EUROPEAN MEDICINES AGENCY
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Questions & Answers

Submission of NCAs legacy data on veterinary medicinal products into the Union Product Database

This document consolidates questions and answers asked by national competent authorities (NCAs) on the submission of legacy data on veterinary medicinal products into the Union Product Database (UPD).

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This document consolidates questions and answers asked by national competent authorities (NCAs) on the submission of legacy data on veterinary medicinal products into the Union Product Database (UPD).

Questions were received during the below-mentioned webinars organised by EMA's Veterinary Medicinal Products Regulation programme to support timely legacy data submission:

- Business process for the submission of legacy data into the UPD, 14 April 2021
- NCAs best practices for legacy data upload into the UPD via the API, 29 April 2021

In addition, the document includes queries discussed during the meetings of the informal NCAs group that was established to fully understand, define and support the process for the NCAs to submit their legacy data into the UPD.

This is a living document which is intended to be updated with additional questions and answers as and when they become available.

Please submit any questions related to the NCAs legacy data submission into UPD to vetchange.programme@ema.europa.eu

1. Process and format

1.1. What are the options for NCAs to upload legacy data on veterinary medicinal products?

In the context of the submission of legacy data on veterinary medicinal products, the following solutions are available (refer to the Chapter 4 of the EU Implementation Guide (IG):

1. The application programming interface (API) - fully automatic via NCA IT system communicating with the UPD API
2. File upload:
    - FHIR message in XML format is created locally
    - Connection to UPD API is established via HTTP client (e.g. Postman)
    - Manual upload of the XML file via the HTTP client
3. UPD user interface (UI) - data keyed in manually.

1.2. What is the format of the file to upload NCAs legacy data on veterinary medicinal products?

The format of the file for the upload of legacy data is XML using the FHIR standard.

1.3. Will the UPD system ensure that CMS cannot modify the EU common data as provided by RMS?

Yes. However, the FHIR concept does not provide for the separation of common and national data elements, and we need to keep in mind that the UPD implements a layer of customisation, meaning that the UPD will *ignore* common data, if a CMS uploads common data - even if the CMS provides data in the FHIR message.

1.4. How will the concerned Member State (CMS) be informed that the reference Member State (RMS) has created an entry in the UPD and then find the MRP/DCP products to enrich them with the national data?

In the context of API/UI, once the RMS has uploaded their products into UPD, the CMS can retrieve their products based on a number of search criteria e.g. procedure number. Please refer to the API webinar of 29 April 2021 for practical examples.

1.5. Should the RMS indicate the CMS(s) when uploading legacy data?

It is required that the RMS indicates all the CMS when providing the common data set. This would allow the notification to be provided to the relevant Member State and also to 'clone' the product for the individual applicable country and generate the relevant Permanent ID.

RMS countries can request information on the CMS list from the Communication and Tracking System (CTS) by emailing their request to cts.helpdesk@bfarm.de

The CTS team will provide the CMS list in Excel format including the product name in English, procedure type and links to the Product Information documents e.g. SPC, package leaflet etc.

Please note: at this point, the CTS cannot guarantee the data provided is entirely comprehensive and accurate.

1.6. How to provide certain mandatory NCAs legacy data which is not available electronically?

In order to alleviate the challenges faced by the NCAs for the initial input of data on authorised veterinary medicinal products, the UPD will allow a phased submission of data for all products and will not enforce an 'all-or-reject' approach. NCAs will be able to perform a preliminary data submission into the UPD via the API, user interface, or manual upload of compatible messages. In cases, where certain information is not available, data fields values such as 'data

not provided' may be accepted. Please refer to the Explanatory note on the Veterinary EU Implementation Guide published in May 2021. In case of a preliminary submission, NCAs will then need to enrich incomplete datasets submitted via the same or a different route of transmission by 28 January 2022.

1.7. Which fields will be required/mandatory for national legacy products intended for animals which are exclusively kept as pets, in accordance with Article 5(6) of Regulation 2019/6?

Product information for Article 5(6) products does not have to be provided before 28 January 2024. In view of this deadline, the information Member States should provide for these products has not been defined and further guidance will be made available at a later stage.

