EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Union Product Database

UPD webinar on variations not requiring assessment for marketing authorisation holders

Presented by Olivier Simoen, Ana Vicente and Alejandro Platt on 8 September 2022

Webinar's agenda

Objective: to demonstrate the VNRA functionality in UPD and creation of a parallel traded product

#	Topic	Presenter	Timing	
	Connection to virtual room and technical checks		10:00	10:05
1	Webinar's objective and agenda	A. Platt	10:05	10:15
2	UPD project overview	O. Simoen	10:15	10:30
3	Update on VNRAs and demonstration of VNRAs and the creation of a parallel traded product	A. Vicente	10:30	11:00
4	How to find information and help	A. Platt	11:00	11:10
5	Q&A session	A. Platt	11:10	11:30

UPD Project Overview

- Reminder of programme and project context
- Project schedule
- Project status

Context and Objectives

- The Union Product Database (UPD) is a legal requirement as per Art. 55 of Regulation (EU) 2019/6 (VMP-Reg): "*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 (VMPs) within scope of VMP-Reg to both individual users and other, centralised/NCA systems;
  - To be the common database to collect, store and provide information on availability of VMPs;
  - To use structured data and controlled vocabularies in the UPD and 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;

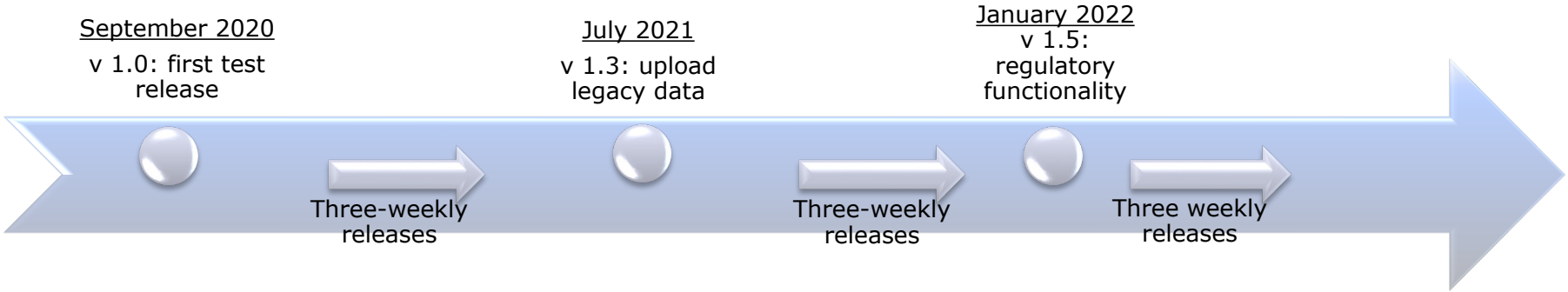
Main Functionalities

- 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.

Information in the UPD

- Categories of products in scope:
  - VMPs authorised within the Union by the Commission and by the competent authorities;
  - Homeopathic VMPs registered in accordance with Chapter V within the Union by the competent authorities
  - VMPs 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 VNRAs: approval/rejection by NCAs…

System Development Timeline



Release plan

- Scope of the next release (version 1.6.8) in production from today *(8 September)*
  - Prioritised defect fixes
  - Parallel trade (include multiple wholesalers)
  - UPD-BR-092 - VNRA Product Owner
  - UPD-BR-066 - VNRA Download submitted metadata
  - Detailed list of functionality please see UPD Release Notes

- Subsequent releases:
  - Functionality as prioritised by the UPD Product Owner Group
    - More automation of VNRA
    - API functionality to approve/reject VNRA
    - See planned scope for the next releases in release plan (annex 1)

Update on VNRAs and demonstration

- Current status and upcoming functionalities
- Demo: end-to-end flow of submission of VNRA related to contact details of a MAH in UAT environment – version 1.6.8

Overview

1. Update on status of VNRAs:

   a) Valid scenarios under current implementation

   b) Invalid scenarios under the current implementation

   c) What is coming next?

