EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Union Product Database

Follow up webinar for marketing authorisation holders

Presented by Olivier Simoen, Alejandro Platt and Ana Vicente on 25 January 2022

An agency of the European Union

Webinar's objective and agenda

- To demonstrate the VNRA functionality in UPD v 1.5.3

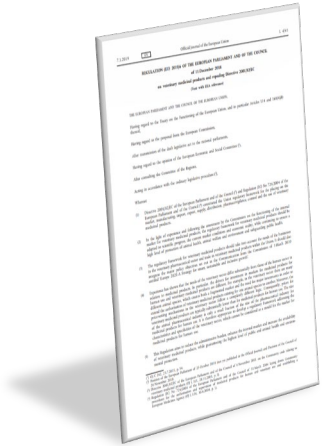
#	Topic	Presenter	Timing	
	Connection to virtual room and technical checks		15:00	15:05
1	Webinar's objective and agenda	I. Zanetti	15:05	15:15
2	UPD project overview	O. Simoen	15:15	15:30
3	Status report on legacy data upload	A. Platt	15:30	15:35
4	Demonstration of the UPD functionalities for MAHs	A. Vicente	15:35	16:15
4	Q&A session	I. Zanetti	16:15	16:30

UPD Project Overview

- Reminder of programme and project context
- Project schedule
- 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



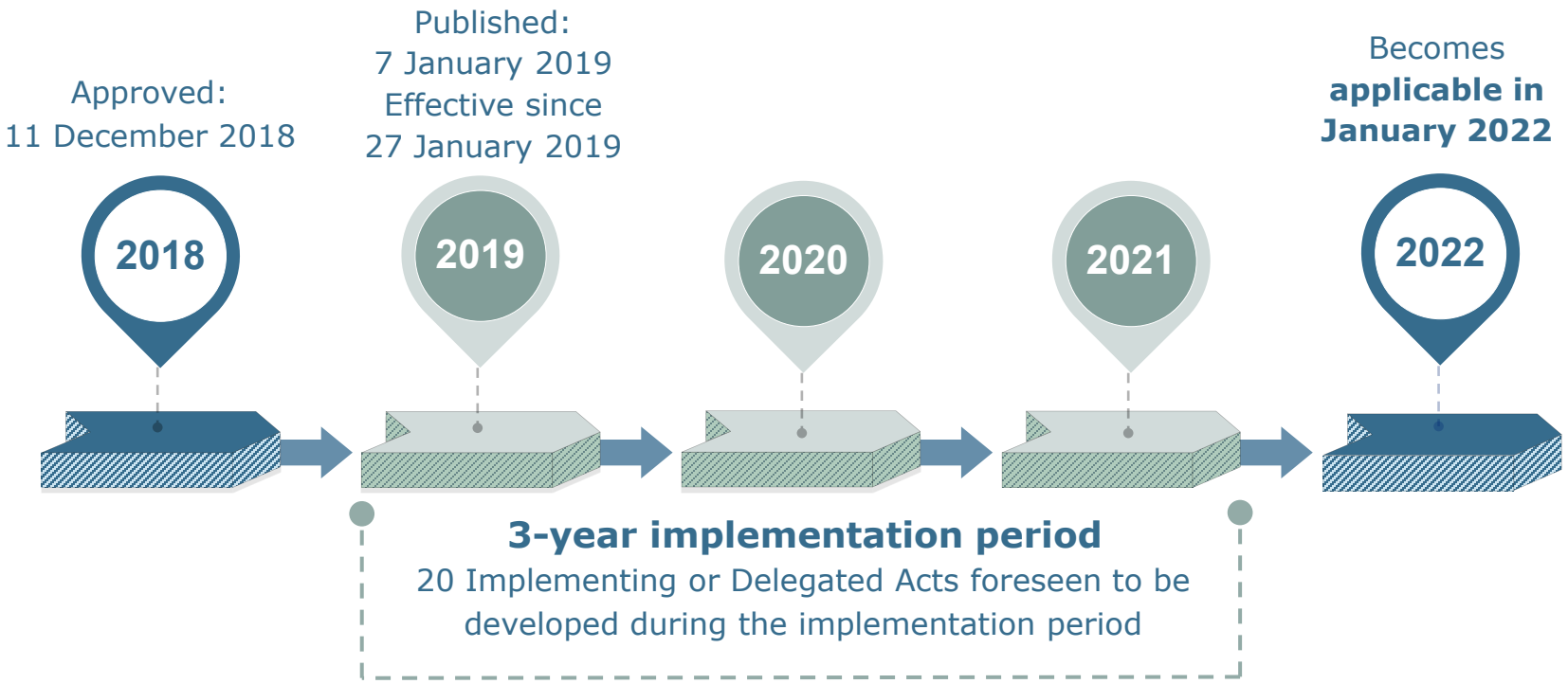
provides for a modern, innovative and fit for purpose legal framework

