2021 04 27

Union Product Database (UPD)

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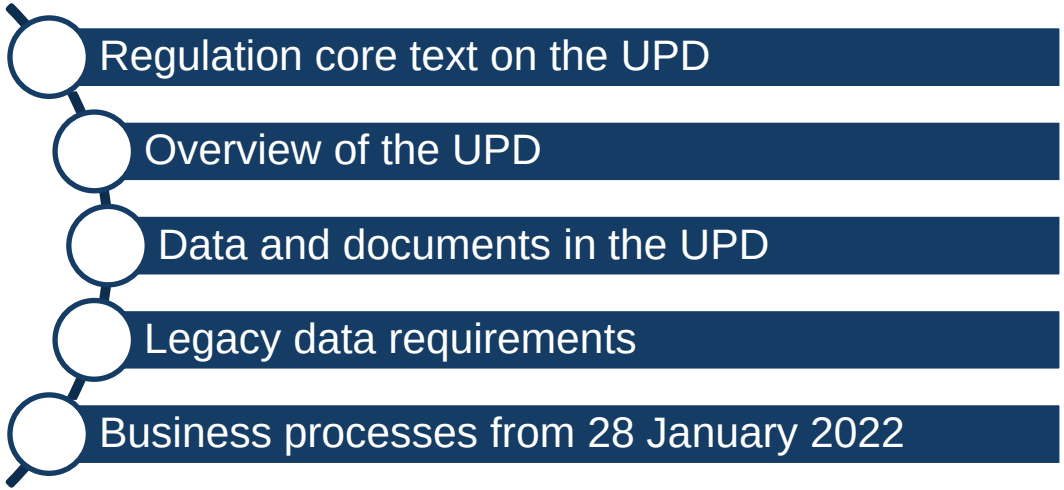
Outline



More information can be found at: EMA webpage on Implementing the Union Product Database

Some objectives of the UPD

Regulation (EU) 2019/6 on veterinary medicinal products "*aims to reduce the administrative burden, enhance the internal market and increase the availability of veterinary medicinal products, while guaranteeing the highest level of public and animal health and environmental protection*" and the UPD will contribute to this goal by:

- Improving transparency of veterinary medicinal products approved for distribution in the EU
- Supporting harmonisation of product information
- Implementing a reliable tool that veterinary practitioners can use to elaborate treatment options, also in case of unavailability of a specific product in a particular Member State
- Providing self service access for industry for certain regulatory activities and enabling the management of variations that do not require assessment

Regulation 2019/6

Article 55 - Union database on veterinary medicinal products

1. **The Agency shall establish and, in collaboration with the Member States, maintain, a Union database on veterinary medicinal products (‘product database’).**

Regulation 2019/6

Article 55 - Union database on veterinary medicinal products

2. The product database shall contain at least the following information:

(a) for veterinary medicinal products authorised within the Union by the Commission and by the competent authorities:

- **(i) name of the veterinary medicinal product;**
- **(ii) active substance or substances, and the strength of the veterinary medicinal product;**
- **(iii) summary of product characteristics;**
- **(iv) package leaflet;**
- **(v) the assessment report;**
- **(vi) list of sites where the veterinary medicinal product is manufactured; and**
- **(vii) the dates of the placing of the veterinary medicinal product on the market in a Member State;**

(b) for homeopathic veterinary medicinal products registered in accordance with Chapter V within the Union by the competent authorities:

- **(i) name of the registered homeopathic veterinary medicinal product;**
- **(ii) package leaflet; and**
- **(iii) lists of sites where the registered homeopathic veterinary medicinal product is manufactured;**

(c) veterinary medicinal products allowed to be used in a Member State in accordance with Article 5(6);

(d) the annual volume of sales and information on the availability for each veterinary medicinal product.

