EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Veterinary Medicines Division

# EU Implementation Guide (Vet EU IG) on veterinary medicines product data in the Union Product Database

Implementation of the requirements of Regulation (EU) 2019/6 for the Union database on veterinary medicinal products in the European Economic Area

## Chapter 2: Format for the electronic submission of veterinary medicinal product information

Version 1.3

**Overview of changes:**

Based on user experience gained and feedback received so far, the chapter has been revised extensively to provide more guidance, clarification, examples and helpful tips. Some of the key changes are listed below, but users are advised to read and consult the whole document:

- *Annex 2 Product information documents requirements*
    - The size of files to be uploaded e.g. Product Information, PuAR is increased from 2MB to 10MB.
    - Revised structure of the file name that a) allows Competent Authority users to upload multiple documents via the UPD user interface and b) removes the MAH burden to amend multiple PDFs specifying the product identifier in the custom tab each time.
- *Section Strength (quantitative composition)*
    - Addition of new fields in UPD for Strength text (Presentation), Strength text (Concentration) and Reference Strength text and the clarification of its main use.

For full, complete list of changes made compared to version 1.2 please see the table on pages 5-6 of this document.

**Official address** Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
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## Table of contents

# Changes made compared to version 1.2

| Section | Heading | Change applied |
|---|---|---|
| Glossary | --- | Definition of CMS added. |
| 1.6 | Legal Status for the Supply | Examples have been updated with the veterinary ones and the name of the section changed to be aligned with the RMS term |
| 2. | Authorisation/registration/entitlement information | Added the option veterinary medicinal products intended for animals which are exclusively kept as pets as referred to in Article 5(6) |
| 2.1 | Authorisation/registration/entitlement type | Removed the option "Minor Use Minor Species" |
| 2.13.1 | Procedure number | Provided a clarification about the characters allowed (case insensitive) |
| 2.13.2 | Procedure type | Changes provided for registered homeopathic procedure type and updated example for this procedure type, new information added for exemption to marketing authorisation for veterinary medicinal products intended for animals and parallel trade procedure |
| 4.3.2 | Strength (quantitative composition) | Added examples and clarifications |
| 4.3.2.1.2 | Strength text (Presentation) | New value/table added |
| 4.3.2.2.2 | Strength text (Concentration) | New value/table added |
| 4.3.3.2.2 | Reference strength text | New value/table added |
| 4.3.3.1 | Reference (active) substance | Conformance updated from mandatory to Conditional |
| 5.4 | Legal status for the supply (package level) | Added examples |
| 5.7.2<br>5.7.3 | Availability status<br>Availability status date | References to provision of 'Placing on the market' and 'Placing on the market date' have been removed until such functionality gets analysed and implemented |
| Annex 1 | 4.3.3.1 Reference(active) substance | Conformance updated from mandatory to Conditional |
| Annex 1 | 4.3.2.1.2. Strength text (presentation) | Added new rows information |

| Section | Heading | Change applied |
|---|---|---|
| | 4.3.2.2.2 Strength text (concentration)<br>4.3.3.2.2 Reference strength text | |
| Annex 2 | Product information documents requirements | New process updated for the bulk upload functionality |
| Annex 2 | Table with Product information Document Type & Regulating Authority Submission Unit Type | Updated table:<br>adding a new column with Term ID of Document type value and deleted the option "epar" on the document type |
| Annex 2 | Maximum size allowed to upload documents | Updated from 2MB to 10MB. |

# Glossary

| | |
|---|---|
| ATC vet code: | veterinary Anatomical Therapeutic Chemical code |
| CA: | Competent authority |
| CAP: | Centrally authorised product |
| Class: | A group of related data attributes |
| CP: | Centralised procedure |
| CMS: | Concerned member state |
| DCP: | Decentralised procedure |
| eAF: | electronic Application Form |
| EC: | European Commission |
| EEA: | European Economic Area |
| EMA: | European Medicines Agency |
| EU: | European Union |
| FHIR: | Fast Healthcare Interoperability Resources |
| GMP: | Good manufacturing practice |
| ID: | Identifier |
| IG: | Implementation guide |
| IS/LI/NO: | Iceland, Liechtenstein, Norway |
| ISO: | International Organization for Standardization |
| LOC ID: | Location Identifier |
| MA: | Marketing Authorisation |
| MAA: | Marketing Authorisation Application |
| MAH: | Marketing Authorisation Holder |
| MRP: | Mutual recognition procedure |
| NAP: | Nationally Authorised Product |
| NCA: | National competent authority |
| NP: | National procedure |
| OMS: | Organisations Management Service |
| ORG ID: | Organisation identifier |
| Package ID: | Packaged Medicinal Product Identifier |
| PL: | Package leaflet |
| PMS: | Product Management Services |
| PSMF: | Pharmacovigilance system master file |
| QPPV: | Qualified person responsible for pharmacovigilance |
| RMS: | Reference member state |
| RMS: | Referentials Management Services |
| SRP: | Subsequent Recognition Procedure |
| SMS: | Substance Management Service |
| SPC: | Summary of Product Characteristics |
| SPOR: | Substances Products Organisations Referentials |
| UPD: | Union Product Database |
| Vet EU IG: | European Union Implementation Guide (IG) on veterinary medicinal product data |

# Scope of this guidance

This document provides detailed guidance on the data elements and associated business rules for the **submission of** information on **medicinal products** authorised **for veterinary use** into the Union Product Database (UPD), as required in Regulation (EU) 2019/6 and Commission Implementing Regulation (EU) 2021/16.

The EU Implementation Guide (Vet EU IG) on veterinary medicines product data *Chapter 2* describes the data fields and the business rules and specifications for the **creation of a new veterinary medicinal product in the context of regulatory entitlements and the maintenance of veterinary medicinal products** after 28 January 2022.

Annex 1 of this document describes the fields relevant for "common data", also referred to as European data, and for "national data" for veterinary medicinal products authorised through the MRP/DCP and subsequent recognition procedures (Subsequent Recognition Procedures (SRP)).

Since this document is applicable to different types of veterinary medicinal products (see below), please note that:

- wherever the terms marketing authorisation (MA), authorised and marketing authorisation holder (MAH) are used, they also refer to registration, registered and registration holders for homeopathic products, as relevant;
- where the document refers to information stated in the Summary of Product Characteristics (SPC), this also applies to the package leaflet (PL) for registered homeopathic veterinary medicinal products and, where applicable, to relevant regulatory documents for veterinary medicinal products intended for animals which are exclusively kept as pets (Article 5(6)).

## *Veterinary medicinal products in scope of the UPD*

Regulation (EU) 2019/6 mandates competent authorities (national competent authorities and the European Medicines Agency on behalf of the European Commission) to electronically submit and maintain information on all medicinal products for veterinary use into the UPD.

Veterinary medicinal products in the scope of the legal obligations laid down in Article 55 of Regulation (EU) 2019/6 include:

- 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.

Veterinary medicinal products outside the scope include:

- veterinary medicinal products for which the regulatory assessment is ongoing and has not been completed, with the exception of those involved in MRP/DCP and Subsequent Recognition Procedures (SRP), where the EU common data of an approved veterinary medicinal product is entered into the UPD at the end of the approval process as provisional data, already before the product has been authorised in each individual Member State;

- veterinary medicinal products containing autologous or allogeneic cells or tissues that have not been subjected to an industrial process;
- veterinary medicinal products based on radioactive isotopes;
- feed additives as defined in point (a) of Article 2(2) of Regulation (EC) No 1831/2003 of the European Parliament and of the Council;
- veterinary medicinal products intended for research and development;
- medicated feed and intermediate products as defined in points (a) and (b) of Article 3(2) of Regulation (EU) 2019/4.

# Identification of a veterinary medicinal product in the UPD

In the UPD, a veterinary medicinal product is identified based on the following two levels:

- Level 1 identifies veterinary medicinal products at a high level of granular information and based on a set of data which is regarded as common to the product (defined as European in Annex I);
- Level 2 identifies the product on a more granular level with a more detailed set of data which is nationally specific and related to the authorisation number as assigned by the competent authority (defined as National in Annex I), e.g. applicable to a specific territory and based on the national dataset for MRP/DCP procedure.

In the context of the initial submission, i.e. when creating a new veterinary medicinal product, the relevant competent authority should specify the veterinary medicinal product information as described in this guidance. The UPD system will generate and associate relevant UPD Identifiers (IDs) to the appropriate levels based on the dataset provided. Subsequently, such UPD IDs shall be used by the applicable UPD stakeholders/users to update, maintain, search, retrieve, view and access veterinary medicinal product information in the UPD based on different levels of granular information in line with the principles outlined in the UPD access policy and the user roles-permissions-matrix as described in Chapter 1 and 3 of the Vet EU IG.

The UPD Level 1 and 2 IDs are generated in UPD based on the following defining characteristics and principles:

## UPD ID Level 1: the Product identifier

As defined in point 3.2 of Annex III of Commission Implementing Regulation (EU) 2021/16, the **Product Identifier** (or Product ID) refers to a Unique identifier for the same veterinary medicinal products across Member States to enable grouping of veterinary medicinal products authorised under the decentralised, mutual recognition, or subsequent recognition procedures or which underwent harmonisation of their summaries of product characteristics.

Each individual veterinary medicinal product entry is assigned with this unique identifier for the same product data set, regardless of the country of authorisation and based on a common set of data: this is referred as to UPD Level 1 in this guidance. Such Product Identifier remains unchanged through the lifecycle of the veterinary medicinal product and is a supplementary stable ID to any existing authorisation number as assigned by a competent authority and authorising body, even in case of transfer of marketing authorisation or transfer of Reference member state (RMS) for MRP/DCP/SRP. The following are the defining characteristics triggering the generation of the Product Identifier:

- Initial regulatory procedure number[1], if available
- Active substance[2] (or group of active substances contained in the same medicinal product)
- Pharmaceutical form[3] (as intended for authorisation)
- Medicinal product strength[4,5] (as intended for authorisation)

The full data set which is carried by the Product Identifier is presented in Annex I of this document and referred as to the 'European/common data'. The following principles apply:

- The Product Identifier will stay stable over time.
- When one of the defining characteristics as described above is different from any existing dataset at the time of initial submission, this constitutes a different high-level product description in the UPD and hence a different Product ID is assigned. Any subsequent changes to any of the defining characteristics following initial submission will generate a new version of the same Product ID (e.g., changes to the procedure number following transfer to a different RMS for a product within MRP/DCP/SRP or any specific corrections made by the RMS);
- When the defining characteristics as described above are the same, but any other European/common data as presented in the Annex I of this document is changed, the same Product Identifier is assigned e.g. a product is authorised for different target species, but with same strength, pharmaceutical form, active substance.
- Once the Product Identifier is assigned and linked to a veterinary medicinal product entry using the above-mentioned defining characteristics, the Product Identifier remains unchanged during the entire lifecycle of the product. In certain cases, the name attribute of the veterinary medicinal product and the name of the product owner may be subject to change during the lifecycle of the medicinal product, however this will not constitute a new product entry in the database but only a new version of the same Product ID. For nationally authorised products (NAPs), the Product Identifier is to be aligned with the concept of individual veterinary medicinal products in regulatory application procedures (e.g. electronic application forms).
- Whenever two veterinary medicinal products have the same attributes described above but are considered two different regulatory procedures by the competent authority (e.g. duplicate products), these should be considered two different veterinary medicinal products in the UPD with two different Product Identifiers and product lifecycles i.e. the procedure number may be referenced as different.

## UPD ID Level 2: the Permanent Identifier

As defined in point 3.1 of Annex III of Commission Implementing Regulation (EU) 2021/16, a **Permanent Identifier** (or Permanent ID) is a unique identifier of the veterinary medicinal product in the Union product database. This Permanent Identifier ensures that the veterinary medicinal products authorised in several Member States from the same MRP/DCP or SRP are separately identified based

[1] For MRP/DCP/SRP products, the core number should be used, without the procedure type suffix (e.g. SE/V/0123/001). For NP this number is not mandatory.
[2] A group of active substances contained in the same veterinary medicinal product includes fixed dose combinations or medicinal products with more than one pharmaceutical product
[3] This definition applies to the authorised pharmaceutical form that can include one or more routes of administration, e.g. solution for injection / solution for infusion.
[4] Medicinal product strength may be expressed in different ways (e.g. strength per concentration / strength per unit of presentation). In this scenario, the strength expressed as authorised should be taken as reference to determine the UPD-product ID.
[5] Includes products with more than one manufactured item in the same medicinal product

on a set of national information as authorised in the country by the relevant competent authority and representing the so-called 'national dataset'.

The following are the defining characteristics triggering the generation of the Permanent Identifier:

- Product ID (level 1)
- Country of authorisation (Note: EU in the case of Centrally Authorised Products)

The full data set which is carried by the Permanent Identifier is presented in the Annex I of this document and referred as to the 'national data'.

- When one of the defining characteristics as described above is different at time of the initial submission, this constitutes a different product in the UPD and hence a different Permanent Identifier is assigned by the system;
- Once the Permanent Identifier is assigned and linked to a veterinary medicinal product entry using the above-mentioned defining characteristics, the Permanent Identifier remains unchanged during the entire lifecycle of the product. In certain cases and following certain regulatory procedure, some attribute of the national dataset of the veterinary medicinal product may be subject to changes, however this will not constitute a new product entry in the database but a new version of the instance of the medicinal product will be assigned by the system (e.g. in case of a transfer of a marketing authorisation);
- When the defining characteristics as described above are the same but any other national data as presented in the Annex I of this document is different, the same Permanent Identifier is assigned e.g. a product is authorised with different legal status;
- The Permanent Identifier is generated by the system upon the Product identifier and a link is maintained in the UPD.

A veterinary medicinal product entry in the UPD database is determined by the combination of the Product Identifier and the Permanent Identifier regardless of the authorisation procedure.

For products authorised in EEA countries following the centralised procedure (i.e. CAPs transposed in Norway, Iceland and Lichtenstein), the same Product Identifier and Permanent ID will be applicable to EEA countries.

## UPD ID Level 3: the Package Identifier

The **Package Identifier** (or Package ID) defines the product at package level, as required by Article 15(2) of Commission Implementing Regulation (EU) 2021/16.

The following are the defining characteristics triggering the generation of the Package Identifier:

- Pack size (if applicable)
- The unit of presentation (of the pack)
- The manufacture item quantity
- The manufactured dose form

The full data set which is carried by the Package Identifier is presented in section 5. Packaged medicinal product.

- When one of the defining characteristics as described above is different, this constitutes a different package in the UPD and hence a different Package Identifier is assigned by the system;

- Once the Package Identifier is assigned and linked to a veterinary medicinal product entry using the above-mentioned defining characteristics, the Package Identifier remains unchanged during the entire lifecycle of the product;

The following figure provides a visual representation of the UPD IDs:

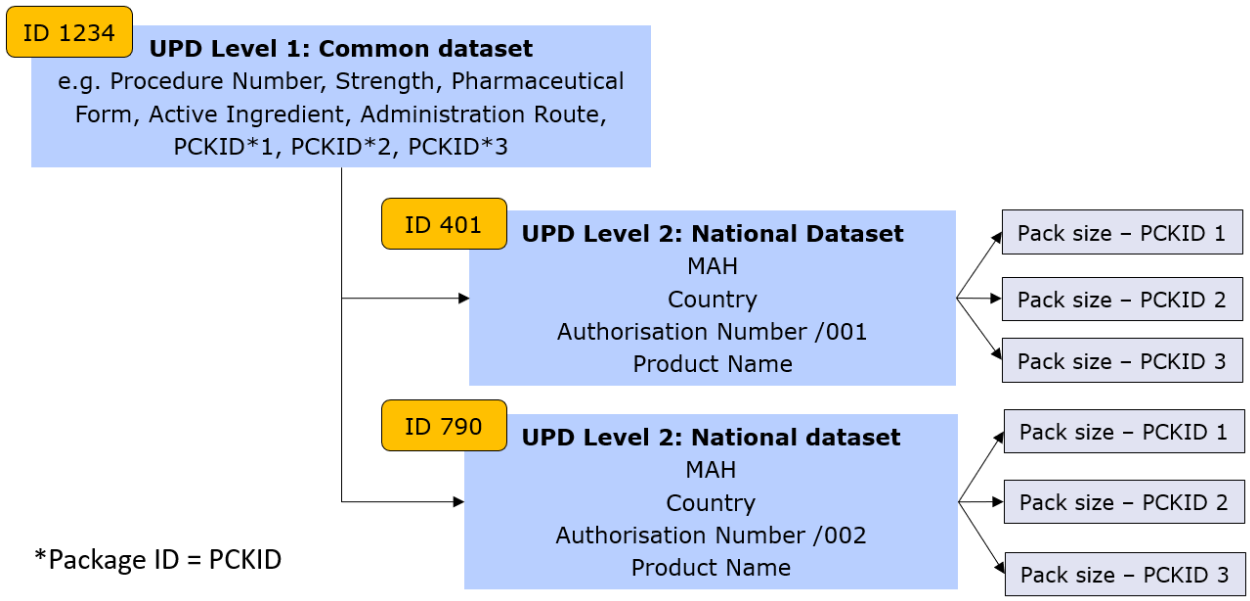


**Figure 1.** UPD Product Identifiers

| Procedure Type | Number of product ID assigned | Number of permanent ID assigned |
|---|---|---|
| CAPs | 1 for EU and EEA | 1 for EU and EEA |
| MRP/DCP/SRP | 1 | N (n= number of MS involved as either Reference member state (RMS) or Concerned member state (CMS)) |
| NAP | 1 | 1 per country |

## Confidentiality

Article 56 of Regulation (EU) 2019/6 provides requirements for the access management to the Union Product Database. The public should have a wide access to the information related to veterinary medicinal products: "*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*."

Veterinary healthcare professionals, who are part of the general public, should be able to conduct advanced searches by one or more criteria based on the data fields contained in the Union product database. For more information on access rights, the UPD Access Policy should be consulted.

# User guide

This section provides the description of the format, the business guidance and conventions for the electronic submission of veterinary medicinal product data and documents into the UPD.

The electronic submission of veterinary medicinal products into the UPD is based on the Health Level 7 (HL7) Fast Healthcare Interoperability Resources (FHIR), this guide aims at implementing and defining the European requirements for the submission of veterinary medicinal products in the HL7 FHIR message for the implementation of the UPD. The FHIR message is based on the IDMP standards for human medicines with suitable modifications for veterinary products and the UPD.

The description of the requirements for each set of information and each data element is presented in the following tabular format:

| Tag | Description |
|---|---|
| User Guidance | The definition of the data element, the convention and the condition under which the information should be provided in the context of the initial submission of a new veterinary medicinal product into UPD and during the maintenance of the product information. |
| Repeatable | The cardinality of the data elements specifying whether multiple values for the information can be applied. A class could be repeatable but with individual data fields repeatable or not. The complete set of the data fields is repeated in case the class is repeatable. |
| Conformance | Whether the information should be provided on mandatory, conditional or optional basis. A class could be conditional and data fields belonging to the class could be mandatory. Once the conditions for the class are fulfilled, all mandatory data fields shall be fulfilled. If the conditions are not fulfilled, none of the data fields belonging to the class shall be provided. |
| Data Type | The type of data that should be specified as defined in the FHIR message (e.g. *CodeableConcept* refers to use of controlled terminologies; string refers to free text data; numeric values). |
| Value | The values applicable to the data element (e.g. reference to the SMS, OMS or relevant RMS list). |
| ISO Path | The mapping of the ISO IDMP technical specifications. |
| FHIR Path | The FHIR data model path as presented in the FHIR resource list. |

As outlined above, the Vet EU IG refers to the use of controlled vocabulary elements from RMS by the UPD. Where applicable, the values to complete the relevant field must be selected from the term IDs as listed in the applicable Referentials Management Service list.

Although the guidance remains user interface agnostic by document term and list identifiers, it is expected that for many users some form of user interface would allow them to search, lookup and in any case select the values for the fields in a user-friendly way. For creation of new veterinary medicinal products, only terms in RMS with CURRENT status shall be accepted in UPD, unless specified otherwise. If needed, new terms can be requested via the SPOR portal.

The Vet EU IG also refers to the use of controlled terminology to manage Organisation data. All references to organisations within the UPD are defined based on location identifiers as maintained in OMS. A location identifier refers to a unique location for an organisation.

Information on organisations and their location relevant for veterinary medicinal products cannot be submitted directly into the UPD. Such information is maintained in OMS. The link to organisations and locations relevant for a specific veterinary medicinal product is established by entering the OMS location identifier in the UPD product record. If a specific location needed to record a given veterinary medicinal product is not yet available in OMS, the details must first be registered in OMS via the SPOR portal according to the OMS specific process. UPD will consider location identifiers whose status is either active or inactive.

Each of the resources in the FHIR website and in the SPOR API specification, as described in this guidance, is identified by its own unique technical identifier.

