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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 4: Process and format for the submission of legacy data on veterinary medicinal products

Version 1.2

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Changes made compared to the previous version:

1. Veterinary medicinal product legacy data – Conformance: alignment with relevant changes applied to Vet EU IG Chapter 2 in data elements FHIR conformance due to Parallel Trade products (i.e. data elements: 1.10 Pharmacovigilance Contact (QPPV), 2.8 Product Owner (organisation), 3.3 Target species, 5 Packaged medicinal product).
2. Guidance watermarked "OBSOLETE".

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 (Vet EU IG) on veterinary medicines product data in the Union Product Database Chapter 2 on the Format for the electronic submission of veterinary medicinal product information describes the business rules, data fields and specifications 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 in a veterinary medicinal product authorised in a Member State with a marketing authorisation or registration valid before 28 January 2022. The following aspects, as outlined in the Vet EU IG Chapter 2, also apply 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 (level 1), the UPD permanent ID (level 2) and package ID (level 3);
- The confidentiality arrangements conform to Article 56 of Regulation (EU) 2019/6;
- The information model for veterinary medicinal products in 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 formal 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.

NOTE: in the context of the legacy data provision in the UPD, the required data is presented in Section 4 of this document. Any other information not presented in section 4 but described in the Vet EU IG Chapter 2 may be provided on voluntary basis as part of the legacy data submission.

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) (as a fully automated submission solution);
- the UPD user interface (UI) (as a fully manual submission solution);
- an XML file upload (as a semi-automated submission solution).

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 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, before the submission of the veterinary medicinal product data into the UPD.

Data mapping is the process of matching data objects between (or more) distinct sets of data. Mapping and matching the underlying data (i.e. Referentials, Organisations and Substance data) against SPOR terminology is a precondition 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 described here 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 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 developing 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. 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 requires enrichment for 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 outcome of the applicable change requests.