gives incentives to stimulate innovation

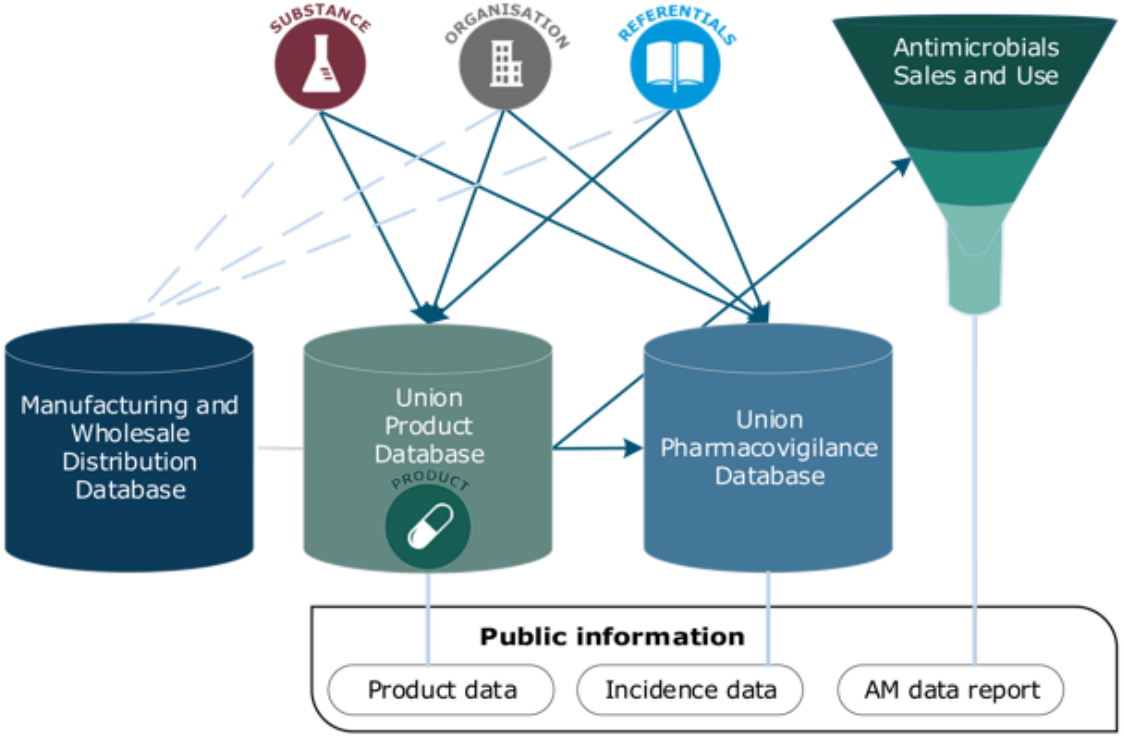
gives incentives to increase the availability of veterinary medicines