The Vet EU IG references FHIR resources. It is to be noted that only a subset of the data fields within the entire FHIR resources applies to the submission of veterinary medicinal products into the UPD and this subset is described in the following sections. When FHIR data fields not referenced within the EU Vet IG are included in a submission message, the system will accept the message and will silently suppress or ignore the 'not applicable' data elements within the resources provided so that all the applicable business rules governing the data elements adhere to the provisions laid down in the sections below.

Additional information on the technical aspects such as cardinality, data types, etc. refer to Chapter 5: Technical Specification and the HL7 FHIR specification.

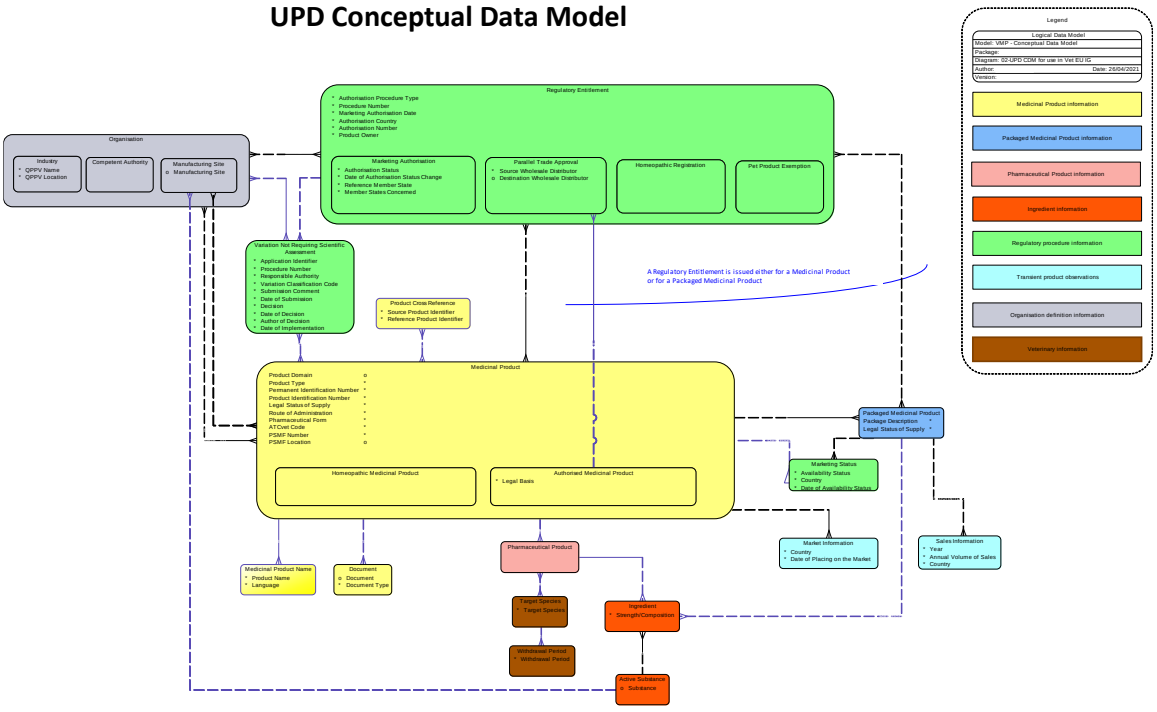


**Figure 2.** Information model for veterinary medicinal products UPD

## *Referencesto FHIR versions*

The next major release of FHIR will be Release 5 (FHIR R5). FHIR documentation referenced in the Vet EU IG refer to the most recent intermediate release of R5, specifically 'Release 5 Preview #2'. Although

FHIR R5 will continue to evolve during 2021, only a small subset of FHIR resources are relevant to the Vet EU IG, and are not expected to be impacted by the evolving R5 release. It is expected that all Vet EU IG requirements will have been incorporated into the next intermediate release of R5, namely 'Release 5 Preview #4'.

Proposed changes to R5 are captured at http://hl7.org/fhir/2020May/resourcelist.html (section Medication Definition) and are then promoted to the next intermediate release.

# 1. Veterinary medicinal product

The full information on Veterinary Medicinal Product as presented in the FHIR resource is shown in the figure below.

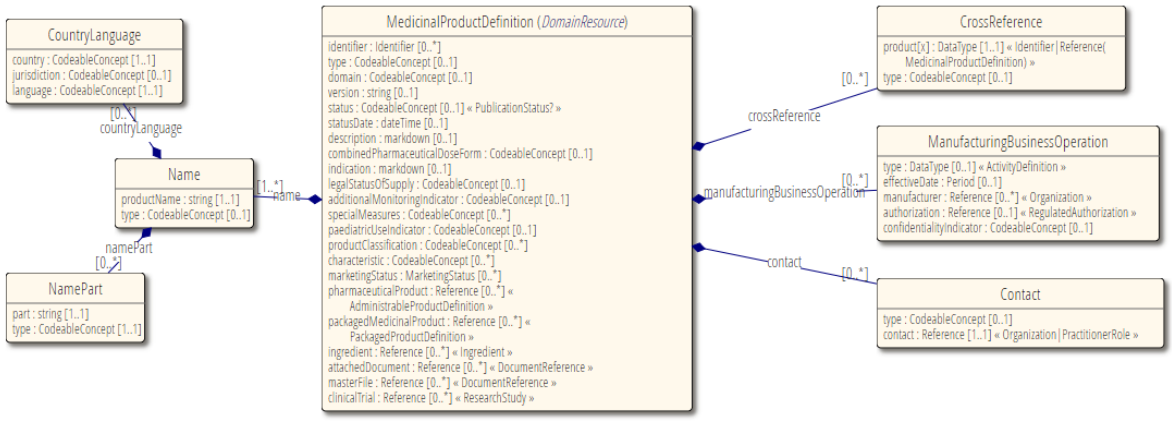


**Figure 3.** FHIR Resource *MedicinalProductDefinition* (see section References to FHIR versions)

## *1.1. Domain*

Domain describes whether the type of medicinal product is for human or veterinary use.

| Tag | Description |
|---|---|
| User Guidance | The domain must be provided as a term ID.<br>In the context of the implementation of UPD only medicinal product for veterinary use must be provided and therefore the value "veterinary use" applies and cannot be changed as part of the maintenance of the veterinary medicinal product. |
| Repeatable | No |
| Conformance | Mandatory |
| Data Type | CodeableConcept |
| Value | The value must be 100000000013 as per the listed in Domain (RMS List ID 100000000004). |
| ISO Path | N/A |
| FHIR Path | MedicinalProductDefinition.domain |

***Example:***

Veterinary use (100000000013)

## 1.2. Product record status

The product record status describes if the marketing authorisation procedure for the veterinary products is finalised at the time of the submission of the veterinary medicinal product data into UPD and therefore prescribes whether the product is eligible for publication.

| Tag | Description |
|---|---|
| User Guidance | The product record status must be provided as a term ID and based on the following values:<br>• Provisional: initial product state applicable to products approved under DCP/MRP/SRP procedure, but not yet authorised in each individual Member State.<br>• Current: Initial status for the following products when they are submitted to the UPD: CAP, NAP, registered homeopathic products, products allowed to be used in a member State in accordance with Article 5(6) of Regulation (EU) 2019/6 and parallel traded products.<br>This status is also applicable to products approved under DCP/MRP/SRP whose national information has been recorded in UPD by the CMSs once their marketing authorisations have been granted.<br>Once 'Current' status is reached, it cannot longer return to 'Provisional' status.<br>A product will remain in 'Current' status unless it is deleted by a user.<br>• Nullified: status applicable to any product that is deleted by a user. |
| Repeatable | No |
| Conformance | Mandatory |
| Data Type | CodeableConcept |
| Value | Listed in Record Status (RMS List ID 200000005003); only terms listed above to be used |
| ISO Path | N/A |
| FHIR Path | MedicinalProductDefinition.status |

***Example(s):***

Provisional (200000005005), Current (200000005004), Nullified (200000005007)

## 1.3. Product identifier

The product identifier enables grouping of products based on the common/European data set as described in 'Identification of a veterinary medicinal product in the UPD' section of this document.

It is applicable to all veterinary medicinal product submitted into UPD regardless of the type of the authorisation procedure.

| Tag | Description |
|---|---|
| User Guidance | The product identifier as assigned by the UPD must be specified when updating a product in the UPD. |

| Tag | Description |
|---|---|
| | The Product Identifier data element must not be supplied as it is system generated. |
| Repeatable | No |
| Conformance | Identifier generated by the system. It must not be provided at the time of creation, it must be provided when updating the product. |
| Data Type | Identifier (max. 4000 characters) |
| Value(s) | ID generated by the system.<br><br>MedicinalProductDefinition.identifier.system value is "http://ema.europa.eu/fhir/vmpId" |
| FHIR Path | MedicinalProductDefinition.identifier |

## *1.4. Permanent identifier*

As defined in point 3.1 of Annex III of Commission Implementing Regulation (EU) 2021/16, a Permanent Identifier (or Permanent ID) is a unique identifier of the veterinary medicinal product in the Union product database. This Permanent Identifier differentiates between the veterinary medicinal products authorised in multiple Member States from the same MRP/DCP or SRP (same Product ID (Level 1). It is generated based on the Product ID (Level 1) with the addition of the national information as authorised in the country by the relevant competent authority and representing the so-called 'national dataset'.

| Tag | Description |
|---|---|
| User Guidance | The permanent identifier as assigned by the UPD must be specified when updating a national data set of the veterinary medicinal product in the UPD.<br><br>The Permanent Identifier data element is system generated. |
| Repeatable | No |
| Conformance | ID generated by the system. It must not be provided at the time of creation, it must be provided when updating the product. |
| Data Type | Identifier (max. 4000 characters) |
| Value(s) | ID generated by the system |
| FHIR Path | MedicinalProductDefinition.id |

## *1.5. (Authorised) pharmaceutical form*

| Tag | Description |
|---|---|
| User Guidance | The authorised pharmaceutical dose form(s) must be provided as a term ID. Pharmaceutical form might be authorised by regulatory authorities or submitted for authorisation and reflected in regulatory documentation as follows:<br><br>• Pharmaceutical dose form: when the authorised dose form involves a single administrable dose form and no previous reconstitution with another pharmaceutical form is needed prior to administration to the animal. In this case the RMS list "Pharmaceutical Dose Form" must be used. |

| Tag | Description |
|---|---|
| | • Combined pharmaceutical dose form: when two or more pharmaceutical forms as uniquely described in the manufactured items are intended to be combined and reconstituted into a single administrable pharmaceutical form. In this case the RMS list "Combined Pharmaceutical Dose form" must be used.<br>• Combined term: in special cases (e.g., identical products which may be distinguished only by reference to the container), the information about the immediate container can be included in the authorised pharmaceutical form. In this case the RMS list "Combined Term" must be used.<br>• Combined Package: veterinary medicinal products may consist of two pharmaceutical products that correspond with two different administrable dose forms (e.g., hard capsule and cream) that form individual entities which do not need combining for administering to the animal. In this case the RMS list "Combination Package" must be used. |
| Repeatable | No |
| Conformance | Mandatory |
| Data Type | CodeableConcept |
| Value(s) | As applicable from one of the following SPOR RMS lists:<br>• Pharmaceutical Dose Form (RMS list ID 200000000004)<br>• Combined Pharmaceutical Dose Form (RMS list ID 200000000006)<br>• Combined Term (RMS list ID 200000000007)<br>• Combination Package (RMS list ID 200000000008) |
| ISO Path | /MedicinalProduct/CombinedPharmaceuticalDoseForm |
| FHIR Path | MedicinalProductDefinition.extension.authorisedDoseForm<br>Note: Please refer to Chapter V – Technical Specifications for the details of the extension URL. |

***Example(s):***

- Solution for injection (100000073863) or Tablet (100000073664) from RMS list Pharmaceutical Dose Form),
- Powder and solvent for suspension for injection (100000073869) from RMS list Combined Pharmaceutical Dose Form,
- Eye drops, solution in single-dose container (100000073997) from RMS list Combined Term,
- Capsule, soft + tablet (200000003175) from RMS list Combination Package

## *1.6. Legal status for the supply*

| Tag | Description |
|---|---|
| User Guidance | The legal status of the medicinal product supply, as authorised by the competent authority and applicable in the region, must be specified using a term ID.<br>• For centrally authorised products (CAPs), this information is equivalent to the text in the relevant section of the product information. |

| Tag | Description |
|---|---|
| | • For nationally authorised products (NAPs), this information may be equivalent to the text from different sources that include the Summary of Product Characteristics (SPC), Package Leaflet (PL) or other documents in or annexes to the relevant national register of veterinary medicinal products.<br>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.<br>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 can be left empty, or the term "Veterinary medicinal product subject to veterinary prescription except for some pack sizes" can be specified<br>Further detailed status for the supply could be relevant in future versions of the UPD. |
| Repeatable | No |
| Conformance | Conditional |
| Data Type | CodeableConcept |
| Value(s) | 'Veterinary Medicinal product not subject to veterinary prescription', 'Veterinary medicinal product subject to veterinary prescription', 'Veterinary medicinal product subject to veterinary prescription except for some pack sizes' from the RMS list Legal Status for the Supply (RMS list ID 100000072051) |
| ISO Path | /MedicinalProduct/MarketingAuthorisation/LegalStatusOfSupply |
| FHIR Path | MedicinalProductDefinition.legalStatusOfSupply |

***Example(s):***

Veterinary medicinal product subject to veterinary prescription (200000017698),

Veterinary medicinal product not subject to veterinary prescription (200000017695),

Veterinary medicinal product subject to veterinary prescription except for some pack sizes (200000017699)

## *1.7. Product classification*

The product classification describes a set of classifications (regulatory and non-regulatory) which applies to the veterinary medicinal product, defined in the UPD by legal basis and ATC vet code.

### 1.7.1. (Marketing authorisation application) Legal basis

| Tag | Description |
|---|---|
| User Guidance | The legal basis for the marketing authorisation must be provided, e. g. for generic, hybrid, applications based on informed consent or on bibliographic data, as well as marketing authorisations for limited market and in exceptional circumstances.<br><br>The legal basis for the marketing authorisation must be provided as applicable as a term ID.<br><br>The legal basis is not applicable to parallel trade and homeopathic medicinal products and products intended only for pets under Article 5(6). |
| Repeatable | No |
| Conformance | Conditional |
| Data Type | CodeableConcept |
| Value | As listed in Marketing Authorisation Application Legal Basis (RMS list ID 100000116045) |
| ISO Path | /MedicinalProduct/ProductClassification/ |
| FHIR Path | RegulatedAuthorization.basis |

***Example(s):***

Applications for limited markets (Article 23 of Regulation (EU) 2019/6) (200000013185); Full application - known active substance (Article 8 of Regulation (EU) 2019/6)

### 1.7.2. ATC vet code(s)

| Tag | Description |
|---|---|
| User Guidance | The ATC vet code(s) as indicated in the appropriate section of the corresponding SPC or other regulatory document must be provided (if available) as a term ID.<br>If multiple values apply to the same veterinary medicinal product, then multiple values must be selected.<br>Deprecated (i.e., non-current) ATC vet codes may be referenced.<br>All five levels of an ATC vet code can technically be used; however, the most granular level of information is expected to be provided as available.<br>ATC vet code is not applicable to parallel trade and to authorised and registered veterinary homeopathic medicinal products.<br>If ATC vet code is not available because not yet assigned by the ATC code list maintenance organisation and not yet available in RMS, the field should be left empty but information on its unavailability must be provided in the ATC vet code flag (i.e. at least one of ATC vet code OR the ATC vet code flag must be provided if applicable). |
| Repeatable | Yes |
| Conformance | Conditional |
| Data Type | CodeableConcept |

| Tag | Description |
|---|---|
| Value(s) | As listed in Anatomical Therapeutic Chemical classification system – Veterinary (RMS list ID 100000116677) |
| ISO Path | /MedicinalProduct/ProductClassification |
| FHIR Path | MedicinalProductDefinition.productClassification |

***Example(s):***

ATC vet code QXXXXXX should be selected from the RMS list; in RMS this will be uniquely identified by a specific RMS code (e.g. 100000093537).

### 1.7.3. ATC vet code(s) flag

| Tag | Description |
|---|---|
| User Guidance | The ATC vet code(s) flag is to indicate that the ATC vet code is not available but has been requested.<br>Only applicable for authorised veterinary medicinal products<br>When ATC vet code is available and is assigned to a medicinal product, the flag is not required. Should it be provided, the value must be set as 'False'.<br>When there is no ATC vet code, but waiting to be assigned, the ATC vet code flag must be provided with the value 'True'. The ATC vet code flag is not applicable to parallel trade and to authorised and registered veterinary homeopathic medicinal products. |
| Repeatable | No |
| Conformance | Conditional |
| Data Type | Boolean |
| Value(s) | true or false |
| ISO Path | MedicinalProductClassification.atcPending |
| FHIR Path | MedicinalProductDefinition.productClassification.extension.atcPending |

## *1.8. Veterinary medicinal product name*

The veterinary medicinal product name is defined based on the following elements and structure:

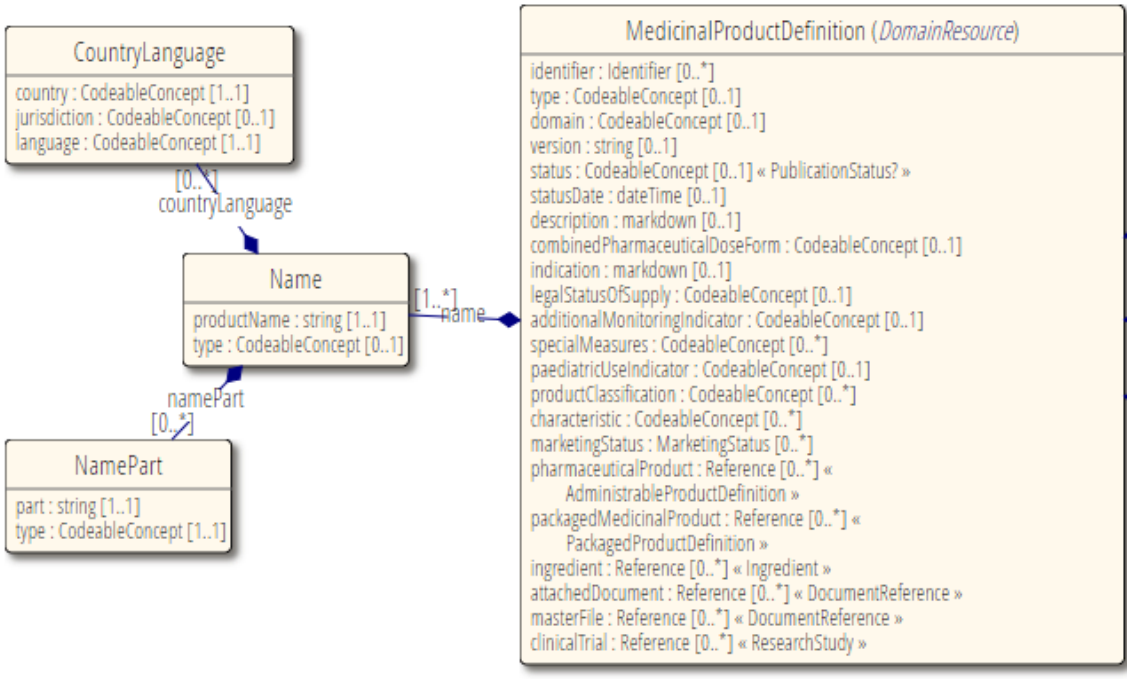


**Figure 4.** *Extract of the Resource MedicinalProductDefinition* (see section *References to FHIR versions*)

The class is mandatory and is capturing the full veterinary medicinal product name in line with the country/language where the name applies. Full veterinary medicinal product name and country must be set for each product in each country and must also be repeated as per applicable languages in multilingual countries (e.g. Belgium).