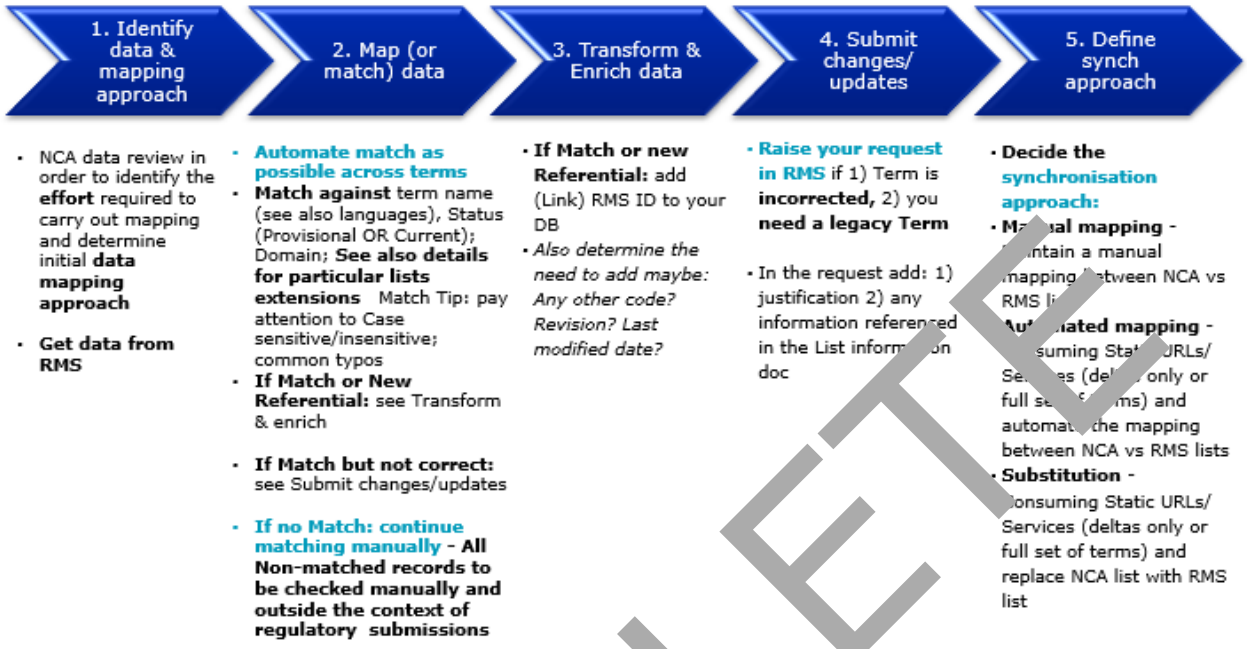
2.5. Define synchronisation approach

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 process is preferable vis-à-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, a 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 mappi eferenti :

- Should the applicable RMS lists not in ude transla ons: i the term name in English is provided the applicable RMS ID shall be used. NCA can upload m ssing translations either manually or via bulk upload as detailed in section 3.8 of the MS Web U er Manual, available on the SPOR website under 'Help'.
- Additional documentation r ated RM is available in Annex I – SPOR Reference Documents.

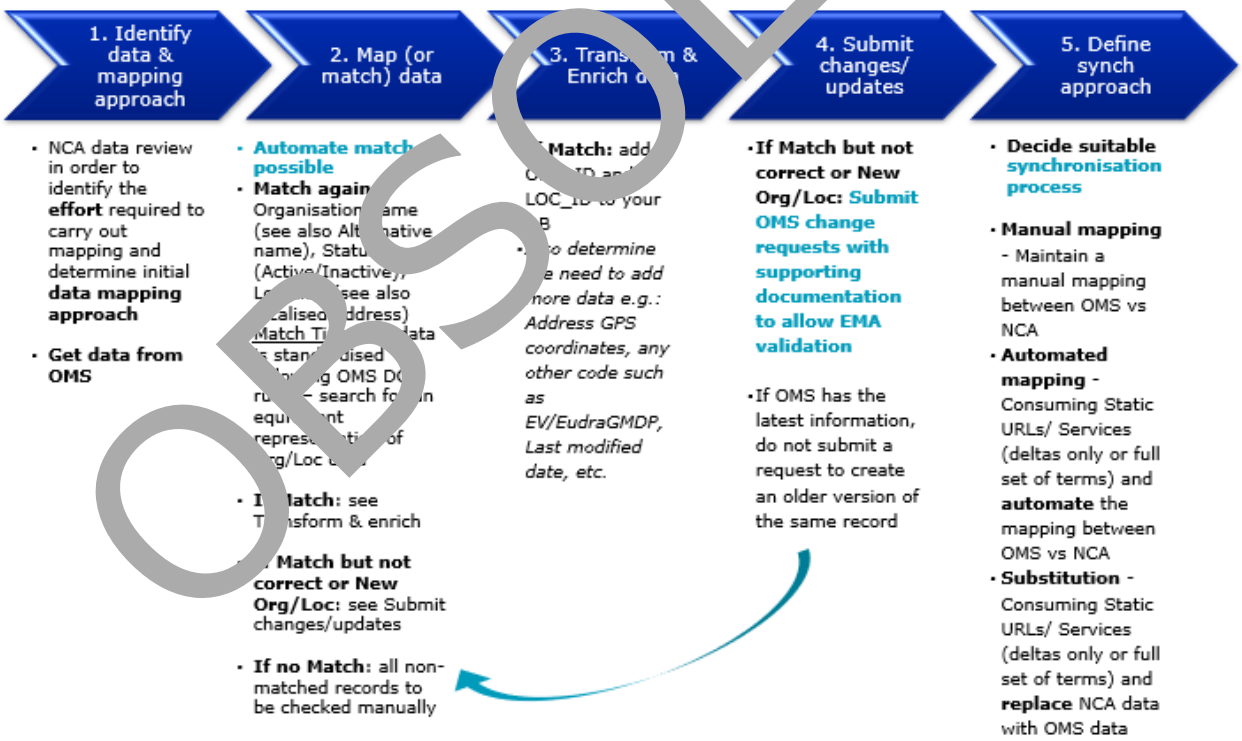
The complete list of RM li s to be mappe (list identifiers are available in the relevant section of Chapter 2):

