HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

Union Product Database

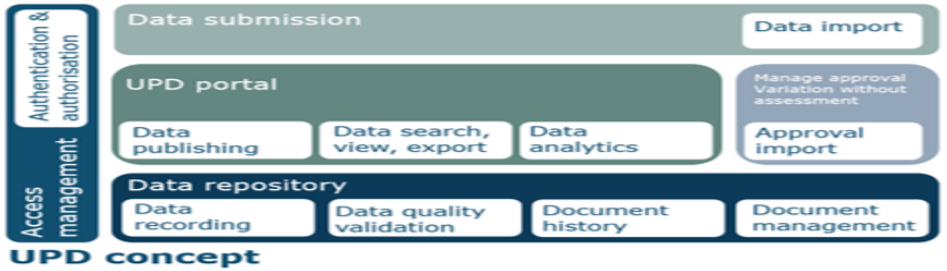
Elaine Hynes

HPRA webinar – Update on the implementation of Regulation 2019/6 in Ireland

19th May 2022

This presentation covers

Data upload progress



UPD concept

EMA Update:

	Product in UPD (Permanent IDs)	National dataset in UPD	National dataset completeness Rate (%)
Decentralised Procedure	23763	15539	
Mutual Recognition Procedure	3586	3510	
National Procedure	12200	12196	
Centralised Procedure	592	592	
Subsequent Recognition Procedure	240	89	
Total	**40381**	**31926**	**79**

HPRA Update:

- All products where IE = RMS are now in UPD. Data refresh planned for end of May
- All CMS products are now in UPD, with the exception of products where the procedure number does not conform with Chapter 2 rules.
- All nationally authorised products are now in UPD. Data refresh planned for end of May
- Documents uploaded for all national and RMS products.

Outstanding:

- CMS products with incorrect procedure numbers
- Products where IE is CMS but no record available in UPD to update.

Examples of ongoing challenges

- Missing products in UPD and impact on VNRA submissions
- VNRA submissions disappearing
- Creation of duplicate products
- Downloading Vnees files
- System bugs e.g. withdrawal periods = 0
- System instability when searching

Future enhancements

- ✓ Bug fixes
- ✓ Enhancements to public website
- ✓ Management of VNRAs that affect data related to: PSMF, QPPV, manufacturers, ATC vet code
- ✓ Downloading submitted metadata for VNRAs
- ✓ Submission of VNRA for products approved under different procedures approved by different NCAs
- ✓ Provision of the MAH by the RMS when creating products
- ✓ Parallel traded products

Key messages

- Missing products – contact NCA/RMS/EMA for guidance.
- System issues are causing processing issues and delays with VNRAs for NCAs
- Data enhancement requests from MAH's, where not urgent will be actioned during the summer months
- Future enhancements will continue throughout 2022 which should improve system stability and usability
- Please contact vetinfo@hpra.ie with any queries / requests

Thank you

hpra.ie/NewVetReg

vetinfo@hpra.ie

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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**.

 **vetchange.programme@ema.europa.eu**

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.

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

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)