Regulation 2019/6

Article 55 - Union database on veterinary medicinal products

3. **The Commission shall, by means of implementing acts, adopt the necessary measures and practical arrangements laying down:**

   (a) the technical specifications of the product database including the electronic data exchange mechanism for exchanging with the existing national systems and the format for electronic submission;

   (b) the practical arrangements for the functioning of the product database, in particular to ensure protection of commercially confidential information and security of exchange of information;

   (c) detailed specifications of the information to be included, updated and shared in the product database and by whom;

   (d) contingency arrangements to be applied in case of unavailability of any of the functionalities of the product database;

   (e) where appropriate, data to be included in the product database in addition to the information referred to in paragraph 2 of this Article.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 145(2).

Regulation 2019/6

Article 56 - Access to the product database

1. **The competent authorities, the Agency and the Commission shall have full access to the information in the product database.**

2. **Marketing authorisation holders shall have full access to the information in the product database as regards their marketing authorisations.**

3. **The general public shall have access to information in the product database, without the possibility to change the information therein, as regards the list of the veterinary medicinal products, the summary of product characteristics, package leaflets and, after the deletion of any commercially confidential information by the competent authority, assessment reports.**

Regulation (EU) 2020/19

Article 155 - Initial input to the product database by competent authorities

At the latest by 28 January 2022, the competent authorities shall submit, electronically, information on all veterinary medicinal products authorised in their Member State at that time to the Agency, using the format referred to in point (a) of Article 55(3).

Regulation (EU) 2020/19

Article 102 - Parallel trade in veterinary medicinal products

….

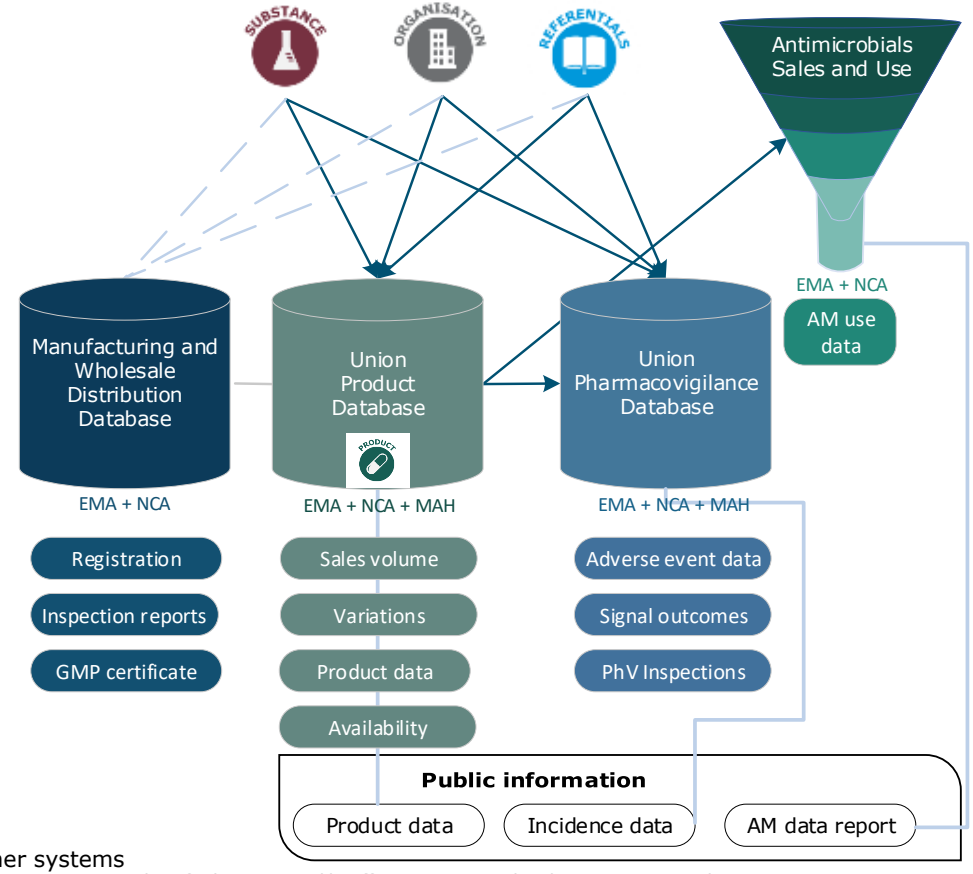
4. Competent authorities of the destination Member State shall, in the product database as referred to in Article 55, make available to public the list of veterinary medicinal products that are parallel traded in that Member State.