      - **Technical grouping**: Submission of VNRA for products approved under different procedures belonging to different National Competent Authorities.
      - **Automation of VNRAs** related to ATCVet code, QPPV and PSMF
      - Ability to select more than once the same VNRA (scope) within the same submission

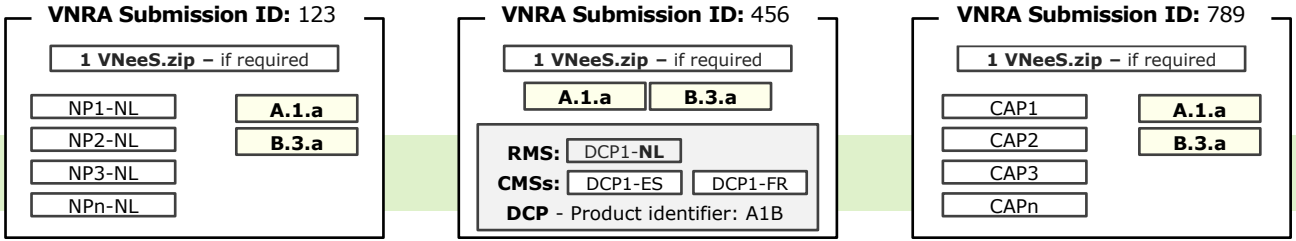
2. Specific scenarios in scope for the demonstration:

   - Submission of VNRA A.1.a for national products approved under a DC procedure
   - Creation of a Parallel traded product

1.a) Valid scenarios under current implementation

A VNRA submission can contain one or several scopes (unique VNRA codes) to one or more UPD products in the following scenarios:

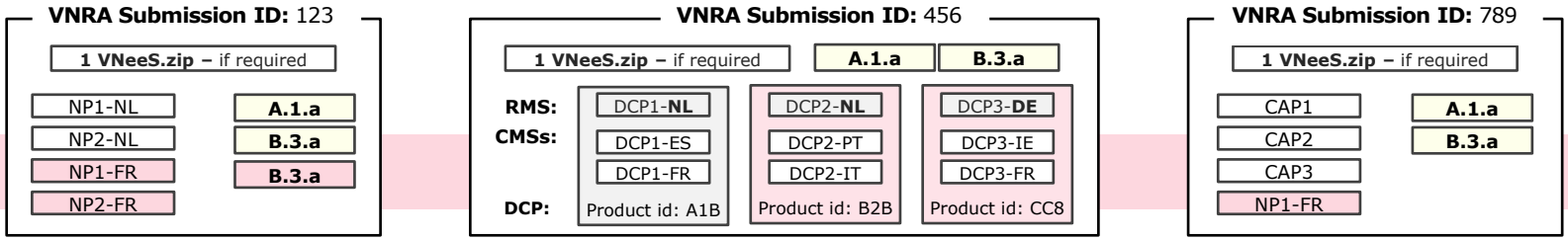
1. National products approved under national procedures belonging to the same Responsible Authority or
2. Centrally authorised products or
3. A product approved under DC/MR/SR procedure (1 Product ID only)



1.b) Invalid scenarios under current implementation

MAH cannot submit VNRAs in the following scenarios:

