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3 Veterinary Medicines Division

# 4 EU Implementation Guide (IG) on veterinary medicines 5 product data in the Union Product Database

6 Implementation of the requirements of Regulation (EU) 2019/6 for the Union
7 database on veterinary medicinal products

## 8 Chapter 4: Process and format for the submission of legacy data on 9 veterinary medicinal products

10 Version 1

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# Scope of this guidance

This document provides detailed guidance on the steps and the data elements for the submission of legacy medicinal products authorised for veterinary use to the UPD.

The EU Implementation Guide on veterinary medicines product data in the Union Product Database (Vet EU IG) Chapter 2 on the Format for the electronic submission of veterinary medicinal product information describes the business rules, data fields and specification for the creation of the complete record of a new veterinary medicinal product in the context of regulatory entitlements after 28 January 2022.

This text, Chapter 4 of the Vet EU IG, provides guidance on the mapping of the underlying terminology and lists the data elements required for the submission of legacy data on veterinary medicinal products that shall be submitted in UPD by 28 January 2022.

For the purpose of this chapter, *legacy data* is defined as any data on a veterinary medicinal product authorised in a Member State before 28 January 2022.

The following aspects, as outlined in the Vet EU IG Chapter 2, apply also to the legacy data submission:

- The scope of the veterinary medicinal products to be provided in accordance with the provisions laid down in Articles 55 and 102 of Regulation (EU) 2019/6;
- The defining characteristics of a veterinary medicinal product that enable the unique identification of a product record by assigning the UPD product ID, permanent ID and package ID;
- The confidentiality arrangements conforming to Article 56 of Regulation (EU) 2019/6;
- The information model for veterinary medicinal products into the UPD, which is based on the SPOR API Technical specification and HL7 FHIR specification, and also described in Chapter 5 on the Technical Specification;
- The format, business guidance and conventions outlined in Chapter 2 of the Vet EU IG on the data elements that fall under the scope of legacy data submission into the UPD.

# 1. Systems to submit legacy veterinary medicinal product data

In the context of the submission of legacy data on veterinary medicinal products, the following solutions are available, as described in Chapter 1 of the Vet EU IG:

- an application programming interface (API)
- the UPD user interface (UI);
- ad-hoc temporary file upload.

As a temporary supporting measure to the initial upload of legacy data, the Agency will accept XML file(s) fully compatible with FHIR format and SPOR terminologies that may be produced in-house by NCAs. The XML file(s) shall be created based on the specifications defined in Chapter 5 of the Vet EU IG (i.e. API and FHIR message specifications). The completed XML file(s) shall be sent to the EMA service desk for upload into the UPD system.

NOTE 1: Should the XML file or any part of it (i.e. terminologies used) be recognised as not being compatible with the requirements when uploaded into the UPD system, the Agency will notify the NCAs and reject such submission.

NOTE 2: The Agency has the capacity to upload XML File(s) only once for each NCA. Therefore, this service shall be considered a temporary supporting measure and will be available only once and at the time of the legacy data provision by the NCAs before January 2022. The NCAs therefore need to prepare for the long-term submission strategy and adapt in-house systems accordingly.

# 2. Mapping of terminologies – User Guidance

This section describes the procedure to map the so-called "UPD underlying terminologies". UPD underlying terminologies refer to the Referentials, Organisations and Substance master data contained within the SPOR data management system at EMA. Regardless of the method that will be used to submit veterinary medicinal product data into the UPD, the competent authority should align and map the nationally employed terminologies to the SPOR data, i.e. the UPD underlying terminologies, prior to the submission of the veterinary medicinal product data into the UPD.

Data mapping is the process of matching data objects between two (or more) distinct sets of data. Mapping and matching the underlying data (i.e. Referentials, Organisations and Substance data) against SPOR terminology is a pre-condition for competent authorities and marketing authorisation holders to fulfil the legal obligation not only for the initial legacy data provision but also, beyond 28 January 2022, to enable maintenance of the data in UPD.

The approach here described is proposed for mapping and matching the nationally employed terminologies against the SPOR systems, however, it does not require or oblige any stakeholders to implement this approach in their in-house systems.

Once all the registration requirements in the SPOR system as described in the Vet EU IG Chapter 1 have been fulfilled, the steps shown below should be followed:


## *2.1. Identifying the data and mapping approach*

As a first step, all veterinary medicinal products which fall within the scope of the submission of data in UPD in accordance with provisions laid down in Articles 55 and 102 of Regulation (EU) 2019/6 and as detailed in the Vet EU IG Chapter 2 should be identified.

