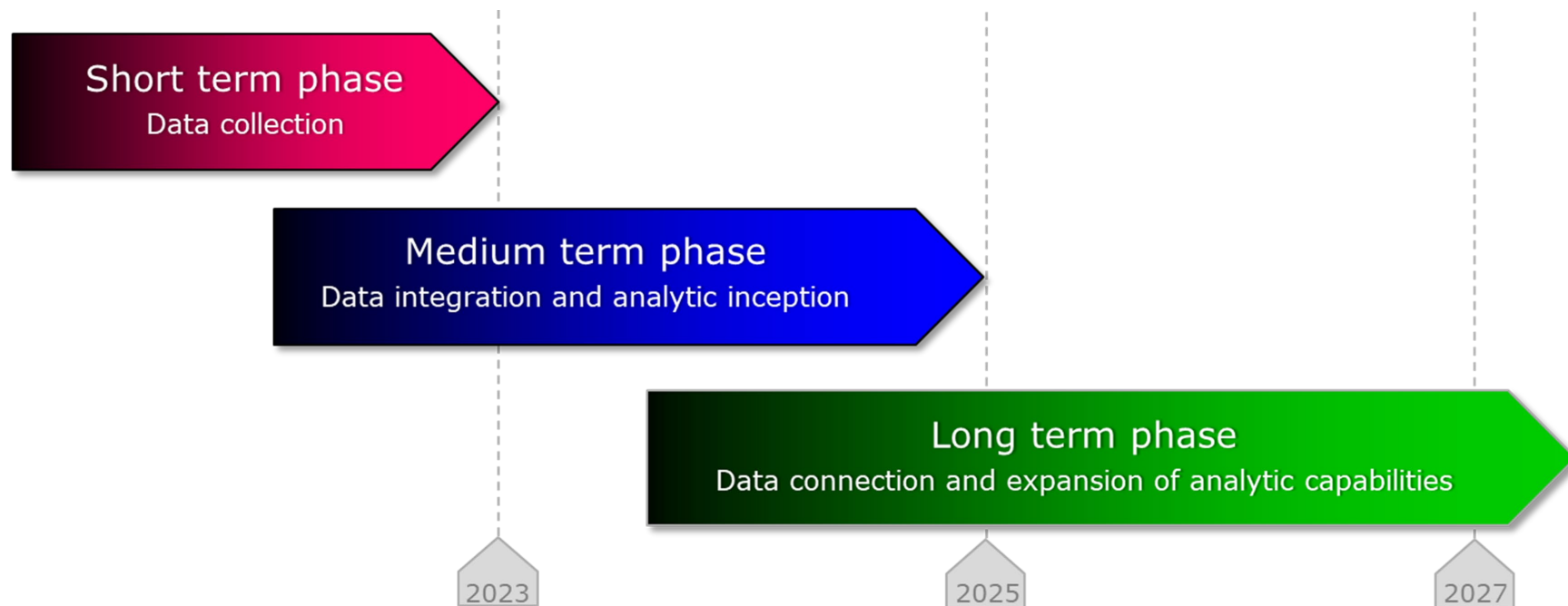


Update on EU Veterinary Big Data Strategy: Pillars





Update on EU Veterinary Big Data Strategy: Timeline





Update on EU Veterinary Big Data Strategy: Status

- Adopted at HMA II meeting (4-6 May 2022)
- To be published on EMA website
- Provision of UPD functionalities ties in with short-term phase described in strategy – we are already on the road to implementation
- 2nd Vet Big Data stakeholder forum to be held in Q4 2022 (save the date announcement to be published in due course)



Update on EU Veterinary Big Data Strategy: Practical use cases to be developed



PHARMACO-
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ANTIMICROBIAL
RESISTANCE



ENVIRONMENTAL
RISK ASSESSMENT



REGULATORY
SUBMISSION



MANUFACTURING/
INSPECTIONS



INNOVATION OF
VMP
DEVELOPMENT



DEMONSTRATING
EFFICACY/
EFFECTIVENESS



WITHDRAWAL
PERIODS /CASCADE
USE



Any questions?

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