- Anatomical Therap c Chem al Classification system - veterinary
- Applic on lega asis
- Com nation packa e
- Combi pharm eutical dose form
- Combined Term
- Contact Party Role
- Country
- Domain
- EU Regulatory Authorisation Procedure
- Ingredient role
- 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:

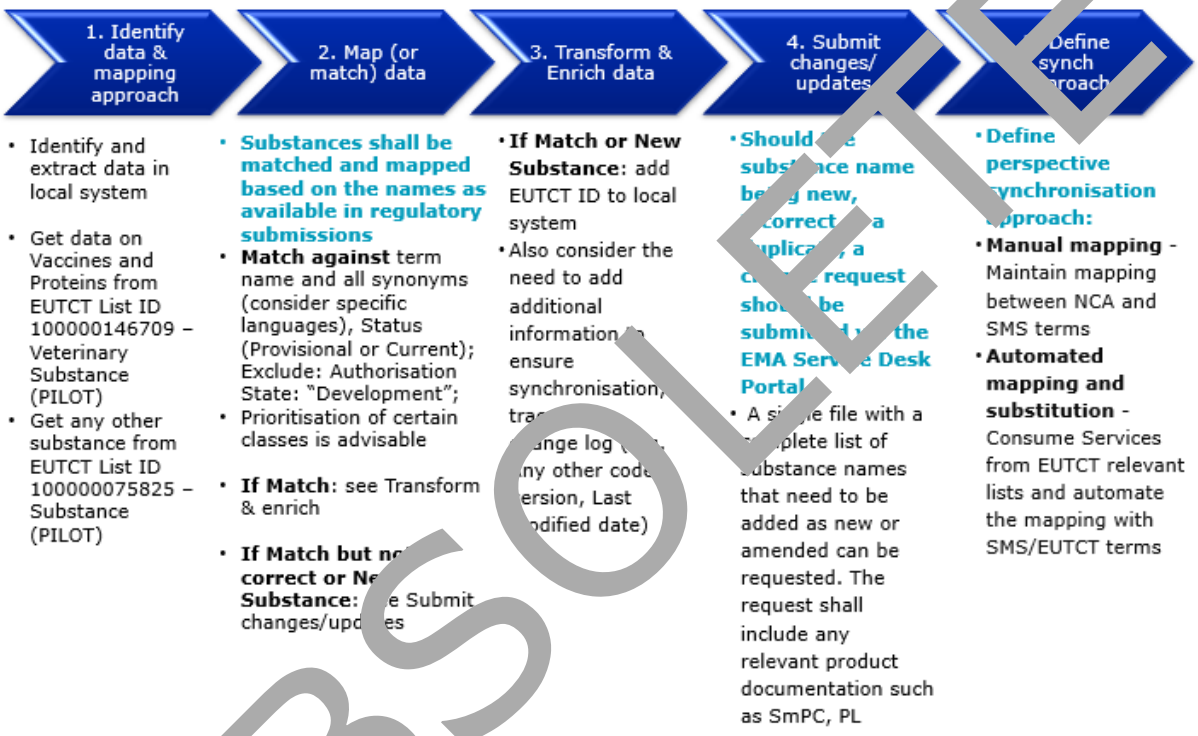
- The browsing of the OMS list (dictionary)
- The OMS content allows for search based on Organisation and Organisation Location IDs, Organisation names and address data (the role of the organisation is not stored in OMS)

- 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 nsidered hen mapping substance names:

- SMS pr vides list c u tance names and IDs and does not include any information on how the s stances ar used within veterinary medicinal products. The role of the substance will be speci d only in th context of the veterinary medicinal product, i.e. in UPD.
- Both CS nd X files can be downloaded from EUTCT
- For veterinary vaccines and protein 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 shall be provided via the EMA Service Desk portal to submit the missing translation(s).