1.8. Is there any indication when to upload the common data by the RMS: for instance 48 hours after the end of the procedure or one week after the end of the procedure?

RMSs are encouraged to upload common data as soon as possible, to allow CMSs enough time to upload national data.

2. Application Programming Interface (API) related

2.1. When will the UPD API go live?

The UPD – compliant with the July 2020 version of EU Implementation Guide, and including document management) is already live. The release notes of the UPD iterative version v 01.02 released on 16 March are available here. The UPD compliant with the May version of EU Implementation Guide will go live in July 2021 (milestone 3).

2.2. When are further API releases expected in 2021 and 2022?

Further API releases will be part of milestone 4 which is planned for October 2021, and milestone 5, planned for January 2022. Afterwards, a new release for the UPD is scheduled approximately every three months.

2.3. How will the legacy data upload via API work?

- **NAPs**

NCAs will upload legacy data/documents (one per product) to **create** NAPs in the UPD. In case of an incomplete preliminary submission, NCAs will then need to enrich incomplete datasets via the same or a different route of transmission by 28 January 2022 (see 1.6).

- **MRP/DCP/SRP**
    - **If NCA = RMS**

- NCAs will perform a one-time upload (via API) of legacy data/documents per product to initially create products in the UPD.
- Only one upload (via API) is necessary to initially create all related MRP/DCP products (RMS/CMS).The UPD will clone (create) in the UPD the products pertaining to the CMS.
- In case of an incomplete preliminary submission, NCAs will then need to enrich incomplete datasets via the API or a different route of transmission by 28 January 2022 (see 1.6).
    - **If NCA = CMS**
- CMS will query the UPD via the API to check if the RMS has already created the national "provisional" product.
- If available, CMS will download via API the UPD identifiers (e.g. product, packages, ingredient, manufactured item, etc.) to be able to build the "UPDATE" message for national specific data updates.
- The UPD will ensure that CMS messages do not overwrite common data and documents.

Note: There will be no *'DELETE'* functionality available, therefore 'CREATE' of a product via the API or UI have to be carried out cautiously. Products can only be nullified.

2.4. When using the API, can the RMS create a new MRP/DCP product and update the national data in the same 'Create' message?

From a user/data entry perspective, this cannot be performed in one step and will need to be performed as two separate steps, first as RMS and then as CMS.

2.5. Will RMS be informed in case an issue occurred when 'cloning' a product for the CMS?

RMS will not be informed if an issue occurred when cloning a product. The issue will be on the UPD side and will need to be addressed by the UPD.

2.6. Does the CMS have to query the UPD API retrieve receive notifications?

Yes, the CMS will need to make queries to receive the notifications.

2.7. How would the feedback process look for non-successful upload?

If the information provided in the payload is incorrect, there are a number of feedback options in place and to be used by the submitter:

1. From the API standpoint there is a validation according to the rules defined in the IG. If rules are violated, the list of violations is returned to the client;
2. If the payload passes the validation, the client can query the system to understand the outcome of the processing of the payload. The outcome can be as follows:
    - the payload is still queued;
    - the payload persistence has failed;
    - the payload persistence is successful and the permanent identifier of the product is available in that same outcome.

2.8. Does UPD have to clone the data multiple times (as many as CMSs are there)? And can a CMS upload to just any clone? How is that coordinated?

Products created are not exact clones and there will be some attributes that will allow to understand which of the products is the one a specific NCA is responsible for maintaining.

2.9. Will the products uploaded via API/file upload be visible via UI immediately after the upload?

The record of a product will appear in the UPD UI after the product has been successfully created. The operation is asynchronous.

2.10. How could we map the generated internal (i.e. children's) identifier to the data structure we sent in initial submission? That is:

- **If the NCA structure contains, i.e. three package resources, in the initial submission NCA send them assigning bundle-scoped "artificial" IDs (e.g.: id1, id2 and id3, in form of uuids)**

- **After the GET with $everything parameter, NCA obtain in the bundle the three packages with their permanent ids assigned by UPD**
- **How NCA correlate each UPD generated id to the original package we sent? Positionally? By some other package property?**
- **Same applies for each other "child" resource (e.g.: ingredients).**

At this point in time, this is not supported by UPD, but it could be captured as a post-MVP requirement.