**Repository**: where do Referential, Organisation and Substance data reside in the national in-house systems;

**Type**: determine whether the Referential, Organisation and Substance data in the in-house system is structured or unstructured (i.e. Access Database, CSV, XML, pdf), codified (i.e. uses codes as identifiers), translated between languages;

**Quality**: understand whether quality control processes are in place and data quality resources dedicated to managing data are available;

**Volume and stability**: determine the quantity of underlying data to be managed and the frequency of the data update and refresh.

The above aspects could guide on the approach to be pursued for the initial data mapping and may support in the identification of the efforts and resources required to carry out mapping and the identification of areas where a level of automation can be utilised.

## *2.2. Data mapping*

This step entails the identification of what data elements need mapping (against RMS, OMS and SMS) and develop the process for how to undertake the mapping in line with your initial data mapping approach (e.g. manual or semi-automated). Whilst human intervention may still be required to verify data matches, each organisation will have a very different data profile and will require mapping tools, more or less advanced, appropriate to their own data requirements.

EMA can only provide guidance on processes but will not be providing any data mapping tools.

## *2.3. Data transformation and enrichment*

The mapping process should highlight any structural differences between your local source data and the SPOR master data. In order to submit changes/updates, the relevant data may need to be structured in line with SPOR data by means of the following actions:

- **Data transformation**: if a change in the data structure is foreseen e.g. split data values if a term in the national database can be mapped to 2 term IDs based on the RMS terminologies;
- **Data enrichment:** if missing data require enrichment and completion e.g. add new data such as 'post code'.

## *2.4. Submit change requests*

The mapping process should highlight any discrepancies or gaps between the local data source and the data available in the SPOR databases. Any necessary missing terms shall be requested to be added in SPOR whilst terms which require amendment(s) shall be submitted as proposed updates. This should be done via a change request to EMA via the SPOR portal for RMS or OMS change requests or via the EMA Service Desk for SMS change requests. The local data source should be amended/mapped in line with the outcomes of the applicable change requests.

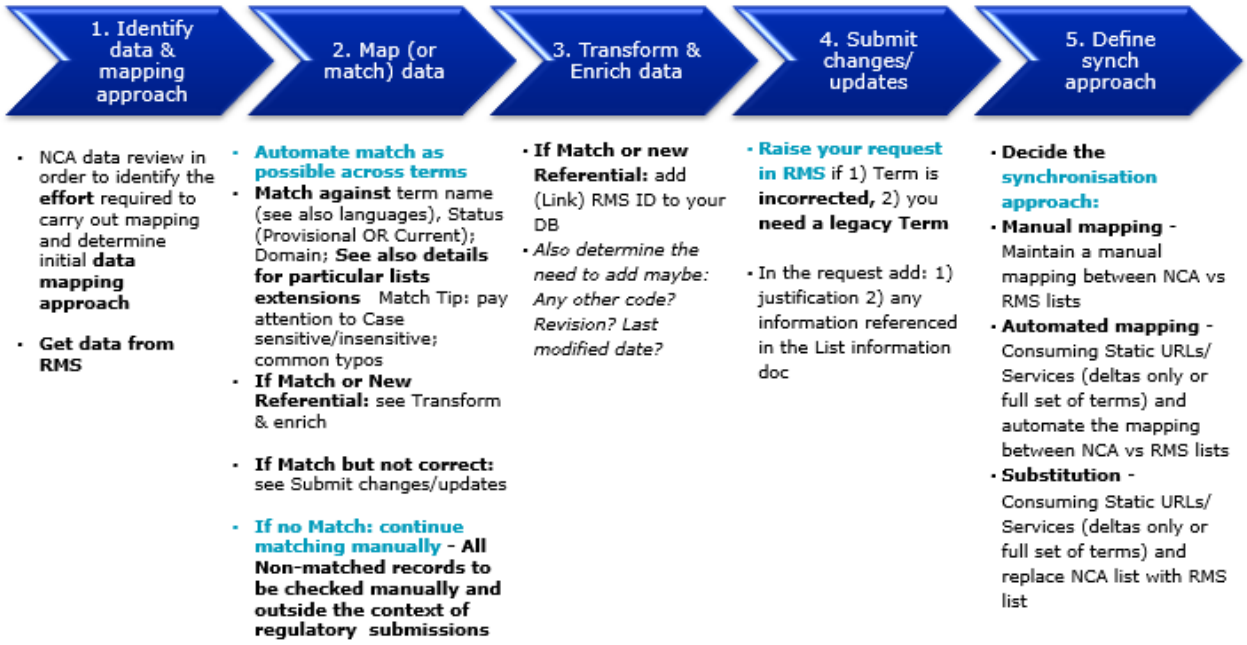
## *2.5. Define synchronisation approach*