….

7. The following information shall be attached to the list referred to in paragraph 4 in respect of all veterinary medicinal products:

(a) name of the veterinary medicinal products;
(b) active substances;
(c) pharmaceutical forms;
(d) classification of the veterinary medicinal products in the destination Member State;
(e) marketing authorisation number of the veterinary medicinal products in the source Member State;
(f) marketing authorisation number of the veterinary medicinal products in the destination Member State;
(g) name or company name and permanent address or registered place of business of the wholesale distributor in the source Member State and of the wholesale distributor in the destination Member State.

Overview



Product types to be included in the UPD

- Authorised veterinary medicinal products (all procedures)
- Registered homeopathic veterinary medicinal products
- Parallel traded veterinary medicinal products
- Veterinary medicinal products intended for animals which are exclusively kept as pets

Overview UPD

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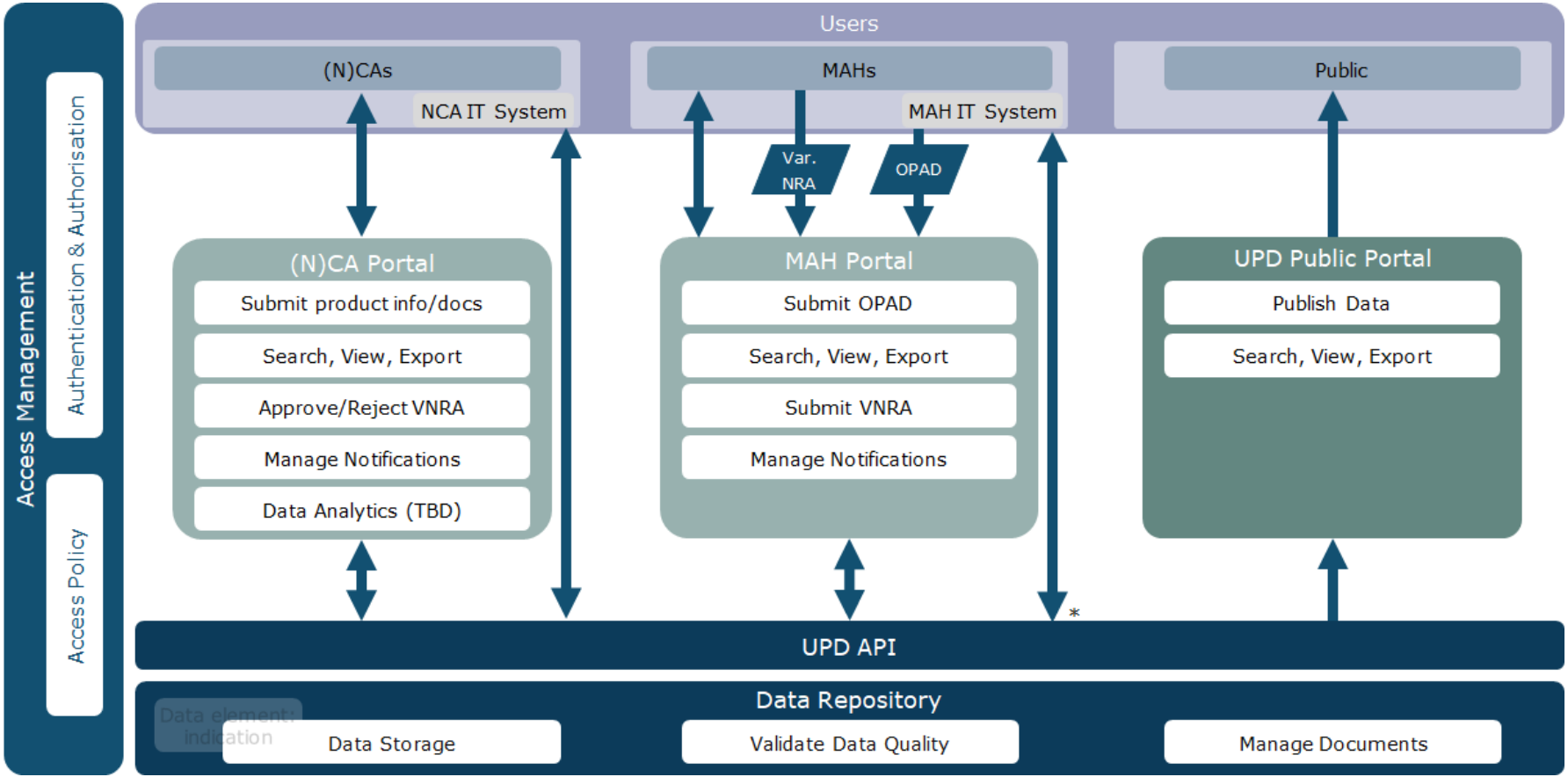


