HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

Union Product Database

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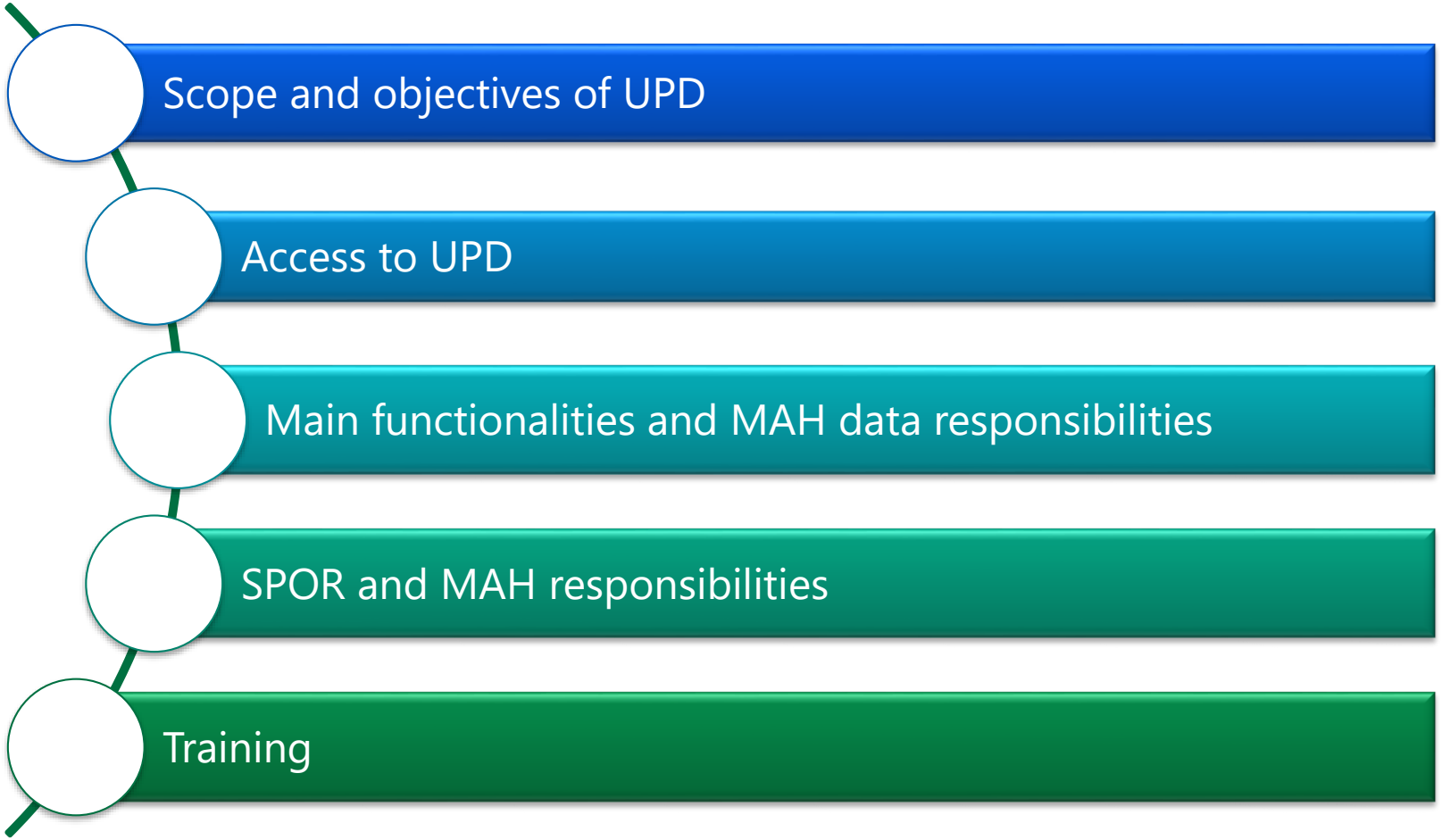
The New Veterinary Regulation Webinar, 31st March 2021