strengthens the EU action to fight antimicrobial resistance

Timeline



VMP-Reg programme – IT systems overview

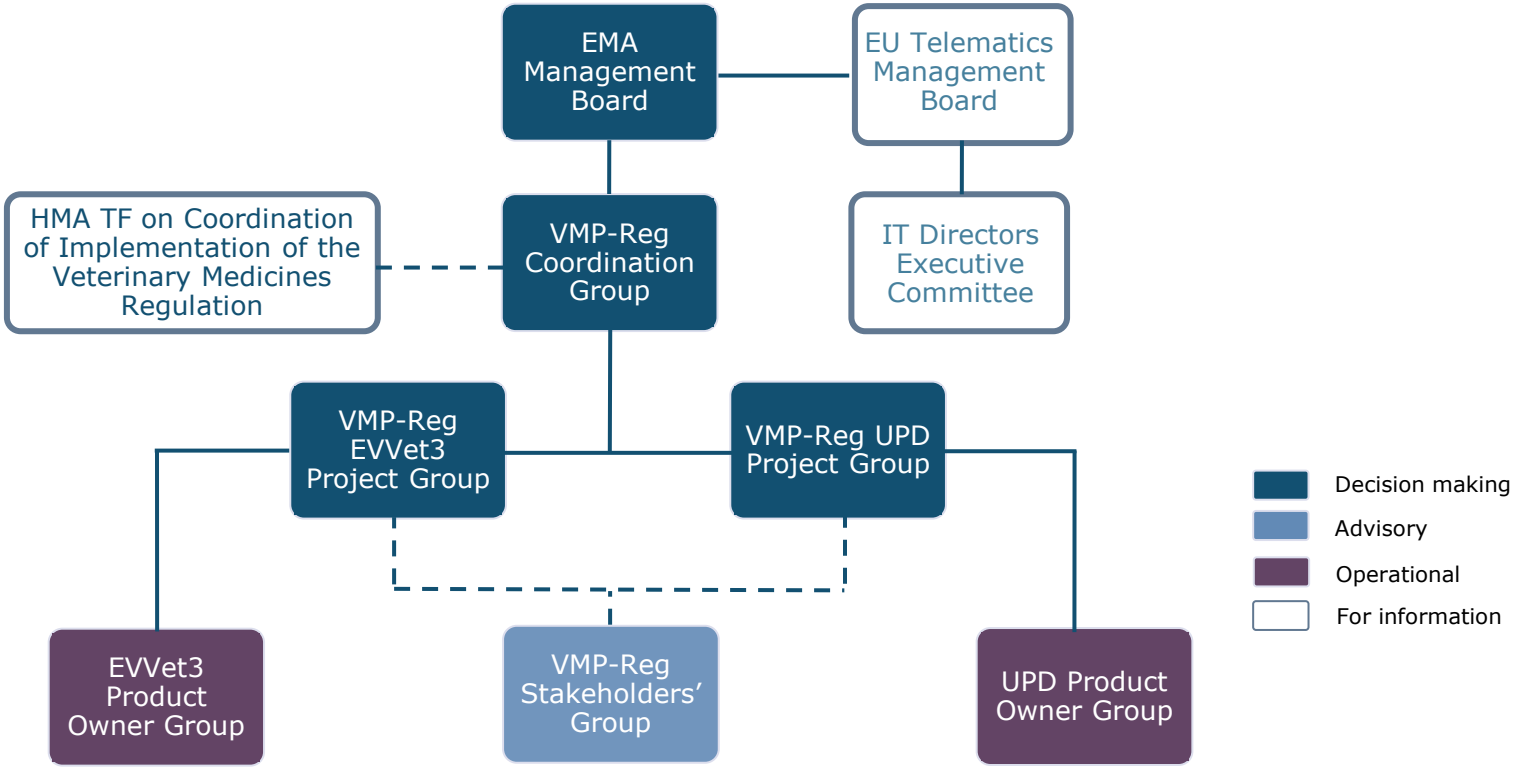


VMP-Reg programme – out of scope

Achievement of the overall objectives of the VMP-Reg, other than those specifically included in the programme scope, in particular but not limited to:

- *The implementation of revised business processes* to fit the VMP-Reg and related IT solutions *in Member State authorities or Industry stakeholder entities*
- *Any required changes to Member State and/or Industry stakeholders' IT systems* to complete the envisaged integration or avoid duplication of data in systems outside the programme scope
- *Quality assurance of any data prior to submission* to the systems in scope of the programme is the responsibility of the Member State authorities and Industry stakeholder entities