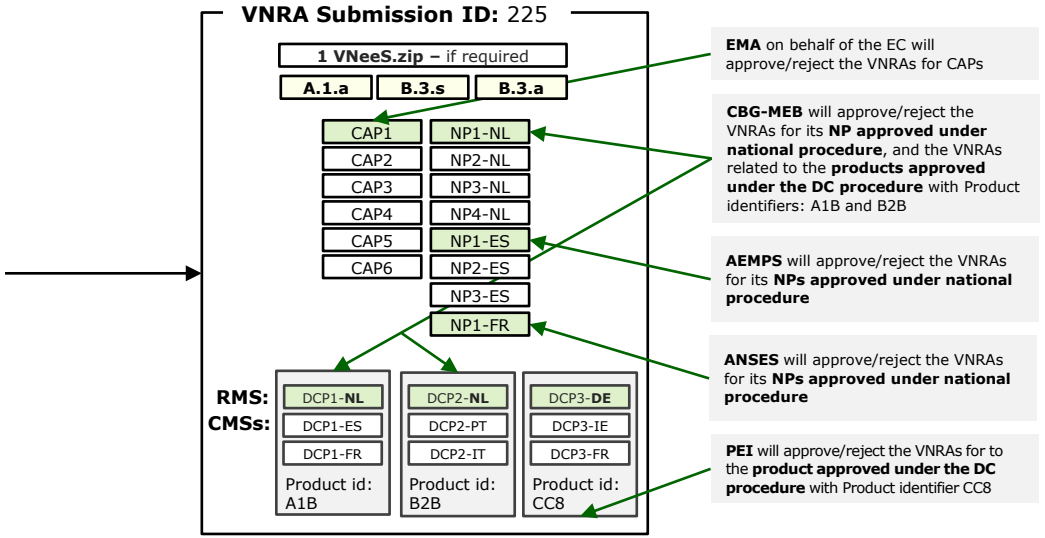
1. The same scope cannot be repeated within the same submission
2. A VNRA submission cannot included products approved under national procedure belonging to different Responsible Authorities
3. A VNRA submission cannot include products approved under different procedures types (NP and/or DC/MR/SR and/or centralised procedures)
4. A VNRA submission cannot include products approved under different DC/MR/SR procedures, even if the RMS is the same



1.c) What's coming next?

Q3-2022 expected in September

Technical grouping - VNRA submission for products approved under different procedures belonging to different Competent Authorities.



A.1.a Change in the name or address or contact details of the marketing authorisation holder
B,3.a Deletion of a manufacturing site for an active substance, intermediate or finished products (…)
B.3.s Deletion of a supplier of packaging components or devices (when mentioned in the dossier)

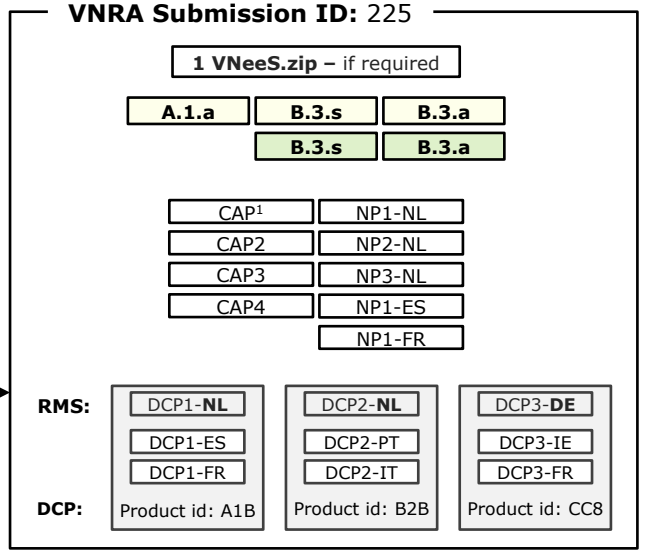
1.c) What's coming next?

Q4-2022

Automation of VNRAs related to pharmacovigilance and ATCvet code

Q1-2023

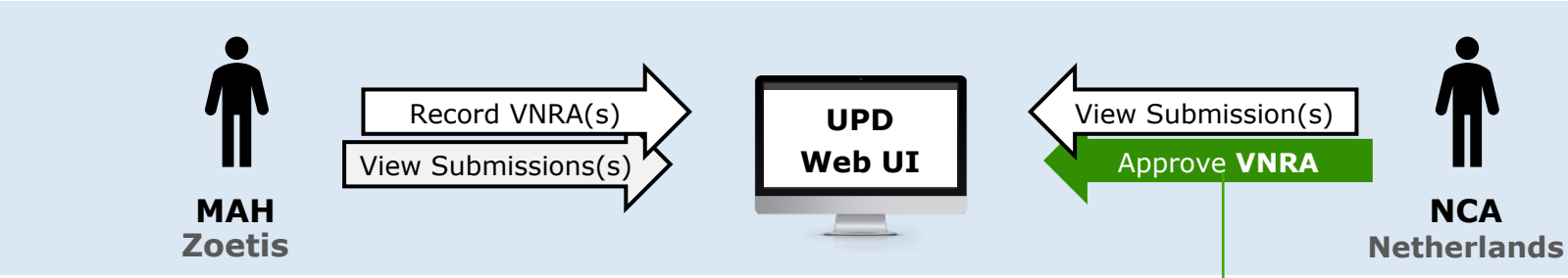
Capability to add the same scope more than once within the same VNRA submission.