Following the initial data mapping and matching, it is advisable that a strategy for the future data synchronisation is defined determining how to prospectively maintain data synchronisation with RMS, OMS and SMS. The steps outlined in sections 2.1. to 2.4. may enable the definition of such strategy. The possible solution may entail a simple manual process, or a more automated solution based on the volume and the stability of the data. Frequency of data updates should be considered to determine whether a continuous data synchronisation processes is preferable vis a vis a periodic batch of changes and also what the consequences might be if an automatic solution is chosen.

The synchronisation approach may be adapted and further developed as more experience, complete view of the processes and systems is gathered.

## 2.6. Practical considerations for RMS data mapping

The figure below summarises the advisable steps to be followed for the mapping of the local data with the RMS solution.




The following is to be considered when mapping referentials:

- Should the applicable RMS lists not include translations: if the term name in English is provided the applicable RMS ID shall be used. NCAs can upload missing translations either manually or via bulk upload as detailed in section 3.8 of the RMS Web User Manual, available on the SPOR website under 'Help'.
- Additional documentation related to RMS is available in Annex I – SPOR Reference Documents.

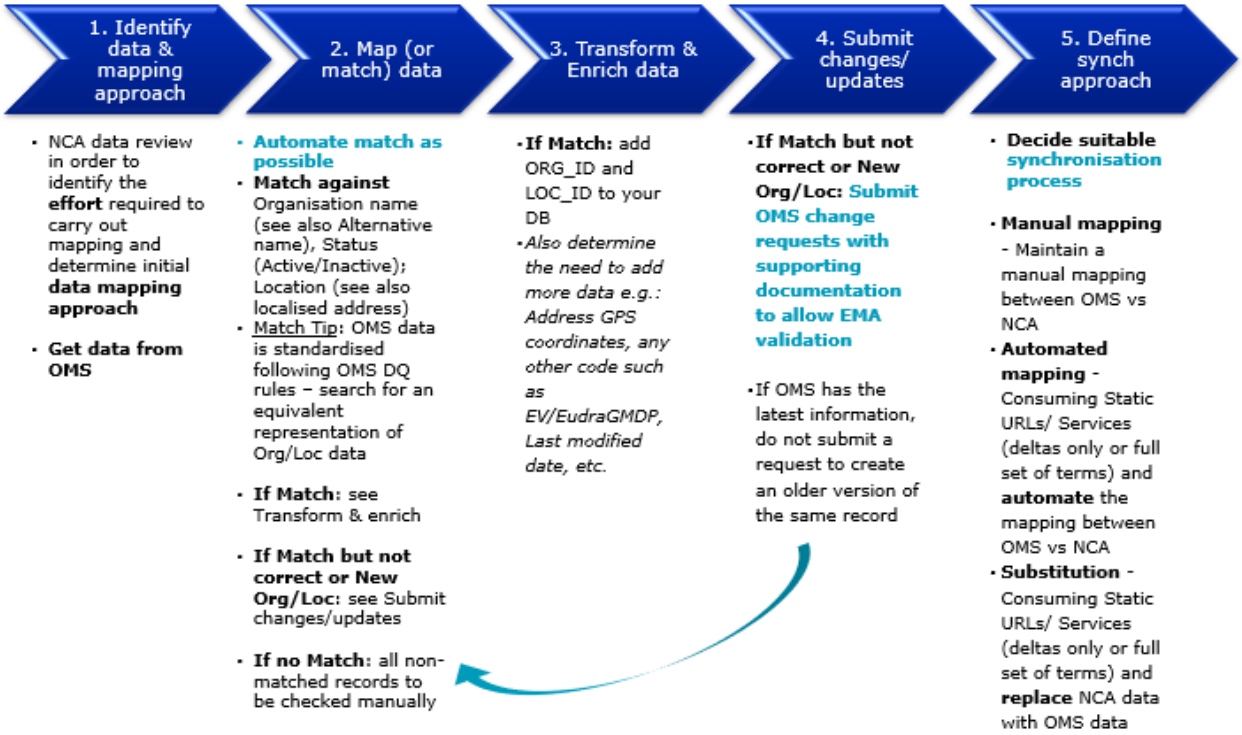
The complete list of RMS lists to be mapped (list identifiers are available in the relevant section of Chapter 2):