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

NOTE: The cleaned Substance data is uploaded to SMS and automatically synchronised with EUTCT. NCAs have access to the substance list via EUTCT only (and in the 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 an 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 the 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 products in UPD.

NOTE: in the context of the legacy data provision in the UPD, the required data is presented in this section, any other information not outlined in this section but described in the Vet EU IG Chapter 2 may be provided in the UPD on a voluntary basis as part of the legacy data submission.

UPD IA Ref	EU Vet IG Chapter 2 Ref.	Data element name	FHIR Path	SPOR list name	Mandatory for Legacy Data (yes/no)	Conformance in Chapter 2	European/ National	Notes on Legacy Data
	1	**Veterinary medicinal product**	**MedicinalProductDefinition**		**yes**	**Mandatory**	**European**	
1.1	1.1	Domain	MedicinalProductDefinition.domain	Domain	yes	Mandatory	European	
	1.2	Product Record Status	MedicinalProductDefinition.status	Record Status	yes	Mandatory	European & National	Default value 'Current' must be specified.
3.2	1.3	Product Identifier	RegulatedAuthorization.case.identifier	UPD ID	yes	Conditional (updates only)	European	
3.1	1.4	Permanent identifier	MedicinalProductDefinition.id	UPD ID	yes	Conditional (updates only)	National	
3.7	1.5	(Authorised) pharmaceutical form	MedicinalProductDefinition.extension.authorisedDoseForm	Combined Term Pharmaceutical dose form Combined pharmaceutical dose form Combination package	yes	Mandatory	European	
3.16	1.6	Legal status of supply	MedicinalProductDefinition.legalStatusOfSupply	Legal status of supply	yes	Conditional (either at product or at pack level)	National	
	1.7	**Product Classification**			**yes**	**Conditional**	**European**	
4.7	1.7.1	Legal basis	RegulatedAuthorization.basis	Marketing Authorisation Application Legal Basis	yes	Conditional	European	
3.9	1.7.2	ATC vet code(s)	MedicinalProductDefinition.productClassification	Anatomical Therapeutic Chemical Classification system - veterinary	yes	Conditional	European	
3.9	1.7.3	ATC vet code(s) flag	MedicinalProductDefinition.productClassificati		yes	Conditional	European	

UPD IA Ref	EU Vet IG Chapter 2 Ref.	Data element name	FHIR Path	SPOR list name	Mandatory for Legacy Data (yes/no)	Conformance in Chapter 2	European/ National	Notes on Legacy Data
			on.extension.atcPending					
	1.8	**Veterinary medicinal product name**			**yes**	**Mandatory**	**European & National**	
1.3	1.8.1	Veterinary medicinal product name	MedicinalProductDefinition.name.productName		yes	Mandatory	European & National	
	1.8.2	Name part			no	Optional	European & National	
	1.8.2.1	Name type	MedicinalProductDefinition.name.namePart.type		no	Mandatory	European & National	
	1.8.2.2	Name part	MedicinalProductDefinition.name.namePart.part		no	Mandatory	European & National	
	1.8.3	**Country/ Language**			**yes**	**Mandatory**	**European & National**	
	1.8.3.1	Country	MedicinalProductDefinition.name.countryLanguage.country	Country	yes	Mandatory	European & National	
	1.8.3.2	Language	MedicinalProductDefinition.name.countryLanguage.language	Language	yes	Mandatory	European & National	
	1.9	**(Pharmacovigilance System) Master File**			**no**	**Conditional**	**European**	
	1.9.1	(PSM) File Status	MedicinalProductDefinition.masterFile(DocumentReference).status		no	Mandatory	European	
	1.9.2	(PSM) File type	MedicinalProductDefinition.masterFile(DocumentReference).type		no	Mandatory	European	
3.11	1.9.3	(PSM) File code	MedicinalProductDefinition.masterFile(Docum		no	Mandatory	European	