This presentation covers



Union Product Database (UPD) & scope

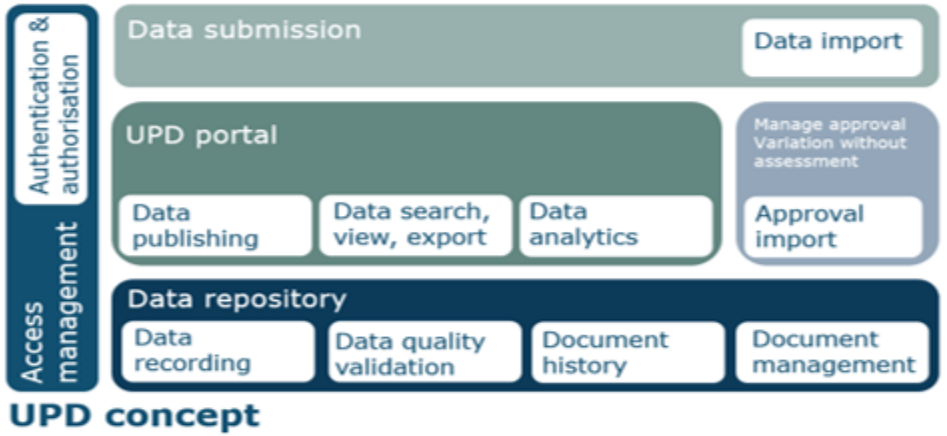
The Union Product Database (UPD) is a legal requirement as per Reg 2019/6, Art 55: "*The Agency shall establish and, in collaboration with the Member States, maintain, a Union database on veterinary medicinal products ('product database').*"

The Commission Implementing Act (EU) 2021/16 of 8 January 2021 lays down the necessary measures and practical arrangements for the UPD and details the specifications to implement in order to fulfil the requirements of the VMP Regulation.

What products are in scope?

- Authorised veterinary medicinal products as referred to in Article 5(1);
- Registered veterinary homeopathic medicinal products as referred to in Article 85(1);
- Veterinary medicinal products intended for animals which are exclusively kept as pets: aquarium or pond animals, ornamental fish, cage birds, homing pigeons, terrarium animals, small rodents, ferrets and rabbits as referred to in Article 5(6);
- Parallel traded veterinary medicinal products as specified in Article 102.

Some objectives of UPD



UPD concept

- **Improved transparency** and **easy access to information** on veterinary medicinal products approved for distribution in the EU
- **Improved data quality** in the regulatory processes
- **Offering self-service access for marketing authorisation holders** for certain regulatory activities and enabling the management of variations that do not require assessment

Access to UPD (Art. 56 & Art. 13 (IA))

The UPD Access policy defines the access rights of different stakeholder groups to UPD data

The document defines **3 access levels**

- European Commission, competent authorities and the Agency
- Marketing Authorisation Holders

3.2	Marketing authorisation holder access	Marketing authorisation holders shall be able to access (read) all information about their veterinary medicinal products following secure authentication and authorisation. They shall also be able to access (write) selected information about their veterinary medicinal product in order to fulfil any post-marketing obligations provided for in Regulation (EU) 2019/6 following secure authentication and authorisation.