2.11. Do you manually copy/paste the FHIR bundle for one product at the time from NCA database and into Postman?

A single FHIR bundle contains a single medicinal product. The exact use of Postman is not in the UPD scope, it is just one of the many HTTP client tools that can be used.

2.12. Do I need to create a personal account to get access to the UPD via API?

Currently, each user of the UPD API functionality requires individual registration. Please refer to the Production API and Registration Process document for detailed instructions in order to get access to the API Manager and relevant APIs.

2.13. Will the UAT API keys expire? If so, are we notified in advance?

For the time being, EMA has no intention to force an expiration of the API keys in the UAT environment.

2.14. What is the production API endpoint?

The production API endpoint is the same as the endpoints in place for UAT but without the **-uat**. See also https://www.ema.europa.eu/en/veterinary-regulatory/overview/veterinary-medicines-regulation/union-product-database-release-notes.

2.15. When I upload documents via API, I don't see any reference to these documents in the medicinal product resource bundle. How do I know there are

documents attached? Will there be a reference in future implementations?

That is a normal behaviour, users can retrieve the document based on the product permanent identifier with:

```
GET
/DocumentReference?related=/MedicinalProductDefinition/{produ
ct-permanent-id}
```

2.16. How will the FHIR messages work for RMS and CMS respectively? How could we give different options for the NCA to fill the FHIR message when CMS; e.g.

- **full dataset, but only the National data to be uploaded (maybe with some feedback on discrepancies on the data compared to the RMS data?)**
- **only national data and the rest of the message as "dummy" data**
- **other ways?**

In order to maintain data in the UPD, the maintainer **must** interact with the UPD in order to understand what is in UPD and make the needed changes in the right way.

If we look beyond the creation of a product, the maintenance (the most common type of interaction for medicinal products in the UPD) **must** be based on all the data elements of the medicinal products in the UPD before it can proceed with updating, adding or removing attributes from the current version of the product. To be clearer, it is important to maintain the ids in place in the UPD when making changes to a resource or an attribute inside a resource.

In that sense, the dummy data are no longer relevant as the client must have a copy with all the elements of the product in UPD before it can attempt any change to that product.

2.17. Does FHIR provide for product information merging?

This feature is not available in FHIR and is made available through customisation layer.

2.18. Are there specific tools instead of Postman already in focus to use in the production setting?

Please note: answer provided by AGES. AT will use a REST-Client which is provided from a JAVA based production environment. Support and helpdesk will still use POSTMAN in certain cases to find bugs and solve problems.

Any HTTP client can be used to support the operation of upload.

2.19. Which catalogue is used for the indications? ICD-10/11, SNOMED?

Indications is not part of the current implementation for the veterinary domain. Whether indications can be harmonised/mapped into structured/controlled terms for human and veterinary domains is a discussion EMA intends to have after January 2022 in collaboration with the Member States and also in collaboration with the potential Electronic Product Information (ePI) project.

3. NCA UI UAT

3.1. Is the NCA User Interface of the UPD available?

The first version of the NCA UI is already available in UAT. Please refer to the UPD Production release notes for version 01.02 March 2021 to find out how to register for access. NCA users are strongly recommended to carry some testing to create/update a product in the UPD UAT before uploading their legacy data in the UPD production environment from July 2021 onwards.

3.2. Is the UPD environment of the current release version stable and includes document management functionality?

The UPD version that has gone live on 16 March provides document management functionality and can be considered stable as EMA does not expect this to change in the upgrade to the May 2021 version of the EU Implementation Guide. The next release of the UPD compliant with the May version of the EU IG will introduce changes to the API functionality and will go live in July 2021 (milestone 3).

4. Product identifier

4.1. Will the product identifier apply to all different package sizes?

Yes, the product identifier will be shared across different package sizes.

4.2. Is the product identifier generated by the UPD system?

Yes, all the UPD identifiers (i.e. Product, Permanent and Package IDs) are generated by the system.