As presented in Annex I of this document, this medicinal product name class applies to both the European and the national dataset. The following applies:

- For MRP/DCP/SRP, the full veterinary medicinal product name in English as used in the procedure should be provided by the RMS as part of the European/common dataset; the additional veterinary medicinal product name translations as apply in the relevant national territory should be provided by the CMS as part of the national dataset;
- For CAP, the name of the veterinary medicinal product in English shall be specified with the country EU. All applicable veterinary medicinal product name translations may be provided as part of the 'European/common' dataset if necessary. For vaccine medicinal product, where applicable, the scientific name of the vaccine shall be provided as additional medicinal product name;
- For NAP, the veterinary medicinal product name in the applicable language shall be specified as part of the common dataset;
- For CAPs products for which the marketing authorisation is transposed in EEA National authorisations, the veterinary medicinal product name applicable to the respective EEA countries must be specified as separate national dataset;
- Any additional veterinary medicinal product name as applicable to third countries shall be specified by MAH as alternative name within the common/European dataset.

| name Class | Description |
|---|---|
| Repeatable | Yes |
| Conformance | Mandatory |

### 1.8.1. Veterinary medicinal product name

| Tag | Description |
|---|---|
| User Guidance | The veterinary medicinal product name (invented name, strength, pharmaceutical dose form), as indicated in the relevant section of the corresponding SPC or other regulatory document, must be specified, in line with the local language of the country where the product is authorised.<br>Any trademark values shall not be included in the full veterinary medicinal product name.<br>For MRP/DCP or Subsequent recognition procedures (SRP), the RMS must enter the product name in English as expressed in the application form and common English SPC and is used as the (preliminary) name during the procedure as part of the common/European dataset. The competent authorities of each involved MS (RMS and CMS) shall provide the nationally authorised name within the national dataset at the time of completion of the national authorisation procedure.<br><br>Veterinary medicinal product name should be provided using the capitalisation as stated in the SPC. |
| Repeatable | No |
| Conformance | Mandatory |
| Data Type | string (maximum length: 4000 characters) |
| Value(s) | The full veterinary medicinal product name as free text. The system shall support special characters. |
| ISO Path | /MedicinalProduct/MedicinalProductName/FullName |
| FHIR Path | MedicinalProductDefinition.name.productName |

***Example(s):***

Metacam 5 mg/ml solution for injection

### 1.8.2. Name part

This section refers to the name parts of the product.

| namePart Class | Description |
|---|---|
| Repeatable | Yes |
| Conformance | Optional |

#### *1.8.2.1 Name type*

| Tag | Description |
|---|---|
| User Guidance | The type of the name part is being described and must be specified as a term ID from RMS. |

| Tag | Description |
|---|---|
| | NOTE: Name type 'Full name' should not be used, and therefore not selected, from the *Medicinal Product Name Part Type* RMS list. |
| Repeatable | No |
| Conformance | Mandatory |
| Data Type | CodeableConcept |
| Value(s) | Listed in the RMS list for "Medicinal Product Name Part Type" (220000000000) |
| FHIR Path | MedicinalProductDefinition.name.namePart.type |

***Example(s):***

Invented name part (220000000002); Scientific name part (220000000003)

#### *1.8.2.2 Name part*

| Tag | Description |
|---|---|
| User Guidance | The Name part of a product name as specified in 1.8.1 shall be specified as applicable. For vaccine authorised via the central procedure, the scientific name part shall be specified if applicable.<br><br>The CA should provide the VMP "Invented name part". |
| Repeatable | No |
| Conformance | Mandatory |
| Data Type | string (maximum length: 4000 characters) |
| Value(s) | The applicable name fragment of the Full name as free text. |
| FHIR Path | MedicinalProductDefinition.name.namePart.part |

***Example(s):***

MetacamInnovax-ND-IBD

### 1.8.3. Country/Language

This section refers to the language used for the description of the veterinary medicinal product name in a specific country. The class Country/Language is mandatory.

Whilst the entire veterinary medicinal product name class is repeatable, the entity *Country / Language* within the class should not be repeatable. For multiple language countries, the name class shall be repeated as applicable.

List of official languages per country is available on the Agency website.

| countryLanguage Class | Description |
|---|---|
| Repeatable | No |
| Conformance | Mandatory |

#### *1.8.3.1 Country*

| Tag | Description |
|---|---|
| User Guidance | The country of the veterinary medicinal product name as approved by the regulatory authority and indicated in the corresponding regulatory document(s), must be specified as a term ID. At least one country must be specified per Veterinary Medicinal Product name as follows:<br>• For products authorised through the MRP/DCP/SRP, the RMS shall specify 'EU' as the country for the common data set and based on the authorised common English text. Once the national procedure is completed RMS and the CMS must specify its own country as part of the national dataset and as applicable;<br>• For products authorised through national procedure, the national country whereof the medicinal product name applies must be specified;<br>• For CAPs products, the country shall be set to EEA for the English medicinal product name. Should each individual translation for a veterinary medicinal product be required, the applicable country where the veterinary medicinal product names apply must be specified. |
| Repeatable | No |
| Conformance | Mandatory |
| Data Type | CodeableConcept |
| Value(s) | As listed in the Country list (RMS list ID 100000000002), or Country Grouping list (RMS list ID 100000000003) or reference to externally maintained list in order to allow international information exchange. . |
| ISO Path | /MedicinalProduct/MedicinalProductName/Country-Language/Country |
| FHIR Path | MedicinalProductDefinition.name.countryLanguage.country |

***Example(s):***

Croatia (100000000373), Spain (100000000529)

#### *1.8.3.2 Language*

| Tag | Description |
|---|---|
| User Guidance | The language of the veterinary medicinal product name for the specified country, as approved by the regulatory authority and in line with the corresponding regulatory document(s) must be specified as a term ID.<br>For MRP/DCP/SRP, RMS shall provide the English as the language of the veterinary medicinal product name within the common data set. |
| Repeatable | No |
| Conformance | Mandatory |
| Data Type | CodeableConcept |
| Value(s) | Listed in Language (RMS list ID 100000072057) |
| ISO Path | /MedicinalProduct/MedicinalProductName/Country-Language/Language |
| FHIR Path | MedicinalProductDefinition.name.countryLanguage.language |

***Example(s):***

Bulgarian (100000072142), Finnish (100000072149), Latvian (100000072205)

## *1.9. (Pharmacovigilance System) Master file (PSMF)*

The Pharmacovigilance system master file (PSMF) reference number and its location information related to the veterinary medicinal product must be specified. The Pharmacovigilance system master file definition is provided in Article 4(31) of Regulation (EU) 2019/6 and the minimum requirements for its content and maintenance are set out in the Commission Implementing Regulation (EU) 2021/1281 of 2 August 2021, in particular Article 17(5), laying down rules for the application of Regulation (EU) 2019/6 of the European Parliament and of the Council as regards good pharmacovigilance practice and on the format, content and summary of the pharmacovigilance system master file for veterinary medicinal products. Note: as per FHIR, the reference to the content is a mandatory attribute of DocumentReference and attachment (of type Attachment) is a required attribute of content. In order to form a valid FHIR structure, you must provide content and attachment leaving those totally empty.

The PSMF reference number and location are not mandatory for legacy data. The PSMF is mandatory for new VMP for which marketing authorisation is granted under Regulation (EU) 2019/6. For legacy data, after 28 January 2022 MAHs should provide the PSMF code and PSMF location as soon as possible, once established, via a variation not requiring assessment.

The PSMF is not applicable to parallel trade medicinal products.

| **Master file class** | Description |
|---|---|
| Repeatable | No |
| Conformance | Conditional |

### 1.9.1. (PSM) File status

| **Tag** | **Description** |
|---|---|
| User Guidance | The status of the file and it must always be set to the literal value “current”. |
| Repeatable | No |
| Conformance | Mandatory |
| Data Type | code |
| Value | Must always be set to the literal value “current”. |
| FHIR Path | MedicinalProductDefinition.masterFile(DocumentReference).status |

### 1.9.2. (PSM) File type

| **Tag** | **Description** |
|---|---|
| User Guidance | The type of file must be specified as the value “Pharmacovigilance System Master File”. |
| Repeatable | No |
| Conformance | Mandatory |
| Data Type | CodeableConcept |
| Value | PharmacoVigilance System Master File (220000000071) from the Master File Type list (RMS list ID 220000000070) |

| Tag | Description |
|---|---|
| ISO Path | /MedicinalProduct/MasterFile/FileType |
| FHIR Path | MedicinalProductDefinition.masterFile(DocumentReference).type |

### 1.9.3. (PSM) File code

| Tag | Description |
|---|---|
| User Guidance | The Pharmacovigilance System Master File (PSMF) reference number/identifier as assigned by the QPPV shall be specified. |
| Repeatable | No |
| Conformance | Mandatory |
| Data Type | Identifier |
| Value(s) | Should be unique for the relevant PSMF for a specific (group of) product(s) an MAH maintains. The recommended format is the following: prefix "PSMF" followed by a reference number allocated by the MAH/QPPV. |
| ISO Path | /MedicinalProduct/MasterFile/FileCode |
| FHIR Path | MedicinalProductDefinition.masterFile(DocumentReference).identifier |
| FHIR Complementary Information | DocumentReference.identifier.system value is "http://ema.europa.eu/fhir/masterFileCode" |

***Example(s):***

PSMF00001; PSMF84264

### 1.9.4. (PSM) File location

Address and country where the pharmacovigilance system master file is located.

| Tag | Description |
|---|---|
| User Guidance | The PSMF location must be specified using the location identifier linked to the organisation (LOC ID) as listed in OMS. |
| Repeatable | No |
| Conformance | Mandatory |
| Data Type | Reference |
| Value(s) | As listed in SPOR OMS service (LOC ID) |
| FHIR Path | MedicinalProductDefinition.masterFile(DocumentReference).custodian |

## *1.10. Pharmacovigilance Contact (QPPV)*

| Master file class | Description |
|---|---|
| Repeatable | No |
| Conformance | Conditional<br>The Pharmacovigilance Contact is not applicable to parallel traded medicinal products. |

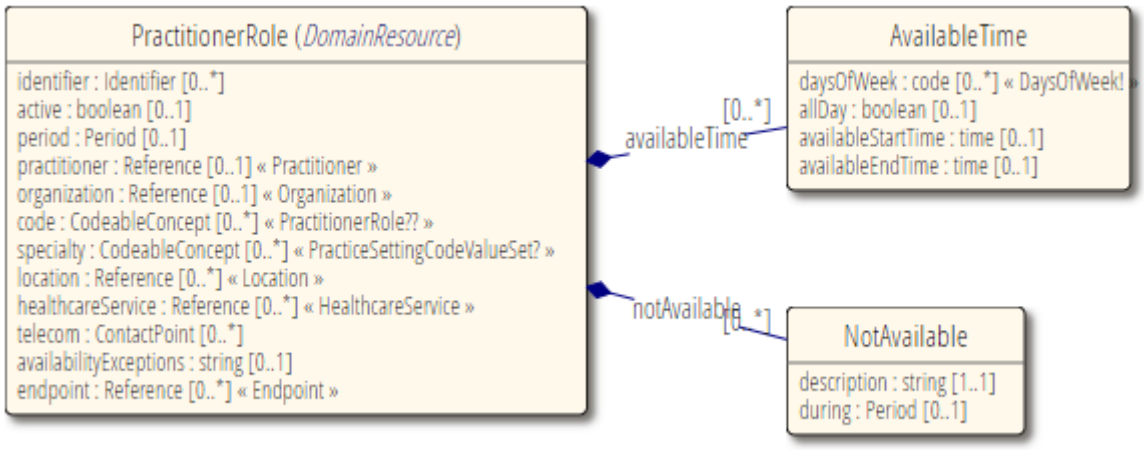


**Figure 5.** *PractitionerRole* (see section *References to FHIR versions*)

### 1.10.1. QPPV name

| Tag | Description |
|---|---|
| User Guidance | The given name and family name of the QPPV must be specified. |
| Repeatable | No |
| Conformance | Mandatory |
| Data Type | string |
| Value(s) | The given name and family name of the QPPV must be specified. |
| ISO Path | /MedicinalProduct/MarketingAuthorisation/MarketingAuthorisationHolder/Contact/ |
| FHIR Path | MedicinalProductDefinition.contact.contact(PractitionerRole).identifier |

***Example(s):***

John Smith

### 1.10.2. QPPV Role

| Tag | Description |
|---|---|
| User Guidance | The type of the contact in the context of the Veterinary Medicinal Product must be specified.<br><br>For each medicinal product the type QPPV must be specified. Only one QPPV can be specified per each veterinary medicinal product. |
| Repeatable | No |
| Conformance | Mandatory |
| Data Type | CodeableConcept |
| Value | Qualified Person in the EEA for Pharmacovigilance (100000155057) from the Contact Party Role list (RMS list ID 100000154441) |
| ISO Path | /MedicinalProduct/MarketingAuthorisation/MarketingAuthorisationHolder/Contact/Role |
| FHIR Path | MedicinalProductDefinition.contact.type |

### 1.10.3. QPPV Location

| Tag | Description |
|---|---|
| User Guidance | The contact details including address and country where the QPPV is operating must be specified using the location identifier (LOC ID) linked to an organisation as listed in OMS. |
| Repeatable | No |
| Conformance | Mandatory |
| Data Type | Reference |
| Value(s) | As listed in SPOR OMS service (LOC ID) |
| FHIR Path | MedicinalProductDefinition.contact.contact(PractitionerRole).organization |

## *1.11. Attached document*

The approved product information document(s) and the public assessment report should be provided to the UPD in the decided format and referenced by documents type. 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) any time from creation of the European/Common dataset until the time of authorisation, as relevant, as part of the national dataset. This submission of national documents does not necessarily have to be happen while uploading the national information of the product. Where, in exceptional circumstances, a SPC is not available for products intended only for pets under Article 5(6), a similar text (i.e. the English common text, package leaflet or other similar document as authorised by the Authorising Body) can be used as an attachment for the submission in UPD.

For registered homeopathic products, only the package leaflet is required.

For parallel traded veterinary medicinal product, the attached document is not applicable.

**Document file format**

The allowed file formats for the product information (i.e. SPC/PL/LAB) and the PuAR are PDF v.1.4 and above, preferable PDF/A.

The FHIR DocumentReference resource is used to describe documents. In the context of UPD implementation by 28 January 2022, this information is within the scope and should be provided according to the rules and guidance described in this section:

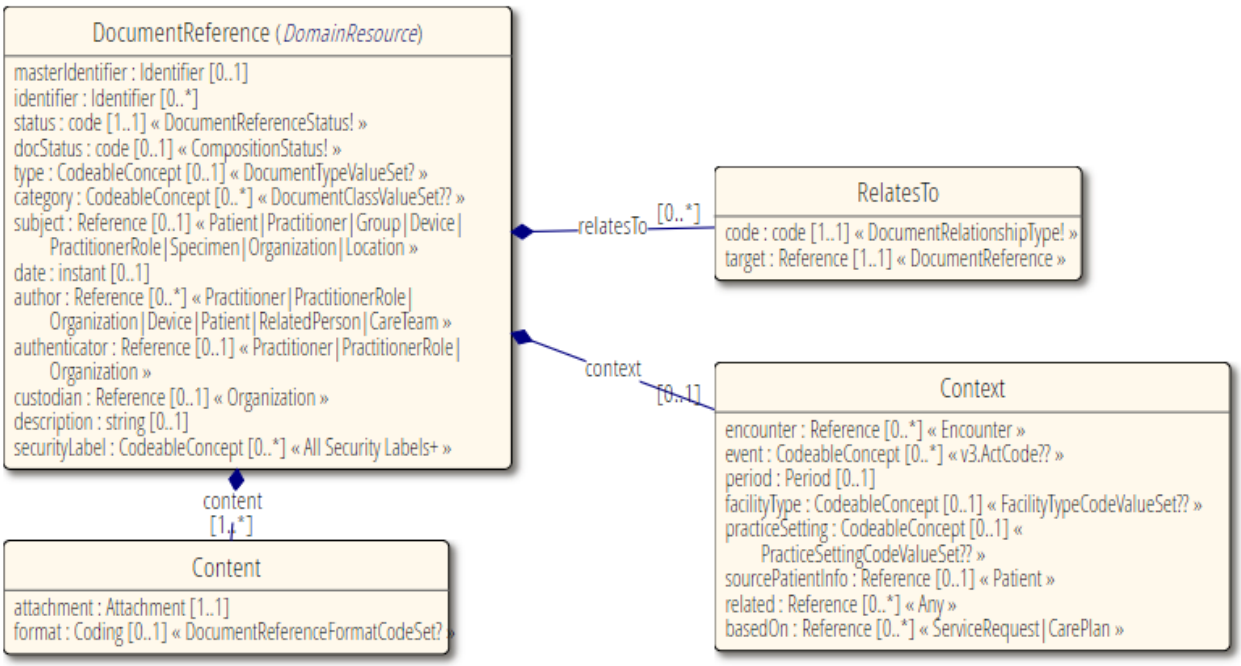


**Figure 6.** *DocumentReference* (see section *References to FHIR versions*)

### 1.11.1. (Attached document) identifier

| Tag | Description |
|---|---|
| User Guidance | A unique identifier will be assigned to a document when it is first uploaded to the UPD and remains stable over time. |
| Repeatable | No |
| Conformance | Conditional. Identifier generated by the system. It must not be provided at the time of creation, but it must be provided when updating the document. |
| Data Type | id |
| Value(s) | Relevant identifier assigned by UPD once document is uploaded |
| ISO Path | /MedicinalProduct/AttachedDocument/Identifier |
| FHIR Path | DocumentReference.id |

### 1.11.2. (Attached document) status

| Tag | Description |
|---|---|
| User Guidance | The status of this document must be specified as a Term ID based on the following values:<br>• "current": This is the current version of this document.<br>• "superseded": This version has been superseded by another version.<br>• "entered-in-error": This version was created in error. |
| Repeatable | No |
| Conformance | Mandatory |
| Data Type | code |

| Tag | Description |
|---|---|
| Value | One of the values available at http://hl7.org/fhir/2020May/valueset-document-reference-status.html<br><br>Only the terms stated above to be used. |
| FHIR Path | DocumentReference.status |

### 1.11.3. (Attached document) type

| Tag | Description |
|---|---|
| User Guidance | The value indicating the type of document must be specified as a term ID based on the following values:<br>• pllab (Package Leaflet and Labelling) - 200000017121<br>• spc (Summary of products characteristics) – 100000155532<br>• lab (Labelling) - 100000155535<br>• pl (Package leaflet) – 100000155538<br>• combined (Combined File of all Documents) - 100000155539<br>• puar (Public Assessment Report) - 200000017122<br><br>The rules related to the document types will be captured here, i.e., there must only be one document per document type per product per language per member state with the exception of the type PuAR for centralised product for which more than a document can be provided regardless of the language and/or member state (e.g. there cannot be 2 SPCs in French in Belgium but there can be more than 1 PuAR for centralised products) |
| Repeatable | No |
| Conformance | Mandatory |
| Data Type | CodeableConcept |
| Value | Listed in Product Information Document Type (RMS list ID 100000155531) and in Regulatory Authority Submission Unit Type (RMS list ID 100000155552) |
| ISO Path | /MedicinalProduct/AttachedDocument/MediaType |
| FHIR Path | DocumentReference.type |

### 1.11.4. (Attached document) country

| Tag | Description |
|---|---|
| User Guidance | The country code of the attached document must be provided based on term ID. At least one country must be specified per document as follows:<br>• For products authorised through the MRP/DCP/SRP, the RMS shall specify 'EU' as the country for the documents that shall provide as a part of the 'European/common' data set. Once the national procedure is completed RMS and the CMS must provide the national documents as part of the national dataset stating the relevant country where the product has been approved in this field. |

| Tag | Description |
|---|---|
| | • For products authorised through national procedure, the national country whereof the document applies must be specified.<br>• For CAPs, the country shall be set to EEA for the English version of the document. |
| Repeatable | No |
| Conformance | Mandatory |
| Data Type | CodeableConcept |
| Value | As listed in the Country list (RMS list ID 100000000002), or Country Grouping list (RMS list ID 100000000003) |
| FHIR Path | DocumentReference.category |

***Example(s):***

Spain (100000000529), European Union (100000000390)

### 1.11.5. (Attached document) content type

| Tag | Description |
|---|---|
| User Guidance | The type of the document file. Only pdf documents are accepted as attached document. |
| Repeatable | No |
| Conformance | Mandatory |
| Data Type | code |
| Value | "application/pdf" should be chosen, and is taken from the list of mime types as required by FHIR, (http://hl7.org/fhir/2020May/valueset-mimetypes.html) |
| FHIR Path | DocumentReference.content.attachment.contentType |

### 1.11.6. (Attached document) language

| Tag | Description |
|---|---|
| User Guidance | The language code of the attached document must be provided based on the term ID.<br>For MRP/DCP/SRP, RMS shall provide English as the language for the documents within the common data set. |
| Repeatable | No<br>If more than one language is required then you must use extension. |
| Conformance | Mandatory |
| Data Type | code |
| Value | FHIR prescribes to use one of the languages as listed part of the list bcp-47, refer to Attachment.language for further details. The language selected must be one of the official EU languages. |
| ISO Path<br>(PMS extension) | /MedicinalProduct/AttachedDocument/Language |

| Tag | Description |
|---|---|
| FHIR Path | DocumentReference.content.attachment.language |

***Example(s):*** fr, en, es, nl

### 1.11.7. (Attached document) content

| Tag | Description |
|---|---|
| User Guidance | The physical document shall be attached to the veterinary medicinal product. |
| Repeatable | No |
| Conformance | Mandatory |
| Data Type | base64Binary |
| Value | Document content encoded in base64. The content type of the binary content must be exactly as the content type specified by the attribute "contentType". |
| FHIR Path | DocumentReference.content.attachment.data |

### 1.11.8. (Attached document) title

| Tag | Description |
|---|---|
| User Guidance | The title for the document must be specified.<br>The following convention in naming the title of the attached document should be followed:<br><country(2-letter ISO 3166-1)>-<document type(Other Names)>-<product name>-<variable part>-<language(2-letter ISO 639-1)>.<file extension (pdf)><br>And any other description as applicable, should be considered in the variable part of the title.<br>The use of spaces within the name of a document (title) is not allowed.<br>Detailed information on the requirements that apply to the product information documents can be found in Annex 2.<br>Competent Authorities interested in performing bulk upload of documents must follow the guidelines outlined in Annex 2. |
| Repeatable | No |
| Conformance | Mandatory |
| Data Type | string |
| Value | The title for the document following the naming convention.<br>• 2 letter country code (RMS list ID 100000000002)<br>• Document type from Product information Document Type (RMS list ID 100000155531) or Regulating Authority Submission Unit Type (RMS list ID 100000155552)<br>• 2 letter language code (RMS list ID 100000072057) |
| FHIR Path | DocumentReference.content.attachment.title |

***Example(s):***

ie-spc-ie/v/0277/001-en.pdf , ema-pi-mydrug-vra0005-pt.pdf, ema-combined-metacam-vra0005-pt.pdf, es-lab-amoxicilina-maymo-cattle-es.pdf

### 1.11.9. (Attached document) related veterinary medicinal products

| Tag | Description |
|---|---|
| User Guidance | References the Permanent ID that the document covers should be specified, as applicable. |
| Repeatable | Yes |
| Conformance | Mandatory |
| Data Type | Identifier |
| Value | The reference to the related medicinal product. |
| FHIR Path | DocumentReference.context.related |

***Example(s):***

MedicinalProductDefinition/601232356524

## *1.12. Product cross-reference*

This class enables a cross-reference to one or more veterinary medicinal products as available into the UPD. The Product cross-reference class is conditional, should the class apply, at least one Reference product identifier must be specified and, in the case of parallel trade, at least one Source product identifier(s).