UPD IA Ref	EU Vet IG Chapter 2 Ref.	Data element name	FHIR Path	SPOR list name	Mandatory for Legacy Data (yes/no)	Conformance in Chapter 2	European/ National	Notes on Legacy Data
			entReference).identifier					
3.12	1.9.4	(PSM) File location	MedicinalProductDefinition.masterFile(DocumentReference).custodian		no	Mandatory	European	
	1.10	**Pharmacovigilance Contact (QPPV)**			**yes**	**Conditional**	**European**	
3.13	1.10.1	QPPV Name	MedicinalProductDefinition.contact.contact(PractitionerRole).identifier		yes	Mandatory	European	
	1.10.2	QPPV Role	MedicinalProductDefinition.contact.type	Contact Party Role	yes	Mandatory	European	
3.14	1.10.3	QPPV Location	MedicinalProductDefinition.contact.contact(PractitionerRole).organization	Organisation	yes	Mandatory	European	
	1.11	**Attached Document**			**yes**	**Conditional**	**European & National**	
	1.11.1	(Attached document) identifier	DocumentReference.id		yes	Conditional (updates only)	European & National	
	1.11.2	(Attached document) status	DocumentReference.status		yes	Mandatory	European & National	
	1.11.3	(Attached document) type	DocumentReference.type	Product information document type	yes	Mandatory	European & National	
	1.11.4	(Attached document) Country	DocumentReference.category	Country list or Country Grouping list	yes	Mandatory	European & National	

UPD IA Ref	EU Vet IG Chapter 2 Ref.	Data element name	FHIR Path	SPOR list name	Mandatory for Legacy Data (yes/no)	Conformance in Chapter 2	European/ National	Notes on Legacy Data
	1.11.5	(Attached document) content type	DocumentReference.content.attachment.contentType		yes	Mandatory	European & National	
	1.11.6	(Attached document) Language	DocumentReference.content.attachment.language	FHIR list bcp-47, refer to Attachment.language	yes	Mandatory	European & National	
	1.11.7	(Attached document) content	DocumentReference.content.attachment.data		yes	Mandatory	European & National	
1.7	1.11.8	(Attached document) title	DocumentReference.content.attachment.title		yes	Mandatory	European & National	
	1.11.9	(Attached document) related veterinary medicinal products	DocumentReference.context.related		yes	Mandatory	European & National	
	1.12	**Product cross-reference**			**yes**	**Conditional**	**European & National**	**parallel traded only**
	1.12.1	Product cross-reference type	MedicinalProductDefinition.crossReference.type	Product cross reference type	yes	Mandatory	European & National	
4.9	1.12.2	Reference product Identifier	MedicinalProductDefinition.crossReference.productReference	UPD ID	yes	Mandatory	European & National	
4.10	1.12.3	Source product identifier	MedicinalProductDefinition.crossReference.productReference	UPD ID	yes	Mandatory	National	
	1.13	**Manufacturing Business Operation**			**yes**	**Conditional**	**European**	**only for batch release**
1.6	1.13.1	Manufacturer	MedicinalProductDefinition.ManufacturingBusinessOperation.manufacturer	OMS	yes	Mandatory	European	only for batch release