A.1.a Change in the name or address or contact details of the marketing authorisation holder
B.3.a Deletion of a manufacturing site for an active substance, intermediate or finished products (…)
B.3.s Deletion of a supplier of packaging components or devices (when mentioned in the dossier)

Scenario 1

VNRA A.1.a submission for products approved under a decentralised procedure



- Download VNRA submission information in a PDF file
- Bulk upload functionality

The system will update automatically the product(s) included in the Submission, and the NCA will need to upload the document(s) provided within the VNeeS file.

Scenario 2

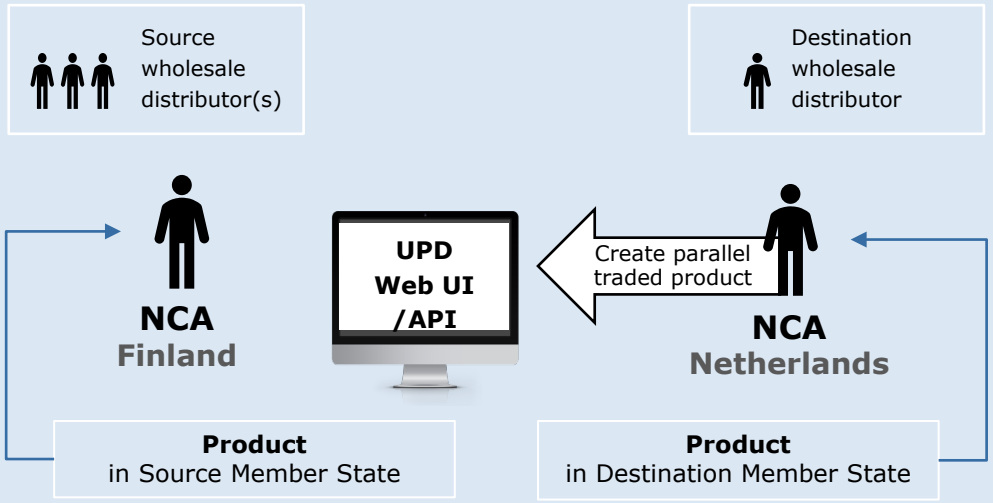
Creation of parallel traded product

Reg 2019/6 Art. 102

Parallel trade in VMPs

Competent authorities of the destination MSs shall make available to public the following information for each of their parallel traded products:

- name;
- active substances;
- pharmaceutical forms;
- classification of the veterinary medicinal products in the destination Member State;
- MA number of the VMPs in the source MS;
- MA number of the VMPs in the destination MS;
- source and destination wholesale distributors.



How to find information and help

Industry supporting materials

- Bite size videos published at the EMA website
- UPD – Introduction webinar for industry
- UPD industry Q&As (under update)
- Variations not requiring assessment Q&As
- Variations requiring assessment Q&As
- Worksharing of variations requiring assessment Q&As
- Best practice guides from CMDv
- UPD Implementation Guide VET EU IG
- VMP-Reg newsletters
- List of contacts per NCA published at the CMDv website
- UPD Release notes (see next slide)

Please share it within your network

Release notes

Examples of queries whose answers are included in Release Notes

1. MAH submitted ticket

> Dear Service Desk,
> this was probably already acknowledged, but still. When it will be possible again to download Volume of Sales CSV file.
> From this Monday I cannot do this.

2. User support investigated
3. Bug had been already identified and recorded in the release notes
4. User Support informed MAH about the bug already recorded

> Please be advised the download of Volume of Sales is currently being affected by a bug, documented as "~~UPD-9741~~" in our defect tracking system and the latest release notes.