Overview of governance structure

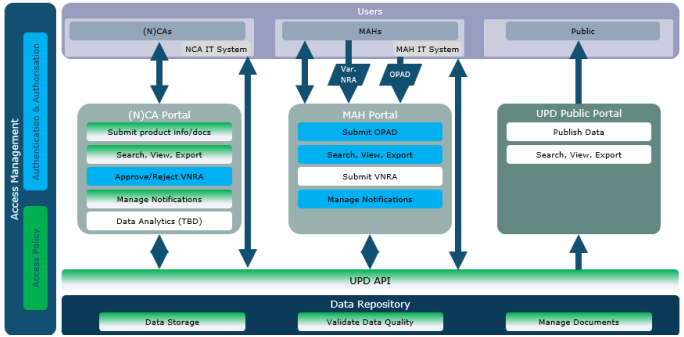


Context and Objectives

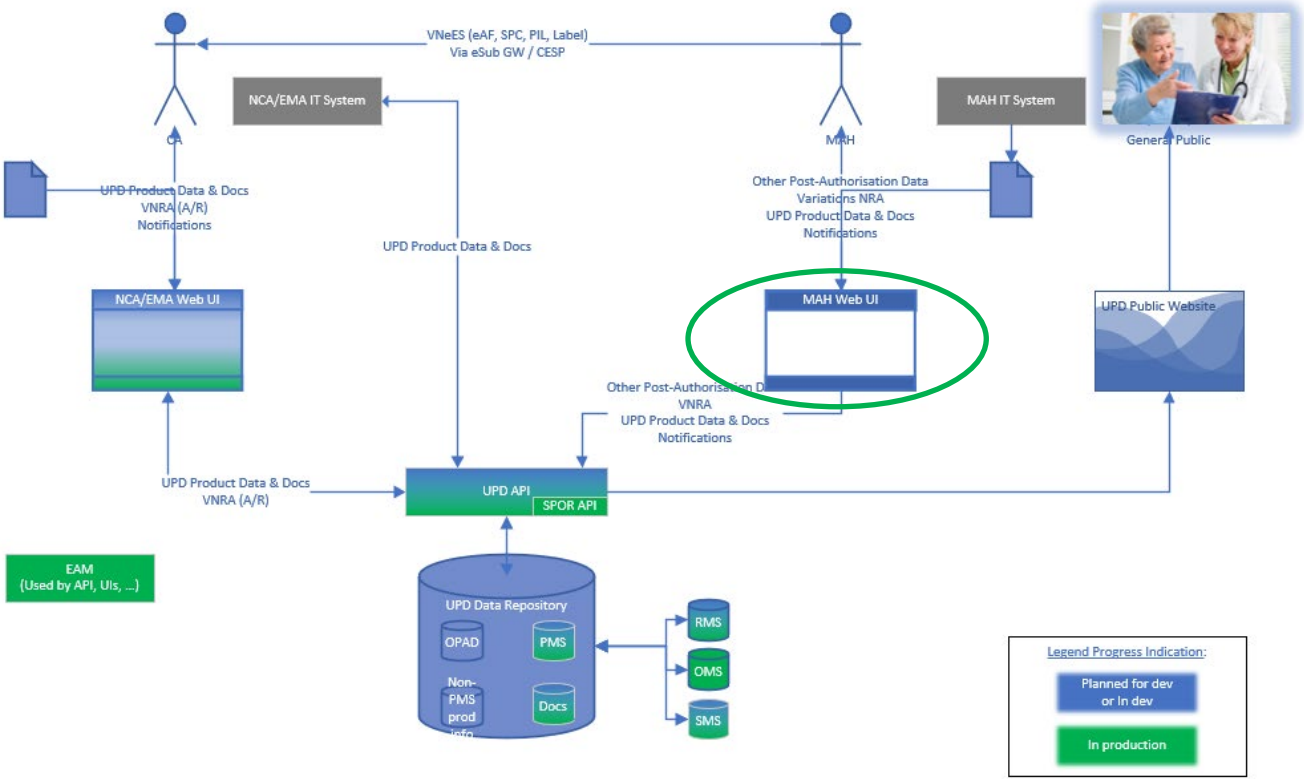
- The Union Product Database (UPD) is a legal requirement as per Reg 2019/6, Art 55: "*The Agency shall establish and, in collaboration with the Member States, maintain, a Union database on veterinary medicinal products ('product database').*"
- From an operational point of view, the objectives of the UPD are:
  - 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

Main Functionalities

- Provision of product information by NCAs, via a Web UI or an API
  - Manual or via provision of a file with the product information (FHIR)
  - 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;
- Support the processing of variations without assessment by MAHs and NCAs;
- Provide access to product information:
  - Public website for general public
  - Restricted area for NCAs and MAHs
- Access management via EAM;
- Usage of SPOR.