- Anatomical Therapeutic Chemical Classification system - veterinary
- Application legal basis
- Combination package
- Combined pharmaceutical dose form
- Combined Term
- Contact Party Role
- Country
- Domain
- EU Regulatory Authorisation Procedure
- Language
- Legal status for the supply

- Manufacturing Activity
- Medicinal Product Name Part Type
- Pharmaceutical dose form
- Product cross reference type
- Product information document type
- Regulatory entitlement status
- Regulatory entitlement type
- Routes and Methods of Administration
- Target Species
- Units of Measurement
- Units of Presentation

## 2.7. Practical considerations for OMS data mapping

The figure below summarises the advisable steps to be followed for the mapping of the local data with the OMS solution.




The following features are to be considered when accessing the OMS web-portal:

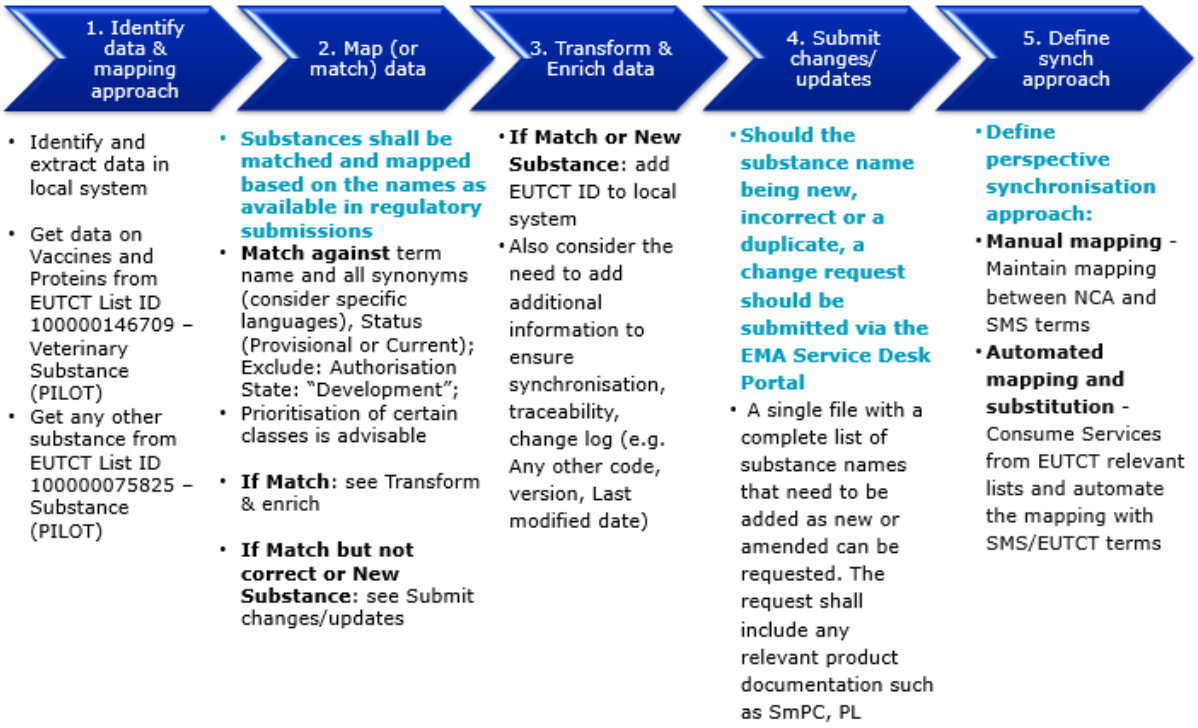
- The browsing of the OMS list (dictionary)
- The OMS content allows for search based on Organisation and Organisation Location IDs, Organisation names and address data (the role of the organisation is not stored in OMS)

- OMS CSV file can be downloaded (without history) for the entire content of OMS Organisations/Locations with Status Active & Inactive and for individual search result (list with Organisations/Locations)
- Marketing Authorisation Holders should ensure that all organisation data (addresses) for products under their responsibility are recorded in OMS and that records are up to date and complete.

Additional documentation related to OMS solution is available in Annex I – SPOR Reference Documents.

## 2.8. Practical considerations for SMS data mapping

The figure below summarises the advisable steps to be followed for the mapping of the local data with the substance list that will be available in the SMS solution.