The product cross-reference class is mandatory in the following conditions:

1. If the veterinary medicinal product (Marketing authorisation application) Legal basis specified in the field 1.7.1. is one of the following values:

- Generic application (Article 18 of Regulation (EU) 2019/6)
- Hybrid application (Article 19 of Regulation (EU) 2019/6)
- Informed consent application (Article 21 of Regulation (EU) 2019/6

at least one valid Permanent ID for the reference veterinary medicinal product as available in the UPD must be provided as applicable. In case the generic or hybrid product refers to more than one reference product, the class is repeatable and data fields "Product cross-reference type" and "reference product identifier" shall be provided for each reference product.

2. If the Authorisation/registration/entitlement type specified for the veterinary medicinal product is "Parallel trade authorisation" the following information must be provided:

- Source product: medicinal product authorised in a different country acting as source of the imported medicinal product in the destination country.
- Medicinal product already authorised in the destination country sharing a common origin with the parallel traded product and which serves as a reference for the parallel traded product intended to be imported into the destination country.

If the above scenarios apply for veterinary medicinal products, product cross-reference should be made using the permanent ID regardless on whether the marketing authorisation of the originator product has been withdrawn from the market as it remains available in the UPD.

| Cross Reference Class | Description |
|---|---|
| Repeatable | Yes |
| Conformance | Conditional based on type of regulatory entitlement and legal basis. |

### 1.12.1. Product cross-reference type

| Tag | Description |
|---|---|
| User Guidance | The type of relation between the veterinary medicinal product submitted and the veterinary medicinal product that is referenced must be specified as a term ID according to the following business rules:<br>• If the (Marketing authorisation application) Legal basis specified for the product is "generic application" then "Generic of";<br>• If the (Marketing authorisation application) Legal basis specified for the product is "hybrid application" then "Hybrid of";<br>• If the (Marketing authorisation application) Legal basis specified for the product is "informed consent application" then "Informed consent reference";<br>• If the Authorisation/registration/entitlement type specified in the field 2.1. is "Parallel trade authorisation", then cross-references should be provided as part of the national data set.<br>– For the cross-reference to the Source product, the reference type should be "parallel trade of".<br>– For the cross-reference to the authorised product in the destination member state, the reference type should be "Parallel trade in reference of".<br>• The provision of the product cross-reference information must be provided as a common data set for all the Authorisation/registration/entitlement type specified in the field 2.1. apart from the "Parallel trade authorisation" that must be provided within the national dataset. |
| Repeatable | No |
| Conformance | Mandatory |
| Data Type | CodeableConcept |
| Value(s) | Listed in Product Cross Reference Type (220000000017) |
| ISO Path | /MedicinalProduct/ProductCross-Reference/ReferencedProductType |
| FHIR Path | MedicinalProductDefinition.crossReference.type |

***Example(s):***

Reference to, Parallel trade in reference of, parallel trade of

### 1.12.2. Reference product identifier

| Tag | Description |
|---|---|
| User Guidance | The permanent ID of the reference veterinary medicinal product as assigned by UPD as applicable to the relevant legal basis specified in the (Marketing authorisation application) Legal basis section.<br><br>In the case of parallel traded veterinary medicinal products, the Permanent identifier of the veterinary medicinal product sharing a common origin in the destination member state which serves as a reference for the parallel traded product intended to be imported into the destination country shall be provided when the Authorisation/registration/entitlement type specified for the product is "Parallel trade authorisation".<br><br>Should the reference product be unavailable in the UPD, the following set of dummy Permanent IDs will be available to serve as reference product identifier:<br><br>Should the reference product be a product authorised outside EEA, (e.g. in UK), the value 600000004380 "VMP authorised outside EEA" should be used as Permanent ID;<br><br>Should the reference product be a product for which the authorisation is not valid, the value 600000004400 "Withdrawn VMP" should be used as Permanent ID;<br><br>Should the reference product be not yet available in the UPD, or the NCA cannot provide this information, the value 600000004401 "VMP data not provided" should be used as Permanent ID. |
| Repeatable | No |
| Conformance | Mandatory |
| Data Type | Reference |
| Value | UPD Permanent ID |
| ISO Path | /MedicinalProduct/ProductCross-Reference/I_MPIDCross-Reference |
| FHIR Path | MedicinalProductDefinition.crossReference.productReference |

***Example(s):***

MedicinalProductDefinition/601232356524

### 1.12.3. Source product identifier

| Tag | Description |
|---|---|
| User Guidance | The permanent ID of the veterinary medicinal product authorised in the source member state in the case of parallel traded veterinary medicinal products. |

| Tag | Description |
|---|---|
| | This information is mandatory when the Authorisation/registration/entitlement type specified for the product is "Parallel trade authorisation". |
| Repeatable | No |
| Conformance | Conditional |
| Data Type | Reference |
| Value | UPD Permanent ID |
| FHIR Path | MedicinalProductDefinition.crossReference.productReference |

***Example(s):***

MedicinalProductDefinition/601232356524

## *1.13. Manufacturing Business Operation*

This section describes how to populate information related to manufacturing sites and their operations.

This section could be completed for each individual manufacturing site that performs any operation with regards to the manufacturing of the finished product as reflected in the latest quality part of the dossier and the eAF. The 'Manufacturing Business Operation' class is mandatory in the context of UPD implementation.

Information on manufacturing sites and their operations is not required for parallel trade and registered homeopathic products.

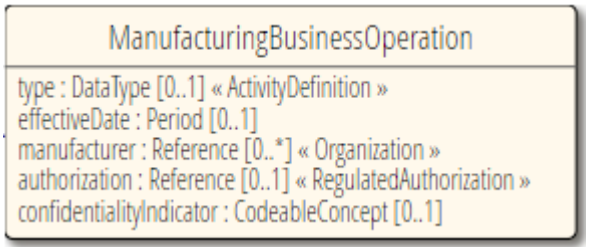


**Figure 7.** *Manufacturing Business Operation* (see section *References to FHIR versions*)

| manufacturingBusinessOperation Class | Description |
|---|---|
| Repeatable | Yes |
| Conformance | Conditional |

### 1.13.1. Manufacturer

| Tag | Description |
|---|---|
| User Guidance | The Manufacturer must be specified using the identifier as listed in OMS |
| Repeatable | No |
| Conformance | Mandatory |
| Data Type | Reference |

| Tag | Description |
|---|---|
| Value(s) | As listed in SPOR OMS service (LOC ID) |
| FHIR Path | MedicinalProductDefinition.manufacturingBusinessOperation.manufacturer |

### 1.13.2. Manufacturing activity

This section describes the operation(s) being performed by the manufacturing site for a veterinary medicinal product (including activities related to the manufacture of the active substance as applicable). Operations to be selected should be in line with the information included in relevant parts of the dossier and the eAF.

This should include manufacturing of any diluent/solvent presented in a separate container, but forming part of the medicinal product, quality control/in-process testing, immediate (primary) and outer (secondary) packaging.

For biotechnological products, include all sites of storage of master and working cell bank, and of preparation of working cell banks.

For details on the applicable manufacturing operations See Compilation of Community Procedures on Inspections and Exchange of Information, (see sections *Interpretation of the Union Format for Manufacturer/Importer Authorisation* and of the Union Format for GMP certificate).

| Tag | Description |
|---|---|
| User Guidance | The type of manufacturing operation must be specified as a term ID.<br>• The applicable manufacturing operation(s) to be completed as available in the eAF.<br>• The manufacturer responsible for batch certification must be always provided.<br>• Manufacturing operations of finished product and/or active substance (include manufacturers of intermediates of the active substance) is to be included as applicable. |
| Repeatable | No |
| Conformance | Mandatory |
| Data Type | CodeableConcept |
| Value(s) | Listed in Manufacturing Activity (100000160406) |
| ISO Path | /MedicinalProduct/ManufacturerEstablishmentOrganisation/ManufacturingBusinessOperation/OperationType |
| FHIR Path | MedicinalProductDefinition.manufacturingBusinessOperation.type |

***Example(s):***

Processing operations for the medicinal product (100000160413), Quality control testing of medicinal product (100000160408), Manufacturer responsible for batch certification (100000160407), Primary packaging (100000160463)

### *1.14. Product version number*

| Tag | Description |
|---|---|
| User Guidance | The product version number identifies the version of a product.<br><br>At the time of creation, this value must not be provided since it is set to 1 by the system, however, it must be specified when updating a product. In this case, the competent authority shall supply the number of the latest version of the product available in the system. |
| Repeatable | No |
| Conformance | Mandatory for updates |
| Data Type | String of number(s) generated by the system. |
| Value | • On create: value doesn't need to be provided as system sets to 1 (and silently ignores if value is provided)<br>• On update: existing version number |
| ISO Path | N/A |
| FHIR Path | MedicinalProductDefinition.version |

***Example(s):***

1; 20

# 2. Authorisation/registration/entitlement information

In this section, information about authorisation/registration/entitlement must be specified. This section relates to:

- **Authorised veterinary medicinal products as referred to in Article 5**

Marketing authorisation is issued by a competent authority, in a member state or a specific region, to an organisation that applied for a marketing authorisation. This is done through a marketing authorisation procedure in order to place a veterinary medicinal product on a market in that specific member state or region. If a marketing authorisation for a veterinary medicinal product is granted, the organisation is referred to as a marketing authorisation holder (MAH).

The individual national competent authorities (NCA) of the Member States of the European Union (EU) and the European Economic Area (EEA), grant national marketing authorisation of veterinary medicines within their territory (i.e. member state). The European Commission grants marketing authorisation to applications submitted through the centralised procedure, for the authorisation of veterinary medicines throughout the EU.

- **Registered veterinary homeopathic products as referred to in Article 85(1)**

Registration is issued by a competent authority, in a member state or a specific region, to an organisation that applied for a registration for homeopathic veterinary medicinal products. This is done through a registration procedure in order to place a homeopathic veterinary medicinal product on a market in that specific member state or region. If a registration for a veterinary medicinal product is granted, the organisation is referred to as a registration holder in this document included in the term marketing authorisation holder (MAH).

The individual national competent authorities (NCA) of the Member States of the European Union (EU) and the European Economic Area (EEA), grant national registration of homeopathic veterinary medicines within their territory (i.e. member state).

- **Veterinary medicinal products intended for animals which are exclusively kept as pets as referred to in Article 5(6)[6]**

A member state may allow exemptions to the marketing authorisation for 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 and not subject to a veterinary prescription. The member state shall prevent unauthorised use of those veterinary medicinal product for other animals.

These veterinary medicinal products intended for animal which are exclusively kept as pets are put on the market by an organisation registered as product owner for marketing authorisation exemption.

- **Parallel traded veterinary medicinal products as referred to in Article 102**

A wholesale distributor can apply for a parallel trade application in the destination member state. An approval of the parallel trade is granted by the competent authority of the destination member state to a wholesale distributor. (Please note, the MAH of the source product is still responsible for the product even if it is registered for parallel trade in another destination country.)

Marketing authorisations can be granted either at product level or at package level depending on the Competent authority that issues the authorisation.

- For those products whose marketing authorisation has been granted at product level, the Competent authority will have to provide at the time of creation of the product one single instance of the regulatory entitlement which must include the entitlement information required. The Marketing authorisation number at package level is to be left empty.
- For the products whose marketing authorisation has been granted at package level, the Competent authority will have to provide at the time of creation of the product an instance of the regulatory entitlement for each package that the product has. These resources must include only the marketing authorisation number assigned to the packages. Additionally, another instance of the regulatory entitlement containing the information common to all the packages must be made available.
- For MRP, DCP and SRP, a single instance of the regulatory entitlement must be created and be placed at product level.

The full information on authorisation/registration/entitlement is shown below:

[6] Creation and maintenance of products intended only for pets under Article 5(6) of Regulation (EU) 2019/6 is not currently available in UPD. It would be added in a later release during Q4 2023.

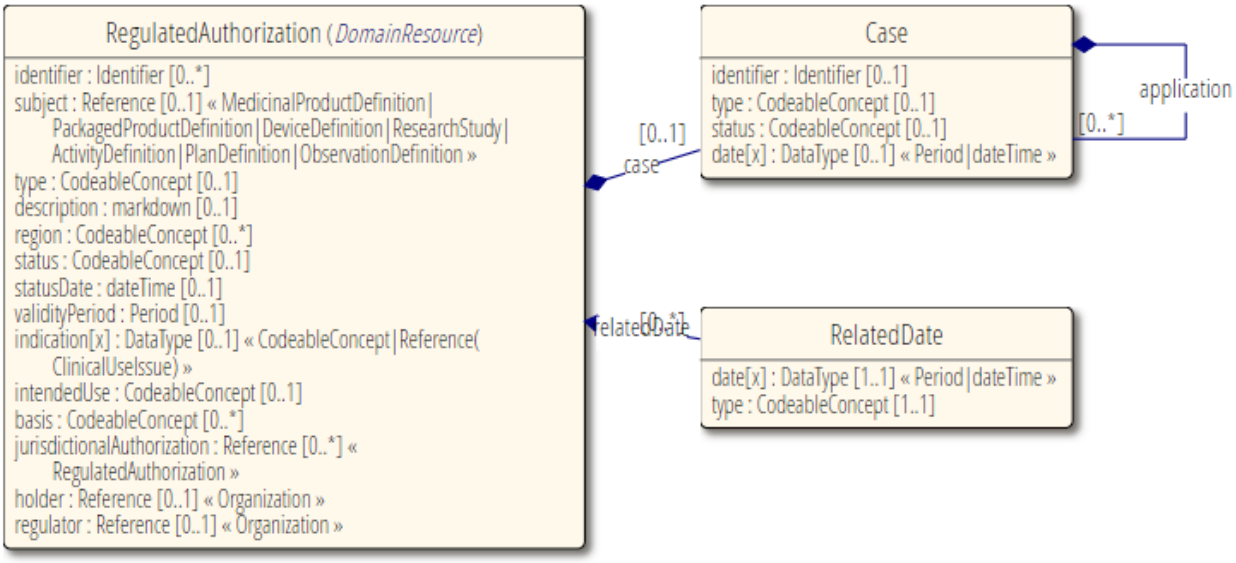


**Figure 8.** *Resource RegulatedAuthorization* (see section *References to FHIR versions*)

In the context of UPD implementation by 28 January 2022, the following elements are in scope and information should be provided according to the rules and guidance described in this section.

| authorisation/registration/entitlement Class | Description |
|---|---|
| Repeatable | Yes |
| Conformance | Mandatory |

## *2.1. Authorisation/registration/entitlement type*

Regulatory applications may be submitted to obtain different types of authorisations or regulatory entitlements which allow the veterinary medicinal product to be placed on the market, such as marketing authorisations etc. in accordance with the current European regulatory framework for veterinary medicinal products. The relevant regulatory entitlement type must be specified in this section.

| Tag | Description |
|---|---|
| User Guidance | The type of regulatory entitlement must be specified as a Term ID. |
| Repeatable | No |
| Conformance | Mandatory |
| Data Type | CodeableConcept |
| Value | The values from the Regulatory Entitlement Type list (220000000060) applicable to veterinary medicinal products are as follows:<br>• Homeopathic Registration<br>• Exemption for veterinary medicinal products intended for animals exclusively kept as pets<br>• Marketing Authorisation<br>• Parallel Trade Authorisation |
| FHIR Path | RegulatedAuthorization.type |

***Examples:***

Marketing authorisation (220000000061), Homeopathic registration (200000015756), Parallel Trade Authorisation (220000000063), Veterinary medicinal products intended for animals exclusively kept as pets (200000016178)

## *2.2. Authorisation/registration/entitlement number*

Marketing authorisation (MA) numbers are assigned by the competent authority and indicated in the SPC or other regulatory document(s).

- If the MA number was assigned by the EU Commission, then the MA number as stated in SPC must be specified. Marketing authorisation number(s) of the corresponding SPC or as stated in the EC decision document must be specified.
- If the MA number was assigned by the national competent authority, then the MA as stated in the corresponding SPC and applicable NCA's database must be specified.
- Only one MA number (the current one) can be referenced in this data element. Any change of an MA number triggered by, for instance, a transfer of MAH (e.g. in Ireland) should be recorded as a new version of the MA number in this field. Where the MA number is assigned at package level, this information must be left blank. Any MA numbers assigned to the individual packages must be provided at the package level as described in the SPC. This is, to avoid duplication of product entries based on the granularity of MA number.