5. Permanent identifier

5.1. Will the Permanent ID be created when the RMS has uploaded the common data?

Yes, the system generates the permanent ID when the 'common data-set' is submitted by RMS. The UPD will then 'clone' the CMS products which can be retrieved by permanent IDs in order to enrich those products with the national data.

5.2. Since the (national) MAH is needed for the Permanent ID and it is not available until given by the CMS, how could the Permanent ID be created after the RMS upload? Could the MAH in RMS be used in this case?

Please see question 5.1 above and refer to the EU IG section related to ID levels.

6. Referential management service (RMS)

6.1. RMS has changed the term of 'Authorization Status' to 'Regulatory Entitlement Status'. Will this be reflected in the UPD and its related documents?

The data elements in UPD will retain the name 'Authorization Status' and in the Vet EU IG the reference will be to the RMS term list 'Regulatory Entitlements Status'.

6.2. What are terms to map legacy data for legal supply for veterinary medicinal products?

The legal status for the supply is usually defined at UPD product level and should be specified as 'Veterinary Medicinal product not subject to veterinary prescription' or 'Veterinary medicinal product subject to veterinary prescription'.

In the scenario that legal status for the supply is defined at package level only (different legal status for different package sizes of the same medicinal product), this information at medicinal product level is to be left empty. For those cases, the legal status for the supply must be entered at package level only (see section 6.4 - Legal Status for the Supply at Packaged Medicinal Product Level of the EU IG). The term 'Veterinary medicinal product subject to veterinary prescription except for some pack sizes' will then be shown at the product level.

Further detailed status of supply could be relevant in future versions of the UPD.

Note: the above terms for the "legal status for the supply" list will be created in RMS already as "provisional", until officially endorsed by the CMDv, so member states can already start mapping for legacy data at level 1.

7. Organisation management service

7.1. Is the Product Owner of a product identified by a LOC ID or ORG ID? Does this mean that a product can be owned by a physical location?

Yes, the MAH information (i.e. Product Owner) should be provided as an OMS Location ID. Hence the national entitlement should state a specific Location of the Organization.

7.2. Is it intended to provide the OMS LOC-IDs in the UPD UAT? Currently you can only search by the ORG-IDs which makes it difficult to select a correct address.

Each organisation in the UPD UAT environment is presented with the associated location addresses that the user can select.

7.3. What location ID should we choose among N of the same organisation?

The organisation location ID equivalent to the address stated in the SPC should be provided.

7.4. Is 'common name' also needed for the 'national' name? Should it be presented in two different fields: 1 national and 1 common.

The name of the medicinal product can be presented as a common name (the country should be set as EU) but also supplemented with the national name.

8. Packaged medicinal product

8.1. How will the package data be entered if the number of blisters in the package is not known and we only know the number of tablets in the package?

The vet IG does not foresee capturing packaging information such as blisters. The aggregated information should be captured at the level of packaged medicinal product as pack size.

9. Attached document

9.1. How would Belgium need to upload VMP name and documentation given the multiple languages (NL - FR - DE)?

The veterinary medicinal product name can be repeated to describe the applicable VMP names in all these languages. There can also be multiple languages attached to the documents or multiple documents attached, each in a single language.

9.2. In order to attach a document to a product, does the product need to already exist in UPD?

For the API use – yes.

9.3. Are there rules in place for the naming of the documents - file name?

Yes, in the new version of the EU IG we recommend a naming convention to provide the document title. This is a free text field and therefore we cannot enforce a technical format, however it is strongly recommended to set the name of the document according to the convention provided for improving future searchability and consistency.

9.4. What are the language requirements for the UPD documents for RMS and CMS respectively?

Please refer to section 1.11 of the Chapter 2 of the EU IG.

For MRP/DCP and Subsequent recognition procedures (SRP), the RMS will attach the English version of the product information (SPC/PL/LAB) agreed at the end

of the procedure as part of the European/Common dataset. All relevant concerned Member States (CMSs) shall attach the nationally approved translations of the document(s) by the time of authorisation, as relevant, as part of the national dataset.

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