The following is to be considered when mapping substance names:

- SMS provides the list of substances names and IDs and does not include any information on how the substances are used within veterinary medicinal products. The role of the substance will be specified only in the context of the veterinary medicinal product, i.e. in UPD.
- Both CSV & XML files can be downloaded from EUTCT
- For Veterinary vaccines and proteins substances, the EUTCT lists do not currently include translations: if the substance name in English is provided for the relevant substance, the EUTCT ID shall be used to provide the veterinary product information in UPD. Meanwhile, a change request to update the existing substance ID shall be provided via the EMA Service Desk portal to submit the missing translation(s).

Additional documentation related to SMS solution is available in Annex I – SPOR Reference Documents.

NOTE: At present, veterinary substances are undergoing cleansing in SMS. This is expected to be completed by end January 2021 at the latest. Once completed, the cleaned Substance data will be

uploaded to SMS and automatically synchronised with EUTCT. NCAs have access to substance list via EUTCT only (and in future SMS access will be provided) which is a (real time) view of what is in SMS. NCAs should map their substance data to EUTCT once the data cleansing is completed. Substance data, especially for immunologicals, is very variable between and within NCA databases, because of the complexity of the substances and the different practices in identifying immunologicals by MAH and NCAs over time. Specifically, NCAs may identify the substance based on different levels of complexity and information which may also be handled in a structured or in unstructured way. In performing the mapping, the NCA should identify, map and record the national substance term to the EUTCT substance ID which refers to the most relevant, appropriate and correct level of information. As a long-term plan, EU-SRS will be synchronised with SMS, loaded with all EU substances and further structured scientific data-fields will be added, however, neither the Substance name nor the Substance ID will change in SMS. Therefore, the initial mapping that will be performed by NCAs in preparation of the Legacy data upload in UPD will stand correct and no further mapping action are foreseen on substance terminology.

Example:

- SMS ID: 300000025059
- Preferred term in SMS: Actinobacillus pleuropneumoniae, serotype 2, strain App2TR98, Inactivated
- Preferred term in EU-SRS: Actinobacillus pleuropneumoniae, serotype 2, strain App2TR98, Inactivated
- Organism (EU-SRS only data field): Actinobacillus pleuropneumoniae
- Serotype (EU-SRS only data field): serotype 2
- Strain (EU-SRS only data field): strain App2TR98

# 3. Veterinary medicinal product legacy data - User guidance

This section outlines the data elements that fall within the scope of the submission of the legacy data on veterinary medicinal product in UPD.

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| IA Annex | EU Vet IG Chapter 2 Ref. | Data element name | FHIR Path | SPOR list name | Mandatory for Legacy Data | Conformance in Chapter 2 | European/ National | Note applicable to Legacy Data |
|---|---|---|---|---|---|---|---|---|
| **Class** | **1** | **Veterinary medicinal product** | **MedicinalProductDefinition** | | **yes** | **Mandatory** | **European** | |
| 1.1 | 1.1 | Domain | MedicinalProductDefinition.domain | Domain | yes | Mandatory | European | |
| 3.7 | 1.3 | (Authorised) pharmaceutical form | AdministrableProductDefinition.administrableDoseForm and/ or MedicinalProductDefinition.combinedPharmaceuticalDoseForm | Combined Term Pharmaceutical dose form Combined pharmaceutical dose form Combination package | yes | Conditional (at least one form based on the 4 lists should be provided) | European | |
| | | | | | | | | |
| 3.16 | 1.4 | Legal status of supply | MedicinalProductDefinition.legalStatusOfSupply | Legal status for the supply | yes | Conditional (either at MP level or at Pack) | National | |
| **Class** | **1.6** | **Product Classification** | | | **yes** | | **European** | |
| 4.7 | 1.6.1 | Legal basis | RegulatedAuthorization.basis | Application legal basis | yes | Mandatory | European | |

| IA Annex | EU Vet IG Chapter 2 Ref. | Data element name | FHIR Path | SPOR list name | Mandatory for Legacy Data | Conformance in Chapter 2 | European/ National | Note applicable to Legacy Data |
|---|---|---|---|---|---|---|---|---|
| 3.9 | 1.6.2 | ATC vet code(s) | MedicinalProductDefinition.classification | Anatomical Therapeutic Chemical Classification system - veterinary | yes | Conditional (either at MP level or at Pack) | European | |
| 3.9 | 1.6.3 | ATC vet code(s) flag | MedicinalProductClassification.atcPending | | yes | Conditional | European | |
| **Class** | **1.7** | **Veterinary medicinal product name** | | | **yes** | **Mandatory** | **European & National** | |
| 1.3 | 1.7.1 | Full name | MedicinalProductDefinition.name.productName | | yes | Mandatory | European & National | |
| | 1.7.2 | Type | MedicinalProductDefinition.name.type | Medicinal Product Name Part Type | yes | Mandatory | European & National | |
| **Class** | **1.7.3** | **Country/Language** | | | **yes** | **Mandatory** | **European & National** | |
| | 1.7.3.1 | Country | MedicinalProductDefinition.name.countryLanguage.country | Country | yes | Mandatory | European & National | |
| | 1.7.3.2 | Language | MedicinalProductDefinition.name.countryLanguage.language | Language | yes | Mandatory | European & National | |