UPD IA Ref	EU Vet IG Chapter 2 Ref.	Data element name	FHIR Path	SPOR list name	Mandatory for Legacy Data (yes/no)	Conformance in Chapter 2	European/ National	Notes on Legacy Data
	1.13.2	Manufacturing activity	MedicinalProductDefinition.manufacturingBusinessOperation.type	Manufacturing Activity	yes	Mandatory	European	only for batch release
	2	**Authorisation/registration/entitlement information**					**European & National**	
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		yes	Conditional	National	
4.4	2.3	Country	RegulatedAuthorization.region	Country	yes	Mandatory	National	
3.3	2.4	Responsible authority (organisation)	RegulatedAuthorization.regulator	OMS	yes	Mandatory	National	
3.4	2.5	Authorisation status	RegulatedAuthorization.status	Regulatory entitlement status	yes	Mandatory	National	
3.5	2.6	Date of authorisation status change	RegulatedAuthorization.statusDate		no	Mandatory	National	
4.3	2.7	Marketing authorisation date	RegulatedAuthorization.relatedDate.dateTime		yes	Mandatory	National	
3.3	2.8	Product Owner (organisation)	RegulatedAuthorization.holder	OMS	yes	Conditional	National	
6.1	2.9	Source wholesale distributor (organisation)	RegulatedAuthorization.parallelTradeSourceWholesaler	OMS	yes	Conditional	National	For parallel traded Product only
6.2	2.10	Destination wholesale	RegulatedAuthorization.parallelTradeDestinationWholesaler	OMS	yes	Conditional	National	For parallel traded Product only

UPD IA Ref	EU Vet IG Chapter 2 Ref.	Data element name	FHIR Path	SPOR list name	Mandatory for Legacy Data (yes/no)	Conformance in Chapter 2	European/ National	Notes on Legacy Data
		distributor (organisation)						
4.5	2.11	Reference member state	RegulatedAuthorization.case.extension.referenceCountry	Country	yes	Conditional	European	
4.6	2.12	Concerned member state	RegulatedAuthorization.case.extension.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	
4.1	2.13.2	Procedure type	RegulatedAuthorization.case.type	EU Regulatory Authorisation Procedure	yes	Mandatory	European & National	
	3	**Pharmaceutical Product**			**yes**	**Mandatory**	**European**	
	3.1	**Ingredient**			**yes**	**Mandatory**	**European**	
3.6	3.2	Route of administration	AdministrableProductDefinition.routeOfAdministration.code	Routes and Methods of Administration	yes	Mandatory	European	
3.8	3.3	Target species	AdministrableProductDefinition.routeOfAdministration.targetSpecies.code	Target Species	yes	Conditional	European	
	3.4	**Withdrawal period**			**yes**	**Conditional**	**European**	Only as a free text

UPD IA Ref	EU Vet IG Chapter 2 Ref.	Data element name	FHIR Path	SPOR list name	Mandatory for Legacy Data (yes/no)	Conformance in Chapter 2	European/ National	Notes on Legacy Data
3.1	3.4.1	Tissue	AdministrableProductDefinition.routeOfAdministration.targetSpecies.withdrawalPeriod.tissue	Tissue	no	Mandatory	European	
3.1	3.4.2	Period	AdministrableProductDefinition.routeOfAdministration.targetSpecies.withdrawalPeriod.value	Units of Measurement	no	Mandatory	European	
	3.4.3	Note	AdministrableProductDefinition.routeOfAdministration.targetSpecies.withdrawalPeriod.supportingInformation		yes	Conditional	European	Mandatory for legacy data
	3.5	Administrable dose form	AdministrableProductDefinition.administrableDoseForm	Pharmaceutical Dose Form	yes	Mandatory	European	For compatibility with the FHIR API version R5#2
	4	**Ingredient**			**yes**	**Mandatory**	**European**	
	4.1	Ingredient role	Ingredient.role		yes	Mandatory	European	
	4.2	Manufacturer			no	Optional	European	
	4.3	**Substance**			**yes**	**Mandatory**	**European**	
1.4	4.3.1	Substance	Ingredient.substance.codeCodeableConcept	SMS	yes	Mandatory	European	
	4.3.2	**Strength (quantitative composition)**			**yes**	**Conditional**	**European**	
1.5	4.3.2.1	Strength (presentation)			yes	Conditional	European	