* Timely availability of the Application Programming Interface ('API') for exchange of other post-authorisation data with MAH IT systems remains to be determined

Post 28th of Jan 2022

28th of Jan 2022

MAH responsibilities for submission in UPD

The adopted Access policy can be found here at EMA webpage.

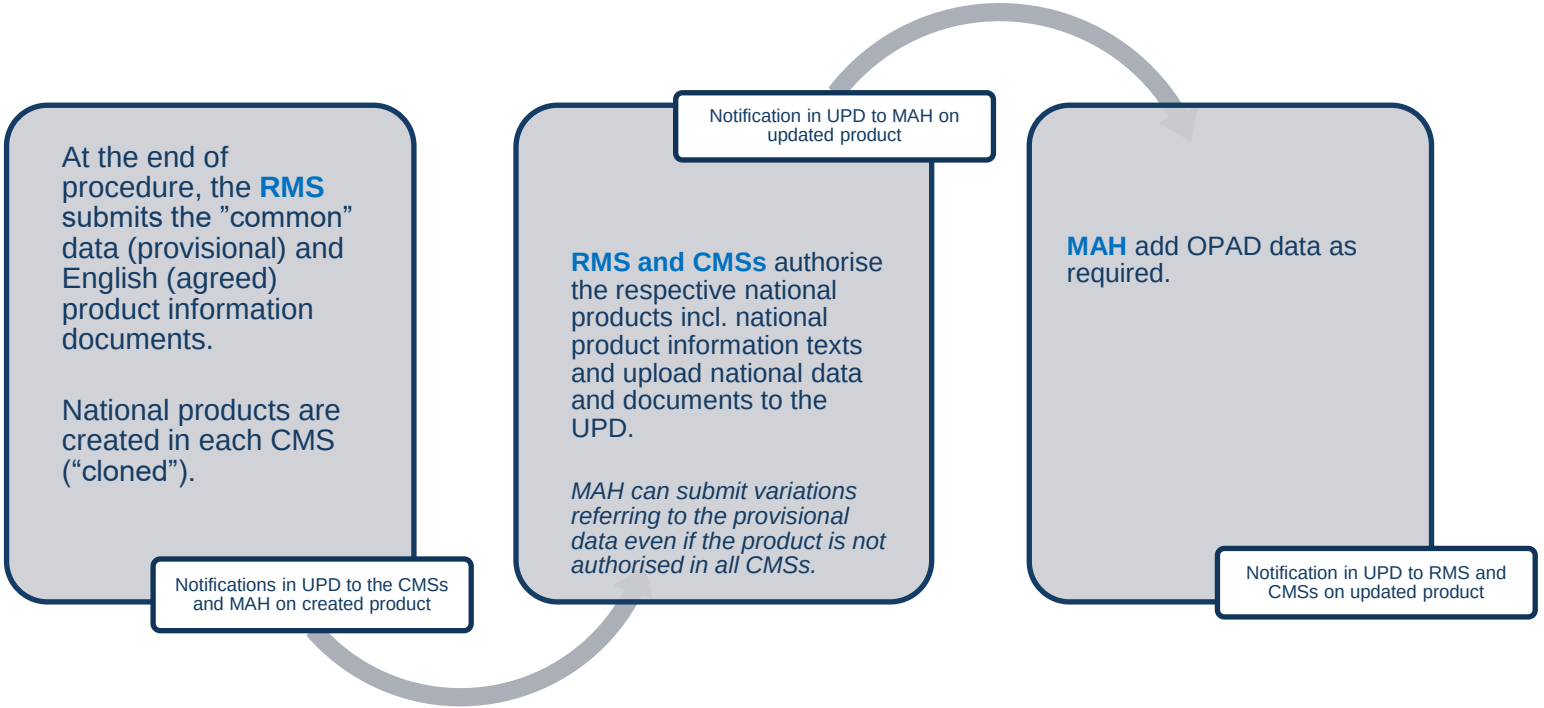
The adopted Regulations e.g. implementing acts for the UPD and VNRA can be found here at EC webpage.