| IA Annex | EU Vet IG Chapter 2 Ref. | Data element name | FHIR Path | SPOR list name | Mandatory for Legacy Data | Conformance in Chapter 2 | European/ National | Note applicable to Legacy Data |
|---|---|---|---|---|---|---|---|---|
| **Class** | **1.9** | **Contact (QPPV)** | | | **yes** | **Mandatory** | **European** | |
| 3.13 | 1.9.1 | Identifier | MedicinalProductDefinition.contact.contact(PractitionerRole).identifier | | yes | Mandatory | European | |
| | 1.9.2 | Role | MedicinalProductDefinition.contact.type | Contact Party Role | yes | Mandatory | European | |
| 3.14 | 1.9.3 | Location | tbd | OMS | yes | Mandatory | European | |
| **Class** | **1.10** | **Attached Document** | | | **yes** | | **European & National** | |
| 1.7 | 1.10.1 | (Attached document) identifier (master) | DocumentReference.masterIdentifier (referenced from MedicinalProductDefinition.AttachedDocument) | | yes | Mandatory | European & National | |
| 1.7 | 1.10.2 | (Attached document) status | DocumentReference.status | | yes | Mandatory | European & National | |

| IA Annex | EU Vet IG Chapter 2 Ref. | Data element name | FHIR Path | SPOR list name | Mandatory for Legacy Data | Conformance in Chapter 2 | European/ National | Note applicable to Legacy Data |
|---|---|---|---|---|---|---|---|---|
| 1.7 | 1.10.3 | (Attached document) type | DocumentReference.type | Product information document type | yes | Mandatory | European & National | |
| 1.7 | 1.10.4 | (Attached document) content type | DocumentReference.content.attachment.contentType | | yes | Mandatory | European & National | |
| 1.7 | 1.10.5 | (Attached document) language | DocumentReference.content.attachment.language | Language | yes | Mandatory | European & National | |
| 1.7 | 1.10.6 | (Attached document) content | DocumentReference.content.attachment.data | | yes | Mandatory | European & National | |
| 1.7 | 1.10.7 | (Attached document) title | DocumentReference.content.attachment.title | | yes | Mandatory | European & National | |
| 1.7 | 1.10.8 | (Attached document) related medicinal products | DocumentReference.context.related | | yes | Mandatory | European & National | |
| **Class** | **1.11** | **Product cross-reference** | | | **yes** | **Conditional** | **European & National** | **For parallel traded Product only** |

| IA Annex | EU Vet IG Chapter 2 Ref. | Data element name | FHIR Path | SPOR list name | Mandatory for Legacy Data | Conformance in Chapter 2 | European/ National | Note applicable to Legacy Data |
|---|---|---|---|---|---|---|---|---|
| 4.9, 4.10 | 1.11.1 | Product cross-reference type | MedicinalProductDefinition.crossReference.type | Product cross reference type | yes | Mandatory | European & National | |
| | 1.11.2 | Reference product Identifier | MedicinalProductDefinition.crossReference. product Reference | | yes | Mandatory | European & National | |
| | 1.11.3 | Source product identifier | MedicinalProductDefinition.crossReference. product Reference | UPD ID | yes | Mandatory | National | |
| **Class** | **1.12** | **Manufacturing Business Operation** | | | **yes** | **Mandatory** | **European & National** | **only for batch release** |
| 1.6 | 1.12.1 | Manufacturer | MedicinalProductDefinition.manufacturingBusinessOperation.manufacturer | OMS | yes | Mandatory | European & National | only for batch release |
| 1.6 | 1.11.2 | Manufacturing activity | MedicinalProductDefinition.manufacturingBusinessOperation.type | Manufacturing Activity | yes | Mandatory | European & National | only for batch release |
| **Class** | **2** | **Authorisation /registration/ entitlement information** | | | **yes** | **European & National** | **European & National** | |