For products that are not authorised veterinary medicinal products, this section should be used for:

- Registration number assigned by a national competent authority for veterinary homeopathic medicinal products;
- Identification number assigned by a national competent authority for products exempted as referred to in Article 5(6);
- Parallel trade approval number assigned by a national competent authority as referred to in Article 102.

| Tag | Description |
|---|---|
| User Guidance | Authorisation/registration/entitlement number must be specified when the authorisation number is assigned at product level by the relevant CA.<br>• Where the authorisation/registration/entitlement number is assigned at Packaged Medicinal Product level, this information must be left blank and the authorisation number must be specified at package level.<br>• Should a regulatory procedure amend the authorisation number, the new applicable number should be specified as an update of the product into UPD. The new authorisation number shall not trigger a new Permanent ID but only a new version of it.<br>• The marketing authorisation number is mandatory to be provided at either the product level or at package level (5.5.1.) as applicable. |
| Repeatable | No |
| Conformance | Conditional |
| Data Type | Identifier |

| Tag | Description |
|---|---|
| Value | The number as assigned by the competent authority of a country/jurisdiction shall be specified as free text (max. 4000 characters).<br><br>For CAPs, the format of the EU number root number must be "EU/2/YY/NNN " or "EU/2/YY/NNNN" (as applicable).<br><br>RegulatedAuthorization.identifier.system value is "http://ema.europa.eu/fhir/MarketingAuthorizationNumber" |
| ISO Path | /MedicinalProduct/MarketingAuthorisation/MarketingAuthorisationNumber |
| FHIR Path | RegulatedAuthorization.identifier<br><br>(with reference to the MedicinalProductDefinition resource) |

***Example(s):***

Examples of MA number at product level: 123456, 9743/2016, EU/2/13/016

## *2.3. Country*

| Tag | Description |
|---|---|
| User Guidance | The country code of the country where the marketing authorisation was granted must be specified as a term ID.<br>• For veterinary medicinal products authorised via the centralised procedure, EEA shall be specified.<br>• For veterinary medicinal products authorised via national or MRP/DCP procedure, the relevant country shall be specified in the national data set. |
| Repeatable | No |
| Conformance | Mandatory |
| Data Type | CodeableConcept |
| Value | As listed in the Country list (RMS list ID 100000000002), or Country Grouping list (RMS list ID 100000000003) |
| ISO Path | /MedicinalProduct/MarketingAuthorisation/Country |
| FHIR Path | RegulatedAuthorization.region |

***Example(s):***

Spain (100000000529), European Economic Area (100000000026)

## *2.4. Responsible authority (organisation)*

| Tag | Description |
|---|---|
| User Guidance | The responsible authority must be specified using the location identifier linked to the organisation (LOC ID) as listed in OMS |
| Repeatable | No |
| Conformance | Mandatory |

| Tag | Description |
|---|---|
| Data Type | Reference |
| Value(s) | As listed in SPOR OMS service (LOC ID)) |
| ISO Path | /MedicinalProduct/MarketingAuthorisation/Organisation(MedicinesRegulatoryAgency)/Identifier |
| FHIR Path | RegulatedAuthorization.regulator |

***Example(s):***

Federal Office of Consumer Protection And Food Safety (LOC-100000087)

## 2.5. Authorisation status

| Tag | Description |
|---|---|
| User Guidance | The status of the marketing authorisation of the medicinal product throughout its lifecycle must be specified as a term ID. The authorisation status of a product could change throughout its lifecycle.<br><br>The applicable authorisation statuses to veterinary medicinal product based on the Regulatory Entitlement Status list from RMS are as follows: pending, valid, surrendered, suspended, revoked, and expired.<br><br>'Pending' status should be used for Authorisation status of Veterinary Medicinal Products approved under MR\|DC or SR procedures that have been created by the RMS at the end of the European phase. |
| Repeatable | No |
| Conformance | Mandatory |
| Data Type | CodeableConcept |
| Value | Must one of pending, valid, surrendered, suspended, revoked, and expired from the list Regulatory Entitlement Status (100000072049). |
| ISO Path | /MedicinalProduct/MarketingAuthorisation/AuthorisationStatus |
| FHIR Path | RegulatedAuthorization.status |

***Example(s):***

Valid (100000072099), Revoked (100000072121), Suspended (100000072122)

## 2.6. Date of authorisation status change

| Tag | Description |
|---|---|
| User Guidance | When an authorisation status is changed, the date when the change legally occurred must be specified.<br>At the time of the initial data entry, the date of the marketing authorisation should be specified. |
| Repeatable | No |
| Conformance | Mandatory |
| Data Type | dateTime |

| Tag | Description |
|---|---|
| Value | A date shall be specified using the ISO 8601 date format.<br><br>ISO 8601 can accommodate year and month should day of the month not be known. (i.e., YYYY-MM). |
| ISO Path | /MedicinalProduct/MarketingAuthorisation/AuthorisationStatusDate |
| FHIR Path | RegulatedAuthorization.statusDate |

## 2.7. Marketing authorisation date

| Tag | Description |
|---|---|
| User Guidance | The date when the first authorisation was granted by the competent authority must be specified. |
| Repeatable | No |
| Conformance | Mandatory |
| Data Type | dateTime |
| Value | A date specified using the ISO 8601 date format.<br><br>RegulatedAuthorization.relatedDate.type.system value is http://ema.europa.eu/fhir/code-systems/authorisation-date-type"<br>RegulatedAuthorization.relatedDate.type.code is "dateOfFirstAuthorisation" |
| ISO Path | /MedicinalProduct/MarketingAuthorisation/DateOfFirstAuthorisation |
| FHIR Path | RegulatedAuthorization.relatedDate.dateDateTime |

## 2.8. Product owner (organisation)

The product owner could be a marketing authorisation holder, a registration holder, an owner of products intended only for pets. Not applicable for parallel traded veterinary medicinal product.

| Tag | Description |
|---|---|
| User Guidance | The Product owner must be specified using the location identifier linked to the organisation (LOC ID) as listed in OMS |
| Repeatable | No |
| Conformance | Conditional |
| Data Type | Reference |
| Value(s) | As listed in SPOR OMS service (LOC ID) |
| ISO Path | MedicinalProduct/MarketingAuthorisation/MarketingAuthorisationHolder(Organisation) |
| FHIR Path | RegulatedAuthorization.holder |

## 2.9. Source wholesale distributor (organisation)

Wholesale distributor who is providing the parallel traded veterinary medicinal product in the source Member State.

| Tag | Description |
|---|---|
| User Guidance | The source wholesale distributor(s) must be specified using the location identifier linked to the organisation (LOC ID) as listed in OMS when the Authorisation/registration/entitlement type specified for the product is "Parallel trade authorisation". |
| Repeatable | Yes |
| Conformance | Conditional based on the authorisation/registration/entitlement type (parallel traded products) |
| Data Type | Reference |
| Value(s) | As listed in SPOR OMS service (LOC ID) |
| FHIR Path | RegulatedAuthorization.extension.parallelTradeSourceWholesaler |

## 2.10. Destination wholesale distributor (organisation)

Wholesale distributor who is receiving the parallel traded veterinary medicinal product and holder of the parallel trade approval in the destination member state.

| Tag | Description |
|---|---|
| User Guidance | The destination wholesale distributor must be specified using the location identifier linked to the organisation (LOC ID) as listed in OMS when the Authorisation/registration/entitlement type specified for the product is "Parallel trade authorisation". |
| Repeatable | No |
| Conformance | Conditional based on the authorisation/registration/entitlement type (parallel traded products) |
| Data Type | Reference |
| Value(s) | As listed in SPOR OMS service (LOC ID) |
| FHIR Path | RegulatedAuthorization.extension.parallelTradeDestinationWholesaler |

## 2.11. Reference member state

Name of the Reference member state to be stated in the case of decentralised procedure (DCP), mutual recognition procedure (MRP) or subsequent recognition procedures (SRP). A Reference member state is also assigned to veterinary medicinal products subject to mutual recognition following SPC harmonisation.

| Tag | Description |
|---|---|
| User Guidance | The name of the Reference member state must be provided as a term ID. |
| Repeatable | No |
| Conformance | Conditional based on the authorisation procedure type. Reference member state is not applicable to parallel trade medicinal products. |
| Data Type | CodeableConcept |
| Value | As listed in Country (100000000002) – values restricted to countries from the EEA. |
| FHIR Path | RegulatedAuthorization.case.extension.referenceCountry |

## 2.12. Concerned member states

Names of the Concerned member states (CMS) should be specified in the case of decentralised procedure (DCP), mutual recognition procedure (MRP) or subsequent recognition procedure (SRP), and mutual recognition following SPC harmonisation.

| Tag | Description |
|---|---|
| User Guidance | A list of Concerned member states must be provided. Each Concerned member state will be included in the list only once as a term ID.<br><br>The Referenced member state cannot be included in the Concerned member state list. |
| Repeatable | Yes |
| Conformance | Conditional based on the authorisation procedure type. Concerned member state is not applicable to parallel trade medicinal products. |
| Data Type | CodeableConcept |
| Value(s) | As listed in Country (100000000002) – values restricted to countries from the EEA. |
| FHIR Path | RegulatedAuthorization.case.extension.concernedCountries |

## 2.13. Marketing authorisation procedure

Marketing Authorisation Procedure class is used for submitting information related to the initial Marketing authorisation approval routes (e.g. Centralised Procedure, Mutual recognition Procedure, Decentralised Procedure and National Procedure) and for the national procedures transfer in a MRP (following SPC harmonisation or referral) that impact the product information as included in this guidance. The class is mandatory for veterinary medicinal products authorised in the EU/EEA.

| Class for Procedure | Description |
|---|---|
| Repeatable | No |
| Conformance | Mandatory |

### 2.13.1. Procedure number

The procedure number assigned by the competent authority to a specific authorisation/registration procedure must be specified. This number is mandatory for centralised procedures, DCP, MRP and Subsequent recognition procedures (SRP), and optional for national procedures.

Procedure number relates exclusively to the initial authorisation procedure registration route and should be completed once. However, in case of a switch from a purely National Procedure to Mutual recognition procedure (MRP) this attribute must be updated if relevant. This number should also be updated in case of RMS transfer.

Mutual recognition, Decentralised and Subsequent Recognition (SRP) procedure number have a format defined in the CMDv procedural guidance for Marketing Authorisation Procedures published on the CMDv website. The structure of the procedure number should be respected in order to ensure a proper formatting of the number.

The format required by UPD is CC/V/nnnn/sss. It is noted that a procedure number is typically CC/V/nnnn/sss/Y/vvv, the last two parts (/Y/vvv) are not used in the UPD since the number should be

the same for all products involved in an MR procedure regardless of if it started with an MRP, DCP or an SRP.

Where:

- CC is the Country code (2 characters) of the Reference member state
- V: medicinal product for veterinary use
- nnnn: the 'Medicinal Product Number' characterising the medicinal product, related to an active principle and to an applicant or "xxxx" as placeholder for specific variations. Four digits must always be used.
- sss: the 'Speciality Number' characterising the strength and/or pharmaceutical form and/or target species. Three digits must always be used.

- Mutual recognition procedure (MRP) number must be specified when the authorisation procedure is entered as 'Mutual Recognition Procedure'.

  Example: IE/V/0234/001 (IE/V/0234/001)
- In case of Subsequent recognition procedures (SRP), this procedure number is to be fulfilled for new concerned Member States as:

  Example: IE/V/0234/001 (IE/V/0234/001)
  In the first Member States the procedure number of the subsequent recognition of the product is not reflected.

- Decentralised authorisation procedure (DCP) number must be specified when the authorisation procedure is entered as Decentralised Procedure. The format of the DCP number should be mentioned as:

  Example: IE/V/0236/001 (IE/V/0236/001)

- EMEA procedure number (i.e. "Agency Product Number") must be specified when the authorisation procedure is entered as Centralised Procedure.

  The format of the EMA procedure number must be EMEA six-digit procedure number (i.e. EMEA/V/C/123456).

- For purely national authorisation procedures, the local procedure number must be provided if any.

| Tag | Description |
|---|---|
| User Guidance | Procedure number should be specified in accordance with information in Electronic Application Form. |
| Repeatable | No |
| Conformance | Conditional (based on the procedure type. Not mandatory for NAP) |
| Data Type | Identifier |
| Value(s) | The applicable procedure number shall be specified as free text but formatted as: CC/V/nnnn/sss or EMEA/V/C/nnnnnn for the core part. Procedure number is case insensitive. RegulatedAuthorization.case.identifier.system value is "http://ema.europa.eu/fhir/procedureIdentifierNumber" |
| ISO Path | /MedicinalProduct/MarketingAuthorisation/MarketingAuthorisationProcedure/ProcedureIdentifier-Number |
| FHIR Path | RegulatedAuthorization.case.identifier |

***Example(s):***

SE/V/1111/003, DE/V/1111/001, DE/V/1111/001, EMEA/V/C/001234

## 2.13.2. Procedure type

The type of procedure through which the initial marketing authorisation in accordance with Article 44, 47, 49, 52, 53 or 54 of the Regulation (EU) 2019/6 was granted must be specified.

- Centralised Procedure is to be specified when entering a centrally authorised medicinal product. The authorisation country code must have been specified as 'EEA' in section 2.3 "Country";
- Decentralised Procedure is to be selected when entering a medicinal product authorised via a decentralised procedure. The authorisation country must have been specified as one of the EEA countries in section 2.3 "Country".
- National procedure is to be specified when entering a nationally authorised medicinal product.
- The authorisation country must have been specified as one of the EEA countries in section 2.3 "Country".
- Mutual Recognition Procedure is to be specified when entering a mutually recognised medicinal product. The authorisation country must have been specified as one of the EEA countries in section 2.3 "Country".
- Subsequent recognition procedure (SRP) is to be selected when entering, after completion of a decentralised or mutual recognition procedures, a medicinal product authorised in additional Concerned member states via a subsequent recognition. The authorisation country must have been specified as one of the EEA countries in section 2.3 "Country".
- Registration procedure for veterinary homeopathic medicinal products is to be specified when entering a Registered homeopathic product. The authorisation country must have been specified as one of the EEA countries in section 2.3 "Country".
- Exemption to marketing authorisation for veterinary medicinal products intended for animals exclusively kept as pets is to be specified when entering products exempted as referred to in Article 5(6). The authorisation country must have been specified as one of the EEA countries in section 2.3 "Country".
- Parallel trade procedure is to be specified when entering a parallel traded product.

| Tag | Description |
|---|---|
| User Guidance | The type of procedure (EU medicinal marketing authorisation approval routes) through which the initial marketing authorisation was granted by the regulatory authority must be specified. |
| Repeatable | No |
| Conformance | Mandatory |
| Data Type | CodeableConcept |
| Value(s) | As listed in EU Regulatory Authorisation Procedure (100000154442) |

| Tag | Description |
|---|---|
| ISO Path | /MedicinalProduct/MarketingAuthorisation/MarketingAuthorisationProcedure/ProcedureType |
| FHIR Path | RegulatedAuthorization.case.type |

***Example(s):***

Centralised Procedure (100000155059), Decentralised Procedure (100000155060),

Mutual Recognition Procedure (100000155061), Subsequent Recognition Procedure (200000016181),

Registration procedure for veterinary homeopathic medicinal products (200000027035), Parallel Trade Procedure (200000026020)

# 3. Pharmaceutical product

The pharmaceutical product section refers to the description of the veterinary medicinal product composition as it is approved for administration to the animal (i.e. the administrable pharmaceutical product). Some attributes that belong to the pharmaceutical product section should be included in the UPD.

The full information on pharmaceutical product is shown below:

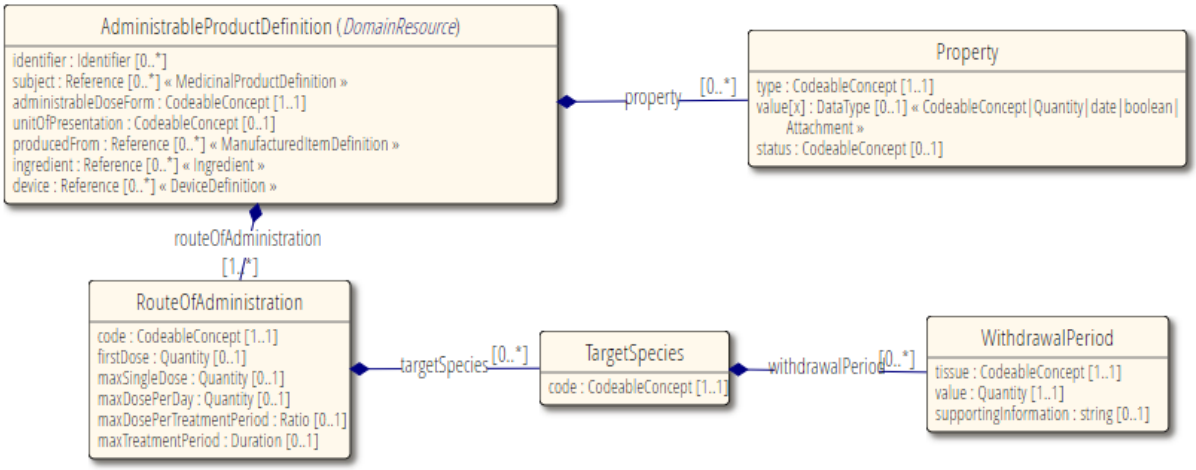


**Figure 9.** *Resource AdministrableProductDefinition* (see section *References to FHIR versions*)

| Pharmaceutical product Class | Description |
|---|---|
| Repeatable | Yes |
| Conformance | Mandatory |

## *3.1. Ingredient*

The ingredient(s) of the pharmaceutical product shall be specified based on the resource Ingredient as outlined in section 4.

## 3.2. Route of administration

| Tag | Description |
|---|---|
| User Guidance | The route of administration must be specified in accordance with the appropriate *Section of the SPC* as a Term ID.<br><br>The Route of administration describes the path by which the medicinal product (or more precisely, in data model terms, (one of) the administrable "pharmaceutical product"(s)) is taken into or makes contact with the body. |
| Repeatable | Yes |
| Conformance | Mandatory |
| Data Type | CodeableConcept |
| Value(s) | As listed in Routes and Methods of Administration (100000073345) |
| ISO Path | /MedicinalProduct/PharmaceuticalProduct/RouteOfAdministration/RouteOfAdministration |
| FHIR Path | AdministrableProductDefinition.routeOfAdministration.code |

***Example(s):***

Oral use (100000073619), Intravenous use (100000073611), Oromucosal use (100000073620), Ocular use (100000073617)

## 3.3. Target species

| Tag | Description |
|---|---|
| User Guidance | The target species as indicated in the appropriate section of the corresponding SPC must be provided as a term ID.<br>If multiple values apply to the same veterinary medicinal product then multiple values must be selected.<br><br>This information is not applicable to parallel trade medicinal products. |
| Repeatable | Yes |
| Conformance | Conditional |
| Data Type | CodeableConcept |
| Value(s) | As listed in Target Species (100000108853) |
| FHIR Path | AdministrableProductDefinition.routeOfAdministration.targetSpecies.code |

***Example(s):***

Cows (100000108888), Honey bees (100000108922)

## 3.4. Withdrawal period

A withdrawal period is established per species and per food commodity (edible tissues) for veterinary medicinal product intended to be used in food-producing animals. Withdrawal period could also be described per route of administration for given species and per treatment posology. For given species or type of production, specific restrictions could apply.

Each withdrawal period will belong to a pharmaceutical product on which route of administration on one or more species are described.

Information on withdrawal period is not required for registered homeopathic products and parallel trade medicinal products.

| withdrawalPeriod Class | Description |
|---|---|
| Repeatable | Yes |
| Conformance | Conditional. It must be provided only when the tissue has extended attributes of "Tissue type" equal to either "Edible and MRL Tissue", "MRL Tissue" or "Edible Tissue". |

### 3.4.1. Tissue

| Tag | Description |
|---|---|
| User Guidance | A withdrawal period must be described per edible tissue when the veterinary medicinal product is intended to be used in food-producing animals. |
| Repeatable | No |
| Conformance | Mandatory |
| Data Type | CodeableConcept |
| Value(s) | As listed in Tissue (100000072054). |
| FHIR Path | AdministrableProductDefinition.routeOfAdministration.targetSpecies.withdrawalPeriod.tissue |

***Example(s):***

Honey (100000072093), Milk (100000072095), Meat and offal (100000072107)

### 3.4.2. Period

| Tag | Description |
|---|---|
| User Guidance | A withdrawal period is a period of time expressed in days or hours or degree days. This information should be provided as applicable and based on the information in the SPC.<br>For multiple languages country, the withdrawal period should be provided in one language and preferably in English only.<br>Based on the information in the SPC, should the period not be applicable, additional information on the withdrawal period must be specified in the 3.4.3 Note field. |

| Tag | Description |
|---|---|
| | There are specific cases where there must be a withdrawal note for a specific tissue but no withdrawal period. For instance, when a certain product is not authorised for use in animals producing milk for human consumption, sometimes there must be a withdrawal note for milk, but no withdrawal period, and zero as a value would be wrong information. In these specific cases, the value should be set as 999. Unit can be set as any term ID, e.g. "year".<br>There are also cases where the commodity/tissue in question can be harvested and consumed immediately after the use of the product, in such cases the withdrawal period is zero day and recorded in the system as 0 day. |
| Repeatable | No |
| Conformance | Mandatory |
| Data Type | Quantity |
| Value(s) | Numeric value and units. Units must be specified as a Term ID listed in Units of Measurement (100000110633) e.g. day, hour, minute, month, year, week |
| FHIR Path | AdministrableProductDefinition.routeOfAdministration.targetSpecies.withdrawalPeriod.value<br><br>In which must be provided:<br>value: numerical value<br>system: http://spor.ema.europa.eu/v1/lists/100000110633<br>code: the unit of measurement for the time dimension. |

***Example(s):***

10 day (100000110784), 12 hour (100000110804)

### 3.4.3. Note

| Tag | Description |
|---|---|
| User Guidance | This field refers to the free text description of a given withdrawal period for a given target species as it is stated in the SPC and can be used to specify additional information on the withdrawal period such as specific posology, specific restrictions for instance "not to be used for cattle producing milk", description of species not authorised for consumption, etc).<br><br>Should the withdrawal period information be provided in 3.4.1 Tissue and in 3.4.2 Period, this information is optional.<br><br>The note should be completed if the value in the field 3.4.2 "Period" is 999. For MRP/DCP/SRP, the note should be provided in English. |
| Repeatable | No |
| Conformance | Conditional |
| Data Type | string |

| Tag | Description |
|---|---|
| Value(s) | Free text. Withdrawal period restrictions as expressed in the SPC (max. 4000 characters) |
| FHIR Path | AdministrableProductDefinition.routeOfAdministration.targetSpecies.withdrawalPeriod.supportingInformation |

***Example(s):***

"Not authorised for use in animals producing milk for human consumption."

"Do not use in pregnant animals, which are intended to produce milk for human consumption, within 2 months of expected parturition."

### *3.5. Administrable dose form*

| Tag | Description |
|---|---|
| User Guidance | The administrable dose form is a mandatory data element in the FHIR API version R5#2: http://hl7.org/fhir/2020May/administrableproductdefinition-definitions.html#AdministrableProductDefinition.administrableDoseForm. For the implementation of the UPD MVP the value 'Pharmaceutical dose form not applicable' (200000018781) must be specified from the RMS list ID 200000000004. |
| Repeatable | No |
| Conformance | Mandatory |
| Data Type | CodeableConcept |
| Value(s) | RMS term name 'Pharmaceutical dose form not applicable' (200000018781) |
| ISO Path | /MedicinalProduct/PharmaceuticalProduct/AdministrableDoseForm |
| FHIR Path | AdministrableProductDefinition.administrableDoseForm |

# 4. Ingredient

The full information on ingredient(s) of a manufactured item is described by the FHIR *Resource Ingredient* as shown below. Note that when describing ingredients of manufactured items, only the active substance should be provided as mandatory. Also, the same ingredient can be referenced in both the manufactured item and data items covered under the pharmaceutical product section, when needed. The class is mandatory.