UPD IA Ref	EU Vet IG Chapter 2 Ref.	Data element name	FHIR Path	SPOR list name	Mandatory for Legacy Data (yes/no)	Conformance in Chapter 2	European/ National	Notes on Legacy Data
	4.3.2.1.1	Strength (presentation single value)	Ingredient.substance.strength.presentation	Units of Presentation	yes	Conditional	European	
1.5	4.3.2.2	Strength (concentration)				Conditional	European	
1.5	4.3.2.2.1	Strength (concentration single value)	Ingredient.substance.strength.concentration	Units of Measurement	yes	Conditional	European	
	4.3.3	**Reference Strength**			**yes**	**Conditional**	**European**	
1.5	4.3.3.1	Reference (Active) Substance	Ingredient.substance.strength.referenceStrength.substanceCodeableConcept	SMS		Mandatory	European	
	4.3.3.1.1	Reference strength (presentation)			yes	Conditional	European	
	4.3.3.1.2	Reference strength (Presentation single value)	Ingredient.substance.strength.referenceStrength.strength	Units of Presentation	yes	Conditional	European	
	4.3.3.2	Reference strength (concentration)			yes	Conditional	European	
	4.3.3.2.1	Reference strength (concentration)	Ingredient.substance.strength.referenceStrength.strength	Units of Measurement	yes	Conditional	European	
	5	**Packaged medicinal product**			**yes**	**Conditional**	**European & National**	
	5.1	Package description	PackagedProductDefinition.description		yes	Mandatory	European & National	

UPD IA Ref	EU Vet IG Chapter 2 Ref.	Data element name	FHIR Path	SPOR list name	Mandatory for Legacy Data (yes/no)	Conformance in Chapter 2	European/ National	Notes on Legacy Data
	5.1.1	Language	PackagedProductDefinition.description.extension.valueCode	Language	yes	Mandatory	European & National	
3.15	5.2	Pack Size (structured values)	PackagedProductDefinition.extension.containedItemQuantity		yes	Conditional	European	
	5.3	Package identifier	PackagedProductDefinition.identifier		yes	Conditional (update only)	European	
3.16	5.4	Legal status of supply	PackagedProductDefinition.legalStatusOfSupply	Legal status of supply	yes	Conditional (at product or package level)	National	Only if applicable to package level
	5.5	**Marketing authorisation (package level)**			**yes**	**Conditional**	**National**	**Only if applicable to package level**
	5.5.1	Marketing authorisation number (package level)	RegulatedAuthorization.identifier		yes	Mandatory	National	Only if applicable to package level
	5.6	**Manufactured item**			**yes**	**Conditional**	**European**	
	5.6.1	Unit of presentation	ManufacturedItemDefinition.unitOfPresentation	Units of Presentation	yes	Conditional	European	
	5.6.2	Manufactured item quantity	PackagedProductDefinition.package.containedItem.amountQuantity		yes	Mandatory	European	
	5.6.3	Manufactured dose form	ManufacturedDoseForm	Pharmaceutical dose form	yes	Mandatory	European	

UPD IA Ref	EU Vet IG Chapter 2 Ref.	Data element name	FHIR Path	SPOR list name	Mandatory for Legacy Data (yes/no)	Conformance in Chapter 2	European/ National	Notes on Legacy Data
	5.6.4	Ingredient			no	Mandatory	European	
	5.7	**Availability status**			**yes**	**Conditional**	**National**	
	5.7.1	Country	PackagedProductDefinition.marketingStatus.country	Country	yes	Mandatory	National	
2.4	5.7.2	Availability status	PackagedProductDefinition.marketingStatus.status	Marketing Status	yes	Mandatory	National	The term "No Data Provided" should be set
2.3	5.7.3	Availability status date	PackagedProductDefinition.marketingStatus.dateRange.start		yes	Mandatory	National	The default value is the date of initial creation of the product into the UPD.

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
- C3 - OMS Guidance on Assessing Organisation Names and Location Data
- 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 European Medicines Agency - YouTube channel.

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

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