Functional system overview

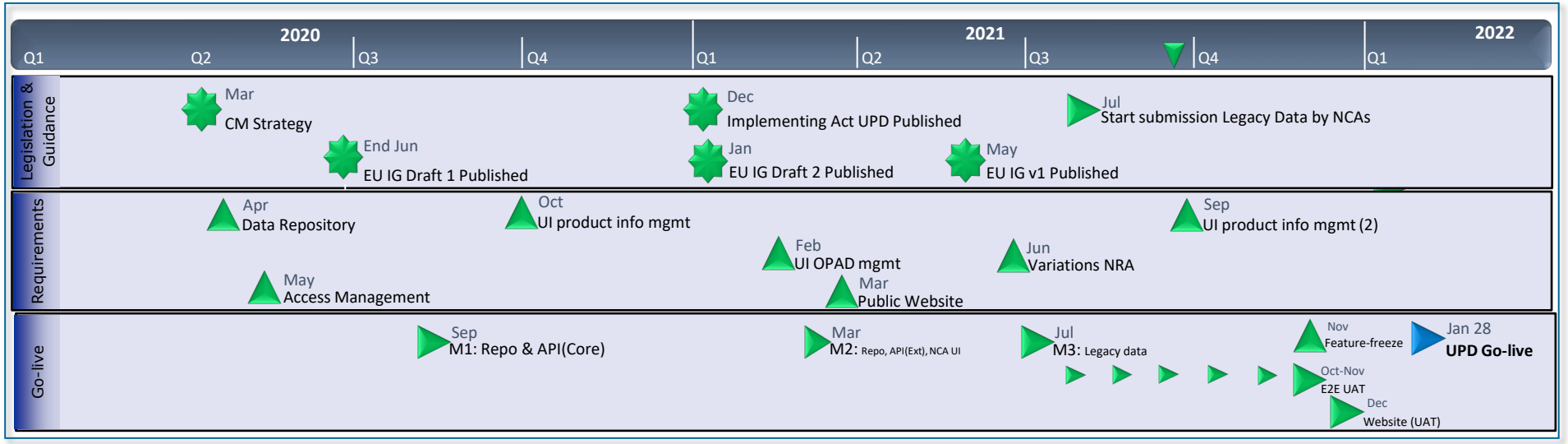


Information in the UPD

- Categories of products in scope:
  - 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…"

- Information in the UPD:
  - Product information
  - Documents: SPC, PL, Labelling, 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, …

Key milestones schedule

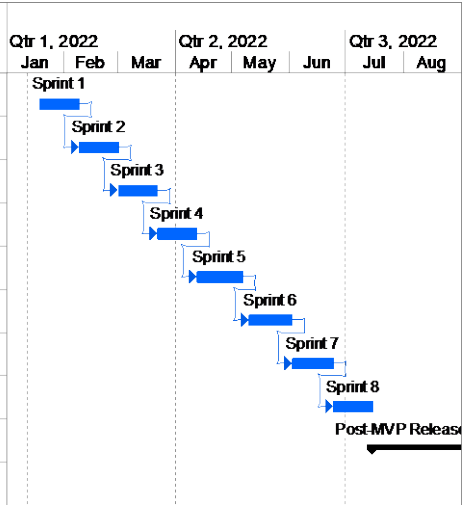


Release for 28 January 2022

- Release planned to go live on 28 January:
  - Version 1.5.3-4
  - Deployed in UAT: 19 January
  - Deployed in production: 21 January
  - Scope: All functionality **with exception** of parallel trade and homeopathics
- Detailed list of functionality please see Release Notes UPD v 1.5.3

Post go-live release plan*:

ID	Iniqu ID	Task Name	Start	Finish
504	1540	Sprint 1	Tue 18/01/22	Mon 07/02/22
505	1541	Sprint 2	Tue 08/02/22	Mon 28/02/22
506	1542	Sprint 3	Tue 01/03/22	Mon 21/03/22
507	1543	Sprint 4	Tue 22/03/22	Mon 11/04/22
518	1546	Sprint 5	Tue 12/04/22	Fri 06/05/22
519	1547	Sprint 6	Tue 10/05/22	Wed 01/06/22
520	1548	Sprint 7	Thu 02/06/22	Thu 23/06/22
521	1549	Sprint 8	Fri 24/06/22	Thu 14/07/22
522	1550	Post-MVP Release 3 (indicative dates)	Fri 15/07/22	Mon 24/10/22
528	1556	Post-MVP Release 4 (indicative dates)	Mon 10/10/22	Wed 01/02/23



*Scope of each release to be prioritised on ongoing basis

- A large percentage (75%) of the team capacity will be allocated to hyper care (user support, quality improvement, etc.) during at least February-April;
- This will gradually diminish during May-July, thereby liberating more capacity for new development;
- Continuation of the current MO to release every three weeks.