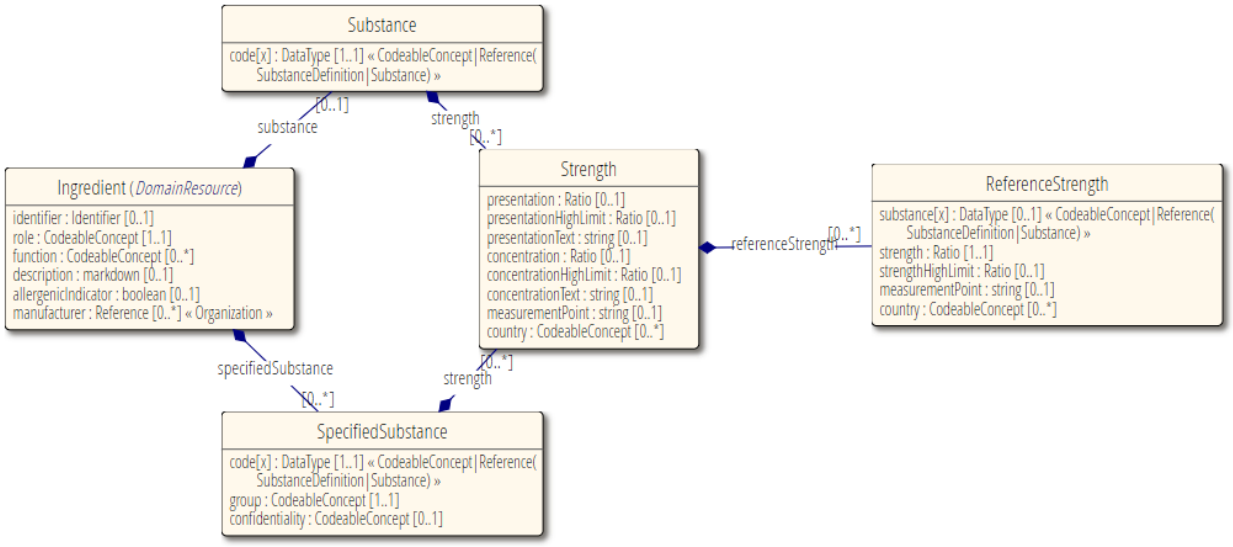


**Figure 10.** *Resource Ingredient* (see section *References to FHIR versions*)

| Ingredient Class | Description |
|---|---|
| Repeatable | Yes |
| Conformance | Mandatory |

For products containing multiple ingredients, the ingredient class should be repeated to describe each individual substance contained in the medicine.

The following information should be provided for at least one active ingredient in each VMP.

## *4.1. Ingredient role*

| Tag | Description |
|---|---|
| User Guidance | The role of the ingredient as part of the manufactured item must be specified as a term ID. |
| Repeatable | No |
| Conformance | Mandatory |
| Data Type | CodeableConcept |
| Value(s) | The value must be as listed in Ingredient Role |
| ISO Path | For the Manufactured Item, the ISO path is: /MedicinalProduct/PackagedMedicinalProduct/PackageItem/ManufacturedItem/Ingredient/IngredientRole<br><br>For the Pharmaceutical product, the ISO path is: /MedicinalProduct/PharmaceuticalProduct/Ingredient/IngredientRole |
| FHIR Path | Ingredient.role |

***Example(s):***

Active (100000072072)

## 4.2. Manufacturer

The manufacturer of the active substance is optional in the first iteration of the UPD. Should this information be provided, the class described in section 1.13 Manufacturing business operation applies. The applicable value for the Manufacturer activity for the manufacturer of the active substance should be any term and sub-terms relevant for active substance.

Examples:

Manufacturer of active substance, manufacturer of active substance intermediate.

## 4.3. Substance

This class refers to the description of the ingredient contained in the veterinary medicinal product based on the information available in the SPC and the quality part of the dossier, *Part 2A of the dossier* stating the composition of the medicinal product.

| Substance Class | Description |
|---|---|
| Repeatable | No |
| Conformance | Mandatory |

### 4.3.1. Substance

| Tag | Description |
|---|---|
| User Guidance | The Active Substances contained within the medicinal product must be specified as a substance ID.<br><br>NOTE: every medicinal product must have at least one active substance.<br><br>Should the veterinary medicinal product contain only inactive ingredients, at least one substance (being the main substance), must be specified as active (e.g. purified water).<br><br>For homeopathic veterinary medicinal products, the active substance must be homeopathic substance (i.e. source material together with the final dilution/trituration).<br><br>For parallel trade products, the active substance of the source product must be provided. |
| Repeatable | No |
| Conformance | Mandatory |
| Data Type | CodeableConcept |
| Value(s) | As listed in SPOR Substance Management System (SMS) |
| ISO Path | For the Manufactured Item, the ISO path is: /MedicinalProduct/PackagedMedicinalProduct/PackageItem/ManufacturedItem/Ingredient/Substance<br><br>For the Pharmaceutical product, the ISO path is: /MedicinalProduct/PharmaceuticalProduct/Ingredient/Substance |

| Tag | Description |
|---|---|
| FHIR Path | Ingredient.substance.codeCodeableConcept |

### 4.3.2. Strength (quantitative composition)

The strength (quantitative composition) of the substance (active substance) should be declared as a quantity of the substance contained in a veterinary medicinal product, as indicated in the relevant parts of the dossier and the SPC.

Should the strength be expressed as a range, the higher dose should be specified.

The strength (quantitative composition) must be provided based on a numerator and denominator value and unit. The unit of the denominator is either a unit of presentation (presentation strength) or a unit of measure/concentration (concentration strength). The expression of strength for a product is expressed as in the SPC in active moiety. Where the active ingredient is an ester, the quantitative composition could be stated in terms of the quantity of that ester. Where the active substance is present in the form of a salt or hydrate, the quantitative composition should be expressed in terms of the active moiety (free base, acid or anhydrous material). In all the cases, the strength of the active moiety should be entered in the reference strength section (refer to section 4.3.3 Reference strength). For active ingredients, the information on the strength must be provided for either the substance or for the reference substance or for both as outlined in the relevant parts of the dossier and the SPC.

Where the active substance is immunological or biological (substance other than immunological), including novel therapies, the strength must be provided based on a quantification of the active substance (titre) -whenever possible the number of organisms, the specific protein content, the mass, the number of International Units (IU)-, or based on biological activity or potency, either per dosage-unit or volume. In these cases, if the strength (quantitative composition) cannot be provided based on a numerator and denominator value and unit then, as an exception, this information can be provided using the free text field.

The following example illustrates this requirement:

EXAMPLE: presentation strength

| **Field** | **Value (presentation strength)** |
|---|---|
| SPC text | Each tablet contains 45,9 mg amoxicillin trihydrate corresponding to 40 mg amoxicillin |
| Active substance | Amoxicillin trihydrate |
| Active substance presentation strength single value or low limit numerator | 45,9 mg |
| Active substance presentation strength single value or low limit denominator | 1 tablet |
| Active substance presentation strength text | empty |
| Reference substance | Amoxicillin |
| Reference substance presentation strength single value or low limit numerator | 40 mg |

| | |
|---|---|
| Reference substance presentation strength single value or low limit denominator | 1 tablet |
| Active substance presentation reference strength text | empty |

EXAMPLE: concentration strength

| **Field** | **Value (concentration strength)** |
|---|---|
| SPC text | Each gram contains 0,54 g oxytetracycline hydrochloride corresponding to 0,5 g oxytetracycline |
| Active substance | oxytetracycline hydrochloride |
| Active substance concentration strength ingle value or low limit numerator | 0,54 g |
| Active substance concentration strength single value or low limit denominator | 1 g |
| Active substance presentation strength text | empty |
| Reference substance | oxytetracycline |
| Reference substance concentration strength single value or low limit numerator | 0,5 g |
| Reference substance concentration strength single value or low limit denominator | 1 g |
| Active substance presentation reference strength text | empty |

EXAMPLE: Text strength

| **Field** | **Value (presentation strength)** |
|---|---|
| SPC text | One dose of 1 ml contains:<br>Influenza A/eq/Ohio/03 [H3N8] (vCP2242) ≥ 5.3 log10 FAID50<br>Influenza A/eq/Richmond/1/07 [H3N8] (vCP3011) ≥ 5.3 log10 FAID50 |
| Active substance | Canarypox virus expressing Influenza A virus, A/equi-2/Kentucky/94 (H3N8), Live |
| Active substance presentation strength single value or low limit numerator | empty |
| Active substance presentation strength single value or low limit denominator | empty |

| | |
|---|---|
| Active substance strength text | 6.5 log10 FAID*50 to 7.5 log10 FAID50 |
| Reference substance | empty |
| Reference substance presentation strength single value or low limit numerator | empty |
| Reference substance presentation strength single value or low limit denominator | empty |
| Reference substance strength text | empty |

EXAMPLE: Concentration strength and text strength

| **Field** | **Value (concentration strength)** |
|---|---|
| SPC text | Each dose of 2 ml contains: Strains of inactivated Influenza A virus/swine/<br>• Bakum/IDT1769/2003 (*H3N2*) ≥ 10.53 log2 GMNU<br>• Haselünne/IDT2617/2003(*H1N1*) ≥ 10.22 log2 GMNU<br>• Bakum/1832/2000 (*H1N2*) ≥ 12.34 log2 GMNU |
| Active substance | Swine influenza virus, A/swine/ Bakum/IDT1769/2003 (*H3N2*), Inactivated<br>Swine influenza virus, A/swine/Haselünne/IDT2617/2003 (H1N1), Inactivated<br>Swine influenza virus, A/swine/ Bakum/1832/2000 (*H1N2*), Inactivated |
| Active substance concentration strength single value or low limit numerator | Value: 10.22<br>Unit of measurement: Log2 Geometric mean of neutralizing units (log2 GMNU) |
| Active substance concentration strength single value or low limit denominator | Value: 2<br>Unit of measurement: millilitre(s) |
| Active substance strength text | min. 10.22 $log_2$ GMNU |
| Reference substance | empty |
| Reference substance presentation strength single value or low limit numerator | empty |
| Reference substance presentation strength single value or low limit denominator | empty |
| Reference substance strength text | empty |

- **Expression of the strength (quantitative composition)**

Based on the strength expressed in the SPC, the strength (quantitative composition) can be expressed as EITHER:

- **Presentation strength (per dosage/unit of presentation) -** strength expressed per unit of presentation.

  The unit of presentation is a qualitative term describing the discrete unit in which a manufactured item is presented.

  *EXAMPLE:*

  250 milligrams per tablet

  10 mg per vial (for solution for injection)

  10 mg per tube (for single use gels)

OR

- **Concentration strength (per unit of measure/concentration)** – the strength is expressed as the amount of the substance per unit of measurement such as millilitre or gram (not unit of presentation)

  If the strength is expressed as per single unit of measurement, e.g. 4 mg/ml, the denominator is 1 ml. For products that have the strength expressed differently, the denominator means the fraction of unit used, e.g. 4 mg/0.8 ml.

  EXAMPLE:

  10 milligrams per millilitre (for parenteral products)

  10 milligrams per 24 hours (for transdermal patches)

  100 Units per millilitre (for insulins)

The provision of the strength(s) of the active ingredient(s) is mandatory. The strength of the active substance as listed in SPC and Part 2A must be specified.

OR

- **Text** – the strength is expressed as text

  If the strength is expressed as a range of units, e.g. 1.4 to 2.5 x $10^6$ cells, or presents the need to have more information than just the value and the unit, e.g. at least 3.6 log to 4.4 log10 PFU.

  EXAMPLE:

  196-265 oocysts/dose (for vaccine for Eimeria parasite product)

  1.4 to 2.5 x $10^6$ cells (for joint inflammation steam cells product)

  min. 2.7 log10, max. 4.5 log10 (for vaccine for fowlpox virus product)

The provision of the strength(s) of the active ingredient(s) is mandatory. The strength of the active substance as listed in SPC and Part 2A must be specified.

#### *4.3.2.1. Strength (presentation)*

When the strength of a substance is described by using a qualitative term describing the discrete unit in which a manufactured item is presented, the below fields should be used to enter this information.

##### 4.3.2.1.1. Strength (presentation single value)

| Tag | Description |
|---|---|
| User Guidance | The strength (quantitative composition) of the active substances must be specified in this field with a numerator and denominator. This information is mandatory if the reference strength outlined in 4.3.3. is not provided.<br><br>The numerator should be expressed by a numeric value and a unit (e.g. mg).<br><br>The denominator should be expressed by a numeric value and a unit (e.g. tablet) where the unit is a unit of presentation.<br><br>This information is not to be provided for parallel trade products. |
| Repeatable | No |
| Conformance | Conditional |
| Data Type | Ratio |
| Value(s) | The units for the denominator must be specified as a numeric value. Term IDs are expressed as listed in Units of Presentation (200000000014) |
| ISO Path | For the Manufactured Item, the ISO path is:<br>/MedicinalProduct/PackagedMedicinalProduct/PackageItem/ManufacturedItem/Ingredient/Substance/Strength/Strength_Presentation<br><br>For the Pharmaceutical product, the ISO path is:<br>/MedicinalProduct/PharmaceuticalProduct/Ingredient/Substance/Strength/Strength_Presentation |
| FHIR Path | Ingredient.substance.strength.presentation |

#### *4.3.2.1.2. Strength text (Presentation)*

| Tag | Description |
|---|---|
| User Guidance | The strength text field of the substances must be specified in this field. This information is mandatory if the strength structured quantitative composition (presentation) outlined in 4.3.2.1 are not provided. Although, it can be specified even when a structured quantitative composition (presentation or concentration) is provided.<br><br>This information is not to be provided for parallel trade products. |
| Repeatable | No |
| Conformance | Conditional |
| Data Type | String (maximum length: 4000 characters) |
| Value(s) | n/a |
| ISO Path | TBC |
| FHIR Path | Ingredient.substance.strength.presentationText |

#### *4.3.2.2. Strength (concentration)*

When the strength of a substance is expressed as the amount of substance per unit of measurement, such as millilitre or gram, the below fields should be used to enter this information.

##### 4.3.2.2.1. Strength (concentration single value)

| Tag | Description |
|---|---|
| User Guidance | The strength (quantitative composition) of the substances must be specified in this field with a numerator and denominator. This information is mandatory if the reference strength outlined in 4.3.3. is not provided.<br><br>The numerator and the denominator should be expressed with a numeric value and a unit of measurement (e.g. mg, ml).<br><br>This information is not to be provided for parallel trade products. |
| Repeatable | No |
| Conformance | Conditional |
| Data Type | Ratio |
| Value(s) | The units for the numerator and the denominator must be specified as a numeric value. Term ID are expressed as listed in Units of Measurement (100000110633) |
| ISO Path | /MedicinalProduct/PharmaceuticalProduct/Ingredient/Substance/Strength/Strength_Concentration |
| FHIR Path | Ingredient.substance.strength.concentration |

***Example(s):***

Solution for injection 20 mg/ml

Concentration strength single value or low limit: numerator 20 mg, denominator 1 ml

#### *4.3.2.2.2. Strength text (Concentration)*

| Tag | Description |
|---|---|
| User Guidance | The strength text field of the substances must be specified in this field. This information is mandatory if the strength structured quantitative composition (concentration) outlined in 4.3.2.2, are not provided. Although, it can be specified even when a structured quantitative composition (presentation or concentration) is provided.<br><br>This information is not to be provided for parallel trade products. |
| Repeatable | No |
| Conformance | Conditional |
| Data Type | String (maximum length: 4000 characters) |

| Tag | Description |
|---|---|
| Value(s) | n/a |
| ISO Path | TBC |
| FHIR Path | Ingredient.substance.strength.concentrationText |

### 4.3.3. Reference strength

If an active substance is in the form of a salt or hydrate or ester, the reference strength must be expressed in terms of the mass [or biological activity in International (or other) units where appropriate] of the active moiety (base, acid or anhydrous material).

The reference substance and reference strength of the active substance(s) contained in the Manufactured Item can be found in section 2. Qualitative and Quantitative Composition of the corresponding SPC and in Part 2A of the dossier.

The reference strength must be provided for active substances only when the strength of the active substance is not specified in section 4.3.2 Strength.

This information is not to be provided for parallel trade products and products intended only for pets under Article 5(6).

EXAMPLE: (presentation strength)

| Field | Value (presentation strength) |
|---|---|
| SPC text | Each tablet contains 45,9 mg amoxicillin trihydrate corresponding to 40 mg amoxicillin |
| Active substance | Amoxicillin trihydrate |
| Active substance presentation strength single value or low limit numerator | 45,9 mg |
| Active substance presentation strength single value or low limit denominator | 1 tablet |
| Reference substance | Amoxicillin |
| Reference substance presentation strength single value or low limit numerator | 40 mg |
| Reference substance presentation strength single value or low limit denominator | 1 tablet |

EXAMPLE: concentration strength

| Field | Value (concentration strength) |
|---|---|
| SPC text | Each gram contains 0,54 g oxytetracycline hydrochloride corresponding to 0,5 g oxytetracycline |
| Active substance | oxytetracycline hydrochloride |

| | |
|---|---|
| Active substance concentration strength single value or low limit numerator | 0,54 g |
| Active substance concentration strength single value or low limit denominator | 1 g |
| Reference substance | oxytetracycline |
| Reference substance concentration strength single value or low limit numerator | 0,5 g |
| Reference substance concentration strength single value or low limit denominator | 1 g |

| referenceStrength Class | Description |
|---|---|
| Repeatable | No |
| Conformance | Conditional |

#### *4.3.3.1. Reference (active) substance*

| Tag | Description |
|---|---|
| User Guidance | The reference substance of the active substance(s) contained in the Manufactured Item, as expressed in section *Qualitative and Quantitative Composition* of the corresponding SPC and the quality part of the dossier, must be specified. |
| Repeatable | No |
| Conformance | Conditional |
| Data Type | CodeableConcept |
| Value(s) | As listed in SMS |
| ISO Path | For the Manufactured Item, the ISO path is: /MedicinalProduct/PackagedMedicinalProduct/PackageItem/ManufacturedItem/Ingredient/Substance/Strength/ReferenceStrength/ReferenceSubstance<br><br>For the Pharmaceutical product, the ISO path is: /MedicinalProduct/PharmaceuticalProduct/Ingredient/Substance/Strength/ ReferenceStrength/ReferenceSubstance |
| FHIR Path | Ingredient.substance.strength.referenceStrength.substanceCodeableConcept |

#### 4.3.3.1.1. Reference strength (Presentation)

When the reference strength of an active substance is described as a qualitative term describing the discrete unit, the below fields must be used to enter this information.

#### 4.3.3.1.2. Reference strength (Presentation single value)

| Tag | Description |
|---|---|
| User Guidance | The reference strength (quantitative composition) of the active substances must be specified in this field with a numerator and denominator.<br>The numerator shall be expressed with a unit of numeric value and a unit of measurement (e.g. mg).<br>The denominator shall be expressed with a unit of numeric value and a unit of presentation (e.g. tablet).<br>The reference strength shall be provided for active substances only and it is mandatory when the substance strength is not provided in section 4.3.2. |
| Repeatable | No |
| Conformance | Conditional |
| Data Type | Ratio |
| Value(s) | The units for the denominator must be specified as a value and a Term ID as listed in Units of Presentation (200000000014) |
| ISO Path | For the Manufactured Item, the ISO path is: /MedicinalProduct/PackagedMedicinalProduct/PackageItem/ManufacturedItem/Ingredient/Substance/Strength/ReferenceStrength<br>For the Pharmaceutical product, the ISO path is: /MedicinalProduct/PharmaceuticalProduct/Ingredient/Substance/Strength/ReferenceStrength |
| FHIR Path | Ingredient.substance.strength.referenceStrength.strength |

Should the SPC provide the strength only based on the moiety, the moiety and its strength shall be provided as Active substance and Strength based on section 4.3.1 and 4.3.2.

### *4.3.3.2. Reference strength (Concentration)*

When the reference strength of an active substance is expressed as the amount of substance per unit of measurement such as millilitre or gram, the below fields should be used to enter this information.