EU Vet Implementation Guide (EU Vet IG)

Chapter 1	Registration and data access requirements for the User Interface (UI) and Application Programming Interface (API)
Chapter 2	Format for the electronic submission of veterinary medicinal product information
Chapter 3	Process for the initial submission and maintenance of veterinary medicinal products information
Chapter 4	Process and format for the submission of legacy data on veterinary medicinal products
Chapter 5	Technical specifications
Chapter 6	Examples

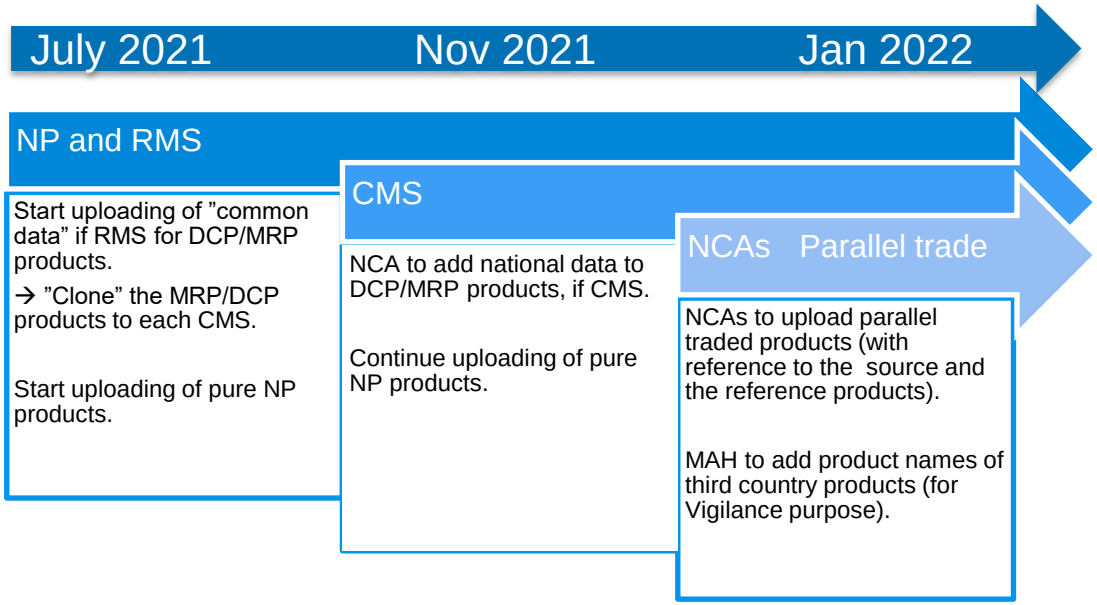
Next version (all chapters) is planned for publication soon, see EMA webpage on Implementing the Union Product Database

Principle for upload to the UPD in DCP/ MRP/SRP



The RMS is responsible for the update of the ”common” data and documents, as applicable, after variation. CMSs to add any national data and documents.