Post go-live release plan

Version	Date (Prod)	Scope
1.5.4	18 February	✓ Prioritised defect fixes
1.6.1	11 March	✓ Prioritised defect fixes
1.6.2	01 April	✓ Prioritised defect fixes ✓ Parallel trade (Create)
1.6.3	22 April	✓ Prioritised defect fixes ✓ Parallel trade (Update) ✓ Homeopathics ✓ UPD-BR-130 - "Decision authority" to display the responsible authority to which the user (who is approving/rejecting) belongs to ✓ UPD-BR-124 - Responsible authority (organisation) displayed as an acronym in the tables of the UPD Portal (UPD-UI)
1.6.4	20 May	✓ Prioritised defect fixes
1.6.5	mid June	✓ Prioritised defect fixes ✓ UPD-BR-070 - VoS: provision and view of volume of sales information on deleted packages ✓ UPD-BR-089 - VNRA PSMF ✓ UPD-BR-090 – VNRA QPPV ✓ UPD-BR-092 - VNRA Product Owner
1.6.6	Early July	✓ Prioritised defect fixes

Post go-live releases

Business Requirement	Description
UPD-BR-070 - Volume of sales: provision and view of volume of sales information on deleted packages	The system shall allow MAHs to retrieve and provide volume of sales information on packages that had been previously deleted.
UPD-BR-089 - (VNRA) - Management of a VNRA that affects data related to the Pharmacovigilance system master file **UPD-BR-090** – (VNRA) - Management of a VNRA that affects data related to the Qualified person responsible for pharmacovigilance **UPD-BR-092** - Variations not requiring assessment (VNRA) - Management of a VNRA that affects data related to the Product Owner	• A Marketing Authorisation Holder (MAH) shall be able to submit a variation not requiring assessment that affects data related to the PSMP/QPPV/Product Owner via the UPD Portal (UPD UI). The system will allow the MAH to provide the relevant information through the submission form. • The System will display the information regarding the changes requested, for both MAHs and Competent Authorities (CAs) in the View Submission screens. • A CA must be able to approve/reject the VNRA in the UPD UI. After approval of the VNRA, the changes requested will be automatically updated. **To be signed-off:** **Mock-ups:** VNRA_PSMF_QPPV.pdf | VNRA_ProductOwner.pdf **Use Cases**: UPD-UC09 - VNRA_Approve_Reject.docx | UPD-UC028 - View VNRA via UI.docx | UPD-UC06 - Submit VRNA_MAH via UI.docx
UPD-BR-124 - Responsible authority (organisation) displayed as an acronym in the tables of the UPD Portal (UPD-UI)	The value of the field Responsible authority (Vet EU IG - ch2 - 2.4) will be displayed in the UPD Portal (UPD-UI) as an acronym and not as the full name of the organisation, when possible.
UPD-BR-130 – VNRA - Create the field " Decision maker" to display the responsible authority to which the user (who is approving/rejecting) belongs to	The System shall display the name of responsible authority to which the User who is approving/rejecting the VNRA belongs to. MAH user should not be able to see the name of the 'Author of the Decision' but they should see the 'Responsible Authority'.

User registration

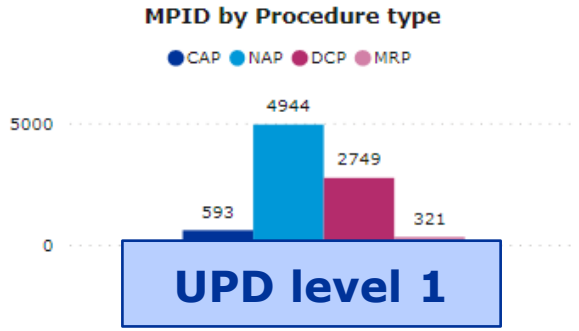
- **User account is needed** (three types):
  - UPD Industry Super User;
  - UPD Industry Edit Search View;
  - UPD Industry Search View

- **Process**:
  - Each organisation requests* "Super User" account (must provide affiliation letter);
  - EMA will approve this "Super User" account from 27 January onwards;
  - The Super User will ***then*** approve all other requests for the organisation;
  - **Strongly recommended to create two Super Users**
  - Detailed instructions in the Release Notes UPD v 1.5.3, section 6.3.