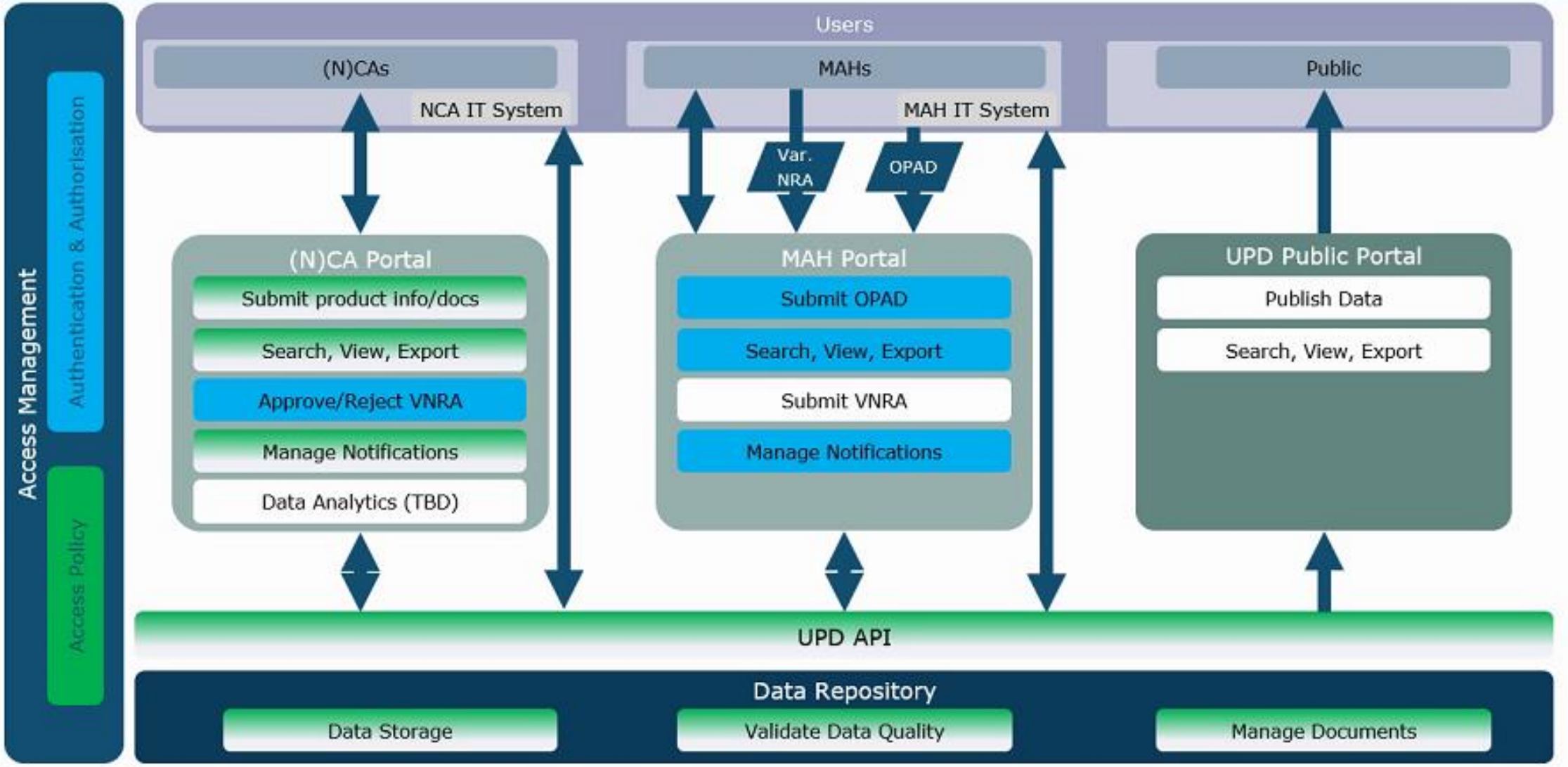
- General Public

Chapter 1 of the EU Vet Implementation guide - registration and data access requirements

RCUD = Read, Create, Update, Delete
Y/N = yes, no
The numbering reflects the field numbering in Annex II and III of the Implementing Regulation.