#### 4.3.3.2.1. Reference strength (Concentration single value)

| Tag | Description |
|---|---|
| User Guidance | The reference strength (quantitative composition) of the active substances must be specified in this field with a numerator and denominator.<br>The numerator and the denominator shall be expressed with a unit of numeric value and a unit of measurement (e.g. mg, ml). |

| Tag | Description |
|---|---|
| | The reference strength shall be provided for active substances only and it is mandatory when the substance strength is not provided in section 4.3.2. |
| Repeatable | No |
| Conformance | Conditional |
| Data Type | Ratio |
| Value(s) | The units for the numerator and the denominator must be specified as a value and a Term ID as listed in Units of Measurement (100000110633). |
| ISO Path | For the Manufactured Item, the ISO path is: /MedicinalProduct/PackagedMedicinalProduct/PackageItem/ManufacturedItem/Ingredient/Substance/Strength/ReferenceStrength<br><br>For the Pharmaceutical product, the ISO path is: /MedicinalProduct/PharmaceuticalProduct/Ingredient/Substance/Strength/ReferenceStrength |
| FHIR Path | Ingredient.substance.strength.referenceStrength.strength |

#### 4.3.3.2.2. Reference strength text

| Tag | Description |
|---|---|
| User Guidance | The reference strength text field of the substances must be specified in this field. This information is mandatory, if a reference substance is selected, when the reference strength structured quantitative composition outlined in 4.3.3.2.1 or 4.3.3.2.2, are not provided. Although, it can be specified even when a structured reference strength quantitative composition (presentation or concentration) is provided.<br><br>This information is not to be provided for parallel trade products. |
| Repeatable | No |
| Conformance | Conditional |
| Data Type | String (maximum length: 4000 characters) |
| Value(s) | n/a |
| ISO Path | TBC |
| FHIR Path | Ingredient.substance.strength.referenceStrength.strength.extension.strengthText |

# 5. Packaged medicinal product

This section describes information about the packaging/container(s) which are an integral part or provided in combination with a medicinal product, as supplied for sale or distribution/supply.

A medicinal product shall be associated to one or more Packaged Medicinal products. The description of the packaged medicinal product is provided as free text.

The structured package description should be provided based on the following elements:

- The package size and the related quantity of units of presentation per package item;
- The manufactured dose form and the related manufactured item quantity.

Any additional information that may be provided for the package description in the SPC (e.g. container description, material of the packaging) should not be provided as part of the structured package description but only presented in the package description as a free text.

Each package which may differ in container material (e.g. plastic or aluminium cap)

To be able to report on sales volume, using at least a User Interface that can be used to upload a generated file, there would be a possibility to use an underlying identifier: the package ID.

Information on the package is not applicable to parallel trade products, hence all the elements within section 5 of this guidance are not applicable.

**For Products authorised through MRP/DCP/SRP the following applies:**

- The English language package description as written in the approved SPC and in the End-of-procedure document is to be provided by the RMS as part of the European/common data set for all the packages authorised under the regulatory procedures. The relevant package IDs will be assigned by the system following submission of the veterinary medicinal product into UPD.
- Optionally, the CMS must specify the description of the package in the applicable local language(s) by the time of authorisation, in line with the national SPC, and as part of the national dataset.

  The packaged veterinary medicinal product information must be provided based on the Resource *PackagedProductDefinition:*

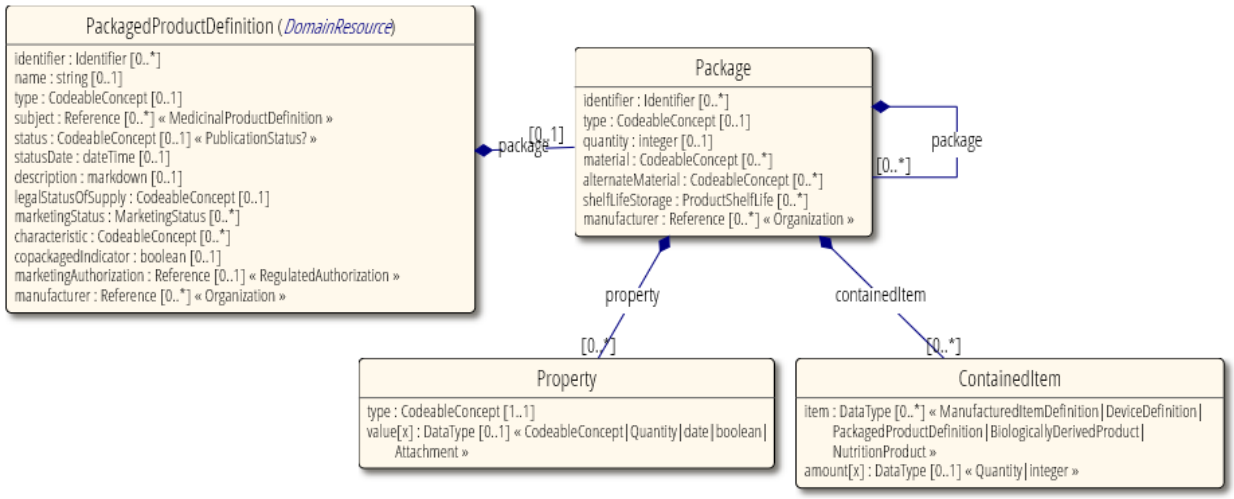


**Figure 11.** *Resource PackagedProductDefinition:* (see section *References to FHIR versions*)

| PackagedProductDefinition class | Description |
|---|---|
| Repeatable | Yes |
| Conformance | Conditional. |

## 5.1. Package description

| Tag | Description |
|---|---|
| User Guidance | The description of the packaged veterinary medicinal product as provided in the relevant section of the corresponding SPC and eAF or other regulatory document, must be specified as text (full text to be copied and pasted for the individual package).<br>The package description information should be provided as consistent as possible for each packages of the same products (e.g. container description, materials of the packaging etc.).<br>The free text description shall contain information regarding only one individual pack size. For multiple pack sizes the package medicinal product resources (i.e. *PackagedProductDefinition)* should be repeated to collect 1 pack size per free text description with the text descriptions making clear the differences between the packs.<br><br>The material of the immediate container or any other relevant information characterizing the package (such as devices, intermediate materials) should be provided in the package description when it is necessary to distinguish different packages having the same structured pack information (e.g. for 20 kg plastic bag and 20 kg aluminum bag, the term 'plastic' and 'aluminum' should be included in this field).<br><br>**Products authorised through MRP/DCP/SRP**<br>• The package description is to be provided by the RMS as part of the European/common data set for all the packages authorised under the regulatory procedures in English.<br>• The English version from the eAF can be used by the RMS to populate by the end of procedure. In many cases it will need to be edited (separated) so that each package description only describes one package.<br>• Optionally, the CMS and the RMS can specify the description of the package in the applicable local language(s) by the time of authorisation, in line with the national SPC, and as part of the national dataset.<br>**Products authorised through NP**<br>• The package description is to be provided by the NCA in the local language(s) of authorisation in line with the national SPC.<br>**Products authorised through the centralised procedure**<br>• The package description is to be provided in English and local languages may be optionally provided by EMA in line with the national translations of the SPC. |
| Repeatable | Yes |
| Conformance | Mandatory |
| Data Type | Markdown |
| Value(s) | The description of the packaged medicinal product must be provided as free text (max. 4000 characters). |
| ISO Path | /MedicinalProduct/PackagedMedicinalProduct/PackageDescription |
| FHIR Path | PackagedProductDefinition.description |

***Example(s):***

1) If text is in the SPC *Section 6.5 Nature and composition of immediate packaging is:*

84 or 100 tablets in an amber glass bottle.

Cardboard box of 1 blister x 10 tablets (10 tablets)

Cardboard box of 2 blisters of 10 tablets (20 tablets)

*The Information to be entered in UPD Package description of first package should be:*

84 tablets in an amber glass bottle.

*The Information to be entered in Package description of second package should be:*

100 tablets in an amber glass bottle.

2) If text in the SPC *Section 6.5 Nature and composition of immediate packaging is:*
Boxes of 1 & 10 vials of lyophilisate and 1 & 10 vials of suspension

*The Information to be entered in UPD Package description of first package is:*

Plastic box of 1 dose + 1 ml vial

Plastic box of 10 x 1 dose + 10 x 1 ml vial

### 5.1.1. Language

This section described how to populate information related to the language of the package description. The provision of the language is mandatory.

| Tag | Description |
|---|---|
| User Guidance | The language of the package description as specified in previous section must be specified. |
| Repeatable | No |
| Conformance | Mandatory |
| Data Type | CodeableConcept |
| Value(s) | As listed in Language (100000072057) |
| FHIR Path | PackagedProductDefinition.description.extension.valueCode (extension URL is http://hl7.org/fhir/StructureDefinition/language) |

## *5.2. Pack size*

The pack size describes the number of units of presentation of a manufactured item in a packaged medicinal product i.e. the numeric value and the unit of presentation.

The pack size of a cardboard of 1 blister of 10 tablets is 10 (numeric value) tablets (Unit of presentation, described in the manufactured item section).

The pack size of a cardboard of 2 blisters of 10 tablets is 20 (numeric value) tablets (Unit of presentation described in the manufactured item section).

The pack size of a box of 2 vials is 2 (numeric value) vials (Unit of presentation described in the manufactured item section).

The pack size of a box of 1 bottle of 250 ml is 1 (numeric value) bottle (Unit of presentation described in the manufactured item section).

The pack size of a box of 5 bottles of 2 mg powder and 5 bottles of 1 ml solvent is equivalent to 5 (numeric value) bottles (Unit of presentation described in the manufactured item section) - (reconstituted).

| Tag | Description |
|---|---|
| User Guidance | For each Packaged Medicinal Product, the pack size defined as the total number of units in the package after reconstitution must be provided if available in the SPC.<br>The applicable numeric value(s) and unit of presentation must be selected from the term ID as listed in the applicable RMS lists.<br>If the pack size is not described in the SPC, the manufactured item quantity (5.6.2) and the manufactured dose form (5.6.3) must be specified as mandatory. |
| Repeatable | Yes |
| Conformance | Conditional |
| Data Type | Identifier |
| Value(s) | Numeric value and unit.<br>The units shall be specified as a Term ID listed in RMS Units of Presentation list as applicable |
| FHIR Path | PackagedProductDefinition.extension.containedItemQuantity |

***Example(s):***

10 (tablets), 20 (tablets), 2 (vials)

## *5.3. Package identifier*

| Tag | Description |
|---|---|
| User Guidance | The package identifier per package as assigned by the UPD must be specified when updating the veterinary medicinal product in the UPD.<br>Identifier generated by the system. It must not be provided at the time of creation, it must be provided when updating the product. |
| Repeatable | No |
| Conformance | Conditional (based on the operation type/endpoint) |
| Data Type | Identifier (max. 4000 characters) |
| Value(s) | Identifier generated by the system. It must not be provided at the time of creation, it must be provided when updating the product. |
| FHIR Path | PackagedProductDefinition.identifier |

## *5.4. Legal status for the supply (package level)*

The legal status for the supply is usually defined at product level. This section is only applicable where individual packages have different legal statuses for the supply.

In this field, the legal status for the medicinal product's supply, as authorised by the competent authority in the region and applicable to the individual package should be specified.

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 or populated with one specified Term.

| Tag | Description |
|---|---|
| User Guidance | The legal status for the medicinal product's supply, as authorised by the competent authority and applicable in the region, must be specified using a term ID as part of the national data set.<br>• For Centralised Authorised Products (CAP), this information is retrieved from Annex II.B - CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE<br>• For Nationally Authorised Products (NAP), this information may be retrieved from different sources that includes from Product information (SPC, Package Leaflet or other annexes) to National Register of Medicinal Products. |
| Repeatable | No |
| Conformance | Conditional |
| Data Type | CodeableConcept |
| Value(s) | As listed in Legal Status for the Supply (100000072051). |
| ISO Path | /MedicinalProduct/MarketingAuthorisation/LegalStatusOfSupply |
| FHIR Path | PackagedProductDefinition.legalStatusOfSupply |

***Example(s):***

Veterinary medicinal product subject to veterinary prescription (200000017698),

Veterinary medicinal product not subject to veterinary prescription (200000017695)

## *5.5. Marketing authorisation (package level)*

There are cases where marketing authorisation is assigned at the level of packaged medicinal product. If any information related to the Marketing Authorisation be regulated by the applicable National Competent Authority at the level of the individual pack of the medicinal product and be different for the other packages (i.e., different from the entire medicinal product), the applicable information must be specified according to the FHIR *Resource RegulatedAuthorization* and guidance provided in section 2. Authorisation/registration/entitlement information.

The individual package authorisation number part must be specified for the individual package in this section.

This might also be used for registered homeopathic, parallel trade and marketing authorisation exemptions (art 5(6)), if applicable.

| Marketing authorisation (package level) Class | Description |
|---|---|
| Repeatable | Yes |
| Conformance | Conditional |

### 5.5.1. Marketing authorisation number (package Level)

| Tag | Description |
|---|---|
| User Guidance | Marketing Authorisation number as assigned to the veterinary medicinal product package must be specified.<br><br>Should the authorisation number be assigned at product level by the relevant CAs, this information would not be applicable and the authorisation number must be provided in 2.2. Authorisation/registration/entitlement number. |
| Repeatable | No |
| Conformance | Mandatory |
| Data Type | Identifier |
| Value(s) | The number assigned by the competent authority of a country/jurisdiction shall be specified as free text (max. 4000 characters).<br>The format of the EU number must be "EU/2/YY/NNN/XXX " or "EU/2/YY/NNNN/XXX" (as applicable)<br><br>RegulatedAuthorization.identifier.system value is "http://ema.europa.eu/fhir/marketingAuthorizationNumber" |
| ISO Path | /MedicinalProduct/PackagedMedicinalProduct/MarketingAuthorisation/MarketingAuthorisationNumber |
| FHIR Path | RegulatedAuthorization.identifier |

Example 1

9743/2016/01-02-03-07

The authorisation number captured at this level should be entered as 9743/2016 whereas 9453/2016/01, 9743/2016/02 etc. will be captured at package level.

Example 2

EU/2/13/016/001

EU/2/13/016/002

EU/2/13/016/003

The authorisation number captured at this level should be entered as EU/2/13/016, whereas EU/2/13/016/001, EU/2/13/016/002, EU/2/13/016/003 will be captured at package level.

## *5.6. Manufactured item*

The pharmaceutical form of the product as it is authorised and "on the shelf" and, where applicable, before transformation into the administrable pharmaceutical form must be described in this section. Thereafter referred to as the manufactured item, as contained in the packaged medicinal product.

A Medicinal Product may contain, in the packaging, one or more manufactured items.

Examples of single manufactured item as included in an authorised product:

- "Film-coated tablet" involves a single manufactured item.

- Solution for Injection involves a single manufactured item.

The full information on Manufactured Item as presented in the FHIR *ManufacturedItemDefinition* is shown in the figure below. Only the elements described below are within the scope of UPD implementation by 28 January 2022:

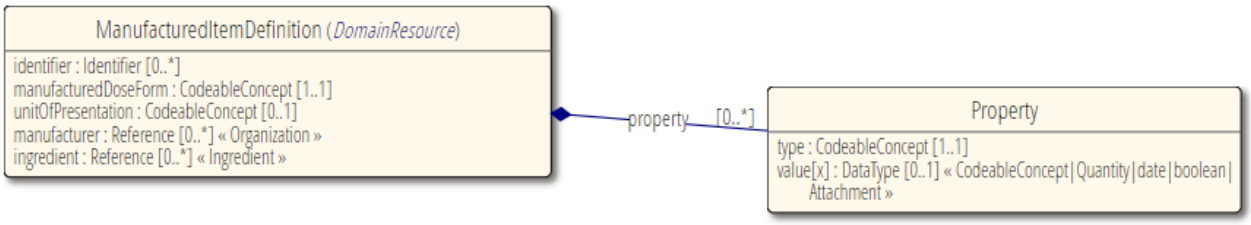


**Figure 12.** *ManufacturedItemDefinition* captured by FHIR (see section *References to FHIR versions*)

If multiple values of manufactured items (e.g. different dose forms) apply to the same authorised medicinal product then multiple manufactured items must be created.

Information on manufactured item is not required for registered homeopathic products, parallel trade medicinal products and products intended only for pets under Article 5(6).

| ManufacturedItemDefinition Class | Description |
|---|---|
| Repeatable | Yes |
| Conformance | Conditional |

### 5.6.1. Unit of presentation

| Tag | Description |
|---|---|
| User Guidance | The unit of presentation describing the unit in which a manufactured item is presented to describe the strength or quantity must be specified as a term ID. |
| Repeatable | No |
| Conformance | Conditional |
| Data Type | CodeableConcept |
| Value(s) | As listed in Units of Presentation (200000000014) |
| ISO Path | /MedicinalProduct/PackagedMedicinalProduct/PackageItem_Container/ManufacturedItem/UnitOfPresentation |
| FHIR Path | ManufacturedItemDefinition.unitOfPresentation (as referenced from PackagedProductDefinition.package.containedItem.item) |

***Example(s):***

Actuation (200000002163), Patch (200000002134), Tablet (200000002152)

### 5.6.2. Manufactured item quantity

| Tag | Description |
|---|---|
| User Guidance | The quantity (count number or volume) of the manufactured item in the medicinal product package, must be specified as a value and units (as per relevant section of the SPC).<br>For solid dose forms and other items measured by counting, discrete countable entities, the unit for quantity is "unit" and the "unit of presentation" is the item counted within the immediate container.<br>For formulations contained in a vial, the unit for quantity is volume/quantity in the vial and the "unit of presentation" is the discrete countable entity, in which a pharmaceutical product or manufactured item is presented. The volume of the liquid within the container should be provided when available, should this information not be available, the capacity/volume of the container shall be provided as manufactured item quantity.<br>Example:<br>• In case of 10 tablets in 2 blisters, the number of tablet/capsules in the immediate package (i.e. the blister) must be specified: 10 tablets<br>• In case of formulations contained in a vial (e.g. powder, liquids) the total quantity or the volume of the formulation in the vial should be expressed: in case of bottles of 250 ml volume containing 200 ml of solution, the quantity 200 ml should be specified. |
| Repeatable | No |
| Conformance | Mandatory |
| Data Type | Quantity |
| Value(s) | Numeric value and unit.<br>The units must be specified as a Term ID listed in Units of Measurement or Units of Presentation as applicable. |
| ISO Path | /MedicinalProduct/PackagedMedicinalProduct/PackageItem_Container/ManufacturedItem/ManufacturedItemQuantity |
| FHIR Path | PackagedProductDefinition.package.containedItem.amountQuantity |

***Example(s):***

10 tablets, 200 ml

### 5.6.3. Manufactured dose form

The manufactured dose form corresponds with the dose form presented in the manufactured item.

***Example 1:***

Medicinal Product ABC 20mg/ml powder and solvent for solution for injection (combined pharmaceutical form) provided in two separate vials will contain two types of manufactured items with the following dose forms:

- Powder for solution for injection
- Solvent for Solution for injection

***Example 2:***

Medicinal Product DEF 500 mg tablets contain a single type of manufactured item with the following manufactured dose form:

- Tablet

| Tag | Description |
|---|---|
| User Guidance | The manufactured dose form described with the authorised pharmaceutical form(s) in the relevant section of the SPC or other regulatory document (description prior to any transformation into the final form administered to the animal) must be specified as a term ID.<br>• If multiple values apply to the same medicinal product then multiple manufactured items must be created.<br>• Deprecated (i.e. non-current) dose form terms may be referenced. |
| Repeatable | No |
| Conformance | Mandatory |
| Data Type | CodeableConcept |
| Value(s) | Listed in Pharmaceutical Dose Form (200000000004). |
| ISO Path | /MedicinalProduct/PackagedMedicinalProduct/PackageItem_Container/ManufacturedItem/ManufacturedDoseForm |
| FHIR Element Name | manufacturedDoseForm |
| FHIR Path | ManufacturedItemDefinition.manufacturedDoseForm (as referenced from PackagedProductDefinition.package.containedItem.item) |

***Example(s):***

- Manufactured pharmaceutical forms identical to the administrable pharmaceutical form: solution for injection, tablet, capsule, inhalation powder
- Manufactured pharmaceutical forms not identical to the administrable pharmaceutical form: gel in sachet, syrup in sachet, emulsion for injection/infusion in pre-filled syringe.

**Examples of the structured package information:**

| **Field** | **Value** |
|---|---|
| SPC text | 2 blisters of 10 tablets each |
| Pack Size | 20 |
| **Manufactured item** | |
| Unit of presentation | tablet |
| Manufactured item quantity | 10 |
| Manufactured dose Form | tablet |

**Examples of the structured package information:**

| Field | Value |
|---|---|
| SPC text | 2 vials of 20mg/5 ml powder and solvent for solution for injection |
| Pack Size | 1 |
| **Manufactured item (1)** | |
| Unit of presentation | vial |
| Manufactured item quantity | 20 mg |
| Manufactured dose Form | Powder for solution for injection |
| **Manufactured item (2)** | |
| Unit of presentation | vial |
| Manufactured item quantity | 5 ml |
| Manufactured dose Form | Solvent for solution for injection |

**Examples of the structured package information:**

| Field | Value |
|---|---|
| SPC text | Cardboard box with 2 glass vials of 10 ml of lyophilised product and 1 glass vial of 21 ml of diluent. |
| Pack Size | 2 *(<- 2 vials/doses after reconstitution)* |
| **Manufactured item (1)** | |
| Unit of presentation | vial |
| Manufactured item quantity | 10 ml |
| Manufactured dose Form | Lyophilised powder |
| **Ingredient 1 (manufactured 1)** | |
| Ingredient role | active |
| substance | Follicle stimulating hormone |
| Substance strength | 500 UI/10 ml |
| **Ingredient 2 (manufactured 1)** | |
| Ingredient role | active |
| substance | Luteinizing hormone |
| Substance strength | 500 UI/10 ml |
| **Manufactured item (2)** | |

| Field | Value |
|---|---|
| Unit of presentation | vial |
| Manufactured item quantity | 21 ml |
| Manufactured dose Form | Solvent for solution |
| **Ingredient 1 (manufactured 2)** | |
| Ingredient role | excipient |
| substance | Chlorocresol |
| Substance strength | 0.021 g/vial |
| **Ingredient 2 (manufactured 2)** | |
| Ingredient role | excipient |
| substance | Sterile, pyrogen-free, normal saline |
| Substance strength | 21ml/vial |

### 5.6.4. Ingredient

The ingredient(s) as packaged in the individual manufactured item must be specified. The Ingredients constituting the manufactured item as apply and based on the SPC, must be provided based on the data elements included in the Resource *Ingredient* and as described in section *4. Ingredient.* The 'Ingredient' class is mandatory. Should the manufactured item contain only inactive ingredients, at least one ingredient (being the main ingredient), must be specified as active (e.g. water for injection).