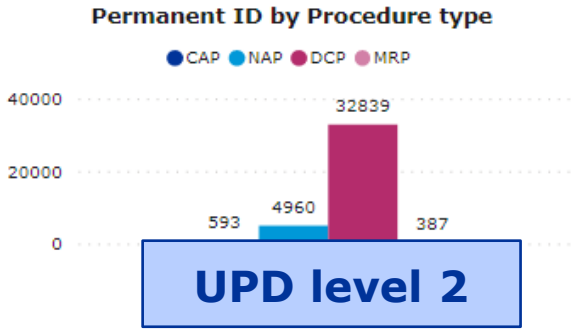
*** You can submit your request before 28 January 2022**

Status report on legacy data upload

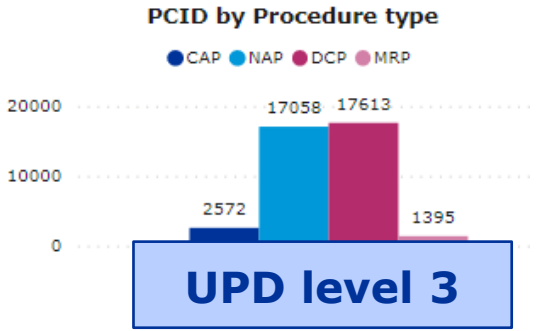
8289	38779	37250
Count of MPID	Count of Permanent ID	Count of PCID (Dataset3)



UPD level 1



UPD level 2



UPD level 3

- **UPD level 1: the product identifier.** Identifies veterinary medicinal products at a high level of granular information and based on a set of data which is regarded as **common to the product** (defined as European in Annex I);
- **UPD level 2: the permanent identifier.** Identifies the product on a more granular level with a more detailed set of data which is **nationally specific** and related to the authorisation number as assigned by the competent authority (defined as National in Annex I), *e.g.* applicable to a specific territory and based on the national dataset for MRP/DCP procedure;
- **UPD level 3: the package identifier.** Defines the product at **package level**, as required by Article 15(2) of Commission Implementing Regulation (EU) 2021/16.

Demonstration of the Web User Interface

- Variations not requiring assessment (VNRAs): end-to-end flow
- Update to Marketing Authorisation Status (MA status)

UAT environment – version 1.5.3

Agenda

- Overview of update of MA status scope;
- Overview of VNRAs scope;
- Specific scenarios in scope for the demonstration:
  - Submission of a VNRA that **will have an impact in UPD** data or documents to a national product (NP)
  - Submission of a VNRA that **will not have an impact in UPD** data or documents to a NP
  - Submission of a VNRA that **will have an impact in UPD** data or documents to products approved under a **decentralised procedure**
- Some remarks on known issues for the release 1.5.3.

Overview of MA status scope

Commission Implementing Regulation (EU) 2021/16

- **Annex I – Functionalities of the UPD:**
  - **2.9 Record marketing authorisation status**: […] **Marketing authorisation holders** shall be able to update the marketing authorisation status of their veterinary medicinal products in case of *suspension* or *revocation* of the marketing authorisations concerned.
- **Data fields impacted in UPD** according to the chapter 2 of the Vet EU Implementation Guide:
  - Authorisation status
  - Date of authorisation status change

Overview of VNRAs

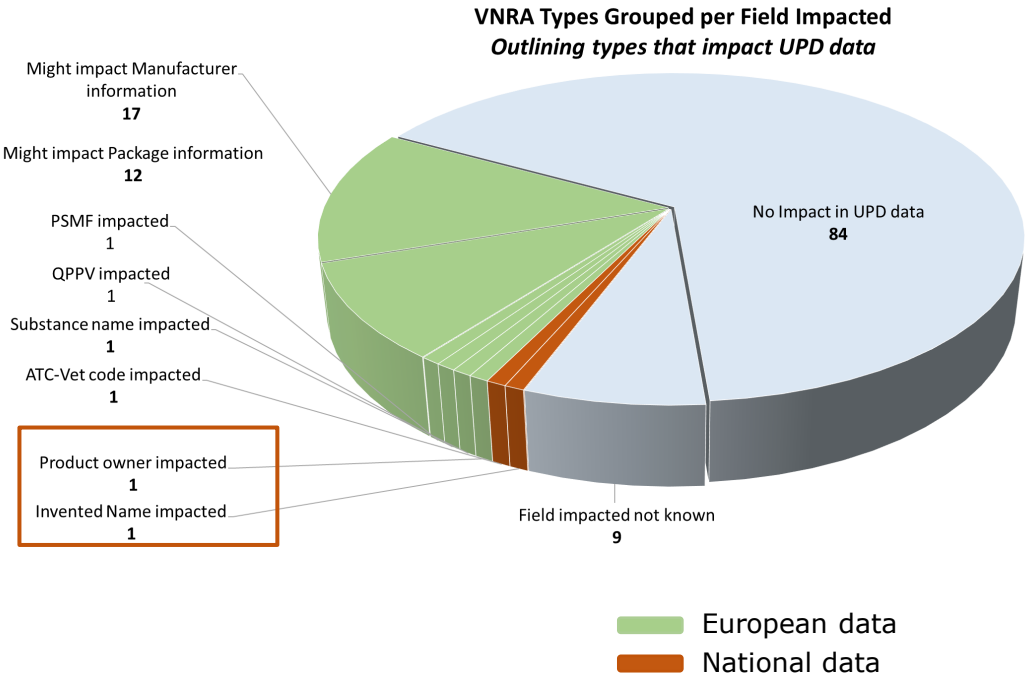
Commission Implementing Regulation (EU) 2021/17