UPD fields[8]	Level 3												Level 2				Level 1			
	RCUD = Read, Create, Update, Delete																			
	Commission				Competent Authorities				Agency				Marketing Authorisation Holders				General Public			
	R	C	U	D	R	C	U	D	R	C	U	D	R	C	U(1)	D	R	C	U	D
1. For all veterinary medicinal products																				
1.1 Product Domain	Y	N	N	N	Y	Y	N	N	Y	Y	N	N	Y	N	N	N	Y	N	N	N
1.2 Product Type	Y	N	N	N	Y	Y	N	N	Y	Y	N	N	Y	N	N	N	Y	N	N	N
1.3 Product Name	Y	N	N	N	Y	Y	Y	N	Y	Y	Y	N	Y	N	N	N	Y	N	N	N
1.4 Active Substance(s)	Y	N	N	N	Y	Y	Y	N	Y	Y	Y	N	Y	N	N	N	Y	N	N	N
1.5 Strength/Composition	Y	N	N	N	Y	Y	Y	N	Y	Y	Y	N	Y	N	N	N	Y	N	N	N
1.6 Manufacturing Sites	Y	N	N	N	Y	Y	Y	N	Y	Y	Y	N	Y(5)	N	N	N	Y(2)	N	N	N
(.) Operation type (for manufacturing site)	Y	N	N	N	Y	Y	Y	N	Y	Y	Y	N	Y(5)	N	N	N	Y(2)	N	N	N
1.7 Documents (SPC, PL, labelling, PuAR)[9]	Y	N	N	N	Y	Y(3)	Y(3)	N	Y	Y	Y	N	Y	N	N	N	Y	N	N	N

UPD Main functionalities



MAH data responsibilities in UPD - Articles 55(2), 58(6) 58(12) and 61 - from Jan 2022 onwards

The EU Vet Implementation guide

- the **dates** when your authorised veterinary medicinal **products are placed on the market,**
- information on the **availability** for each veterinary medicinal product in each relevant Member State
- **update the marketing authorisation status** of their veterinary medicinal products in case of suspension or revocation of the marketing authorisations concerned and the **dates of any suspension or revocation**.
- the **annual volume of sales** for each of your veterinary medicinal products.
- record **variations to the terms of the marketing authorisation that do not require assessment** in the product database
- IA - Art. 18(8)….**ensuring that the data and documents** they record in datasets existing in the Union product database for their veterinary medicinal products are **correct and up to date**.

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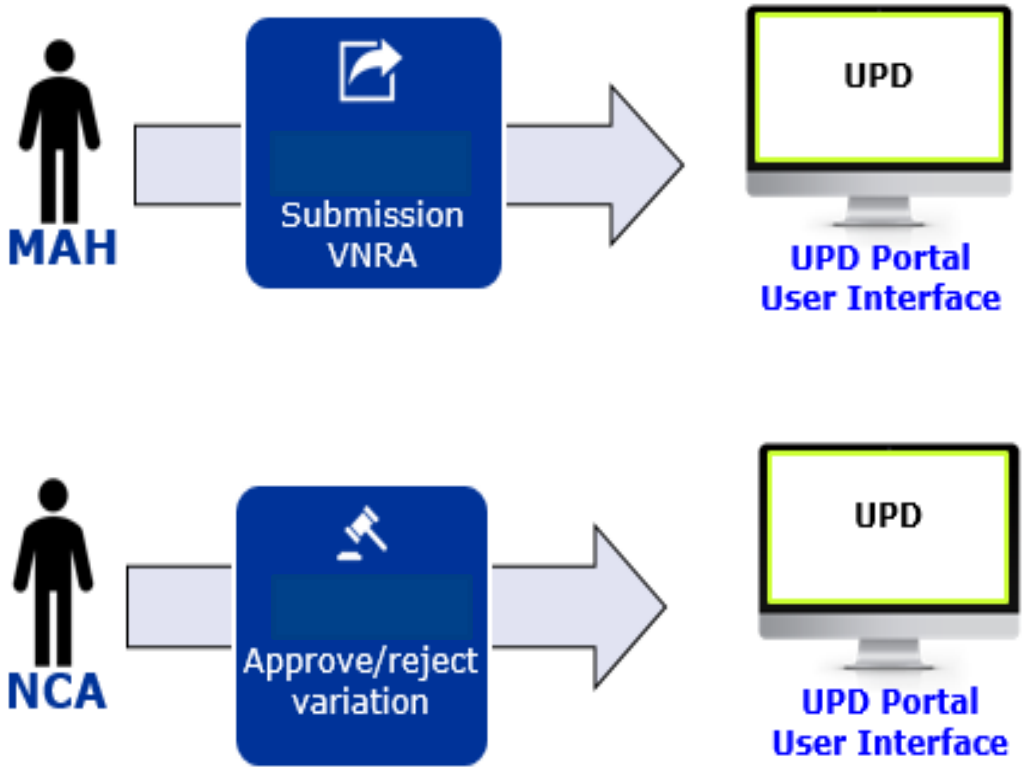
Variations not requiring assessment (VNRA)