Each ingredient must be selected at least once from section 4 in one of the manufactured items.

## *5.7. Availability status*

This section provides information on the availability status of the veterinary medicinal product at package level. Availability status refers to the concepts of veterinary medicinal product being placed in the market and the market cessation as applicable.

The availability status date describes the date from when the status of availability change is effective.

Information on availability status is not required for parallel trade, registered homeopathic products and products intended only for pets under Article 5(6).

| Availability Status Class | Description |
|---|---|
| Repeatable | Yes |
| Conformance | Conditional |

### 5.7.1. Country

| Tag | Description |
|---|---|
| User Guidance | The country code of the country where the product is marketed/not marketed should be specified as a term ID. |

| Tag | Description |
|---|---|
| Repeatable | No |
| Conformance | Mandatory |
| Data Type | CodeableConcept |
| Value(s) | As listed in Country (RMS list ID 100000000002). |
| ISO Path | /MedicinalProduct/PackagedMedicinalProduct/MarketingStatus/Country |
| FHIR Path | PackagedProductDefinition.marketingStatus.country |

***Example(s):***

Croatia (100000000373), Spain (100000000529)

### 5.7.2. Availability status

| Tag | Description |
|---|---|
| User Guidance | The status of the marketing of the veterinary medicinal product in the specified country must be provided by the Marketing Authorisation Holder as a term ID.<br>The term "marketed" should be defined as when the veterinary medicinal product is "released out of the control of the MAH and into the distribution chain in destination of a given country.<br><br>The term "not marketed" should be defined as the "cessation of release into the distribution chain in destination of a given country" with the consequence that the concerned product may no longer be available for supply. It is also the default term when a new product is created.<br><br>The term "temporarily unavailable" should be specified as a disruption of supply from the MAH which would lead to an extended disruption in supply to the retailers for a long period of time (e.g. for instance more than 3 months).<br><br>Since this information is to be provided by the MAH, at the creation of the veterinary medicinal product by the NCAs, this information is not known yet, so the availability status shall be specified with the value "Not marketed".<br><br>In some cases, the availability status will be automatically updated by the system as a result of a change in the marketing authorisation status. A transition of this status to 'Surrendered', 'Suspended', 'Revoked' or 'Expired' will result in a change of the Availability status to 'Not marketed'. |
| Repeatable | No |
| Conformance | Mandatory |
| Data Type | CodeableConcept |
| Value(s) | As listed in Marketing Status (RMS list ID 100000072052) |
| ISO Path | /MedicinalProduct/PackagedMedicinalProduct/MarketingStatus/Status |
| FHIR Path | PackagedProductDefinition.marketingStatus.status |

***Example(s):***

Marketed (100000072083), Not marketed (100000072074), Temporarily unavailable (230000000000) or for legacy data only at the time of the creation No Data Provided (100000072075)

### 5.7.3. Availability status date

| Tag | Description |
|---|---|
| User Guidance | The date of the change of the availability status of the veterinary medicinal product must be provided by the Marketing Authorisation Holder. The first value will be created by the system, at the time of initial entry of the product into the UPD (date for "not marketed" and date for "No data provided").<br><br>When marketing authorisation holders change the status of availability value from the initial submission, the availability status date is mandatory to be provided.<br><br>Since this information is to be provided by the MAH, this information is not known at the creation of the veterinary medicinal product by the NCAs, but the availability status date will anyway be specified as the date of the creation of the veterinary medicinal product (with the value "Not marketed"). |
| Repeatable | No |
| Conformance | Mandatory |
| Data Type | Date |
| Value | A date shall be specified using the ISO 8601 date format.<br><br>ISO 8601 can accommodate year and month should day of the month not be known. (i.e., YYYY-MM). |
| ISO Path | /MedicinalProduct/PackagedMedicinalProduct/MarketingStatus/MarketingDateStart |
| FHIR Path | PackagedProductDefinition.marketingStatus.dateRange.start |

# Annex 1: Common/European and national data set

Note: For products that have been approved under DCP/MRP/SRP, manufacturers are always the same.

Note: for the data field 1.2 Product record status, 2.13.2 Procedure type and 2.8. Product Owner the RMS will provide the value at the time of creation, and subsequent updates will be made by the CMS.

| UPD IA Annex | Vet EU IG Ref. | UPD data element name | Conformance | European/National |
|---|---|---|---|---|
| | **1** | **Veterinary medicinal product** | **Mandatory** | **European** |
| 1.1 | 1.1 | Domain | Mandatory | European |
| | 1.2 | Product Record Status | Mandatory | European & National |
| 3.2 | 1.3 | Product Identifier | Conditional (updates only) | European |
| 3.1 | 1.4 | Permanent identifier | Conditional (updates only) | National |
| 3.7 | 1.5 | (Authorised) pharmaceutical form | Mandatory | European |
| 3.16 | 1.6 | Legal status for the supply | Conditional (either at product or at pack level) | National |
| | **1.7** | **Product Classification** | **Conditional** | **European** |
| 4.7 | 1.7.1 | Legal basis | Conditional | European |
| 3.9 | 1.7.2 | ATC vet code(s) | Conditional | European |
| 3.9 | 1.7.3 | ATC vet code(s) flag | Conditional | European |
| | **1.8** | **Veterinary medicinal product name** | **Mandatory** | **European & National** |
| 1.3 | 1.8.1 | Veterinary medicinal product name | Mandatory | European & National |
| | 1.8.2 | Name part | Optional | European & National |
| | 1.8.2.1 | Name type | Mandatory | European & National |
| | 1.8.2.2 | Name part | Mandatory | European & National |
| | **1.8.3** | **Country/Language** | **Mandatory** | **European & National** |
| | 1.8.3.1 | Country | Mandatory | European & National |
| | 1.8.3.2 | Language | Mandatory | European & National |
| | **1.9** | **(Pharmacovigilance System) Master File** | **Conditional** | **European** |
| | 1.9.1 | (PSM) File Status | Mandatory | European |
| | 1.9.2 | (PSM) File type | Mandatory | European |
| 3.11 | 1.9.3 | (PSM) File code | Mandatory | European |
| 3.12 | 1.9.4 | (PSM) File location | Mandatory | European |
| | **1.10** | **Pharmacovigilance Contact (QPPV)** | **Conditional** | **European** |
| 3.13 | 1.10.1 | QPPV Name | Mandatory | European |
| | 1.10.2 | QPPV Role | Mandatory | European |
| 3.14 | 1.10.3 | QPPV Location | Mandatory | European |
| | **1.11** | **Attached Document** | **Conditional** | **European & National** |
| | 1.11.1 | (Attached document) identifier | Conditional (updates only) | European & National |
| | 1.11.2 | (Attached document) status | Mandatory | European & National |
| | 1.11.3 | (Attached document) type | Mandatory | European & National |
| | 1.11.4 | (Attached document) country | Mandatory | European & National |

| UPD IA Annex | Vet EU IG Ref. | UPD data element name | Conformance | European/National |
|---|---|---|---|---|
| | 1.11.5 | (Attached document) content type | Mandatory | European & National |
| | 1.11.6 | (Attached document) language | Mandatory | European & National |
| | 1.11.7 | (Attached document) content | Mandatory | European & National |
| 1.7 | 1.11.8 | (Attached document) title | Mandatory | European & National |
| | 1.11.9 | (Attached document) related veterinary medicinal products | Mandatory | European & National |
| | **1.12** | **Product cross-reference** | **Conditional** | **European & National** |
| | 1.12.1 | Product cross-reference type | Mandatory | European & National |
| 4.9 | 1.12.2 | Reference product Identifier | Mandatory | European & National |
| 4.10 | 1.12.3 | Source product identifier | Mandatory | National |
| | **1.13** | **Manufacturing Business Operation** | **Conditional** | **European** |
| 1.6 | 1.13.1 | Manufacturer | Mandatory | European |
| | 1.13.2 | Manufacturing activity | Mandatory | European |
| | **2** | **Authorisation/registration/entitlement information** | **Mandatory** | **European & National** |
| 1.2 | 2.1 | Authorisation/registration/ entitlement type | Mandatory | European |
| 4.8 | 2.2 | Authorisation/registration/ entitlement number | Conditional | National |
| 4.4 | 2.3 | Country | Mandatory | National |
| 3.3 | 2.4 | Responsible authority (organisation) | Mandatory | National |
| 3.4 | 2.5 | Authorisation status | Mandatory | National |
| 3.5 | 2.6 | Date of authorisation status change | Mandatory | National |
| 4.3 | 2.7 | Marketing authorisation date | Mandatory | National |
| 3.3 | 2.8 | Product Owner (organisation) | Conditional | European & National |
| 6.1 | 2.9 | Source wholesale distributor (organisation) | Conditional (parallel trade only) | National |
| 6.2 | 2.10 | Destination wholesale distributor (organisation) | Conditional (parallel trade only) | National |
| 4.5 | 2.11 | Reference member state | Conditional | European |
| 4.6 | 2.12 | Concerned member state | Conditional | European |
| | **2.13** | **Marketing authorisation procedure** | **Mandatory** | **European** |
| 4.2 | 2.13.1 | Procedure number | Conditional | European |
| 4.1 | 2.13.2 | Procedure type | Mandatory | European & National |
| | **3** | **Pharmaceutical Product** | **Mandatory** | **European** |
| | **3.1** | **Ingredient** | **Mandatory** | **European** |
| 3.6 | 3.2 | Route of administration | Mandatory | European |
| 3.8 | 3.3 | Target species | Conditional | European |
| | **3.4** | **Withdrawal period** | **Conditional** | **European** |
| 3.1 | 3.4.1 | Tissue | Mandatory | European |
| 3.1 | 3.4.2 | Period | Mandatory | European |
| | 3.4.3 | Note | Conditional | European |
| | **3.5** | **Administrable dose form** | **Mandatory** | **European** |
| | **4** | **Ingredient** | **Mandatory** | **European** |

| UPD IA Annex | Vet EU IG Ref. | UPD data element name | Conformance | European/National |
|---|---|---|---|---|
| | 4.1 | Ingredient role | Mandatory | European |
| 1.6 | 4.2 | Manufacturer | Optional | European |
| | **4.3** | **Substance** | **Mandatory** | **European** |
| 1.4 | 4.3.1 | Substance | Mandatory | European |
| | **4.3.2** | **Strength (quantitative composition)** | **Conditional** | **European** |
| 1.5 | 4.3.2.1 | Strength (presentation) | Conditional | European |
| | 4.3.2.1.1 | Strength (presentation single value) | Conditional | European |
| | 4.3.2.1.2 | Strength text (presentation) | Conditional | European |
| 1.5 | 4.3.2.2 | Strength (concentration) | Conditional | European |
| | 4.3.2.2.1 | Strength (concentration single value) | Conditional | European |
| | 4.3.2.2.2 | Strength text (concentration) | Conditional | European |
| | **4.3.3** | **Reference Strength** | **Conditional** | **European** |
| 1.5 | 4.3.3.1 | Reference (Active) Substance | Conditional | European |
| | 4.3.3.1.1 | Reference strength (presentation) | Conditional | European |
| | 4.3.3.1.2 | Reference strength (Presentation single value) | Conditional | European |
| | 4.3.3.2 | Reference strength (concentration) | Conditional | European |
| | 4.3.3.2.1 | Reference strength (concentration) | Conditional | European |
| | 4.3.3.2.2 | Reference strength text | Conditional | European |
| | **5** | **Packaged medicinal product** | **Conditional** | **European & National** |
| | 5.1 | Package description | Mandatory | European & National |
| | 5.1.1 | Language | Mandatory | European & National |
| 3.15 | 5.2 | Pack Size (structured values) | Conditional | European |
| | 5.3 | Package identifier | Conditional (update only) | European |
| 3.16 | 5.4 | Legal status for the supply | Conditional (at product or package level) | National |
| | **5.5** | **Marketing authorisation (package level)** | **Conditional** | **National** |
| | 5.5.1 | Marketing authorisation number (package level) | Mandatory | National |
| | **5.6** | **Manufactured item** | **Conditional** | **European** |
| | 5.6.1 | Unit of presentation | Conditional | European |
| | 5.6.2 | Manufactured item quantity | Mandatory | European |
| | 5.6.3 | Manufactured dose form | Mandatory | European |
| | 5.6.4 | Ingredient | Mandatory | European |
| | **5.7** | **Availability status** | **Conditional** | **National** |
| | 5.7.1 | Country | Mandatory | National |
| 2.4 | 5.7.2 | Availability status | Mandatory | National |
| 2.3 | 5.7.3 | Availability status date | Mandatory | National |

## Annex 2: Product information documents requirements

This section aims to describe the requirements that apply to the product information documents to be uploaded to the Union Product Database (UPD), including the naming convention.

All documents should be submitted using PDF file format. The file size limit is 10MB.

The name of the document should not contain any 'special' characters; only alphanumeric characters (lower case characters a-z, digits 0-9) and hyphens are allowed. Do not include blank spaces in the file name.

Likewise, the structure of the file name is fixed and should be respected in order to successfully perform bulk uploads of documents. It should be composed of five fixed parts, with an optional variable part in between. Examples will follow afterwards.

- **Country**: is the initial **fixed** part, defined by the 2-letter ISO code, as referenced in the RMS list: 100000000002 and 100000000003, from SPOR system:
    - Source of information: 2-letter ISO 3166-1 Codes for the representation of names of countries and their subdivisions - ISO 3166-1 alpha-2.
    - Exceptions:
        - For centrally authorised products = "ema".
        - For the common the English version of the product information concerning mutual recognition/decentralised/subsequent recognition procedures = "eu".
- **Document type**: is the second **fixed** part.
    - Applicable RMS lists: Product information Document Type & Regulating Authority Submission Unit Type:

| List ID | List Name | Term Name | SPOR Attribute | Document Type Value | Term ID |
|---|---|---|---|---|---|
| 100000155531 | Product Information Document Type | Package Leaflet and Labelling | Other names | pllab | 200000017121 |
| 100000155531 | Product Information Document Type | Summary of Product Characteristics | Other names | spc | 100000155532 |
| 100000155531 | Product Information Document Type | Labelling | Other names | lab | 100000155535 |
| 100000155531 | Product Information Document Type | Package Leaflet | Other Name | pl | 100000155538 |
| 100000155531 | Product Information Document Type | Combined File of all Documents | Short name | combined | 100000155539 |
| 100000155552 | Regulating Authority Submission Unit Type | Public Assessment Report | Other names | puar | 200000017122 |

- **Procedure number or permanent identifier:** is the third **fixed** part. The use of one or the other value, depends on the type of procedure to which the veterinary medicinal product belongs to.
    - For CAPs = Procedure number: the procedure number shall not be added with format defined in Chapter 2 from the Vet EU IG (emea/v/c/nnnnnn) section 2.13.1. , but with the following format: "vnnnnnn" (where "v" represents veterinary medicinal product and "n" represents EMEA six digits procedure number). In cases where the EMEA six digits procedure number starts with "0's", they shall be removed from the file name. For example, for the procedure number "emea/v/c/000033", the following must be added in the third part of the file name: "v33".
    - For DCP/SRP/MRP = Procedure number: the procedure number shall be added with format defined in Chapter 2 from Vet EU IG but without the slashes. For example, for the procedure number "es/v/0190/001" the following must be added in the third part of the file name: "esv0190001".
    - For NAPs, parallel traded, registered homeopathic and pet products. = Permanent identifier.
- **Product name** or procedure type: is the fourth **fixed** part and the use of one or the other value, depends on the type of procedure to which the veterinary medicinal product belongs to.
    - For CAPs = Product name: the veterinary medicinal product name shall be provided based on the definition facilitated in Reg 2019/6: Article 4.21. This fixed part of the file name is not validated by the system. If the name of the veterinary medicinal product contains two or more words, they shall be separated by hyphens.
    - For DCP/SRP/MRP = Procedure type: to identify the veterinary medicinal products under decentralised, subsequent, or mutual recognition procedure, the value "mr" (mutual recognition) shall be added in this part of the file name.
    - For NAPs, parallel traded, registered homeopathic and pet products. – Procedure type: to identify the veterinary medicinal products under national procedure, the value "np" (national procedure) shall be added in this part of the file name.
- Additional (**variable**) information can be included only after the Product Name or Procedure type, e.g, target species, internal identifier and/or date, as deemed useful by the user to distinguish between different file versions.
- **Language**: is the last **fixed** part, defined by the 2-letter ISO code, as referred in the RMS list: 100000072057, from SPOR system.
    - Source of information: ISO 639-1 Codes for the representation of names of languages - ISO 639-1.

Examples of valid document name for files to be uploaded in the UPD:

**Example for centralised procedures:**

- ema-combined-v33-hydrocortisone-aceponate-ecuphar-dog-pt.pdf

  This name corresponds to the Combined file of all documents in Portuguese for a product that has been authorised under centralised procedure, where the target species is the solely variable part provided.

country=ema, document type=combined, procedure number=v33, product name= hydrocortisone-aceponate-ecuphar, variable part=dog, language=pt

**Example for national procedures:**

- es-lab-600010551208-np-amoxicilina-maymo-cattle-es.pdf

  This name corresponds to a Labelling document in Spanish for a product that has been authorised under national procedure, where the product name and the target species is the variable part provided.

  country=es, document type=lab, permanent identifier=600010551208, procedure type=np, variable part=amoxicilina-maymo-cattle, language=es

**Example for mutual recognition/decentralised/subsequent recognition procedures:**

- eu-spc-esv0190001-mr-boflox-cattle-en.pdf

  This name corresponds to a common SPC document in English from a product that could be authorised under mutual recognition/decentralized/subsequent recognition procedures, where the product name and the target species is the variable part.

  country=eu, document type=spc, procedure number= esv0190001, procedure type=mr, variable part=boflox-cattle, language=en

- xi-spc-esv0190001-mr-boflox-en.pdf

  This name corresponds to a national SPC document in English from a product that could be authorised under mutual recognition/decentralized/subsequent recognition procedures, where the product name is the solely variable part.

  country=xi (United Kingdom (Northern Ireland)), document type=spc, procedure number= esv0190001, procedure type=mr, variable part=boflox, language=en

**Example for VRA centralised procedures:**

- ema-combined-v1234-metacam-vra0005-pt.pdf
  This name corresponds to the combined file of all documents in Portuguese for a centrally authorised product undergoing a variation requiring assessment procedure (VRA), where the variation type/counter is the solely variable part.

  country=ema, document type=combined, procedure number=v1234, product name=metacam, variable part=vra0005, language=pt

**Example for VNRA centralised procedures:**

- ema-combined-v745-superdrug-vnra-a3-2022-02-01-pt.pdf
  This name corresponds to the combined file of all documents in Portuguese for a centrally authorised product undergoing a variation not requiring assessment procedure (VNRA), where the variation type/counter and date are the variable parts.

  country=ema, document type=combined, procedure number=v745, product name=superdrug, variable part=vnra-a3-2022-02-01, language=pt

- ema-combined-v99-purevaxrcpchfelv-rim-ref-1234-it.pdf
  The name corresponds to the combined file of all documents in Italian for a centrally authorised product undergoing a variation not requiring assessment procedure (VNRA), where an internal company identifier is the solely the variable part.

country=ema, document type=combined, procedure number=v99, product name= purevaxrcpchfelv, variable part=rim-ref-1234, language=it

To summarise, the product information documents should meet the following conditions:

a) The file format is pdf.

b) The file size does not exceed 10MB.

c) No capitals, special characters nor blank spaces are allowed in the file name.

d) The file name is compliant with the *naming convention*, as specified.

For information, the maximum length accepted for the file's name varies depending on the Window's version installed.

- Latest/newest Window's versions accepts until 255 characters.
- All information can be found in the following link https://docs.microsoft.com/en-us/windows/win32/fileio/naming-a-file