UPD Support Channels

VMP-Reg programme provides dedicated support

- **System related issues** to be submitted via: VMP-Regulation IT systems user support
- **Other systems related issues** to be submitted via EMA Service Desk
- **Regulatory queries** via AskEMA
- **Other issues/questions** to vetchange.programme@ema.europa.eu

Legacy data submission update (MR/DC/SR products)

	Product in UPD (Permanent IDs)	National dataset in UPD	National dataset completeness Rate (%)
Decentralised Procedure	23352	21504	
Mutual Recognition Procedure	3662	3641	
National Procedure	14396	14393	
Centralised Procedure	597	597	
Subsequent Recognition Procedure	426	374	
Total	**42433**	**40509**	**95**

- **42,433** product entries in UPD Production (out of ca. 42,000 expected as per estimates from NCAs in November 2020 ≈ 100%);
- NCAs are being contacted and supported individually in final push towards completion.

Any questions?

Further information

vetchange.programme@ema.europa.eu

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Annex I

Release plan

Version	Date (Prod)	Scope
1.6.8	8 Sep	✓ Prioritised defect fixes ✓ UPD-BR-092 - VNRA Product Owner (Ori v 1.6.5.) ✓ Parallel trade (incl multiple wholesalers) (Ori v 1.6.7) ✓ UPD-BR-066 - Variations not requiring assessment (VNRA) - Download submitted metadata (Ori v 1.6.6)
1.6.10	30 Sep	✓ Prioritised defect fixes ✓ UPD-BR-119 - Submission of VNRA for products approved under different procedures belonging to different National Competent Authorities
1.6.11	21 Oct	✓ Prioritised defect fixes
1.6.12	11 Nov	✓ Prioritised defect fixes ✓ UPD-BR-089 - VNRA PSMF (Ori v. 1.6.5.) ✓ UPD-BR-090 – VNRA QPPV (Ori v. 1.6.5.) ✓ UPD-BR-102 - Enhancement of requirements related to locations (OMS data)
1.6.13	9 Dec	✓ Prioritised defect fixes ✓ UPD-BR-093 - Variations not requiring assessment (VNRA) - Management of a VNRA that affects data related to the ATC Vet code(s) (Ori v. 1.6.11) ✓ UPD-BR-063 - Variations not requiring assessment (VNRA) - API for Competent Authorities and the Commission (approve/reject) (Ori v. 1.6.11)
1.6.14	6 Jan	✓ Prioritised defect fixes ✓ UPD-BR-127 – UPD capability to group products following a harmonisation of the summaries of product characteristics procedure

Release plan

Version	Date (Prod)	Scope
1.6.15	Jan 23	✓ UPD-BR-051 - Automatic sending of notifications
1.6.16	Feb 23	✓ UPD-BR-037 – Extend UPD API capabilities to implement the requirements derived from the Access Policy (Ori v 1.6.14)
1.6.17	Feb 23	✓ UPD-BR-126 - Create new field to link essentially similar products ✓ UPD-BR-166 Ability to select more than once the same VNRA (scope) within the same submission ✓ UPD-BR-147 - An NCA user should be able to retrieve notifications via API ✓ UPD-BR-043 - Create a product from an existing one (via UI) ✓ UPD-BR-173 - QPPV and PSMF information becoming part of national data
TBC	Q1 23	✓ UPD-BR-059 Provision of Third Country Product names ✓ UPD-BR-069 - Extraction by NCAs and MAHs of specific submissions lists (e.g. VNRAs pending to be approve/reject) ✓ UPD-BR-123 - Variations not requiring assessment - enrichment of the form that will allow MAH and NCA to search for submissions ✓ UPD-BR-044 - Update national product information in a CAP product ✓ UPD-BR-118 - Enrichment of the search notifications functionality ✓ UPD-BR-148 - The System shall allow the creation of a DCP product with just the RMS country ✓ UPD-BR-123 - Variations not requiring assessment - enrichment of the form that will allow MAH and NCA to search for submissions
TBC	2023	✓ UPD-BR-087 - Variations not requiring assessment (VNRA) - Management of a VNRA that affects data related to Manufacturers (Ori 1.6.12 but re-scheduled to 2023 as per UPD PG decision 21 Jun 22)