Legacy data upload (all authorised VMPs)



- The data uploaded via API or XML File upload (FHIR message format) or can be added directly via the UPD user interface.
- During the upload period, or by the 28 January 2022 at the latest, updates are needed due to ongoing and upcoming variations.

Data format in UPD

Substance Management Services (SMS)

Product Management Services (PMS)

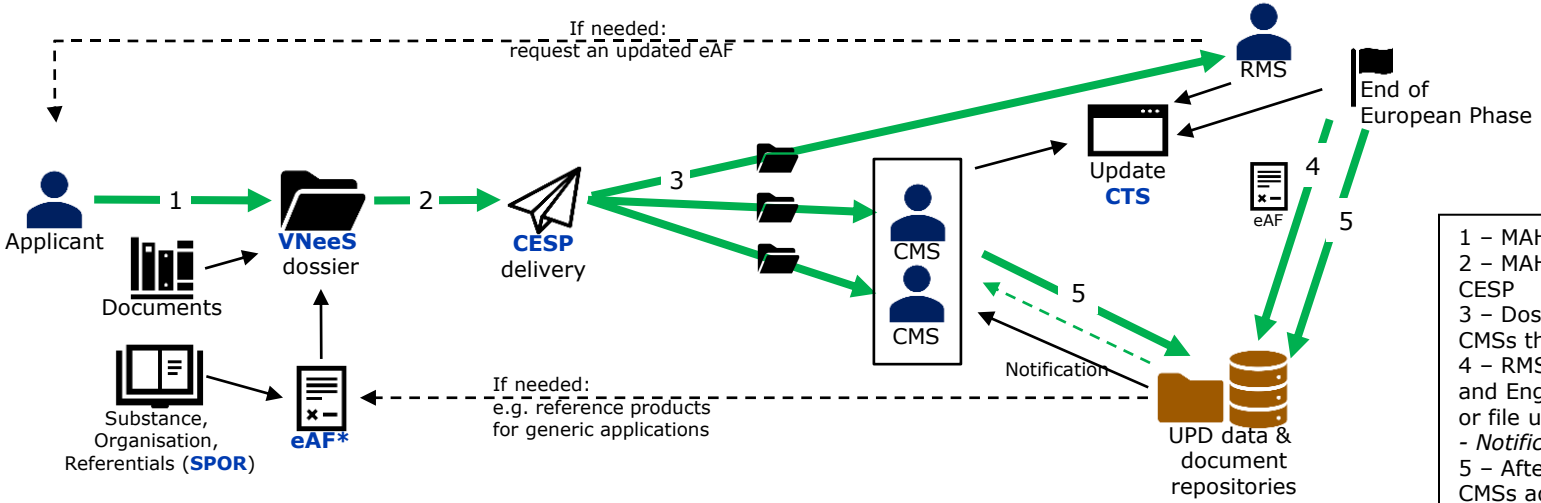
Organisation Management Services (OMS)

Referentials Management Services (RMS)

- UPD data is based on SPOR
- The information structure is based om PMS (IDMP standard) “light” version
- EMA and NCAs need to map to legacy data R, S, and O term IDs
- Applicants/MAHs need to register all organisations in OMS before submissions of applications.

https://spor.ema.europa.eu/sporwi/

New product: MRP/DCP
(Variations Requiring Assessment is similar)