| IA Annex | EU Vet IG Chapter 2 Ref. | Data element name | FHIR Path | SPOR list name | Mandatory for Legacy Data | Conformance in Chapter 2 | European/ National | Note applicable to Legacy Data |
|---|---|---|---|---|---|---|---|---|
| 1.2 | 2.1 | Authorisation/registration/entitlement type | RegulatedAuthorization.type | Regulatory entitlement type | yes | Mandatory | European | |
| 4.8 | 2.2 | Authorisation/registration/entitlement number | RegulatedAuthorization.identifier.value | | yes | Conditional | National | |
| 4.4 | 2.3 | Country | RegulatedAuthorization.region | Country | yes | Mandatory | National | |
| 3.3 | 2.4 | Reponsible authority (organisation) | RegulatedAuthorization.holder | OMS | yes | Mandatory | National | |
| 3.4 | 2.5 | Authorisation status | RegulatedAuthorization.status | Regulatory entitlement status | yes | Mandatory | National | |
| 4.3 | 2.7 | Marketing authorisation date | RegulatedAuthorization.relatedDate.datedateTime | | yes | Mandatory | National | |
| 3.3 | 2.9 | Product Owner (organisaion) | RegulatedAuthorization.holder | OMS | yes | Mandatory | National | |
| 6.1 | 2.10 | Source wholesale distributor (organisation) | RegulatedAuthorization.parallelTradeSourceWholesaler | OMS | yes | Conditional | National | For parallel traded Product only |
| 6.2 | 2.10 | Destination wholesale distributor (organisation) | RegulatedAuthorization.parallelTradeDestinationWholesaler | OMS | yes | Conditional | National | For parallel traded Product only |
| 4.5 | 2.11 | Reference member state | RegulatedAuthorization.c | Country | yes | Conditional | European | |

| IA Annex | EU Vet IG Chapter 2 Ref. | Data element name | FHIR Path | SPOR list name | Mandatory for Legacy Data | Conformance in Chapter 2 | European/ National | Note applicable to Legacy Data |
|---|---|---|---|---|---|---|---|---|
| | | | ase.referenceCountry | | | | | |
| 4.6 | 2.12 | Concerned member state | RegulatedAuthorization.case.concernedCountries | Country | yes | Conditional | European | |
| **Class** | **2.13** | **Marketing authorisation procedure** | | | **yes** | **Mandatory** | **European** | |
| 4.2 | 2.13.1 | Procedure number | RegulatedAuthorization.case.identifier | | yes | Mandatory | European | |
| 3.2 or 3.1? | 2.13.2 | Product Identifier | RegulatedAuthorization.case.identifier | TBC | yes | Conditional | European | |
| 4.1 | 2.13.3 | Procedure type | RegulatedAuthorization.case.type | EU Regulatory Authorisation Procedure | yes | Mandatory | European | |
| **Class** | **3** | **Pharmaceutical Product** | | | **yes** | **Mandatory** | **European** | |
| 3.6 | 3.1 | Route of administration | AdministrableProductDefinition.routeOfAdministration.code | Routes and Methods of Administration | yes | Mandatory | European | |
| 3.8 | 3.2 | Target species | AdministrableProductDefinition.routeOfAdministration.targetSpecies.code | Target Species | yes | Mandatory | European | |
| **Class** | **3.3** | **Withdrawal period** | | | **yes** | **optional** | **European** | Only as a free text |

| IA Annex | EU Vet IG Chapter 2 Ref. | Data element name | FHIR Path | SPOR list name | Mandatory for Legacy Data | Conformance in Chapter 2 | European/ National | Note applicable to Legacy Data |
|---|---|---|---|---|---|---|---|---|
| 3.1 | 3.3.3 | Note | AdministrableProductDefinition.routeOfAdministration.targetSpecies.withdrawalPeriod.supportingInformation | | yes | optional | European | |
| **Class** | **4** | **Ingredient** | | | **yes** | **Mandatory** | **European** | |
| 1.4 or 1.5 | 4.1 | Ingredient role | Ingredient.role | | yes | Mandatory | European | |
| **Class** | **4.3** | **Substance** | | | **yes** | **Mandatory** | **European** | |
| 1.4 | 4.3.1 | Substance | Ingredient.substance.codeCodeableConcept | SMS | yes | Mandatory | European | |
| | 4.3.2 | Strength | | | yes | Conditional | European | |
| **Class** | **4.3.2** | **Strength (quantitative composition)** | | | **yes** | **Conditional** | **European** | |
| 1.5 | 4.3.2 | Strength (presentation) - numerator | Ingredient.substance.strength.presentation.numerator | Units of Measurement | yes | Conditional | European | |
| 1.5 | 4.3.2 | Strength (presentation) - denominator | Ingredient.substance.strength.presentation.denominator | Units of Presentation | yes | Conditional | European | |
| 1.5 | 4.3.2 | Strength (concentration) - numerator | Ingredient.substance.strength.conce | Units of Measurement | yes | Conditional | European | |