The Commission is required under Regulation (EU) 2019/6 to establish a list of changes to the terms of the marketing authorisation, so called variations, that do not require assessment in order to be implemented.

130
VNRA

8	**A.** Administrative changes
108	**B.** Changes to the quality part of the dossier
12	**C.** Changes to the safety, efficacy and pharmacovigilance part of the dossier
2	**D.** Changes to the vaccine antigen master file (VAMF) part of the dossier

Overview of VNRAs



Approx. **71.5%** of VNRAs has no impact in UPD data (fields & docs)

Scenario 1:

- Submission of a VNRA that **will have an impact in UPD -** data or documents - to a national product

VNRA not impacting UPD information | A.4 | Change in ATCvet Code

Scenario 2:

- Submission of a VNRA(s) that **will not have an impact in UPD -** data or documents - to a national product

VNRA not impacting UPD information | B.3.b | Deletion of a manufacturing process for the active substance or the finished product, including an intermediate used in the manufacture of the finished product when an alternative is already approved

Scenario 3:

- Submission of a VNRA(s) to products approved under a decentralised procedure

VNRAs impacting and not impacting UPD information

B.3.b	Deletion of a manufacturing process for the active substance or the finished product, including an intermediate used in the manufacture of the finished product when an alternative is already approved
A.4	Change in ATCvet Code

Remarks of known VNRAs issues - 1.5.3

Specific to VNRA and documented in the Release notes

- Submission and approve/reject VNRA:
  - UPD-8439: **adding more products to the list of VNRA replaces already existing products** and instead should have added to the existing products;
  - UPD-8775, UPD-8776 & UPD-8777: in the "Submit VNRA" screen **when retrieving products, the search by Authorisation Country, Authorisation Status and Product Owner are not working properly;**
  - UPD-8441: **Removing variation from one product removed variations of other product as well**.
  - To be added to the draft release notes 1.5.3: for those **VNRAs that will not have impact in UPD data or documents**, the MAH should not provide a VNeeS file. However, the current version of the Web UI does not support this scenario and **requires always a VNeeS file to be submitted**. As a workaround, until the implementation is ready, the MAH will submit a zip file named '**empty.zip**' that will be ignored by the Competent authorities.
  - UPD-8775: Date of implementation is changed to a common date after submitting the variation if different dates have been input for each combination of variation and product;
  - UPD-8056: **no message if submission for approve/reject was successful or failed**; and first 2-3 times "Submit Approval/Rejection" get an error message and on 2nd-3rd attempt it is accepted;
  - UPD-8771: When a VNRA has been submitted for a product under DCP/MRP/SRP, **the CMS for a product in the submission should not be able to Approve/Reject the VNRA**. Only the RMS should be able to Approve/Reject.

Industry preparedness/supporting materials

Please feel free to share the resources below within your network

- UPD – Introduction webinar for industry
- UPD Q&As for industry
- Variations not requiring assessment Q&As
- Variations requiring assessment Q&As
- Worksharing of variations Q&As
- UPD Implementation Guide (esp. Chapter 7) – VET EU IG
- VMP-Reg newsletters
- Bite size videos to be published at the EMA website.
- Best practice guides from CMDv
- List of contacts per NCA to be published this Friday at the CMDv website
- UPD Release notes 1.5.3

Support after go-live

VMP-Reg programme will provide dedicated post go-live support

- **System related issues** to be submitted via:
  - EMA service desk (VMP-Reg IT systems user support: https://servicedesk.ema.europa.eu/;
  - UPD-User-Support@ema.europa.eu mailbox during the transition, then to be phased-out;

- **Regulatory queries** via AskEMA

- **Other issues/questions** to vetchange.programme@ema.europa.eu *(to be moved to AskEMA in late 2022)*

Any questions?