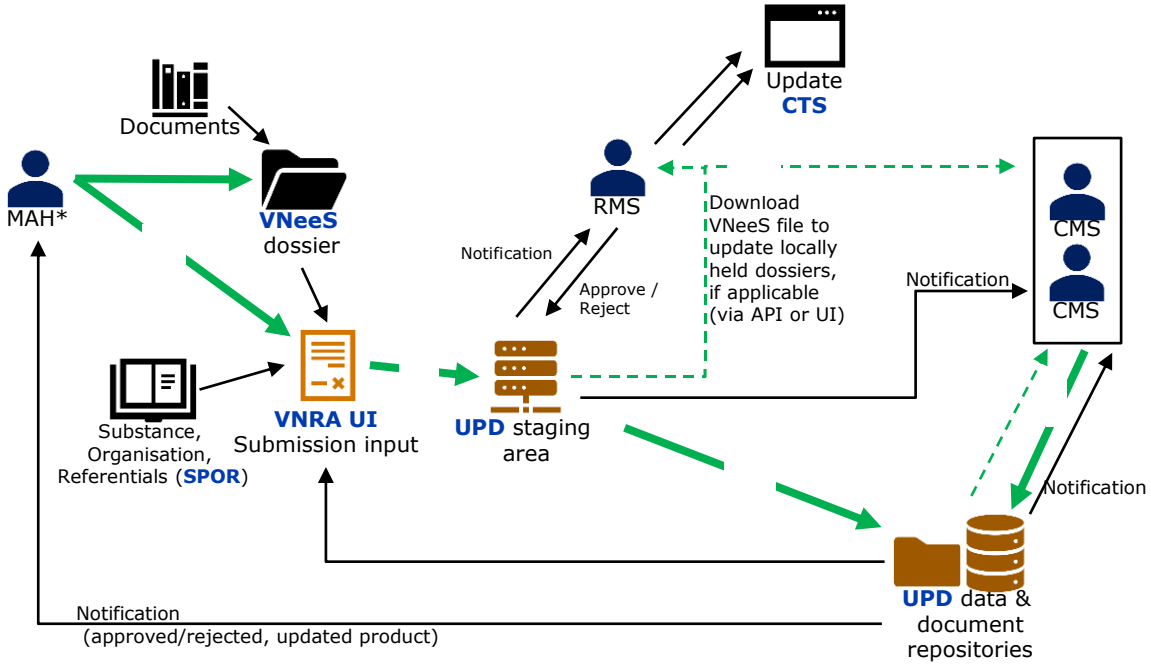
1 – MAH builds VNeeS submission
2 – MAH submits VNeeS dossier via CESP
3 – Dossier received by RMS and CMSs through CESP
4 – RMS uploads **EU-common** data and English version documents (API or file upload or manual entry)
- Notification to CMSs -
5 – After authorisation, RMS and CMSs add **national** data and documents (API or UI)
– if needed, CMS download updated data and documents, if applicable (API or UI)

Data flow Supportive data flow or actions

** Exact scope of the DADI project is still being defined (e.g. integration of application forms to source data from SPOR and UPD)*

Variations Not Requiring Assessment: MRP

i.e. **all** variations not requiring assessment (**VNRA**)



Variation not requiring assessment (VNRA):
1 – MAH prepares VNRA, incl. upload of VNeeS file if dossier changes; submission is pre-populated with current product data from UPD
2 – MAH records VNRA in UPD (staging area), using SPOR elements as needed and attaching documents and/or a VNeeS file, as necessary
- RMS receives notification and approves/rejects; CMS receive notification for info -
3 (optional) – *if needed,* RMS and CMS download VNeeS and VNRA information (API or UI)
4 – if approved, **common** data and English documents of the product are updated in UPD
- Notification to CMSs -
5 – RMS and CMSs amend **national** data and documents (API or UI), if applicable***
– if needed, CMS download updated data and documents, if applicable (API or UI)

** Lead MAH/MAH in RMS submits VNRA on behalf of all MAHs for the MR/DC product, including all documents*
*** Until nationally approved, the status of a new product in the respective MSs will stay as provisional, this will not prevent submission of variations.*
****Updated versions of SPC/PL/LAB documents will be handled by each MS (tdc)*

Training for industry planned in 2021