| IA Annex | EU Vet IG Chapter 2 Ref. | Data element name | FHIR Path | SPOR list name | Mandatory for Legacy Data | Conformance in Chapter 2 | European/ National | Note applicable to Legacy Data |
|---|---|---|---|---|---|---|---|---|
| | | | ntration.numerator | | | | | |
| 1.5 | 4.3.2 | Strength (concentration) - denominator | Ingredient.substance.strength.concentration.denominator | Units of Measurement | yes | Conditional | European | |
| **Class** | **4.3.3** | **Reference Strength** | | | **yes** | **optional** | **European** | |
| | 4.3.3 | Reference Substance | Ingredient.substance.strength.referenceStrength.substanceCodeableConcept | SMS | yes | Conditional | European | |
| 1.5 | 4.3.3 | Reference strength (presentation) - numerator | Ingredient.substance.strength.referenceStrength.strength.numerator | Units of Measurement | yes | Conditional | European | |
| 1.5 | 4.3.3 | Reference strength (presentation) - denominator | Ingredient.substance.strength.referenceStrength.strength.denominator | Units of Presentation | yes | Conditional | European | |
| 1.5 | 4.3.3 | Reference strength (concentration) - numerator | Ingredient.substance.strength.referenceStrength.strength.numerator | Units of Measurement | yes | Conditional | European | |

| IA Annex | EU Vet IG Chapter 2 Ref. | Data element name | FHIR Path | SPOR list name | Mandatory for Legacy Data | Conformance in Chapter 2 | European/ National | Note applicable to Legacy Data |
|---|---|---|---|---|---|---|---|---|
| 1.5 | 4.3.3 | Reference strength (concentration) - denominator | Ingredient.substance.strength.referenceStrength.strength.denominator | Units of Measurement | yes | Conditional | European | |
| 3.1 | 5 | Permanent identifier | MedicinalProductDefinition.id | | yes | Conditional | National | |
| **Class** | **6** | **Packaged medicinal product** | | | **yes** | **Mandatory** | **European & National** | |
| 3.15 | 6.1 | Package description | PackagedProductDefinition.description | | yes | Mandatory | European & National | |
| 3.15 | 6.1.1 | Language | PackagedProductDefinition.description.valueCode | Language | yes | Mandatory | European & National | |
| 3.15 | 6.1.2 | Country | MedicinalProductDefinition.name.countryLanguage.country | Country | yes | Mandatory | European & National | |
| 3.15. | 6.2 | Pack Size (structured values) | PackagedProductDefinition | | yes | Mandatory | European | |
| | 6.3 | Package identifier | PackagedProductDefinition.identifier | | yes | Conditional | European | |
| 3.16 | 6.4 | Legal status of supply | PackagedProductDefinition.legalStatusOfSupply | Legal status for the supply | yes | Conditional | National | Only if applicable to package level |

| IA Annex | EU Vet IG Chapter 2 Ref. | Data element name | FHIR Path | SPOR list name | Mandatory for Legacy Data | Conformance in Chapter 2 | European/ National | Note applicable to Legacy Data |
|---|---|---|---|---|---|---|---|---|
| **Class** | **6.5** | **Marketing authorisation (package level)** | | | **yes** | **Conditional** | **National** | **Only if applicable to package level** |
| | 6.5.1 | Marketing authorisation number (package level) | RegulatedAuthorization.identifier | | yes | Mandatory | National | Only if applicable to package level |

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# Annex I – SPOR Reference Documents

The following reference documents are accessible from the SPOR portal:

- OMS/RMS web user manual – guidance on SPOR services, e.g. searching, exporting data, requesting CRs
- SPOR user registration manual (how to register for SPOR)
- SPOR affiliation template (to register the first industry super user)
- Change Request (CR) Validation in OMS
- Organisation data quality standards in OMS
- SPOR SLAs (SLA are indicative and will be reviewed in future)

The RMS & OMS training videos are available to view on the @emainfo youtube channel

- RMS operating model document (link)
- OMS operating model document (link)

Recordings of the NCA webinars on RMS and OMS are available on EU NTC.