SPOR

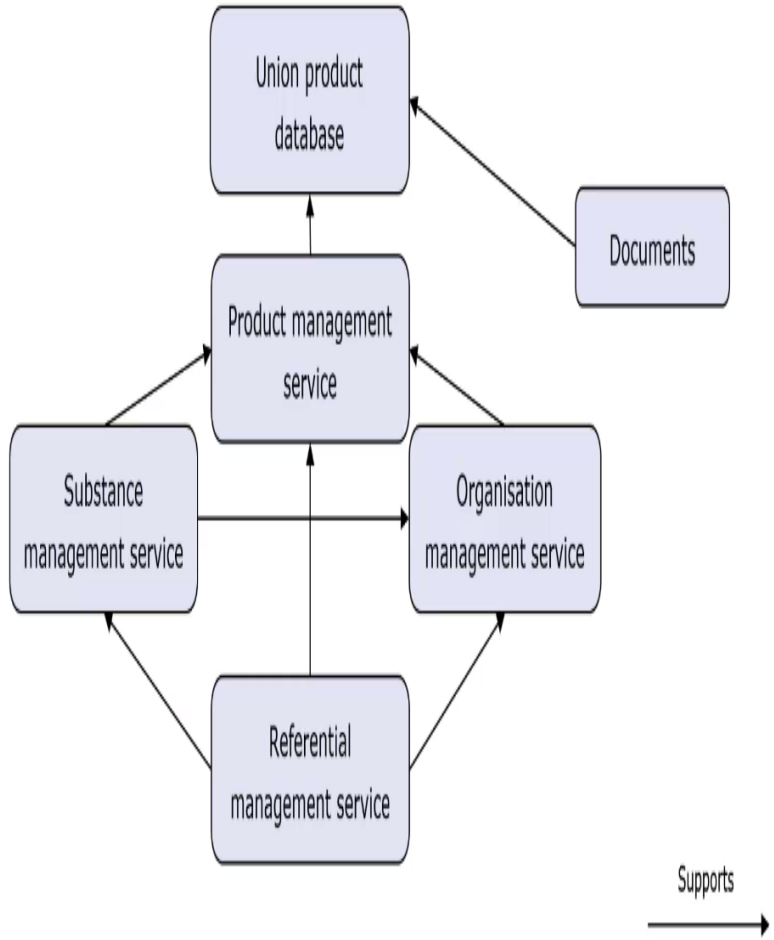
Substances Management Service (SMS)

Products Management Service (PMS) – UPD database

Organisation Management Service (OMS)

The 'OMS web user manual' describing how to register an organisation in OMS can be found on the OMS portal, in section 'Help'.

Referentials Management Service (RMS)



Training

Proposed EMA training events for NCAs and MAHs during 2021

- Registration Process
- Submission of variations not requiring assessment
- User Interface
- Search/view/export and notifications

Key messages

- The Access Policy provides information on the different levels of access in UPD and Chapter 1 of the EU Vet Implementation guide provides information on registration and access requirements
- The EU Vet Implementation guide provides stakeholders, including MAH's with detailed guidance on the submission of information on medicinal products
- More information on VNRA's will be available throughout 2021
- Your organisation data must be registered in OMS
- Training will be available for stakeholders

Thank you

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